

Senate Hearings

Before the Committee on Appropriations

Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations

Fiscal Year 2008

110th CONGRESS, FIRST SESSION

H.R. 3191/S. 1859

DEPARTMENT OF AGRICULTURE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
NONDEPARTMENTAL WITNESSES

Agriculture, Rural Development, Food and Drug Administration and Related Agencies
Appropriations, 2008 (H.R. 3191/S. 1859)

**AGRICULTURE, RURAL DEVELOPMENT, FOOD AND
DRUG ADMINISTRATION AND RELATED AGEN-
CIES APPROPRIATIONS FOR FISCAL YEAR 2008**

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

ON

H.R. 3191/S. 1859

AN ACT MAKING APPROPRIATIONS FOR AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES PROGRAMS FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 2008, AND FOR OTHER PURPOSES

**Department of Agriculture
Department of Health and Human Services: Food and Drug
Administration
Nondepartmental witnesses**

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CONTENTS

TUESDAY, FEBRUARY 27, 2007

	Page
Department of Agriculture: Office of the Secretary	1
Department of Health and Human Services: Food and Drug Administration ...	479
Nondepartmental Witnesses	721

**AGRICULTURE, RURAL DEVELOPMENT, FOOD
AND DRUG ADMINISTRATION, AND RE-
LATED AGENCIES APPROPRIATIONS FOR
FISCAL YEAR 2008**

TUESDAY, FEBRUARY 27, 2007

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10:02 a.m., in room SD-192, Dirksen Senate Office Building, Hon. Herb Kohl (chairman) presiding.

Present: Senators Kohl, Harkin, Dorgan, Feinstein, Nelson, Reed, Bennett, Specter, and Craig.

DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

STATEMENT OF HON. MIKE JOHANNNS, SECRETARY

ACCOMPANIED BY:

**CHARLES CONNER, DEPUTY SECRETARY
W. SCOTT STEELE, BUDGET OFFICER
DR. KEITH COLLINS, CHIEF ECONOMIST**

OPENING STATEMENT OF SENATOR HERB KOHL

Senator KOHL. Good morning. Today we will begin hearings for the fiscal year 2008 budget. Our first panel will include Secretary Johannns and other distinguished guests from the Department of Agriculture, and following that we'll hear from FDA Commissioner von Eschenbach on that agency's budget.

This is our first hearing for the year and it will be the only general hearing on the fiscal year 2008 budget. The other hearings that we'll have will focus more on issue-specific areas such as food safety, conservation, and food aid. I hope this is a change in format that will allow us to study certain issues in more detail.

As everyone knows, the fiscal year 2007 appropriations process was finished only a few weeks ago. While we understand the President's request for 2008 is not changed by that action, our bills by necessity build on previous year's action, and so we'll need specifics as soon as possible regarding how the USDA and the FDA will carry out this year's programs. I hope you will all work as quickly as you can to make sure that that information is available to us.

The President's budget includes fiscal year 2008 discretionary spending levels of more than \$16 billion for USDA and more than \$1.6 billion for FDA. This includes an increase of \$43 million for

the Food Safety and Inspection Service, an increase of more than \$260 million for the Farm Service Agency, and an increase of \$180 million for WIC. However, the budget also proposes the elimination of the Commodity Supplemental Food Program, which was proposed last year and which was rejected by this subcommittee.

I would note that while the budget does include some new fee proposals, they are presented in such a way that there is little effect on 2008 funding levels. This is an improvement over previous years. However, there are a few legislative proposals, such as those regarding WIC and other programs, that will cause us some concern. So, Mr. Secretary, I look forward to your comments on those.

There are a number of other issues in the budget that we will need to discuss, for example, eliminating the direct single family housing program, and a number of other rural development programs which are problematic.

This has already been a busy year, with much yet to come. As we move through the appropriations process, I pledge to you that we will maintain a constructive dialogue with USDA and FDA. I can tell you that we intend to send our bills to the President well in advance of September 30, so we all need to work together so we can come to an agreement on administration priorities and congressional prerogatives as easily and as swiftly as possible.

Having said that, I'd like now to turn to my good friend and the ranking member, Senator Bennett. As I've said many times, I want to publicly thank him and his staff for the helpful and bipartisan manner in which he has guided this subcommittee over the past few years, and I assure him and everyone else on this subcommittee that I intend to continue that very admirable practice.

So, Senator Bennett, I would ask if you have any opening comments, and then we will turn to other members for their opening statements before we ask the Secretary to share his thoughts with us. We'll recognize members in turn based on their arrival, and in moving from majority to minority for the first round of questions I ask that we use the 5-minute rule. So, Senator Bennett.

STATEMENT OF SENATOR ROBERT F. BENNETT

Senator BENNETT. Thank you very much, Mr. Chairman, and I congratulate you on your assuming again the chairmanship of this subcommittee. I tried to follow your lead in the way that we ran things, and I am very grateful to you for your kind words. I believe we have an excellent working relationship on a bipartisan basis and I'm sure it will continue.

I want to welcome Senator Nelson and Senator Reed, new members of this subcommittee. I think they will add a great deal to our deliberations. We are entering a very busy time for USDA and the FDA because in the next few months Congress will consider and, one hopes, pass the farm bill, the Prescription Drug User Fee Act, and the Medical Device User Fee Modernization Act. These are some of the most important reauthorizations that the Congress will deal with, and while it's the responsibility of the authorizers to address these issues, naturally that will strongly influence the work of this subcommittee.

Now that the fiscal 2007 appropriations are in fact finally behind us and we focus on 2008, I'm delighted, Mr. Chairman, with your

commitment to get this bill done in a timely fashion. We've done it before, and either the full committee or the House was unable to follow our excellent example and get things done in a timely fashion, but I know you will do that and I'll do everything I can to help you.

So this morning I welcome Secretary Johanns and those accompanying him, and look forward to his testimony, and I also look forward to the second panel with Dr. von Eschenbach and those who will accompany him.

This is a unique subcommittee. The life of every person in this country comes in direct contact with some of the product regulated or the programs carried out as a result of the appropriations we made in this subcommittee, and I don't think any other subcommittee can say that. Every single American is affected here, so that's how we will evaluate the budget proposals of USDA and FDA.

Now, taking advantage of this opportunity, I want to offer some praise to three USDA employees in Utah, so that the record will show that I recognize their contribution: Bruce Richardson, who is the Farm Service Agency State Executive Director; Jack Cox, the Rural Development State Director; and Sylvia Gillan, the Natural Resources Conservation Service State Conservationist. Mr. Secretary, these are all three good people, and I wanted to make that comment for the record.

Thank you very much for your courtesy, Mr. Chairman.

Senator KOHL. Thank you, Senator Bennett. We'll turn to Senators for their comments, starting with Senator Dorgan. Then we'll recognize Senator Craig, then Senator Nelson, then Senator Reed, and then Senator Feinstein. Thank you.

STATEMENT OF SENATOR BYRON L. DORGAN

Senator DORGAN. Mr. Chairman, thank you. Thank you and the ranking member, and let me say that I sure do support the notion of getting this bill done, getting it done on time, getting it through the Senate, in conference, and getting to the President for signature. The mess that was created last year, it cannot be repeated, and the mess doesn't belong to any one person certainly, but we've got to finish all of these appropriations bills on time.

I'm going to be asking Secretary Johanns some questions about disaster relief, as he might well expect. The three times I've gotten it through the Senate Appropriations Committee, twice through the full Senate, twice have gotten to conference, and it was blocked in conference. And I know the President at that point had opposed disaster relief. I'm going to ask Secretary Johanns about that today.

I also want to ask some questions about the issue of opening the market to live Canadian cattle above 30 months of age, which will I'm told result in about 1.3 million head of Canadian cattle coming in this year, at a time when we have just heard of the ninth—I guess actually tenth case, if you consider the Canadian cow in the State of Washington—the tenth case of BSE in Canada. I just held a hearing on that subject in North Dakota last week, and I am very much opposed to the proposed rule offered by the USDA. I hope we

can overturn that rule. I guess I hope the comment period will persuade the Secretary not to proceed.

But both of these are very important issues. I want to especially focus on the issue of disaster relief, and I will wait until I question Secretary Johanns. Let me thank the Secretary and the other members of USDA who have come here.

And, Mr. Collins, we had a discussion in North Dakota about you, as a matter of fact. Someone was quoting the USDA Economist, and I asked who, and they told me your name. I said, "Well, I know him." And I used to teach economics, but I was able to recover and move on. So we had a discussion about you. But let me thank you for being here again, as you have for many years, and being willing to visit with us about the agriculture economy.

Secretary Johanns, welcome.

Senator KOHL. Thank you, Senator Dorgan.

Senator Craig.

STATEMENT OF SENATOR LARRY CRAIG

Senator CRAIG. Well, Mr. Chairman, because I certainly want to hear from the witnesses, and we have a lot to cover, I will be brief. But let me join with my colleague, Senator Bennett, in welcoming you to the chairmanship of this committee. We do cover a lot of areas of major importance to a good number of citizens in our country.

We come to Ag Appropriations at a time when the business of crafting a new farm bill—and, Mr. Secretary, we're pleased that the work you have done puts you into the middle of that process. That's where a Secretary of Agriculture ought to be, and frankly, some of our Secretaries have not been there, and Congress has been doing the work in part on its own.

But I think it is a cooperative kind of shaping of policy that is going to be extremely important for American agriculture and U.S. consumers in the future; and, I must also say, and the role agriculture is increasingly playing in the production of energy. That is where I spend a fair amount of my time these days, on that issue, and it is exciting for me to see a future in which agriculture becomes an increasingly major contributor to energy independence in this country, and policy is certainly going to reflect that, loan guarantees, the whole combination of things.

Mr. Chairman, I recently said before a hearing that I felt that maybe we ought to take DOE's authority under Title 17 of the Energy Policy Act and give it to USDA. They seem to know how to get loan guarantees done, know how to do them, and that's not a criticism as much as it is an observation of where we are on that issue. That's important, and of course we'll hear from FDA in a few moments. That, too, is critical to us.

I would hope that as we look at policy—and here is where my friend from North Dakota and I oftentimes agree more than disagree—Mr. Secretary, and as we shape policy that will be reflected in the new farm bill, that we be as much focused on our domestic needs as we are to our international trade obligations. I know there are certain pressures there as it relates to where we may or may not be in the discussion of trade with our neighbors from around the world.

At the same time, I find it increasingly difficult to give and not get in return. And, having said that, the ability of American agriculture to produce is tied in part with trade. I know there needs to be balances, but there also needs to be balances.

Mr. Chairman, thank you very much. I look forward to the testimony of you, Mr. Secretary.

Senator KOHL. Thank you, Senator Craig.

Senator Nelson.

STATEMENT OF SENATOR BEN NELSON

Senator NELSON. Thank you, Mr. Chairman.

Mr. Secretary, panelists, good to have you here today. The future of agriculture I think is not only based on what we want in terms of food, but also what we need in terms of fuel. You've already heard me suggest changing the name of the bill from a farm bill to the Food and Fuel Security Act of 2007, to focus more on what it is we intend to do with American agriculture as we move forward.

I'm hopeful today that you will be able, as a result of this hearing, to establish that the planning in this bill is based on the contingencies of everything going okay as well as if everything goes bad. All too often we look at the current market situation, we see \$4 corn, the countercyclical payments, they're not what they have been, so we therefore don't need the money. If everything—as my dad used to say, the problem is, when everything is going bad you never think it will go good; when everything is going very, very well, you never think it's going to go bad again.

And I'm hopeful that this bill doesn't constitute that kind of a bill, so that we are in a position, if things do change and the market changes dramatically and things are going downhill, that this bill will protect American agriculture. Because if we continue to import at the level we are and we can't export at the level that we're unable to export to right now, I don't know whether we're close, but maybe you can enlighten us on this in your testimony, whether we are right at becoming net importers of our food. And if that's the case, I have said if you like importing 70 percent of your oil, you'll love importing 70 percent of your food.

So that's why I think it has to be about food security, produced here at home, and fuel security. Thank you, Mr. Chairman.

Senator KOHL. Thank you, Senator Nelson.

Senator Reed.

STATEMENT OF SENATOR JACK REED

Senator REED. Thank you very much, Mr. Chairman. I'm eager to hear the testimony of our witnesses, and welcome them here this morning. Thank you.

Senator KOHL. Senator Feinstein.

STATEMENT OF SENATOR DIANNE FEINSTEIN

Senator FEINSTEIN. Thank you, Mr. Chairman. I have just a brief comment.

Mr. Secretary, I want to thank you for your prompt declaration of a secretarial emergency in the California frost situation. The

Governor has submitted costs of approximately \$1.3 billion so far. It is a very major frost problem for the State, and of course we don't know how many of the trees are going to be taken out or crops prevented for the next 3 years because of the absence of bud wood, so it's an ongoing struggle.

I wanted to mention one point, and that one point, and I'm going to ask you some questions about it, is that since USDA transferred responsibility for port inspections to the Department of Homeland Security, the number of inspections has gone down seriously in California. I just sent my staff to the State, and the number one problem they came back with is the concern over the absence of adequate inspections and the belief that next year is going to be a very bad year, with infiltrating pests coming through the borders.

My information is that 60 percent of agricultural inspection specialists indicated they were doing fewer inspections since the transfer, and there's a problem. They don't believe that Customs and Border Patrol respect their work.

As you know, Mexican fruit fly larvae have been picked up, and it took 4 months for it to be identified, is what it was. And of course the problem is that a resulting quarantine, quarantines vast areas of the State, so I'm going to ask you a little bit about that when my time for questions comes up.

Thank you very much for being here. Thank you, Mr. Chairman.

PREPARED STATEMENT

Senator KOHL. Thank you very much, Senator Feinstein.

And now we turn to the Secretary for your remarks.

The subcommittee has received a statement from Senator Cochran which will be placed in the record.

[The statement follows:]

PREPARED STATEMENT OF SENATOR THAD COCHRAN

Mr. Chairman, thank you for holding this hearing on the fiscal year 2008 United States Department of Agriculture and Food and Drug Administration budgets. I welcome Secretary Johanns and Commissioner von Eschenbach back to the Committee.

An important aspect of the Agriculture Appropriations bill is the funding it provides for agriculture research. This research is a critical part of ensuring that U.S. producers remain the leaders in food and fiber production. The funding this bill invests in agriculture research is a small sum compared to the economic benefit it has on a farmer's bottom line. I am concerned about the Administration's proposal to combine the Agricultural Research Service and the Cooperative State Research, Education, and Extension Service into a single agency. The current structure of the Agriculture Research Service is working well and I believe it is important for the Agriculture Research Service to maintain its independent role in the Department of Agriculture.

I was pleased that the fiscal year 2007 Senate Agriculture Appropriations bill fully funded the Wetlands Reserve Program. It is unfortunate that Congress was unable to complete this bill. The Wetlands Reserve Program has taken 1,750,000 acres of marginal croplands out of production and converted to more beneficial uses of enhanced flood protection, carbon sequestration, improved water quality, and wildlife habitat. Many of these acres are located in the Lower Mississippi River Flyway, the Nation's largest waterfowl flyway for wintering habitat.

Last year, the Natural Resource Conservation Service adjusted the method it uses to appraise land for consideration under the Wetlands Reserve Program. I have heard from many constituents in my State and conservation organizations that this change would shift acres away from this important flyway to areas with significantly higher appraisal value. I would like to work with the Department to find a

solution that would ensure this important program is implemented the way Congress intended.

The Food and Drug Administration has the important role of protecting the public by ensuring the safety and efficacy of drugs and our Nation's food supply. Commissioner von Eschenbach, I look forward to your comments on the FDA's plan and priorities for the upcoming fiscal year. One example of the FDA's commitment to protecting the public is the Center for Food Safety and Applied Nutrition's research on the safety of natural products used as dietary supplements by many Americans. The National Center for Natural Products Research at the University of Mississippi is a partner with the FDA to provide research-based information on plant-derived products. With many new dietary supplements coming to the market, this research is increasingly important.

STATEMENT OF SECRETARY MIKE JOHANNIS

Secretary JOHANNIS. Thank you very much. Mr. Chairman and distinguished members of the committee, it's an honor to be here. I am joined today by some gentlemen that can assist me in answering questions. To my right is our deputy, Chuck Conner; to my left, Scott Steele, who is our budget officer; and of course you all know Dr. Collins, our chief economist.

I am happy to report over the past year we've made a lot of progress in meeting the needs of the Nation by improving the rural economy and strengthening U.S. agriculture. Based on our conversations with Americans on the farm and off the farm, we developed a comprehensive list of farm bill proposals to strengthen the farm economy in rural America, and those were announced on the last day of January this year.

My primary focus of course will be on the budget, but I would like to take just a few minutes to give an overview of the proposals. The 2007 farm bill proposals and the 2008 budget were developed on parallel tracks. The administration's farm bill proposals represent the final phase of what was a 2-year process. We listened to producers and stakeholders all across the country, and we took a reform-minded and a fiscally responsible approach to making farm policy more equitable and predictable and protected from challenge in the world trade arena.

While I firmly believe that the current law was the right policy for the time, times do change and times have changed. When the 2002 farm bill was passed, commodity prices were low, exports had declined for several years, and the debt-to-asset ratio was nearly 15 percent.

Today we see a different economic picture. Commodity prices are strong for most program crops. Exports have set records now several years in a row, including a record of \$68 billion in 2006, and projections suggest we will reach another record of \$77 billion in 2007. We are experiencing the lowest debt-to-asset ratio actually in recorded history. It's at about 11 percent for 2006.

Add to all of this the enormous impact of renewable energy on the economy, and it's clear a lot of things have changed since 2002. The time has come to move forward with a farm program that's market-oriented and considers more than commodity prices when determining the appropriate level of support.

Our farm bill proposals bolster this administration's commitment to conservation, with an additional \$7.8 billion over 10 years for conservation purposes. We propose an additional \$1.6 billion over 10 years to advance the development and production of renewable

energy. This will help to achieve the President's goal of reducing our dependence on gasoline by 20 percent in 10 years.

We propose funding to support \$1.6 billion in loans to rehabilitate over 1,200 rural critical access hospitals. Another \$400 million would be focused on trade, making sure that our producers have a level playing field.

These are just a few highlights. When combined, we spend about \$10 billion less than what was spent under the 2002 bill over the last 5 years, excluding the ad hoc disaster assistance. It would be about \$18.5 billion less if you include that. But, importantly, we uphold the President's plan to eliminate the deficit in 5 years. On the other hand, looking forward, our proposals would provide about \$5 billion more than the projected mandatory spending if the 2002 farm bill were just simply extended.

And this brings me to a quick review of the budget. The 2008 budget accommodates the farm bill proposals by including an additional \$500 million per year in the total for the Commodity Credit Corporation. That was put there as a place-holder, anticipating the release of our proposals, the discretionary appropriation request pending before this committee, which does not include the Forest Service, is \$16 billion. It funds the highest priorities while exercising necessary fiscal discipline.

I would like to note that the President's budget was developed prior to congressional action on funding for the remainder of fiscal year 2007. Therefore, our printed materials reflect an estimate for 2007 under terms of the Continuing Resolution that provided funding through February 15.

Now that action has been taken on funding the balance of 2007, I do want to thank the committee for addressing some really critical needs. Key among these resources are resources to ensure our meat and poultry inspection system can meet the demand for inspections, support for the Census of Agriculture, and funding to permit the Department to participate in reconstruction efforts in Iraq and Afghanistan.

Utilizing \$91 million in emergency supplemental funding, USDA has significantly increased our efforts relative to avian influenza overseas. The 2008 budget requests \$82 million to continue and enhance ongoing efforts to fight AI, an increase of \$32 million over the 2007 level. This funding will be used for surveillance and diagnostics work, preparedness, response efforts, international veterinary capacity-building, and research relative to poultry vaccines.

The budget proposes \$341 million for USDA's part of the President's Food and Ag Defense Initiative. This includes \$325 million, an increase of \$148 million, to enhance our ongoing efforts to detect and respond to food emergencies and threats to agriculture. To keep USDA in the forefront of avian disease research, the budget also requests \$16 million to complete the planning and design of the Consolidated Poultry Research Facility in Athens, Georgia.

We are making considerable progress in ensuring the safety of meat, poultry, and egg products. The Centers for Disease Control and Prevention has reported significant declines in foodborne illnesses. In order to continue protecting the Nation's supply of meat and poultry and egg products, this budget meets the demand for inspection services. The budget also requests funding to expand the

Food Emergency Response Network, to increase the capability of State and local labs to handle large volumes of testing that would be needed in the event of a widespread food emergency.

Moving on to energy, renewable energy supported by American agriculture and forestry does hold tremendous promise for our country. The budget proposes \$397 million in loans, grants, and research, an increase of \$161 million for our renewable energy programs. This amount includes \$70 million for energy research. The majority of this will be focused on cellulosic energy. In addition to this research, the budget makes available over \$320 million in grants and guaranteed loans to assist efforts to support the commercialization of renewable energy.

In the farm program area, our discretionary budget supports \$3.4 billion in direct and guaranteed farm loans, which reflects the actual usage in recent years. The budget also requests \$1.5 billion for the Farm Service Agency to deliver our farm programs. The level of funding is necessary to support approximately the same number of staff as we had in 2007.

In 2008, crop insurance is expected to provide coverage for nearly \$68 billion in agricultural production, double the amount of coverage provided in 2000. Recognizing the needs of all partners in the crop insurance system, the 2008 budget fully supports activities to ensure the integrity of the crop insurance program. These efforts have achieved savings of more than \$456 million since the 2000 crop year, and program abuses have been curbed.

Expanding access to global markets is essential for agriculture. Our budget proposals for 2008 support our continued commitment to trade expansion activities. Increased funding is proposed to permit FAS to maintain its overseas office presence and continue its representation and advocacy on behalf of U.S. agriculture.

The budget includes \$100 million for the McGovern-Dole International Food for Education and Child Nutrition Program. Additionally, we request funding in the Office of the Secretary to support the department's efforts in Afghanistan and in Iraq. In order to respond to emergency food needs during 2007, supplemental appropriations of \$350 million are requested for the Public Law 480 Title II donations program.

The 2008 budget includes discretionary funding for conservation technical assistance to meet high priority natural resource concerns. It supports about \$4 billion in mandatory funding to continue implementation of the conservation programs. In aggregate, funding in the budget will support enrollment of an additional 17.8 million acres in conservation programs, bringing total enrollment to 215 million acres. That's the highest enrollment in history.

For rural development, the 2008 budget provides a \$15 billion program level of activities to improve the economic opportunities and quality of life in rural America. The assistance will be used to finance home ownership, rural business, renewable energy, electric, telecommunications, water and wastewater disposal, other community facilities, and it will also support revitalization of our multi-family housing portfolio.

In the research area, the 2008 budget funds the highest priority research. It also increases the use of competition to improve the quality of research, including a total of \$257 million for the Na-

tional Research Initiative. The budget includes \$104 million in increases for high priority research in areas such as food and ag defense, avian influenza, bioenergy, animal genomics and genetics.

Finally, the budget includes an increase of \$25 million to support the 2007 Census of Agriculture.

The budget does fully fund the expected requirements of our three major nutrition programs: WIC, food stamps, and the school lunch program. For WIC, which is our largest discretionary program, the budget proposes \$5.5 billion in program level to support the estimated 8.3 million participants. For food stamps, the budget includes resources to fully fund the estimated food cost inflation and participation, and provides a \$3 billion contingency in case costs exceed the estimated level. We expect an increased level of school lunch participation due to the increased number of school age children, so we include an additional \$632 million for our Children Nutrition Programs.

We have had tremendous response to MyPyramid, and I'm confident the awareness of eating a nutritious diet and being active will improve the health of Americans. So in order to continue this success, the budget includes a small increase to make enhancements to MyPyramid.

PREPARED STATEMENTS

Let me just wrap up and say I want to emphasize that the budget before you strengthens agriculture and rural economies. It protects our food supply. It builds on our conservation efforts, and provides for the neediest of our citizens. With that, those of us at the table would be happy to respond to your questions verbally or to submit answers in writing where appropriate. Thank you, Mr. Chairman.

[The statements follow:]

PREPARED STATEMENT OF MIKE JOHANNIS

Mr. Chairman and distinguished members of this Committee, I am pleased to appear before you to discuss the fiscal year 2008 budget for the Department of Agriculture (USDA).

I am joined today by Deputy Secretary Chuck Conner; Scott Steele, our Budget Officer; and Keith Collins, our Chief Economist.

It is a pleasure to come before the Committee to discuss U.S. agriculture and our efforts to make it stronger. I want to thank the Committee again this year for its support of USDA and for the long history of effective cooperation between this Committee and the Department in support of American agriculture. I look forward to working with you, Mr. Chairman, as well as the other Members to make progress on these issues during the 2008 budget process and to ensure strong programs for our Nation's farm sector and many other USDA programs.

Over the past year, USDA has worked with and heard from people throughout the Nation about the importance of agriculture to the economy and the everyday life of all Americans. I am happy to report that we have made much progress in meeting the needs of the Nation, improving the rural economy, and strengthening U.S. agriculture. I would like to point out that:

- Under President Bush's economic policy, rural America and U.S. agriculture has prospered.
- Renewable energy production has grown dramatically and is contributing to the energy security of the United States as well as improving the farm economy.
- Utilizing \$91 million in emergency supplemental funding, USDA significantly increased its efforts to prepare for a potential influenza pandemic and participated in the worldwide effort to stop the spread of the H5N1 virus overseas.
- We are making considerable progress in ensuring the safety of meat, poultry, and egg products. Recalls of meat and poultry and processed egg products have

been cut in half during the last 4 years due to improved oversight and the downward trend is continuing.

- U.S. agricultural exports again reached a record level in 2006, and are forecast to set another record in 2007. The 2007 forecast level represents an increase of more than 50 percent since 2000.
- We have continued our efforts to open new markets. During the past year, Trade Promotion Agreements were signed with Colombia and Peru, and negotiations were completed with Panama.
- We remain committed to our objective of achieving fundamental reform of agricultural trading practices through the Doha Round of multilateral trade negotiations. Although no major breakthroughs have been achieved, we are actively engaged in discussions with our trading partners on technical aspects of each of the three pillars in the agricultural area. We continue to believe a successful outcome is achievable.
- We are continuing to regain our beef export market. Markets have been reopened or maintained in the countries that closed their borders to U.S. beef products after the first detection of BSE. Recent progress has been made in such countries as Russia, Columbia, Peru, and Panama.
- We have had tremendous response to MyPyramid, and I am confident that as awareness of the importance of eating a nutritious diet and being physically active increases, so will the health of Americans.

On January 31, 2007, I announced a comprehensive set of 2007 Farm Bill proposals for strengthening the farm economy and rural America. The 2008 budget is based on the current Farm Bill. However, beginning in 2008, the budget incorporates a \$500 million increase each year in the Commodity Credit Corporation (CCC) estimates to accommodate the cost of new Farm Bill proposals to be allocated among the various titles of the bill.

2008 Budget

The President and the Congress are facing many challenges. The President's 2008 budget meets these challenges by funding our highest, most important priorities, while exercising the fiscal discipline that is absolutely necessary to achieve the President's goals of strengthening the economy and balancing the budget.

Today, I will be focusing on the proposals contained in the 2008 budget. Let me take a moment to briefly point out how this budget supports our highest priority programs—programs that achieve results. This budget:

- Fulfills our commitment to reduce trade barriers and expand overseas markets;
- Supports the President's vision for energy independence by significantly increasing funding for biofuels;
- Continues programs vital to the protection of agriculture from disease, pests, and human threats, including avian influenza and BSE;
- Supports policies that ensure Americans continue to enjoy a safe and wholesome food supply;
- Provides sufficient resources to fully fund expected participation and food cost inflation in our major nutrition assistance programs;
- Enhances the environment by providing a record level of funding to enroll a record number of acres into conservation programs;
- Builds a strong rural economy by supporting policies that enhance job creation, improve rural infrastructure, and increase homeownership opportunities; and
- Supports on-going basic and applied sciences that provide the technology and information necessary for the development of innovative solutions facing American agriculture;

USDA also shares the responsibility of controlling Federal spending. This means doing more with less, eliminating programs that are not getting the job done, cutting out wasteful spending, and reforming the earmark process. We are pleased that the House Joint Resolution for 2007 continuing appropriations significantly reduced USDA's earmarks, and hopes that the Committee will continue those worthy efforts. So, you will see throughout the 2008 budget proposals that terminate or reduce spending. These proposals will produce real savings in both mandatory and discretionary spending.

The President's 2008 budget, which was released on February 5, 2007, proposes to increase USDA's total budget authority from \$88 billion in 2007 to \$91 billion in 2008. For the Department's discretionary budget, the overall request is \$20 billion, about the same level as in 2007 level. The discretionary appropriation request pending before this Committee, which does not include the Forest Service, is \$16 billion.

I would now like to focus on some specific program highlights.

Pathogenic Avian Influenza (AI)

The infrastructure developed in response to outbreaks of highly pathogenic AI has enabled the Department to strengthen its global leadership in combating its spread and keeping it from entering the United States. Utilizing the supplemental funding provided in fiscal year 2006, the Department has worked closely with international agencies and other countries to enhance the international capacity and technical skills necessary to keep AI at bay. Domestic efforts have built upon USDA programs that have been in place for more than two decades to prevent an outbreak of dangerous strains of AI in our country.

The 2008 budget requests a total of approximately \$82 million to continue and enhance on-going efforts related to AI, an increase of \$32 million over the amount estimated for 2007, not including supplemental funds. Of the increase, \$20 million is related to continuing activities related to highly pathogenic AI, including: surveillance and diagnostics work; preparedness and response efforts; and international veterinary capacity building. An additional increase of \$6 million is requested for the development of methods to detect AI in the environment and further AI research, including development of poultry vaccines. Another \$6 million increase is requested to expand activities related to the on-going program for low pathogenic AI. Low pathogenic AI is of concern for its potential costs to the poultry industry and potential ability to mutate into highly pathogenic AI.

Food and Agriculture Defense Initiative

USDA continues to be vigilant in ensuring the safety of agriculture. The Department is a strong partner in the Administration's efforts to prepare for any potential bioterrorist attack. We have established effective working relationships with other Federal agencies to ensure an appropriate Government response to a wide array of threats.

To protect American agriculture and the food supply from intentional terrorist threats and unintentional introductions, the budget proposes \$341 million for USDA's part of the President's Food and Agriculture Defense Initiative. Funding for ongoing programs is \$325 million, an increase of nearly \$148 million from the 2007 level. Of the total amount for on-going programs, an increase of about \$36 million for Food Defense would enhance the Food Safety and Inspection Service's (FSIS) ability to detect and respond to food emergencies and for USDA research agencies to conduct related research. For Agriculture Defense, the budget includes an increase of about \$39 million for research on emerging and exotic diseases to, among other things, improve animal vaccines and facilitate rapid response to agricultural threats. An additional \$72 million would be used to improve USDA's ability to safeguard the agricultural sector through enhanced monitoring and surveillance of pest and disease threats, improved response capabilities, and other efforts, such as an expansion of the National Veterinary Stockpile.

In order to keep USDA in the forefront of avian disease research, the budget requests an increase of \$16 million for planning and design of the Consolidated Poultry Research Facility in Athens, Georgia. This facility is critically needed to conduct research on exotic and emerging avian diseases that could have devastating effects on animal and human health.

Food Safety

Americans enjoy one of the safest food supplies in the world. Data from the Centers for Disease Control and Prevention shows improvements based on historical reductions in the incidence of foodborne illness. The continued reduction in illnesses from pathogens associated with the consumption of meat, poultry, and egg products is a tremendous success story. These results demonstrate that we are moving in the right direction. USDA is committed to continuing this positive trend in the future. We will continue to pursue the development and implementation of risk-based inspection systems that are grounded in science. These systems will make us smarter about where we focus our resources and our expertise to make the most difference.

The 2008 budget requests record funding of nearly \$1.1 billion, an increase of \$104 million over 2007, for FSIS to protect the Nation's supply of meat, poultry and egg products. This includes \$930 million in appropriated funds. About 80 percent of the increase in funds is for pay, including monies required for Federal and State inspection programs to meet the demand for inspection services. The budget requests an increase of \$21.7 million to expand the Food Emergency Response Network (FERN and strengthen food and agriculture defense. With this funding, FSIS will continue to develop the network of food laboratories and the result will be an increase in the capability of a network of coordinated Federal, State and local laboratories to handle large volumes of testing that would be needed for biosurveillance or in the event of a widespread food emergency.

The budget estimates that \$135 million in existing user fees for voluntary inspection will be collected. For 2008, we will be submitting authorizing legislation to Congress to collect an additional \$96 million in user fees. The budget does not assume the use of these fees. Discretionary funding to cover the total cost of the program is included in the request. This includes legislation to authorize a licensing fee to collect \$92 million from meat, poultry, and egg products establishments. In addition, it would also authorize the agency to recover \$4 million for the cost of providing additional inspection services from establishments as a result of performance failures, such as sampling violations, recalls, or an outbreak of foodborne illness.

Energy

Another priority for the Department and the Administration is a continued focus on expanding renewable energy. I sit before you today with the belief that renewable energy, supported by American agriculture and forestry, holds tremendous potential for the Nation's future. We are starting to see that the benefits of renewable energy are far-reaching and will continue to grow as energy production from renewable sources continues to expand in the near future. Renewable fuels reduce our dependence on foreign oil, which contributes to our Nation's security. Renewable fuels are environmentally friendly and produce fewer emissions of greenhouse gases than fossil fuels. Furthermore, renewable fuels are often produced in rural areas, providing a source of income for farmers, ranchers and rural Americans.

USDA is committed to ensuring that renewable fuels production continues to help meet the Nation's energy and security needs. The budget includes \$396 million, an increase of \$161 million, for the Department's energy initiatives. Part of USDA's commitment is demonstrated through research activities. The 2008 budget includes \$70 million, an increase of \$29 million, for energy research supported by ARS and CSREES. A majority of this research will focus on improving cellulosic ethanol production by improving feedstock growth potential and introducing new ways to harvest, handle, and transport the feedstock to production facilities. In addition, USDA is working to improve the conversion efficiency of biomass feedstocks into biofuels and bioproducts. This research will lead to new opportunities to expand renewable fuel's potential to meet the Nation's energy needs, while creating significant opportunities for farmers, ranchers, and rural communities.

In addition to this research, the budget would make available nearly \$320 million in grants, guaranteed loans, and other efforts to support the commercialization of renewable energy production. Through the Rural Development mission area, USDA is making financial support available to leverage private sector funding for small and large-scale, renewable energy generation activities. This financial support provides incentives for individuals and cooperatives to choose renewable energy production methods. USDA has also encouraged the development of various renewable energy projects, including ethanol plants and wind farms. We remain committed to expanding these opportunities to improve the Nation's energy security and environment, while providing additional possibilities to U.S. agricultural and rural communities.

Farm Commodity and Agriculture Credit Programs

Rising crop prices, particularly for corn, has had a major impact on farm program costs, which is due to the rapid growth in ethanol production. As a result, farmers are relying more on the market for revenue rather than payments from the Government. As such, net outlays for the farm commodity programs funded through the Commodity Credit Corporation (CCC) are expected to decline significantly in 2007 and 2008 as rising prices for corn and other major commodities are reducing outlays. Compared to estimates made when the 2002 Farm Bill was enacted, actual spending for CCC funded programs, which excludes some conservation programs, has been about \$17 billion below the 2002 projections when ad hoc disaster assistance is excluded. Beginning in 2008, the budget incorporates a \$500 million increase each year in the CCC estimates to accommodate the cost of the new Farm Bill proposals. This additional funding will be spread among various titles of the Farm Bill.

USDA's farm credit programs provide an important safety net for farmers by providing a source of credit when they are temporarily unable to obtain credit from commercial sources. The 2008 budget supports about \$3.4 billion in direct and guaranteed farm loans. The 2008 budget proposes loan levels that generally reflect actual usage in recent years.

The budget requests \$1.5 billion for the Farm Service Agency to deliver farm programs. This level of funding will support approximately the same number of staff years as in 2007 and includes the funding to support ongoing operational needs based on current programs and the current delivery system. Once the parameters

of the new Farm Bill are known, we may need to re-evaluate resource needs for program implementation, including staffing and information technology (IT).

Crop Insurance

Crop insurance is designed to be the primary Federal risk management tool for farmers and ranchers. In 2008, crop insurance is expected to provide coverage for nearly \$68 billion in risk protection, double the amount of coverage provided as recently as 2000. This growth has been accomplished, in part, through the development of new and innovative plans of insurance. These innovations have expanded coverage to new crops or improved the coverage available under existing policies.

Over the years, Congress has challenged USDA to expand the availability of crop insurance to under-served commodities, in particular, to livestock and pasture, rangeland, and forage. I am happy to say that USDA is meeting that challenge. Currently, the crop insurance program offers protection for swine, fed cattle, feeder cattle; and, new for 2007, lamb. Also new for 2007, the crop insurance program is offering two innovative programs covering pasture, rangeland, and forage.

In order to build on these successes, Risk Management Agency's (RMA) aging information technology (IT) system needs to be modernized. The existing IT system has been in service for more than a decade and needs to be upgraded to address evolving programmatic needs. That system was designed for a much smaller and simpler program. As a result, RMA must use numerous manual over-rides and work-arounds to support the new insurance products. This manual intervention increases the costs to maintain and operate the system. It also increases the risk of data errors that could jeopardize the integrity of the crop insurance program. The 2008 budget includes a legislative proposal to initiate a small participation fee in the Federal crop insurance program to fund modernization and maintenance of a new IT system. The fee would generate about \$15 million annually, which would initially supplement the annual appropriation to modernize the IT system. However, in future years, the fee would replace appropriated funding for IT maintenance.

In addition, the 2008 budget includes about \$79 million in discretionary funding to administer the Federal crop insurance program, compared to about \$76 million for 2007. The increase would accommodate pay costs and inflationary increases. The budget also includes a general provision to fund data mining and the common information management system through the crop insurance mandatory account.

International Programs

Expanding access to global markets is essential for U.S. food and agricultural products, and plays a critical role in our efforts to provide a prosperous future for America's farmers and ranchers. In this regard, we must ensure that our producers and exporters have the tools they need to compete for a greater share of the benefits flowing from trade agreements and the resulting expansion in global markets.

Our 2008 budget proposals support our continued commitment to trade expansion activities. Increased funding is provided for the Foreign Agricultural Service (FAS) to maintain its overseas office presence and continue its representation and advocacy activities on behalf of American agriculture.

The FAS budget includes funding to restore the Cochran Fellowship Program to its traditional annual appropriated level of \$5 million and also provides funding for FAS trade capacity building activities. Those activities assist developing countries to strengthen their agricultural policy making and regulatory systems adhere to internationally recognized standards and become better trading partners. By assisting them to adopt policies that meet World Trade Organization standards and adopt regulatory systems that are transparent and science-based, we improve access for U.S. products to their markets.

For the foreign food assistance programs, the budget continues to place the highest priority on meeting emergency and economic development needs of developing countries. Appropriated funding for the McGovern-Dole International Food for Education and Child Nutrition Program is increased to \$100 million, which will allow USDA to extend school feeding and educational benefits to about 2.5 million women and children during 2008. The program is helping children in countries with severe educational and nutritional needs. In recent years, more than 13 million children throughout the world have received benefits from the McGovern-Dole program and its predecessor, the Global Food for Education Initiative.

In order to respond to emergency food needs during 2007, supplemental appropriations of \$350 million are being requested for the Public Law 480 Title II donations program. The additional funding will be used to address urgent humanitarian needs in the Darfur region of Sudan, including for refugees and others in Chad and surrounding areas who are affected by the violence. The funding will also assist in

meeting other critical food needs, particularly in the Horn of Africa, southern Africa, and Afghanistan.

For 2008, the budget requests appropriated funding of \$1.2 billion for the Public Law 480 Title II program, which is expected to support the donation of 2.5 million metric tons of food commodities. In addition, to help improve the timeliness, efficiency, and effectiveness of the U.S. Government's response to emergency situations, increased flexibility is requested in the purchasing of Title II commodities.

In addition, the budget requests funding in the Office of the Secretary to support the Department's efforts to assist in agricultural reconstruction activities in Afghanistan and Iraq. USDA is providing technical advisors assigned to the Ministry of Agriculture in Iraq who are assisting in agricultural planning, extension, and food safety and inspection. Other agricultural advisors are serving on the Provincial Reconstruction Teams (PRTs) working in the rural provinces of Afghanistan and Iraq on activities such as irrigation system rehabilitation, post-harvest loss reduction, marketing system improvements, and livestock health. These advisors are providing much needed, valuable assistance in addressing a wide range of problems brought on by years of neglect and mismanagement in the agricultural sectors of these two countries.

Conservation

USDA also fosters environmental stewardship through conservation programs supported with mandatory CCC funding. The 2008 budget reflects an unprecedented commitment to conservation and includes nearly \$4 billion in mandatory funding to provide conservation financial and technical assistance on a cumulative total of 215 million acres, the greatest amount of conservation assistance provided in the Nation's history.

Within the total amount of mandatory funds, the budget proposes over \$455 million for the Wetlands Reserve Program (WRP), an increase of \$191 million, or nearly 72 percent over 2007. The projected WRP enrollment for 2008 would be the largest ever, involving up to 250,000 acres, and will bring the total acreage enrolled in the program to 2,275,000 acres, the maximum level authorized by the 2002 Farm Bill. The WRP is the principal supporter of the President's goal to restore, protect, and enhance 3 million acres of wetlands by 2009.

The Conservation Reserve Program (CRP) accounts for more than half of the mandatory funds with total funding of just over \$2 billion. Enrollment in CRP is expected to decline by about 9 percent to 33.6 million acres in 2008. Although continuous sign-ups will be maintained, no general signups are assumed for 2007 and 2008 due to the increase in corn production to meet the demand for ethanol. Funding for the Environmental Quality Incentives Program will be maintained at \$1 billion to treat more than 170 million acres in 2008. The budget requests an increase of \$57 million for the Conservation Security Program for total funding of \$316 million. This level of funding will continue support to the more than 19,000 contracts signed in prior years.

The 2008 budget includes \$825 million in discretionary funding for on-going conservation work, a decrease of \$94 million below the 2007 level. This level of funding supports programs that provide the highest quality technical assistance to farmers and ranchers and address the most serious natural resource concerns. The budget includes a proposal to reduce the number of Federal coordinator positions funded under the Resource Conservation and Development (RC&D) program, for a savings of \$36 million. Under this proposal, the number of authorized RC&D areas would be maintained at the current level of 375, but coordinators would provide assistance to multiple areas by focusing on programmatic oversight.

Rural Development

Through Rural Development (RD) programs, USDA improves the economy and quality of life in all of rural America by supporting essential housing and public facilities, such as water and sewer systems, health clinics, and electric and telecommunication systems. In addition, RD promotes economic development by providing guaranteed loans to businesses in coordination with the private sector.

The 2008 budget supports \$14.9 billion for the RD programs. This is about \$985 million more than the amount estimated to be available for 2007. At the requested level, most key rural development programs would be maintained at their historic operating levels.

The 2008 budget does, however, contain some important changes in policy and funding priorities. In particular, the 2008 budget significantly increases funding for single-family guaranteed loans. Guaranteed loans, which are unsubsidized, have accounted for almost all of the growth in USDA's homeownership assistance. Due to the success of guaranteed single-family loans in meeting the needs of rural citizens,

the budget does not include funding for direct single-family loans, a reduction of nearly \$1.2 billion. While not funding direct loans is a change in policy for USDA, it is consistent with Federal housing policy as reflected in the programs administered by the Departments of Housing and Urban Development and Veterans Affairs. Moreover, it reflects recent changes in the home mortgage market that allow more low-income families to qualify for private sector loans. USDA's single family guaranteed program is expected to provide 39,000 homeownership opportunities in 2008.

With regard to multi-family housing, the 2008 budget includes \$567 million for rental assistance payments. This funding is needed to provide for a higher rate of renewals due to recent action to reduce the renewal period from 5 to 1 year. The 2008 budget also includes \$27.8 million to continue the Administration's initiative to revitalize USDA's portfolio of multi-family housing projects, which are home to close to half a million low-income families. A recent Supreme Court decision allows project sponsors to prepay their loans and convert their projects to uses other than low-income housing, putting tenants at risk of higher rents and potential loss of housing. The Administration's initiative includes providing housing vouchers to protect the rents of tenants of projects that are withdrawn from the portfolio, as well as the restructuring of existing loans in exchange for the project sponsor's agreement to stay in the program and make improvements to their projects. A pilot program, as authorized by the 2006 Appropriations Act is already underway. The Administration plans to resubmit to the Congress draft legislation to authorize debt restructuring and other revitalization incentives.

For the on-going electric and telecommunications programs, the 2008 budget supports about \$4.8 billion in direct loans, of which \$4.1 billion would be for the electric programs. Most electric loans would be at interest rates that are currently comparable to the direct municipal and direct Treasury rate programs. Combined, these programs would simplify the overall program with essentially no adverse impact on borrowers. The electric program would focus on financing the distribution and transmission of power and the improvement of existing generation facilities. The commercial sector should be relied on for financing new power generation. For the water and waste disposal program, the 2008 budget provides for \$349 million in grants and almost \$1.1 billion in direct loans. This reflects a lower grant-to-loan ratio than the current program because the Administration is re-proposing its plan to reduce interest rates in exchange for a reduced amount of grants. For most rural communities, which receive a combination of loan and grant assistance, the reduction in interest rates would be of greater benefit because it would reduce the overall debt servicing costs of their projects.

The 2008 budget includes additional funding for the renewable energy and energy efficiency loan and grant program. It includes \$15 million for grants and supports \$195 million in guaranteed loans, compared to \$11 million for grants and \$175 million in loans estimated to be available for 2007.

The business and industry guaranteed loan program would be increased to \$1 billion, which is the historic funding level for this program. This program and the intermediary re-lending program have been an important source of job creation in rural communities.

Research

Over the last century, productivity has been a major focus of agricultural research. Driven by advances in plant and animal genetics, nutrition, and health, this research has paid off with major gains. Agricultural research is taking on the challenges of a new century and USDA's leadership will continue through innovative research in bioenergy production, obesity prevention, and food and agricultural defense.

Advances in science have opened new frontiers in agricultural research that have put solutions to national challenges within our reach. It is important that we seize the opportunity by focusing our resources and efforts on the highest priority work relevant to the needs of producers and consumers of agricultural products. Our budget requests over \$1 billion for the Agricultural Research Service. The proposed level includes \$104 million in increases for high priority research on food and agricultural defense, bioenergy, plant and animal genomics and genetics, and human nutrition and obesity prevention. These lines of investigation have great potential to benefit producers and consumers; assure an abundant, safe, and inexpensive supply of food; and ensure the preservation of our natural resource base. The budget proposes elimination of \$293 million of earmarked research and facility projects in ARS.

A key factor in the success of agricultural research has been our continuing partnership with the land-grant universities and other performers of agricultural, natural resource and food research. These institutions provide a unique set of expertise

in the range of scientific disciplines needed to address complex issues facing the food, agriculture and natural resource communities. Further, these partnerships foster the transfer of knowledge through higher education and the unique system of Extension that has been so successful in America. Our budget continues our support for university-based research, higher education and extension programs and addresses the need to focus those resources on the highest priorities. Under our proposal we are placing a greater emphasis on merit-based, peer-reviewed grants to achieve the highest quality research from taxpayer dollars. In addition, \$157 million of earmarked Cooperative State Research, Education, and Extension Service research grants and lower priority projects would be eliminated.

A major element of the research budget is an increase of \$68 million, for total funding of \$257 million, for the National Research Initiative—the Nation’s premier competitive, peer-reviewed research program for fundamental and applied sciences in agriculture. This increase includes funding for bioenergy and biobased fuels, one of the Department’s highest priority initiatives. It also supports integrated projects that focus on water quality, food safety, organic transition, and pest management. In total, \$29 million would be added to CSREES programs for research in bioenergy.

A longstanding part of USDA support for the university research partnership has been through the Hatch Act and McIntire-Stennis Act formula grant programs. As stated above, the budget continues funding for these programs with a proposal to emphasize funding for competitively awarded multi-state research programs to ensure the highest quality research proposals are supported. We will be working in close consultation with our university partners to craft the details of these modifications.

The budget includes an increase of \$25 million to support the 2007 Census of Agriculture, the most comprehensive source of statistically reliable information regarding our Nation’s agriculture. With information collected at the national, State, and county levels, the Census provides invaluable, comprehensive data on the agricultural economy which are relied upon to keep agricultural markets stable and efficient.

Nutrition Assistance

The budget contains sufficient resources to fully fund expected participation and food cost inflation for the Department’s three major nutrition assistance programs—Food Stamps; Women, Infants and Children (WIC); and Child Nutrition. Participation levels fluctuate with economic conditions and the budget keeps pace. WIC participation is expected to grow slowly in 2008 to a total of 8.3 million participants, while Food Stamp participation is estimated at 26.2 million, roughly the 2007 level. School Lunch participation is estimated to grow about 2 percent to keep pace with the growing student population, as it has in recent years, to a new record level of 31.5 million children per day.

For Food Stamps, legislation will be proposed that would exclude all retirement and education savings accounts from eligibility determinations regardless of how other programs treat them. By 2010, this would allow about 98,000 additional people to participate who, otherwise, would have been ineligible unless they spent down their retirement and education savings. This would add an estimated \$44 million in costs for 2008 and about \$138 million in 2010 when fully implemented. The 2008 budget also repropose legislation to restrict participation among certain households with incomes or resources above normal eligibility thresholds. Affected households are those that do not receive cash Temporary Assistance for Needy Families (TANF) benefits, but become categorically eligible for food stamps because they receive a TANF-funded service, such as a one-time referral. This change would reduce costs by an estimated \$65 million in 2008, with additional savings in subsequent years.

The WIC request provides full funding for all those estimated to be eligible and seeking services. At the same time, the Department will work with stakeholders to contain costs and continue to improve the program’s performance. WIC legislative proposals include limiting administrative funding to the 2006 per participant level and limiting categorical eligibility to those with incomes under 250 percent of poverty.

The 2008 budget repropose elimination of the Commodity Supplemental Food Program (CSFP), which is not available nationwide and duplicates two of the Nation’s largest Federal nutrition assistance programs—Food Stamps and WIC. Eligible women, infants and children participating in CSFP will be encouraged to migrate to the WIC Program. Eligible elderly CSFP recipients will be encouraged to migrate to the Food Stamp Program, where most are believed to be eligible. The budget includes temporary transitional benefits for CSFP participants 60 years of age or older equaling \$20 per month for the lesser of 6 months or until the recipient starts participating in the Food Stamp Program.

As I mentioned earlier, we have had a great deal of success in promoting healthy eating habits and active lifestyles with MyPyramid. The MyPyramid website has received 2.6 billion hits since it was made available in April 2005. In order to continue this success, the budget includes an increase of \$2 million to make enhancements to MyPyramid and to begin planning for the 2010 Dietary Guidelines for Americans. This supports two pillars of President Bush's HealthierUS Initiative, to eat a nutritious diet and to be physically active, and will help reduce obesity in America.

Department Management

The 2008 budget continues our progress in improving the overall management of the Department. Increased funding is being sought for selected key priorities including:

- Replacing the Department's outdated, core financial system and supporting systems that no longer meet all Federal standards for financial reporting and management. The budget requests funding to begin a multi-year implementation of a replacement system that will provide consistency and increase efficiencies for financial reporting across the Department. The new system will strengthen internal controls, eliminate material weaknesses, and diminish improper payments, which will improve the Department's overall financial management.
- Expanding Civil Rights compliance reviews of agency hiring practices and program activities. These reviews allow the Department to identify and address issues of inequality and unfairness in personnel decisions and the delivery of its program benefits.
- Continuing capital improvements to USDA facilities to ensure that employees and customers have a safe and modern working environment.

In closing, I want to emphasize that the USDA budget fully supports the President's goals to strengthen the economy, increase security, and restrain spending. The budget before you addresses these goals by funding our highest priorities. These funding priorities strengthen agriculture and rural economies, protect our food supply, build on our conservation efforts, and provide for the neediest individuals.

That concludes my statement. I look forward to working with Members and staff of the Committee and will be glad to answer questions you may have on our budget proposals.

PREPARED STATEMENT OF BOYD K. RUTHERFORD, ASSISTANT SECRETARY FOR ADMINISTRATION, DEPARTMENT OF AGRICULTURE

Mr. Chairman and members of the Subcommittee, thank you for the opportunity to submit this statement supporting the President's budget proposal for fiscal year 2008 for the Department of Agriculture's (USDA) Departmental Administration.

Departmental Administration (DA) is at the core of USDA's management initiatives. Through a strong commitment to the President's Management Agenda, we have realigned our services to provide continued leadership and better program management, resulting in greater efficiencies, enhanced internal controls and effective customer service. DA enhances Department-wide strategies by ensuring appropriate administrative policy and by providing essential management to all agencies and staff offices. This is accomplished through our Department-wide management services, which include: human capital management; facilities operations; security services; procurement and property management; small business utilization; Administrative Law support; and ethics guidance.

FISCAL YEAR 2008 OBJECTIVES

DA has the following objectives for fiscal year 2008 that contribute to the Department's ability to successfully fulfill its mission:

- Ensure USDA has a diverse, ethical, results-oriented workforce able to meet mission priorities and work cooperatively with USDA partners and the private sector.
- Ensure USDA has a trained acquisition workforce with the procurement policies and systems needed to ensure responsiveness, high quality, cost-effectiveness, and accountability using an increasingly diverse vendor pool and range of products.
- Promote the efficient and economical use of USDA's resources to support customers, promote organizational productivity, and ensure accountability.
- Provide the policies, technical guidance, and operating environment that enhance the safety and security of USDA personnel, information and facilities, and the continuity of its vital programs and operations.
- Provide formal adjudicative support.

- Expand the implementation of the BioPreferredSM Program within USDA and other Federal agencies. The BioPreferredSM Program, authorized in the 2002 Farm Bill, is a Federal procurement program that requires that Federal agencies provide a preference for the purchase of USDA designated biobased products. In fiscal year 2008 DA will be jointly focused on establishing USDA as a leader in biobased purchases and providing support and guidance to other Federal agencies and to biobased manufacturers.

FISCAL YEAR 2008 REQUEST

DA's fiscal year 2008 budget request is divided into three separate appropriations: DA Direct; Agricultural Building and Facilities and Rental Payments; and Hazardous Material Management.

DA DIRECT

The DA Direct fiscal year 2008 budget is \$24,608,000, which funds personnel and office operations costs. The increased request will address the following:

- An increase to cover personnel costs for 2007 and 2008. This appropriation funds administrative support in the National Capital Area and on-going programs in human capital management and small business utilization across the Department.
- An increase for Continuity of Operations (COOP) for the Office of the Secretary, providing guidance and training to the mission areas, and providing support and training to USDA's National Emergency Preparedness Team. These efforts will ensure USDA is compliant with Executive Orders and Presidential Directives associated with Emergency Preparedness and requirements for Executive Branch COOP.

AGRICULTURE BUILDINGS AND FACILITIES AND RENTAL PAYMENTS

The fiscal year 2008 budget request for Agricultural Building and Facilities and Rental Payments is \$216,837,000, of which \$156,590,000 is for rental payments to the General Services Administration (GSA) and Department of Homeland Security for security payments and \$60,247,000 for Building Operations and Maintenance.

The increased request addresses the following:

- An increase for the Central Rent Account is needed to fund the estimated cost of GSA space assignments and physical security costs payable to the Department of Homeland Security, increased lease expenses, maintenance services, and preventative maintenance services of the fire alarm and switchgear systems located at the USDA Headquarters Complex.
- An increase for repairs and maintenance projects for the USDA South Building. The South Building of the Headquarters Complex was built between 1930 and 1936 and houses approximately 4,600 employees. It is in much need of repair and maintenance. Repairs are needed to bring several major systems up to current code requirements and to generally improve employee safety. Providing a safe and healthy work environment for our employees supports our Human Capital Objective.
- An increase to cover the rising cost for steam and electric utilities for the USDA Headquarters Complex. GSA has notified USDA to expect significant increases in 2007 and 2008 utility costs. In 2005, the price of GSA's district steam increased by 22 percent. Paying utility costs from current Building Operations funding will reduce funding available to address the existing maintenance and repair needs for the facilities and possibly contribute to future system failures.
- An increase for annual contract increases due to the Fair Labor Standards Act and collective bargaining. This request is needed to pay mandatory increases for payroll and other fixed and discretionary costs associated with operating USDA facilities. This request supports DA's continuing efforts to provide high quality services so that USDA personnel have the space, facilities, mail and property services, personnel support and resources needed to deliver their program services in a timely and effective manner.
- An increase to support the Building Operations and Maintenance staffs in performing preventive and routine maintenance and repairs in the USDA Headquarters Complex, including the George Washington Carver Center. This increase will cover rising general operating costs and preventive maintenance repairs to major systems within the Headquarters' Complex. The lack of funding in previous years for major repairs has led to a series of system failures which includes: repairs for building roofs and major plumbing, electrical, heating, and air conditioning systems. Instead of being able to address these matters before they fail, the Department is often patching and repairing damage resulting from

the failure of systems long past their useful life. Routine maintenance and minor repairs to major systems, when done on a timely basis, prolong the life of equipment and avoid costly repairs and replacement if the equipment is allowed to fail.

- An increase for the 2007 and 2008 pay costs. This increase is necessary to be able to maintain this office's current staffing levels without compromising its efforts to provide a safe workplace for USDA Headquarters and the George Washington Carver Center.

HAZARDOUS MATERIALS MANAGEMENT

The fiscal year 2008 budget request for Hazardous Material Management is \$12,200,000. The increase represents pay costs. This request will fund clean-up activities under the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA") and the Resource Conservation and Recovery Act ("RCRA"). The purposes of the Hazardous Materials Management Program are to cleanup and restore USDA-managed lands.

CONCLUSION

The goal of DA is to provide the tools necessary for USDA to accomplish its mission of providing effective leadership on food safety, agriculture, and natural resources. Accordingly, we respectfully ask for your support in this effort.

Thank you for this opportunity to present Departmental Administration's fiscal year 2008 request.

PREPARED STATEMENT OF DAVID M. COMBS, CHIEF INFORMATION OFFICER

INTRODUCTION

Mr. Chairman and members of the Subcommittee, thank you for the opportunity to share with you our progress on using information technology (IT) to improve service delivery to the customers of the Department of Agriculture (USDA), while implementing Enterprise Architecture (EA) principles and Electronic Government (eGovernment) throughout the Department.

USDA participates in 22 of the 30 government-wide President's Management Agenda (PMA) eGovernment initiatives and eight of the nine lines-of-business. At the same time, under the framework of the Department's EA, the Office of the Chief Information Officer (OCIO) is managing USDA IT investments to promote collaboration across common lines-of-business, reducing duplication through our internal Enterprise Shared Services, and finding savings by leveraging the USDA's size/economies-of-scale in Department-wide IT acquisitions.

The President's fiscal year 2008 budget request for OCIO is \$16.4 million to continue to guide the Department's IT Strategy. We are requesting approximately \$663,000 to cover pay costs.

USDA'S FISCAL YEAR 2008 INFORMATION TECHNOLOGY INVESTMENT SUMMARY

During the fiscal year 2008 USDA budget preparation process, OCIO staff scrutinized agency IT investment plans to ensure alignment with USDA program delivery plans as well as the USDA EA. In fiscal year 2008, the Department is requesting about \$2.1 billion for IT. Components of the IT portfolio include:

- \$816 million (39 percent of fiscal year 2008 IT spending) for transfer to the States for the development and maintenance of automated systems to support Food Stamps, WIC, and related programs.
- \$1.3 billion in IT discretionary funding as broken down, includes:
 - \$467 million (36 percent) for support services (e.g. architects, design engineers, project managers, and consultants). The Department seeks to use small businesses, especially disabled veteran owned businesses for these services.
 - \$373 million (27 percent) for Federal IT personnel costs.
 - \$170 million (13 percent) for computer and network equipment, such as routers, servers, workstations and printers.
 - \$188 million (15 percent) for out-sourced services (e.g. telecommunications, help desk services, technical design and architect services).
 - \$93 million (7 percent) for software to support our data centers, desktops, helpdesks and other hardware.

Overall, the IT related proposals in this request represent about 3 percent of the total \$67 billion proposed for IT investments for the Federal Government in fiscal year 2008.

SERVICE CENTER MODERNIZATION INITIATIVE—(SCMI)

The Common Computing Environment (CCE) initiative is managed by OCIO working in collaboration with the Service Center Agencies' (SCA). CCE supports over 36,000 Federal employees from the SCA and Information Technology Services (ITS), volunteers and partners in the delivery of over \$55 billion in programs through our field office delivery system. The infrastructure is flexible and built around maximizing information sharing both within USDA and with other Federal, State and local agencies, the private sector, and USDA customers.

The CCE is the commonly defined, commonly acquired, and commonly deployed IT infrastructure for the USDA county-based SCA, namely the Farm Service Agency (FSA), Natural Resources Conservation Service (NRCS), and Rural Development (RD). CCE was established to maximize data sharing, leverage investments and support true "one-stop shopping" for customers of the county-based agencies, and is managed by the ITS of OCIO. ITS serves as one unified organization dedicated to supporting both the shared and the diverse IT requirements of the SCA and their partner organizations.

Several of ITS' significant accomplishments in 2006 include:

- Deployment of database management systems in support of several FSA applications was completed.
- Completion of the Software Update Service (SUS) migration for large offices was completed. SUS keeps computers up-to-date with the latest critical updates, security updates, and service packs. To date, a total of 89 security patches have been tested, certified and deployed since SUS went live on August 2004.
- Completed and awarded a Blanket Purchase Agreement (BPA) for operational contract support. This allows for the consolidation of many existing legacy contracts resulting in cost savings and increased operational efficiency. Another BPA was awarded that allows for the SCA to purchase hardware such as workstations and certain peripherals as their need dictates and as their funds allow. Over \$13.7 million was spent on workstations at the end of fiscal year 2006.
- Deployed the Encrypted File System (EFS) to all laptops and tablet personal computers (PC) in the end user computer environment. EFS provides for the encryption of files, thus reducing the risk of compromising sensitivity data in the event of a lost or stolen laptop or tablet PC.
- Conducted a disaster recovery test to simulate a loss of the Kansas City Web Farm; one major FSA financial application was successfully restored in St. Louis. Participated in the Kansas City Regional Inter-Agency Continuity of Operations Plan (COOP) Exercise. The Federal exercise tested COOP essential functions in the Greater Kansas City metropolitan area and their ability to efficiently perform their duties during emergency situations. More than 600 officials representing over 30 Federal agencies participated in the exercise. This was the third annual exercise and it exists as the largest interagency COOP exercise outside of Washington, DC.

ITS management of CCE is maturing into a fee-for-service activity, while still supporting the "one-stop shopping" aims of the SCMI. This support includes contract consolidation, BPAs, and negotiating with the SCA for needed levels of service, while at the same time researching and implementing ways to achieve economies of scale. Because of the establishment of ITS as a fee-for-service entity, funds necessary to maintain the SCA shared IT infrastructure will be based upon the level of service delivery the SCA choose to effect.

To that end, the fiscal year 2008 CCE budget is requesting no funds. For fiscal year 2008, the funds normally requested in the CCE appropriation can be found in the individual agencies' budget requests.

ITS provides unified management of the shared IT infrastructure of the SCA, including CCE but also non-CCE legacy technologies, and manages the use of the CCE funds. While the responsibility for developing IT applications remains with the agencies with little or no involvement from ITS, ITS does deploy the applications, provides the platforms they run on, and provides those components of the infrastructure that make them available, reliable, and secure.

The organization measures its success against service level agreements with each of the SCA that define performance metrics and customer expectations. This provides openness to the agencies regarding the costs of IT infrastructure, maximum leverage for large-scale system management techniques and technologies, and a basis for continuous improvement. To implement these agreements, ITS and the SCA negotiated the service lines, the appropriate metrics, and acceptable levels of service.

Going forward in fiscal year 2008 and beyond, ITS will determine the agency obligations based on the service usage. This will be a more equitable method that can also provide the agencies with the information they need to reduce costs by effectively managing their IT infrastructure use.

Congressional support for the CCE initiative has been key to its success. As we move forward with ITS, Congressional support will remain critical.

TELECOMMUNICATIONS

USDA continues to evolve its telecommunications services to meet customer needs and provide secure infrastructure for the President's expanding eGovernment initiatives. Following the successful deployment of the Department's enterprise telecommunications network, the Universal Telecommunications Network (UTN), all USDA agencies are accessing the Internet via the UTN. USDA agencies continue to move their existing networks to the UTN. Agency network migration and optimization activities are achieved through a UTN Technical Review Board that is aligned with the Department's IT governance methodology.

We are also developing a Department-wide strategy for Voice over Internet Protocol (VoIP). During fiscal year 2007, we will complete an enterprise "roadmap" for USDA agencies to use in their businesses cases for VoIP investments. Additionally, USDA is heavily engaged in the General Services Administration (GSA) Network acquisition (which we expect will help further reduce our costs) and transition activities as well as migration activities for the transition to Internet Protocol version 6.

NATIONAL INFORMATION TECHNOLOGY DATA CENTER (NITC) HOSTING

NITC continues to be USDA's centralized source for IT services offering 24/7 operations and customer support. The organization began fee-for-services operations in July 1973. NITC serves the needs of over 25 USDA agencies, and more than 15 non-USDA agencies. Our customer portfolio grew by 10.5 percent in fiscal year 2006 to a total of \$85.6 million.

Certified by GSA as a Level 4 Facility, as delineated in the Department of Justice Security Level standards, NITC operates as a Tier IV Electrically and Tier III Mechanically data center. An electrical upgrade has been completed that eliminates any single point of failure, increases availability, and adds redundancy.

Recently NITC received an Office of Inspector General Unqualified Opinion in 2006 for Internal Controls, the Commissioner's Special Citation from the Food and Drug Administration for software development work, the Office of Small and Disadvantaged Business Utilization Award for Service Disabled Veterans, an ePermits Award, and a customer survey response of 85 percent satisfied or highly satisfied.

INFORMATION SECURITY

For many years USDA has been slow to meet all Federal information security requirements. To address this situation, we have significantly improved the posture of our security program by shifting funds and developing policies and procedures. But there is still a tremendous amount of work to be done. The Federal Information Security Management Act (FISMA) and the Office of Management and Budget (OMB) Circular A-130 require all Federal agencies, to certify and accredit (C&A) their systems. Through this effort we have improved our security plans, updated and corrected our security documentation, tested our networks and applications for security weaknesses, and successfully engaged our business organizations in the discipline of security management.

USDA IT security staffs are now in the process of addressing security issues that arose through our C&A activities. Action plans have been established to mitigate specific security weaknesses and implement improved controls, and to meet the FISMA performance measures designed by OMB. These plans also support the remediation of information security weaknesses identified during the Department's implementation of the Circular A-123 review. Within the OCIO, we have established a rigorous process to track agencies in these corrective actions and to ensure they are completed in a timely and efficient manner.

In order to eliminate the root causes for our security weaknesses, we must mature our information security processes. Automated tools are necessary to quickly and efficiently address cyber security risks. We must improve our ability to secure our data with monitoring devices and automated processes that assist in preventing disruption by intrusion or the introduction of malicious programs. During fiscal year 2006, we deployed an improved incident tracking system to help us better manage and report detected breaches. We will continue to maintain a rigorous security training and awareness program which requires annual participation by all USDA and contract personnel.

Through good preventative planning, such as system C&A combined with improving the Department's overall operational response to security challenges, we are reducing the risk associated with the electronic use and delivery of USDA information and services. Congressional support for the initiatives we have planned is critical to their achieving the desired outcome.

ELECTRONIC GOVERNMENT

We continue to move aggressively to implement inter-agency and inter-Departmental services to support common needs. The primary goals of our approach are to reduce costs and improve the quality of interactions with our customers.

USDA, along with our partners in the other Federal agencies, has worked hard over the past 5 years to simplify citizen's access and interaction with their government. The results of these efforts are remarkable. As part of our support of the PMA's promise of easy access to the government, customers may now easily locate USDA's online information and services at www.usda.gov, and with "MyUSDA", visitors can customize USDA's Web-site to provide immediate access to the information they regularly want to see. Currently, 59 Web-sites have moved to the Department's Web standards, and another 31 agency sites are in the process of doing so. Our efforts reduced the burden on citizens, partners, and employees by simplifying access to the Department's information and services and streamlining internal processes. In addition, USDA is a partner in 30 inter-Departmental projects to improve citizen access to government. All fourteen USDA rulemaking agencies migrated in 2006 to the Federal Docket Management System which provides citizens easy access to USDA regulatory action. As a result, the public can review and comment on USDA regulatory actions through Regulations.gov.

USDA posts all discretionary grants to Grants.gov which provides a single location for citizens to find funding opportunities and the ability to apply online for them using common forms, processes, and systems.

USDA is a major geospatial data producer and contributor to the Federal Government's www.geodata.gov. USDA's partnership with the initiative allows cross-Departmental sharing of geospatial information and the opportunity for reducing costs.

Through the USDA eAuthentication Service all USDA employees and over 130,000 customers use a secure, single sign-on to access applications, thereby reducing our customer support needs through improved security and usability. In addition to the 230 USDA applications, users can also use their eAuthentication credentials to access any of the 24 systems integrated with the Federal E-Authentication Federation. The eAuthentication Service is a component of the streamlined implementation of Homeland Security Presidential Directive 12 (HSPD-12).

AgLearn is USDA's implementation of the E-Training initiative. The consolidation of training and learning management functions within AgLearn allows agencies to cooperate in developing, tracking, and purchasing training. Training that has proved successful for one agency can easily be made available for others, eliminating redundant costs for course development and sharing subject matter expertise to a broader audience and the coordination of agency purchases of online courseware provides volume discounts. USDA provides its mandatory training through AgLearn including the annual Ethics, Security Awareness, and Privacy Basics. In an average month, more than 16,000 AgLearn users complete nearly 27,000 training events. This has significantly reduced the overall USDA training costs normally associated with courses that require travel.

ENTERPRISE ARCHITECTURE (EA) AND IT MANAGEMENT PROGRAMS

USDA is managing its EA as a high-level roadmap to achieve our organizational and business needs within an efficient IT environment. USDA's EA program identifies similar processes and opportunities to improve and when possible share and reuse IT solutions across our agencies. We continue to assemble and refine the data needed, at both the Departmental level and within individual agencies, to better organize and analyze our business processes, information needs, and supporting technologies. The USDA EA Program is fully integrated with the Department's IT Capital Planning and Investment Control (CPIC) process. USDA's central CPIC body reviews, monitors and approves all major IT investments to ensure alignment with the Department's strategic goals and objectives. The EA provides a formal basis for evaluating a single investment against other investments in terms of its contribution to enhanced delivery of customer services and opportunities for collaboration and reuse. In addition to strengthening the CPIC process, EA enables USDA to improve key Department-wide enterprise hardware, software, and service agreements.

The quality of this work is supported by an IT Project Management Program. USDA has trained 480 project managers who have helped us keep our IT projects on schedule and within budget.

CONCLUSION

Mr. Chairman, we are always looking for creative ways to improve our services, reduce our costs and be good stewards of the tax payers dollars. With the continued support of this Subcommittee and the Congress, I am confident that we will continue to be successful in achieving our objectives.

PREPARED STATEMENT OF CHARLES R. CHRISTOPHERSON, JR., CHIEF FINANCIAL OFFICER, OFFICE OF THE CHIEF FINANCIAL OFFICER

Mr. Chairman and members of the Subcommittee, I am pleased to present the fiscal year 2008 budget request for the United States Department of Agriculture (USDA), Office of the Chief Financial Officer (OCFO) and the Department's Working Capital Fund (WCF).

The myriad of programs at the Department of Agriculture create a large financial organization. If compared to companies in the private sector, USDA would be both the ninth largest company and the ninth largest bank in the United States. Under the Chief Financial Officers Act of 1990 (CFO Act), the Chief Financial Officer (CFO) is responsible for the financial management of the Department including financial policy, personnel, systems, and budget execution. First, this testimony will address the key areas of my responsibility under the CFO Act and then proceed into the specific budget of the OCFO and WCF.

The President's budget for the Department of Agriculture is a comprehensive effort that involves the input of each mission area and staff office. The budgeting office does an exceptional job at managing and compiling the vast amount of financial information from each of the agencies within the Department. Over the years, the budget of the Department has remained relatively flat. The budget for fiscal year 2008 is lean and focused on the highest priorities of the Department.

Summary of Financial Operations and Processes

In the area of financial operations and policy, the Department of Agriculture continues to make vast improvements in business processes, improper payments, and internal controls. For fiscal year 2006, the Department of Agriculture attained another clean opinion on its annual financial statements.

Also during 2006, USDA achieved compliance with OMB Circular A-123, Appendix A by completing the assessment of Internal Controls over Financial Reporting in a single-year. This effort involved over 1,000 USDA employees from 29 agencies and staff offices. These employees documented over 5,000 controls within 13 financial cycles, 76 processes, and 92 financially significant systems. A significant number of the controls documented during this process were also tested. The assessment resulted in identifying four materials weaknesses which are:

- Obligations—Forest Service and Commodity Credit Corporation
- Management Estimates and Accruals—Forest Service and Commodity Credit Corporation
- Producer Payments and Commodity Loans—Commodity Credit Corporation
- Information Technology Controls—All Organizations
 - Software Change Controls
 - Disaster Recovery
 - Access Control—Logical
 - Access Control—Physical

To manage the internal controls and eliminate material weaknesses, the Department has instituted a Senior Management Control Council, Chaired by the Deputy Secretary and Co-Chaired by the CFO with its committee members comprised of the highest ranking officials in each of our agencies and staff offices. The members of this committee are dedicated to the proper management and safe keeping of the funds of our Nation's tax paying citizens.

In order to provide the most effective and efficient financial operations, this last year we started a dedicated effort of refining several of our processes and are actively moving to uniform processes, procedures, and systems across USDA. For example, this year we formed a grants committee to document the grants process across all mission areas of the Department. In the near future, a formal USDA process, with all of the correct internal controls, will be formally documented and we will start reducing the 13 grant systems into one. This will not be a new system, but one developed from a system currently in use in one of the agencies. The agency

that currently operates that system will retain the management of the system while OCFO will manage the policy, process changes, and approve system modifications. We are also moving toward uniform processes for loans, contract invoices, and insurance.

For all processes, we are moving toward solutions that provide electronic interfaces with the customers, automate document flow and approvals, and automate payments. The majority of the work will be accomplished with USDA employees and software that we currently own.

Over this last year, we strengthened our policy on measuring improper payments to be in better alignment with the Improper Payments Act. Under the Act, agencies are required to measure both incorrect payment amounts and incomplete qualifying paperwork. Under this new policy, the Department continued to reduce incorrect payment amounts, but incomplete qualifying paperwork increased. The majority of the paperwork errors are in the Farm Service Agency. So as not to misinterpret the outcome of the information and to show the Department's commitment to correcting the paperwork problem, we met with House and Senate Committees. During these meetings we communicated both the results and the corrective plan. The agency continues to move forward with the corrections and we expect to see a vast reduction in paperwork issues in this year's review.

Financial Systems

The Department's current primary financial systems were developed in the late 1970's and early 1980's. For the 2008 OCFO budget, includes a request to continue the replacement of financial systems that are critical for payments, reporting, and fiscal management.

Two financial systems are in need of replacement at USDA. The first is the core financial system; the second is the farm payments system. Currently the core financial system is comprised of nine general ledger systems which have not been supported by the vendor for several years. The systems do not meet Federal financial system requirements, and are showing the early signs of failure. The primary objective of the Financial Management Modernization Initiative (FMMI) is to replace this 20 year old, outdated mainframe technology providing for Department-wide expanded functional capability, full integration of critical system components and high-quality production and customer support. FMMI also addresses a critical and growing need for better integration of program, financial, and budgetary information to support more efficient and effective management of USDA's missions and improved delivery of programs against established performance goals and objectives. Based on both the risk and the savings, we have accelerated the implementation timeline of this system to a 3 year implementation.

The farm payments system is in critical need of modernization through replacement. This system manages the requirements and interactions of over 120 farm programs to create producer payments. The systems are homegrown, in an outdated programming language, and on hardware that is no longer manufactured. In addition, the systems cannot be modified to meet current Federal IT security requirements. Over the years, core financial software vendors have improved their products to support broader operational flexibility and requirements. Included in the request for proposals (RFP) for FMMI are the requirements and business cases to address the basic requirements of a modern farm programs system. We believe that the new financial system will provide a strong foundation to a modern and upgradeable payment system to support the farm programs.

These critical systems are in the early phases of failure and require a multi-year implementation cycle. It is very important that the funds for these systems are approved at their requested fiscal year 2008 budget levels.

Financial Personnel

Employee turnover in the Department for fiscal year 2005 equaled 8.36 percent. The majority of this turnover is related to retirements in the Department (4.6 percent). I believe that it is also safe to speculate that USDA turnover is impacted by promotions due to retirements in other government entities. We project that turnover due to retirements will increase by approximately 1 percent each year which equals approximately 8 percent (at least 12 percent with other elements of turnover) by fiscal year 2009. This high level of turnover places a significant amount of responsibility on our management teams, as they must transition knowledge based jobs. To address the transition and the shrinking workforce, the Office of the Chief Financial Officer is training the financial workforce, standardizing and documenting processes, and competing work skills that are available in the private sector.

Employee Training.—Office of the Chief Financial Officer has started training employees in the skills of Lean Six Sigma, which is characterized as an improvement

methodology because it uses data to identify waste and non-value added activities; reduce them, while improving service delivery. Through the Lean Six Sigma process, employees' document current business processes and then refine the process for a zero tolerance for errors; while using fewer resources and improving customer service. In addition, the Office of the Chief Financial Officer holds various training sessions every year in order to address the knowledge gap in financial and USDA knowledge due to the high turnover rate.

Competitive Sourcing.—Competitive sourcing provides a resource to supplement skills and resources of the Department's workforce. The Center for Naval Analysis conducted a study titled Long-run Costs and Performance Effects of Competitive Sourcing, and found that competition drove costs down over 30 percent while improving performance. The process is designed to select the competitor who can provide the most cost effective service delivery methodology to the Department and ultimately the taxpayers. Returns on investment are even greater for the activities that agencies have identified most frequently from competition: IT, maintenance/property management, logistics, HR/personnel servicing and education, and financial management. Two-year savings per Full-Time Equivalent studied in these categories generally range from \$25,000 to \$33,000. As required skill sets and technology change, the Federal sector, by using an external firm, can be flexible in the knowledge skill sets of technology teams by adjusting the requirements of the vendor's contract. Our veteran owned companies, small and disadvantaged businesses, as well as other private companies have been important to the past success of our government and will continue important technical skills in the future.

Recruitment.—Last, we need to continue to recruit employees from our nation's universities into the Federal workforce. These young employees bring excitement to the work environment and complementary technical skills to our knowledge based employees. Since the Federal requirements for accounting are slightly different than those taught in the universities, we will partner with the USDA Graduate School to provide the additional Federal knowledge.

This comprehensive approach to address the high turnover in the financial workforce should provide the Department with the employees required for the management and safeguarding of the assets appropriated by the Congress.

National Finance Center

Before we move to the budget request, I would be remiss if I did not discuss the National Finance Center. The National Finance Center (NFC), located in New Orleans, provides payroll processing and related services for approximately 33 percent of the Federal civilian workforce in more than 175 government entities. In fiscal year 2006, the NFC processed \$30 billion in payroll for approximately 595,000 Federal employees. The NFC provides a human resources suite of services to approximately 150,000 employees of which 72,000 are USDA employees in Farm Service Agency, Rural Development, Natural Resources Conservation Service, and Forest Service; and 69,400 Department of Homeland Security employees in Transportation Security Administration (TSA), Coast Guard and Headquarters. The NFC services the Office of Personnel Management performing health benefit reconciliations and health care premium processing on a Government-wide level. Finally, the NFC provides personnel transaction processing services for several agencies including TSA, Coast Guard and Federal Emergency Management Agency (FEMA).

The National Finance Center continues to prove the efficiencies and effectiveness of a very focused shared services operation. The payroll, human capital, and data center operations continue to be a low cost provider with a very high level of customer satisfaction. During fiscal year 2006, the NFC operations returned to New Orleans after relocating due to Hurricane Katrina. At the time of the return, the New Orleans area was still in the early stages of rebuild. The NFC employees have endured long lines at the limited number of grocery facilities, the constraints of living in FEMA trailers, slow payments of insurance proceeds, inflation in the cost of property insurance, and other hurdles. In addition, employees have increased workload as the employee vacancy rate has increased due to separations and retirements. Even with all of these hurdles, the work from the three CFO operations at the NFC is exceptional. We are very proud of these employees and consider them pioneers in the rebuild of New Orleans. Last year's significant results for the National Finance Center include:

- Reduction of backlogs to pre-Katrina levels.
- Implementation of the Department of Justice to the payroll system (30,000 employees).
- First stage implementation of Forest Service to the Human Resource Line of Business suite of services.

—Selection of and significant progress on the Primary Computer Facility (PCF). As disclosed in our report to Congress, the Primary Computer Facility is located at the Denver Federal Center. The project is on target to complete the relocation of the systems from the temporary disaster recovery facilities to the PCF by June 2007.

Budget of the Office of the Chief Financial Officer

The OCFO is responsible for the financial management of an enterprise with almost \$75 billion in annual spending, over 106,000 full time equivalents (staff years) and over \$134 billion in assets.

Areas of focus for fiscal year 2008 include supporting shared services that reduce the cost to USDA mission areas and the Federal Government; strengthening the financial operations of the program areas; completing uniform processes and procedures; creating efficient IT solutions; remediation of deficiencies in internal controls, and progressing in the implementation of the systems in critical need of replacement.

Our fiscal year 2008 operating budget request is for \$30.8 million, which includes increases for 2007 and 2008 pay costs as well as the replacement of the core financial system. Approximately 90 percent of the OCFO's obligations are for the salaries and benefits of the OCFO employees. OCFO is a labor intensive staff office with very little ability to absorb pay cost increases without holding a large number of positions vacant for the entire fiscal year; thereby adversely affecting its ability to lead the Department in the areas of financial management, oversight, and guidance necessary to prevent fraud, waste, and abuse; reduce risk of improper payments, plan for financial systems, and to institute proper internal financial controls. The pay-related increases requested are necessary for us to accomplish key outcomes and to successfully meet our goals for fiscal year 2008.

OCFO is requesting an increase in funding to partially fund the implementation of the system used to replace our core financial management systems and provide a foundation to the farm payments system. These systems are in critical need of replacement. As I stated above, this core system is replacing nine general ledger systems currently operating in USDA and provides the foundation system for the modernization of the farm payment system. Currently these systems do not meet the requirement of financial systems as required by the Federal Financial Management Improvement Act, are showing early signs of failure, and are no longer supported by the vendor. If the current systems fail, the Department will not be able to report required financial information, manage receipts, or produce payments. This system will also replace the four general ledger systems and five payment modules currently contained in the farm payment systems (all of which are no longer supported by the vendor). Continued reliance upon this old technology poses unacceptable risks to USDA financial operations and data. I greatly appreciate your support in the replacement of these key systems.

USDA Working Capital Fund

The CFO is responsible for the budget of the Department's Working Capital Fund (WCF). The WCF serves as the Department's principal investment engine to achieve progress in developing and implementing new corporate systems.

Unobligated Funds.—Under the authority of Congress, USDA is allowed to transfer unobligated balances from discretionary accounts into the WCF. For fiscal year 2005 the transfer was approximately \$2 million and for fiscal year 2006 the transfer was approximately \$4 million. During that same period we have received capital project requests for unobligated funds in excess of \$30 million. While all of the requests appear to be very important, we have placed a priority to statutory obligations. The first obligation is for the capital required to meet the reporting requirements of the Transparency Act passed by Congress in this fiscal year. The next priority is to meet a small amount of the capital requirements of the PCF. As previously reported to Congress, the PCF will be operational by June of this year. The information concerning the transfer of unobligated funds and the capital requests for these funds will be reported to the Committees on Appropriations in the near future.

Working Capital Funds—Capital.—For fiscal year 2007, request for the hardware to support corporate systems and facilities equaled \$84.5 million. The Department's available balance for allocation was \$24.8 million. The Department graded the investments with statutory, security, and disaster recovery receiving the highest scores for funding. Statutory investments include NFC's PFC, NFC's backup facility, and Homeland Security Operation Plan system. We are grateful for the support and look forward to working with the Committee as we repair and improve our corporate systems.

Working Capital Funds—Operations.—In addition to the investments in corporate systems, the WCF supports the operations of our shared service activities. These services include financial management, information technology, payroll, human capital systems, communications, administration, as well as record keeping and item processing. It is our objective to use this financing mechanism to provide to the mission areas and the Federal Government the most effective cost-efficient services available.

The President's fiscal year 2007 budget estimates that total costs for recurring operations in the WCF in fiscal year 2008 will be \$534.3 million, a 3.7 percent increase over the fiscal year 2007 estimate. The majority of this increase is to move the Department to a uniform human resource system hosted at the National Finance Center and an increase in the cost of services at the National Information Technology Center. Also included in the fund are such services as: video and teleconferencing production services provided by the Broadcast and Media Technology Center in the Office of Communications; personal property, mail, duplicating, and acquisition system provided by Department Administration.

I would like to point out that the WCF financing mechanism, as a reimbursement for goods and services provided, gives us an opportunity to refine our estimates as newer and better information becomes available regarding customer demand and costs. Our office is working with activity centers to review fiscal year 2008 estimates with the goal of reducing the cost of individual services that are provided to USDA agencies. It was with this objective in mind that we were able to submit an operating estimate for fiscal year 2008 that is consistent with expected inflation.

One thing we have done to impose more discipline on costs is to require individual activities to begin compiling and reporting costs for specific business lines within their respective activities. This method is being developed and refined as we move forward in fiscal year 2007 and will be a critical element as we revisit fiscal year 2008 cost estimates. As we begin development of the fiscal year 2009 budget this spring, we will be reexamining fiscal year 2008 estimates for more economies and savings. As has been the practice for the last 2 fiscal years, we will establish spending targets for WCF activities that take into account the Department's spending priorities among its agencies reflected in the President's budget.

Last year, we expressed to the Committee our appreciation for all of the assistance and support provided to the Department in the wake of Hurricane Katrina. It was a critical ingredient in our ability to resume normal business operations and recover from that event. We have continued to strengthen our business continuity practices, and we are working to ensure that in the event of the need to respond to a similar natural disaster in the future we are positioned even better to respond and ensure uninterrupted service to our customers. For your continued support in that effort, we are grateful.

Thank you, Mr. Chairman, for the opportunity to share the results we have achieved and our fiscal year 2008 budget request with the Subcommittee. We have very dedicated employees that are passionate about nature and conservation, food assistance and the Nation's health, rural America and renewable energy, food production and safety, and the vast benefits of scientific research. The budget for such a large Department is an effort based on the goals of our 5 year strategic plan, the highest priorities of each mission area, and replacing critical support infrastructure. We look forward to working together with you and the Subcommittee in fulfilling the vision for financial management and accountability we all have for USDA.

PREPARED STATEMENT OF MARGO M. MCKAY, ASSISTANT SECRETARY FOR CIVIL RIGHTS, OFFICE OF THE ASSISTANT SECRETARY FOR CIVIL RIGHTS

Mr. Chairman and members of the Subcommittee, thank you for the opportunity to submit this statement supporting the President's fiscal year 2008 budget proposal for the United States Department of Agriculture's (USDA) Office of the Assistant Secretary for Civil Rights (ASCR).

The Office of the ASCR provides policy guidance, leadership, outreach, coordination, training, and complaint prevention and processing for USDA. Our mission is to provide equal opportunity, equal access and fair treatment for all USDA customers and employees.

The Office of Civil Rights, under the ASCR, has made significant progress in complaint processing and complaint prevention. Overall USDA experienced a 15 percent decrease in the number of new Equal Employment Opportunity (EEO) complaints filed during fiscal year 2006 as compared to fiscal year 2005. The decrease in EEO complaint filing is attributed to factors such as increased usage of the Alternative

Disputes Resolution (ADR) process, improved compliance and accountability, and an overall decrease in the size of the workforce.

We have also strengthened our compliance and outreach efforts. In August 2006, we convened our Third Annual Partners' Meeting. This is a principal outreach effort for organizations representing underserved populations, including minority, small and limited resource farmers. These meetings continue dialogue with USDA stakeholders, providing a forum through which the voices and concerns of underserved constituents can be heard by USDA, and avenues can be found for resolving long-standing issues of access and accountability.

FISCAL YEAR 2008 OBJECTIVES

The Office of Civil Rights (CR) has the following strategic objectives for fiscal year 2008 that contributes to the Department's success. They are to:

- Ensure employees and applicants are provided equal opportunities in all aspects of employment activities.
- Ensure USDA employment activities are conducted in a nondiscriminatory manner and agencies comply with CR/EEO laws, rules and regulations related to women, minorities, and persons with disabilities.
- Ensure equal access to USDA programs.
- Ensure Program and EEO complaints are timely processed.
- Ensure complaints are processed in an efficient and cost-effective manner.
- Increase USDA-wide awareness and use of Alternative Dispute Resolution (ADR), and resolution of conflicts through ADR in the early stages of workplace and program disputes (non-civil rights).
- Establish effective outreach programs in the Department to ensure equal and timely access to USDA programs and services for all customers, with special emphasis on the minority and underserved.

FISCAL YEAR 2008 KEY OUTCOMES

CR plans to achieve the following key outcomes in fiscal year 2008:

- Decrease in the number of individual EEO and Program complaints filed.
- Reduction in the average number of days to process Program and EEO complaints to issuance of Report of Investigation and Final Agency Decisions.
- Increase in the efficiency and cost-effectiveness of processing of Program and EEO complaints within the regulatory timeframes.
- Increase in ADR usage.
- Increase the number of minority, underserved, and socially disadvantaged persons made aware of USDA programs and services.

FISCAL YEAR 2008 BUDGET REQUEST

The fiscal year 2008 Appropriation request for CR is \$23.1 million. The funding request includes increases for the following:

- Civil Rights Enterprise System Improvements.*—Funds for the Civil Rights Enterprise System are requested to continue the expansion of the complaints processing system. Funding is necessary to support the President's Management Agenda initiative of expanding electronic government by improving complainant/customer access to information about the complaints and providing a more accountable mechanism for EEO and Program complaint filing. USDA agencies will be able to interface on a Web-based system that will provide customers and employees real-time data regarding their discrimination complaints. The system encompasses a planned multi-year phased approach projected through fiscal year 2009. After fiscal year 2009, the implementation of the system will be complete and funds will only be needed to support operation and maintenance.
- Compliance Monitoring Activities.*—Funding is needed to meet new requirements designed to meet the affirmative employment goals of the Equal Employment Opportunity Commission's Management Directive 715. In addition, CR will undertake significant compliance activities in the field offices. Compliance reviews will result in civil rights complaint prevention and new complaint reductions.
- Pay cost.*—Funding is needed for the 2007 and 2008 pay raises.

I would like to emphasize the importance of the Subcommittee's approval of the President's \$23.1 million budget for CR. The proposed budget will help ensure that USDA continues to make substantial progress toward providing fair and equitable delivery of our services and programs to our customers and protecting the civil rights of USDA employees.

PREPARED STATEMENT OF TERRI TEUBER, DIRECTOR, OFFICE OF COMMUNICATIONS

Mr. Chairman and members of the Subcommittee, I am pleased to discuss the fiscal year 2008 budget request for the Department of Agriculture's Office of Communications (OC).

When Congress wrote the law establishing the U.S. Department of Agriculture in 1862, it said the Department's "... general designs and duties shall be to acquire and to diffuse among the people of the United States useful information on subjects connected with agriculture in the most general and comprehensive sense of the word." OC coordinates the implementation of that original mandate.

OC coordinates communications with the public about USDA's programs, functions, and initiatives, providing vital information to the customers and constituency groups who depend on the Department's services for their well-being. For example, OC is coordinating the Department's communications efforts relating to the threat of avian influenza (AI) and is prepared, if necessary, to activate a Joint Information Center (JIC) funded through the Supplemental Appropriation, which would support the Department in meeting its obligations in the event of an AI detection and/or outbreak. This effort is a follow-on to efforts OC has undertaken in the past to inform the public of the Department's actions taken to protect animal and human health. OC assisted in addressing such serious issues as bovine spongiform encephalopathy (BSE), which have been of interest to consumers around the world. In addition, OC also coordinates the communications activities of USDA's seven major mission areas and provides leadership for communications within the Department to USDA employees.

OC is adopting new technologies to meet the increased demands for the dissemination of accurate information in a timely manner. Using the Internet, radio, television and teleconference facilities, we are able to ensure that the millions of Americans whose lives are affected by USDA's programs receive the latest and most complete information. As the continuing concern over AI and BSE incidents demonstrate, these technologies are a critical resource used by the Secretary and the agencies to provide timely information, which helps to maintain consumer confidence and stabilize agricultural markets.

OC's 5-year strategic goal is to provide maximum support to all mission areas of the Department in the development of programs and in creating awareness among the American public about USDA's initiatives and services. This is essential to providing effective customer services and efficient program delivery. As a result, we expect more citizens, especially those in underserved communities and geographic areas, to access helpful USDA services and information. A central element of this support is OC's active participation in the Department's eGovernment initiative as part of the President's Management Agenda. OC plays a key role in ensuring that the Department's eGovernment implementation results in the public's improved access to more current, accurate, relevant, and organized USDA products, services, and information. The USDA.gov portal, managed by OC, is customer- or citizen-centric, allowing OC to target information by audience preference, subject and personalization. On average, 1.5 million citizens access the site weekly. The demand by citizens and other constituencies for information, via USDA.gov, Web casting, electronic mail distribution, teleconferences, and publications, is expected to continue to increase.

OC will continue to take an active role in policy and program management discussions by coordinating the public communication of USDA initiatives. We will continue to provide centralized operations for the production, review, and distribution of USDA information to its customers and the general public. Also, we will monitor and evaluate the results of these communications. Our staff is instructed to use the most effective and efficient communications technology, methods, and standards in carrying out communications plans.

Also, we are focusing on improved communications with USDA employees, especially those away from headquarters, which will enhance their understanding of USDA's general goals and policy priorities, programs and services, and cross-cutting initiatives.

Our office will continue to work hard to meet our performance goals and objectives. We will work to communicate updated USDA regulations and guidelines, conduct regular training sessions for USDA communications staff about using communication technologies and processes to enhance public service, foster accountability for communications management performance throughout USDA, and continue to work to create a more efficient, effective and centralized OC.

Increasing availability of USDA information and products to underserved communities and geographic areas through USDA's outreach efforts is integral to our per-

formance efforts. OC will continue to provide equal opportunity for employment and promote an atmosphere that values individuals.

FISCAL YEAR 2008 BUDGET REQUEST

OC is requesting a budget of \$9,720,000, which includes an increase to cover fiscal year 2007 and fiscal year 2008 pay costs.

As more than 89 percent of OC's obligations are for salaries and benefits, the requested increase is vital to support and maintain staffing levels for current and projected demands for our products and services. While OC has realized some cost savings by replacing high grade employees who have retired with lower grade employees, our current budget leaves little flexibility for absorbing increased costs. In fact, OC would not be able to absorb the increased salary costs in fiscal year 2008 without placing considerable constraints on daily operations or affecting staff size and therefore the timely delivery of information to the public.

Our central task is to ensure the development of communications strategies, which are vital to the overall formation, awareness and acceptance of USDA programs and policies. OC has led the adoption of content management software which speeds the addition of new material, improves our quality control measures to ensure the accuracy of the information available through USDA.gov, and reduces the staff time required for overall maintenance of the site.

This improved control greatly reduces the time necessary to post important information to the media and the public while providing a greater ability to ensure the accuracy of the information. This allows OC to use a large document and Web repository, sharing resources and information with mission areas and agencies as well as the public.

OC looks forward to continuing our commitment to the American public by providing timely, accurate information about our programs and services.

This concludes my statement, Mr. Chairman. I will be pleased to respond to any questions.

PREPARED STATEMENT OF KEITH COLLINS, CHIEF ECONOMIST

Mr. Chairman and members of the Subcommittee, thank you for the opportunity to discuss the general economic situation in U.S. agriculture as background for the Subcommittee's review of the Department of Agriculture's (USDA) fiscal year 2008 budget submission. I will review the major factors affecting agricultural markets in the coming year and their implications for financial conditions in U.S. agriculture.

U.S. agriculture continues to prosper following the economic slowdown at the start of this decade. With solid growth in domestic and export demand, large crop harvests, and record-high cattle, broiler and milk prices, net cash farm income reached a record high \$81.5 billion in 2004. In 2005, net cash farm income was nearly as high and the second highest on record despite a large increase in crop stocks which reduced crop prices; multiple hurricanes that shut down the central marketing infrastructure of the country; sharply higher energy prices that raised production, marketing and processing costs; continued loss of Asian beef markets; and the emergence of global Avian Influenza (AI) concerns. In 2006, net cash farm income is estimated at \$66.7 billion, down from the previous 2 years, reflecting lower milk prices and government payments, smaller crop harvests, plus higher production expenses, especially energy costs.

In 2007, global economic growth and food demand is expected to remain strong. However, growing demand for biofuels is expected to be the key factor driving crop prices. Markets for most major crops will experience stronger prices as stock levels decline. In addition, continued expansion of livestock production following several years of profitable returns could lead to slightly lower market prices for cattle and hogs. Weather, energy costs, higher interest rates, and a slow recovery of foreign markets due to animal health concerns are also likely to be factors affecting economic performance. Together, these factors suggest that net cash farm income will rise modestly in 2007. Rising expenses will cause financial stress for some farming operations, particularly livestock and poultry producers, but the overall farm economy is expected to perform above long-term average levels with net cash farm income forecast at \$67.2 billion, farm household income remaining strong, and farm net worth continuing to increase.

Global Economic Growth and Farm Product Demand

The U.S. economy grew at 3.4 percent in 2006, up from 2005's 3.2 percent but below 2004's 3.9 percent. For 2007, U.S. Gross Domestic Product (GDP) growth is expected to be slightly less than last year. The decline in the rate of growth in 2007

from last year is expected to be due to slower growth in consumption, weak housing, and tight energy markets. Increased tightness in labor markets is likely also to be a factor. As the unemployment rate remains low, productivity growth and output growth usually remain at or just below trend.

Real foreign economic growth accelerated in 2006 to 4.0 percent from 2005's strong growth rate of 3.7 percent, with many areas improving, particularly Western Europe and Asia. This year, Western Europe is expected to grow at above 2 percent for the second consecutive year, the first time this has happened since 1999–2000. Growth in Japan, Canada, and Mexico are expected to be slightly below 2006. Asia, excluding Japan, will likely grow at 7 percent in 2007, above trend for the 4th consecutive year. Foreign economic growth is expected to be 3.7 percent in 2007, down slightly from 2006, but well above trend, as has been the case beginning in 2004.

With the U.S. economy expected to have another year of steady growth, consumption expenditures on food continue to rise, although the rate of growth is likely to decline to near 4.4 percent from the unusually high 6 percent growth in 2006. Growth was less than 2.5 percent during the economic slowdown in 2001 and 2002. This year, slower growth in consumer spending on food is likely, as consumers face heavy debt loads and high energy costs and are less likely to use household assets to finance consumption. Consumer spending, which accounts for two-thirds of GDP, increased by 4.4 percent in the last quarter of 2006, well above the third-quarter, but a slowdown is expected in the first quarter of 2007.

U.S. Agricultural Trade

Turning to foreign demand for U.S. agricultural products, our latest quarterly forecast for farm exports in fiscal year 2007, released in March, is a record-high \$78 billion, up \$9.3 billion from fiscal year 2006's record. Gains are expected across the board in grains and feeds, livestock, and horticultural products.

U.S. agricultural imports are forecast at a record \$70 billion, \$6 billion more than in fiscal year 2006. The agricultural trade surplus for fiscal year 2007 is forecast at \$8 billion, up from \$4.7 billion in fiscal year 2006.

While the agricultural export-weighted value of the dollar appreciated in the first half of 2006, it has depreciated steadily since July, continuing its declining long-term trend from 2001. The current period of strong foreign economic growth and continued effects of the decline in the value of the dollar from several years ago should result in higher U.S. agricultural exports in the future and a modestly improving trade balance. However, strong consumption growth in the United States and consumers' desire for year-round fruits and vegetables, as well as more variety, suggest the trade surplus in the future will be smaller than in the past. USDA's long-run projections issued February 14, 2007, forecast U.S. agricultural exports rising to nearly \$94.8 billion by fiscal year 2016 and imports rising at an even faster pace to \$92.7 billion, leaving a trade surplus of \$2.1 billion.

Major Crops: Supply, Demand, and Price

The 2005/06 marketing year began with relatively ample world crop supplies. Thus, despite declines in production of grains and cotton, stocks remained relatively stable year-to-year. Global oilseed production was record high in 2005/06, boosting stocks to record levels. As a result of these generally plentiful supplies, market prices were relatively flat. In 2006/2007, global wheat and coarse grain production declined as weather problems affected output. World oilseed production set another record and world cotton production rose slightly. Global total use this year is expected to rise for rice, coarse grains, oilseeds, and cotton. Global wheat use is expected to decline modestly, reflecting tighter supplies and higher prices. With generally lower production and rising consumption, global stocks of most major commodities, except oilseeds, will decline in 2006/2007, and grain (wheat and coarse grain) stocks will fall well below last year's levels. In the United States, supplies for feed grains, cotton, and rice are well below their record levels in 2005/2006. U.S. wheat supplies are down sharply from 2005/2006, but soybean supplies set another record.

With world grain consumption during 2006/2007 expected to exceed last year's record high and again exceed world production, world grain stocks as a percent of total use are expected to fall to 15.5 percent, compared with 19.5 percent in 2005/2006. The picture for oilseeds is quite different as global soybean production is forecast to be record high for the third consecutive year, exceed consumption, and result in higher global stocks. For soybeans, global stocks as a percent of use is forecast to exceed the high set in 1986. World cotton stocks are expected to decline slightly as consumption exceeds production for the second consecutive season.

For the United States, good grain and oilseed harvests and strong demand have supported above average farm income in recent years. Current market prospects

look even brighter as growth in demand, particularly for producing biofuels, has pushed grain prices to 10-year highs. High grain prices and demand for vegetable oil have also pushed soybean prices higher, despite the higher soybean supplies.

U.S. soybean stocks are expected to be record high at the end of 2006/2007, rising 132 percent above the level of 2 years ago. This jump reflects the bumper harvest this past fall and the highest beginning stocks in 20 years. This stock buildup is projected despite expected record soybean crush and exports. Still, U.S. soybean prices this winter have been strong in the face of the prospective stock buildup, reflecting higher corn prices, purchases by index funds, and strong, biodiesel-driven soybean oil prices. For the year as a whole, the farm price received for soybeans is expected to average \$6.30 per bushel compared with \$5.66 last marketing year. Despite prospects for record production in the Southern Hemisphere and the increase in U.S. stocks, soybean prices will likely remain strong in the second half of the year, reflecting relatively high corn prices.

For 2007/2008, high corn prices relative to soybeans likely will cause a sharp swing away from soybean planting. We expect a reduction in soybean planted area of about 5 million acres. Lower planted area, combined with trend yields, would result in production below expected use; consequently, carryover levels would decline significantly. Reduced production, lower stocks, and high corn prices should keep soybean prices strong into 2007/2008.

The U.S. corn market in 2006/2007 is expected to see a second year of declining carryover as ending stocks fall markedly from 2005/2006. Corn prices have risen sharply since September 2006 when the market began to reflect the extraordinary ongoing expansion in corn-based ethanol production capacity. Additional factors supporting the rapid rise in corn prices have been the decline in 2006-crop corn acreage and yield and strong export demand. Farm-level corn prices are expected to average \$3.20 per bushel this marketing year, up substantially from \$2.00 per bushel last year. The increase in prices nearly eliminated loan deficiency payments (LDPs) and marketing loan gains (MLGs) for 2006-crop corn. As of March 2007, LDPs and MLGs totaled only \$3 million on 2006-crop corn with all of these payments occurring in the first weeks of the marketing year. For the 2005 crop, LDPs and MLGs totaled \$4.6 billion, with 97 percent of that year's production receiving an average payment of \$0.42 per bushel.

Biofuels is now the most important influence on corn and other crop markets. Ethanol production this marketing year is expected to account for 20 percent of U.S. corn production. The USDA's long-term projections to 2016, released on February 14, 2007, project ethanol production will account for 30 percent of corn use by 2009/2010 and drive corn prices to \$3.75 per bushel. Biodiesel production has increased from less than a half million gallons in 1999 to over 225 million in 2006, equivalent to 8 percent of soybean oil production.

In 2004, ethanol accounted for about 2 percent of motor gasoline use in the United States on a volume basis. Under the Department of Energy's Annual Energy Outlook 2007, ethanol use is expected to grow to over 7 percent of motor gasoline use by 2010. The USDA projections to 2016 put corn-based ethanol production at 11 billion gallons by 2010/2011. This would be a 3-fold increase in corn ethanol production since 2004/2005.

As a result of higher prices and returns for corn fueled by the expansion in ethanol use, corn area is expected to expand by about 9 million acres in 2007. Much of this increase will come from soybeans. Additionally, area for cotton, hay, and other crops are all expected to decline to meet the demand for more corn production. Even with higher acreage and production, corn ending stocks are likely to tighten again in 2007/2008 and remain at relatively tight levels in the coming years as ethanol demand continues to be strong.

The 2006/2007 wheat market reflects tighter world supplies, but continued strong demand. U.S. wheat stocks at the end of this marketing year are projected to decline from their levels in 2005/2006 as a result of weather problems that reduced yields in 2006. Farm prices are forecast to average \$4.25 per bushel, up from \$3.42 in 2005/2006 and \$3.40 in 2004/2005. Prices in 2006/2007 have been boosted by weather problems in the United States and in Australia that reduced this year's production. Wheat prices have also benefited from rising corn prices.

For 2007/2008, wheat acreage, which has been trending downward over the past 25 years, is expected to increase by nearly 3 million acres due to higher prices last fall that encouraged more seeding of winter wheat. Heavy fall rains limited seeding in the eastern Corn Belt, but the area is up for all classes of winter wheat. Yield prospects for the 2007 crop remain favorable at this time as winter storms have brought much needed precipitation to the Central and Southern Plains. Global wheat production prospects are also good with most major wheat producing countries expected to expand acreage in 2007 because of strong prices. Weather in most

of the major-producing countries has remained favorable for winter seeded crops. This suggests global wheat production will rise in 2007/2008. Based on trend yields, U.S. wheat production is expected to rebound in 2007, hitting its highest level since 2003. Despite higher expected demand, especially for feeding, ending stocks are expected to increase. Prices, however, are expected to be higher than in 2006/2007 as higher corn prices put a floor under wheat feeding value.

U.S. cotton production fell 9 percent in 2006/2007 from the previous year's record, however, carryover stocks are still expected to rise for the third consecutive year and reach nearly 9 million bales. The increase is the result of declining domestic textile mill use and cotton exports. U.S. cotton mill use continues to trend down as textile mill activity continues to move offshore. Mill use this year is forecast at 5 million bales, compared with 5.9 million last season. Exports are forecast to decline by over 20 percent from last year's record to 14.0 million bales. Lower exports are due mainly to reduced import demand by China, the largest U.S. customer. Farm prices of cotton have been running about the same as year-ago levels. For 2007/2008, lower acreage and production are expected to support prices. With the prospect of stronger exports due to rising world demand, ending stocks will likely decline.

Tighter domestic rice supplies and higher global prices have helped to boost U.S. farm prices in 2006/2007. The global rice market is a major factor contributing to strong U.S. farm prices as global ending stocks are expected to be the lowest since 1983/1984 and the lowest stocks-to-use ratio since 1981/1982. The season-average-farm price is forecast at \$9.85 per cwt, over \$2 per cwt above the year earlier average price and the highest since 1996/1997. Rice ending stocks are forecast at 31 million cwt, down from carry-in stocks of 43 million cwt. Medium and short grain stocks, at about 8 million cwt, are the tightest since 1998/1999.

A reduction in area in 2006 led to a decline in production. Higher fuel and fertilizer prices, difficulty acquiring bank loans, and weather-related problems in some areas—especially Louisiana and parts of Arkansas—accounted for much of the area decline in the South. A second consecutive cold, wet spring prevented California growers from boosting rice acreage, despite high prices and expectations of tight global supplies of medium-grain rice.

On the demand side, impact in some markets from the discovery of trace elements of a genetically engineered strain of rice—Liberty Link Rice 601 (LL601)—in U.S. long-grain supplies and reduced production are behind expectations of weaker U.S. exports in 2006/2007—forecast at 102 million cwt, down 12 percent from the year earlier. Despite an expected drop in exports to Europe due to the European Union's rejection of U.S. rice due to LL601, U.S. exports to markets in the Western Hemisphere, Northeast Asia, and the Middle East are expected to be strong.

For 2007/2008, U.S. farm prices of rice are expected to strengthen on continued tight domestic supplies and firm global prices. Planted area is expected to be about the same as 2006 with a rebound in California, but a reduction in area in the South. Higher net returns for competing crops—mostly corn, restrictions on the planting of Clearfield CL131 seed and low government payments could lead to reduced rice planted area in the South. Total use and ending stocks are expected to be about the same as 2006/2007.

Farm program costs for the 2006 program crops are sharply lower due to higher grains and oilseeds prices. Counter-cyclical payments are projected at \$1.5 billion, down from \$4.7 billion from the 2005 crops. Outlays for 2006-crop marketing loan benefits are projected at \$900 million, down substantially from \$6.3 billion for the 2005 crops. Program crop producers also receive more than \$5.2 billion annually in direct payments.

The 2006/2007 sugar market has differed from other crops this year as prices have declined, returning from the extreme highs attained when hurricanes drastically reduced supplies in 2005/2006. To meet this year's demand and help relieve market tightness, USDA increased import quotas above the minimums established under the World Trade Organization. However, 2006/2007 sugar imports, forecast at 2 million tons, would be down from 3.4 million tons last year.

Farm sales of fruits, nuts, vegetables, and nursery and greenhouse products are expected to remain steady at \$53 billion in 2007, accounting for 40 percent of all crop cash receipts. Fiscal year 2007 U.S. horticultural exports are forecast at \$18.4 billion and imports at \$31.2 billion, indicating a continuing widening of the sector's traditional trade deficit.

Livestock & Livestock Products: Production, Demand, and Price

Turning to livestock and poultry markets, U.S. red meat and poultry exports are expected to reach a record high in 2007. Pork exports are forecast to lead the way, increasing for the 17 consecutive year and exceeding 3.1 billion pounds carcass

weight or 14.6 percent of production. After depressed sales in early 2006, poultry sales increased as foreign concerns about AI abated and United States broiler meat prices declined. Broiler exports likely will increase to 5.4 billion pounds in 2007, but fall short of the record 5.6 billion pounds exported in 2001. Beef exports are expected to increase with the gradual expansion of exports to Japan and Korea. However, Korea's import restrictions and Japan's age limits on imported beef from the United States continue to limit growth. Although total beef exports are expected to increase 17 percent to 1.3 billion pounds in 2007, the level of exports will remain below the 2003 pre-bovine spongiform encephalopathy level of 2.5 billion pounds.

Total U.S. production of meat and poultry is expected to be record-high in calendar year 2007, but nearly flat growth in supplies of broiler meat are expected to support higher broiler prices and help maintain cattle and hog prices near last year's levels. For livestock and poultry producers, feed prices will be an important component of producer production decisions in the upcoming year.

Beef production is currently forecast to increase 1.6 percent in 2006 as both slaughter numbers increase. Slaughter weights could decline in 2006 due to higher feed prices. Steer prices will likely remain near last year's \$85.41 per cwt and average \$84–\$89 per cwt. Poor forage conditions resulted in higher cow slaughter during 2006 as many producers lacked sufficient forage resources to support their herds. Herd expansion is expected to be slow as the January Cattle report indicated a small calf crop and producers expected to retain 0.5 percent fewer heifers for addition to the beef breeding herd.

Pork production in 2007 will expand about 2.6 percent, marking the 7 year of expansion as producers continue to respond to favorable returns over the last several years. Given farrowing intentions reported in the most recent Hogs and Pigs report, inventories will continue to expand, albeit at slower rates. The increase in 2007 production primarily will reflect increased slaughter as weight gains will be limited as producers respond to higher feed prices. Hog prices are expected to reflect the increased production, declining from 2006's \$47.26 per cwt to average \$45–47 per cwt.

Broiler producers have endured several periods of low returns due to relatively low broiler prices in 2005 and 2006 and higher feed costs. Consequently, producers reduced chicks placed in 2006, resulting in the lowest rate of production growth since the early 1980s. Production growth in 2007 is expected to be even slower. With tighter broiler meat supplies, prices are expected to average 72–77 cents per pound in 2007, up 16 percent from 2006.

Milk producers are expected to respond to higher feed prices and lower 2006 milk prices by modestly reducing cow inventories and as a result, the rate of growth of milk production in 2007 will be slower than in 2006. Production in 2006 increased almost 3 percent and the all-milk price declined to \$12.90 per cwt from \$15.15 per cwt in 2005. Output per cow in 2006 was affected by abnormally high temperatures in much of the country during the summer, but growth is expected to follow a more normal pattern in 2007. Demand for dairy products, both domestically and for export, is expected to remain relatively firm in 2007. Commercial exports of nonfat dry milk and whey are likely to remain strong, reflecting limited supplies from competing exporters. Domestic demand for cheese and butter is also likely to remain firm, thus, prices of cheese, butter, nonfat dry milk, and whey are all forecast higher in 2007 and will support the all-milk price at \$15.05–\$15.65 per cwt. With product prices above support, no Commodity Credit Corporation net removals are forecast.

Implications for the Financial Situation of U.S. Agriculture

Net cash farm income declined to \$66.7 billion in 2006 from the record and near record levels of 2004 and 2005 but is expected to be slightly higher at \$67.2 billion in 2007. This year strong crop prices and a modest increase in livestock receipts are expected to lead to a \$16 billion rise in cash receipts to a record-high \$258.7 billion. This large increase in cash receipts is not translating into a large increase in net cash farm income because much of the increase in market receipts is expected to be offset by higher cash expenses and declining government payments.

In 2005, government payments to producers were a record high \$24.3 billion, declined to \$16.3 billion in 2006, and are expected to fall to \$12.4 billion in 2007. In 2005, increased marketing loan costs, higher counter-cyclical payments, ad hoc disaster assistance, and tobacco program buyout payments, all contributed to higher government payments. Lower ad hoc disaster payments, marketing assistance loan outlays, and counter-cyclical payments will combine to reduce direct government payments in 2007, as they did in 2006.

Cash production expenses are expected to rise 6 percent, or \$12.2 billion, in 2007 following increases of 5 percent in 2006 and 7 percent in 2005. Energy-related inputs (fertilizer, lime, fuels, oils, and electricity) increased by \$1.9 billion in 2006 and are expected to rise by nearly \$1 billion in 2007. Fuels and oils expenses are ex-

pected to moderate in 2007 as the Department of Energy projects that diesel prices in 2007 will fall by 1.8 percent from 2006.

Farm household income is also expected to recover in 2007, after its first decline in 7 years in 2006. At over \$80,700 in 2006, farm household income would still be 20 percent higher than in 2003 and well above the average of all U.S. households.

Farm real estate values are expected to rise again in 2007, following a 7.5 percent gain in 2006. Another land value increase would continue the recent strong improvement in the farm sector balance sheet. The ratio of real estate value to net cash farm income, a concept similar to a price-to-earnings ratio, is forecast to remain high in 2007, near the highest level since the early 1980s. Between 2003 and 2006, farm net worth went up by \$510 billion or about \$170 billion per year, which is far more than the annual increase in farm income and farm debt. In 2007, increases in farm real estate values are expected to slow to 4.7 percent and farm net worth is expected to increase by \$66 billion. Farm net worth is expected to reach another record high at \$1.76 trillion by the end of 2007, and the debt-to-equity ratio is forecast to remain at 13.4 percent, which would be the lowest on record.

A return to slightly above average national farm income, for the second consecutive year, is likely to keep U.S. agriculture on a sustainable foundation. Most production sectors in U.S. agriculture are expected to see net cash income the same or higher in 2007, with hogs being the main exception. Farm prosperity in the coming year will be influenced by the durability of the United States foreign economic growth, oil prices, the value of the dollar, the ongoing biofuels production expansion and its impacts for feed costs, and trade-related animal health issues. The outcome of trade and farm bill negotiations will also be crucial determinants of the future direction of U.S. agriculture.

FISCAL YEAR 2008 BUDGET REQUEST

The Office of the Chief Economist (OCE) advises the Secretary of Agriculture on the economic implications of USDA policies, programs and proposed legislation. OCE serves as the focal point for the Nation's agricultural economic intelligence and projections, risk analysis, global change issues, and cost-benefit analysis related to domestic and international food and agriculture, provides policy direction for the Department's bioenergy and biobased product programs, and is responsible for coordination, review and clearance of all commodity and aggregate agricultural and food-related data used to develop outlook and situation material within the Department.

The OCE budget request for fiscal year 2008 is \$11,347,000, which includes an increase of \$360,000 for 2007 and 2008 pay costs. The budget request also includes an increase of \$500,000 for the Methane-to-Markets Initiative. The Methane-to-Markets Partnership is designed to promote cost-effective, near-term methane recovery internationally through partnerships with fourteen other countries, including Russia, China, the United Kingdom, Italy, Mexico, and Brazil. Under this initiative, USDA will promote the international adoption of technologies to reduce methane emissions from animal waste systems and demonstrate United States leadership in reducing methane emissions.

USDA support for the Methane-to-Markets Partnership will be used to: identify and promote areas of bilateral, multilateral, and private sector collaboration on methane recovery and use; develop emissions estimates and identify the largest relevant emission sources to facilitate project development; identify cost-effective opportunities to recover methane emissions and potential financing mechanisms to encourage investment; improve the legal, regulatory, financial, institutional and other conditions necessary to attract investment in methane recovery and utilization projects; identify and implement collaborative projects aimed at addressing specific challenges to methane recovery, such as raising awareness in key stakeholders, removing barriers to project development and implementation, identifying project opportunities, and demonstrating technologies; and develop and implement a process for evaluating progress and reporting results.

That completes my comments and thank you.

Farm Economic Indicators

Commodity Prices 1/	Unit	1999/00	2000/01	2001/02	2002/03	2003/04	2004/05	2005/06	2006/07
Wheat	\$/bu	2.48	2.62	2.78	3.56	3.40	3.40	3.42	4.25
Corn	\$/bu	1.82	1.85	1.97	2.32	2.42	2.06	2.00	3.20
Soybeans	\$/bu	4.63	4.54	4.38	5.53	7.34	5.74	5.66	6.30
Rice	\$/cwt	5.93	5.61	4.25	4.49	8.08	7.33	7.65	9.85
Cotton (Upland)	cents/lb	45.00	49.8	29.8	44.5	61.8	41.6	47.7	47.8 2/
		2000	2001	2002	2003	2004	2005	2006	2007F
Hogs	\$/cwt	44.70	45.81	34.92	39.45	52.51	50.05	47.26	45.47
Steers	\$/cwt	69.65	72.71	67.04	84.69	84.75	87.28	85.41	84.89
Broilers	cents/lb	56.2	59.1	55.6	62.0	74.1	70.8	64.4	72.77
Milk	\$/cwt	12.40	15.04	12.18	12.55	16.05	15.15	12.90-13.80	15.05-15.65
Gasoline	\$/gallon	1.53	1.47	1.39	1.60	1.89	2.31	2.62	2.53
Diesel	\$/gallon	1.49	1.40	1.32	1.50	1.81	2.41	2.71	2.66
Natural gas (whtd)	\$/K cu. ft.	3.70	4.01	2.95	4.89	5.50	7.45	6.41	6.83
Electricity	\$/kwh	8.24	8.62	8.45	8.70	8.97	9.45	10.40	10.65

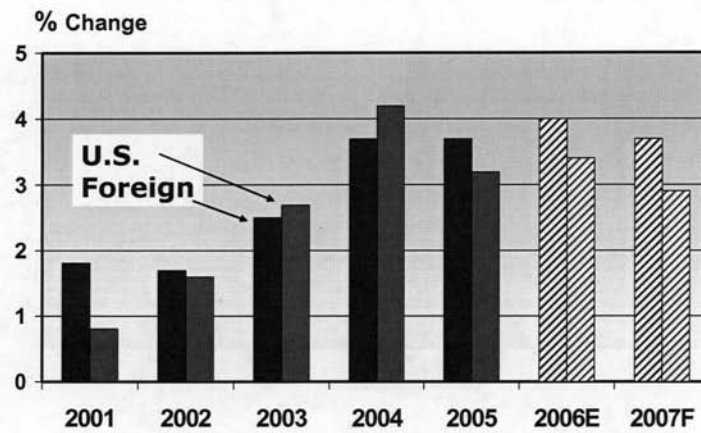
Ag. Trade (Bil. \$)	FY99	FY00	FY01	FY02	FY03	FY04	FY05	FY06	FY07F
Total exports	49.1	50.7	52.7	53.3	56.2	62.4	62.5	68.7	78.0
Asia	18.5	19.7	20.1	19.4	21.6	24.3	22.5	25.0	28.7
Canada	7.0	7.5	8.0	8.6	9.1	9.5	10.4	11.6	13.0
Mexico	5.7	6.3	7.3	7.1	7.7	8.4	9.3	10.4	12.6
Total imports	37.3	38.9	39.0	41.0	45.7	52.7	57.7	64.0	70.0
Farm Income (Bil. \$)	1999	2000	2001	2002	2003	2004	2005	2006	2007F
Cash receipts	187.6	192.0	200.1	195.0	216.6	241.2	238.9	242.7	258.7
Gov't payments	21.5	22.9	20.7	11.2	17.2	13.3	24.3	16.3	12.4
Gross cash income	224.0	228.6	235.6	221.0	249.5	271.7	280.9	277.1	289.8
Cash expenses	166.6	172.1	176.0	171.6	177.9	186.2	199.7	210.4	222.6
Net cash income	57.5	56.5	59.5	49.5	71.6	85.5	81.2	66.7	67.2

F=forecast.

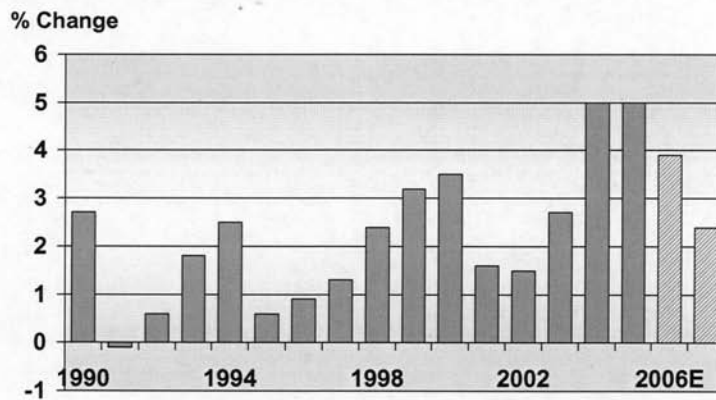
1/ Agricultural commodity price forecasts are from USDA, World Agricultural Supply and Demand Estimates report, March 2007. Crop prices are the midpoint of the forecast range. Energy prices are from Energy Information Administration, Short Term Energy Outlook, March 6, 2007.

2/ August 2006 through January 2007 average.

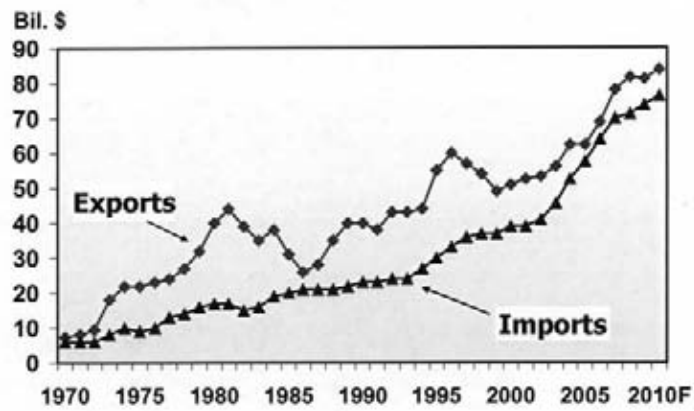
U.S. & Foreign GDP Growth



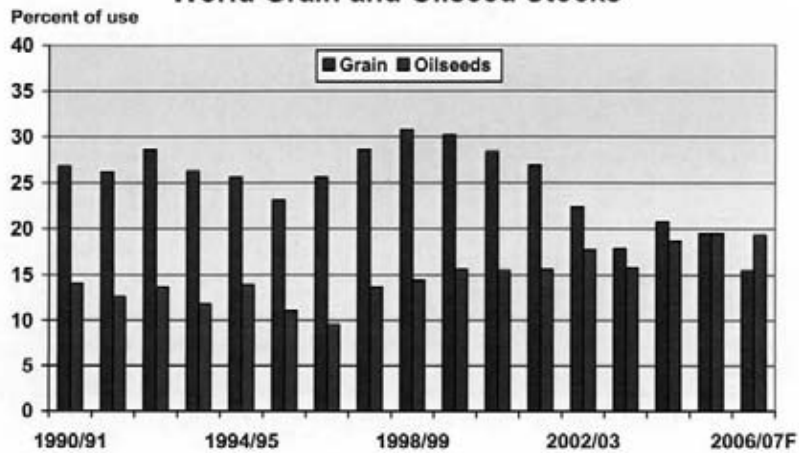
Real Consumption Spending on Food



U.S. Agricultural Trade

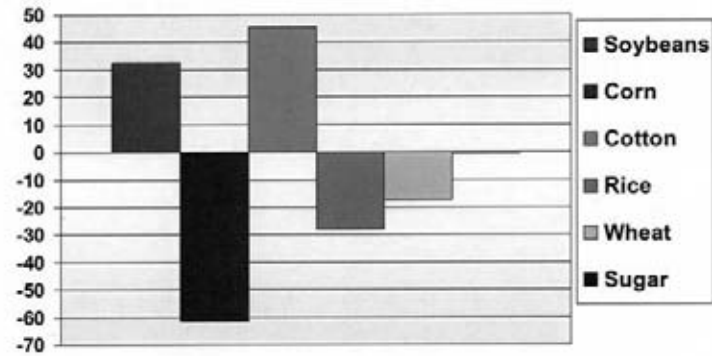


World Grain and Oilseed Stocks

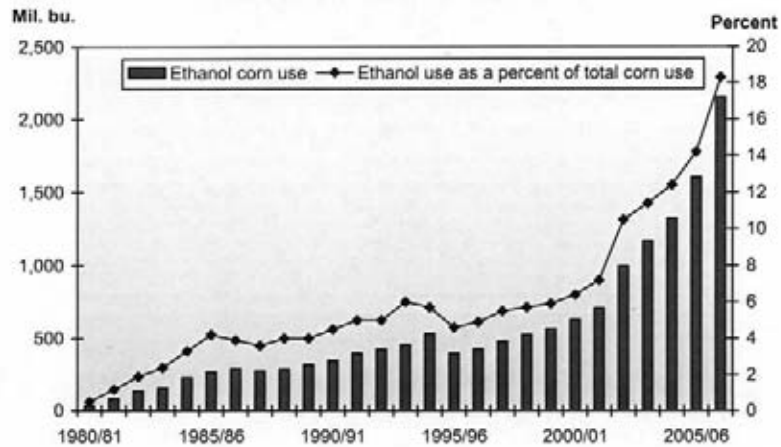


U.S. Crop Carryover Stocks Forecast 2006/07F v. 2005/06

Percent change



Corn Used in Ethanol Production

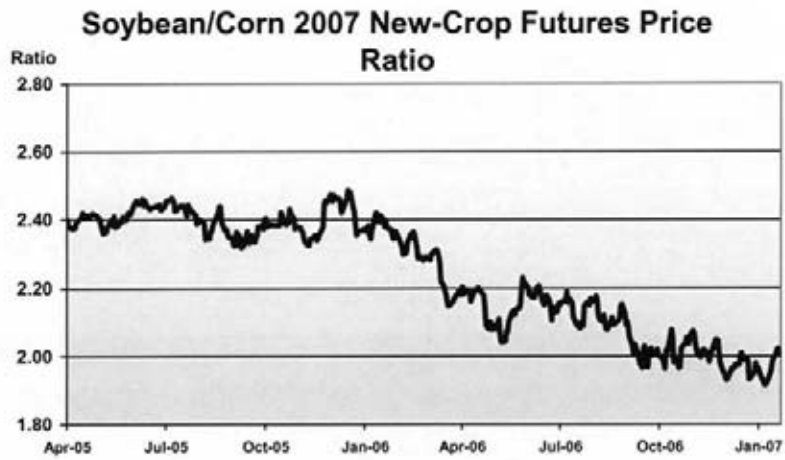


December 2007 Corn Futures Prices
(Chicago Board of Trade)

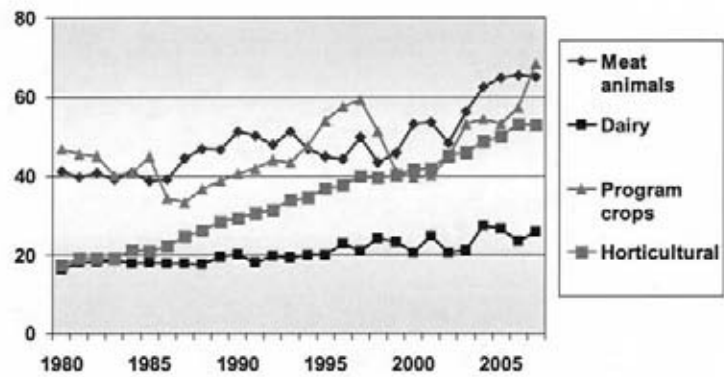


November 2007 Soybean Futures Prices
(Chicago Board of Trade)

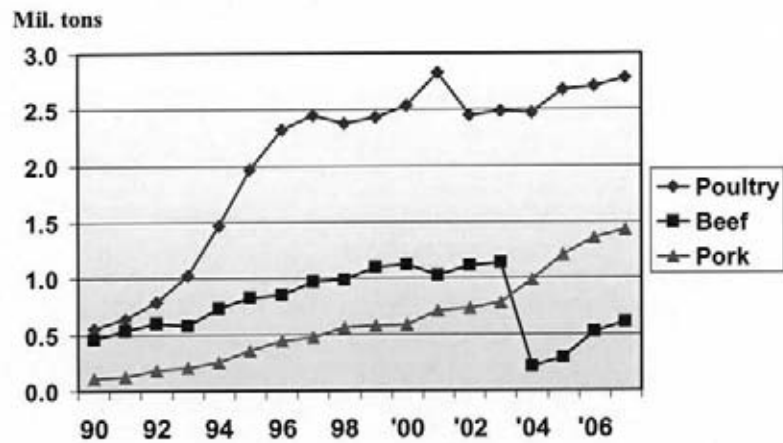




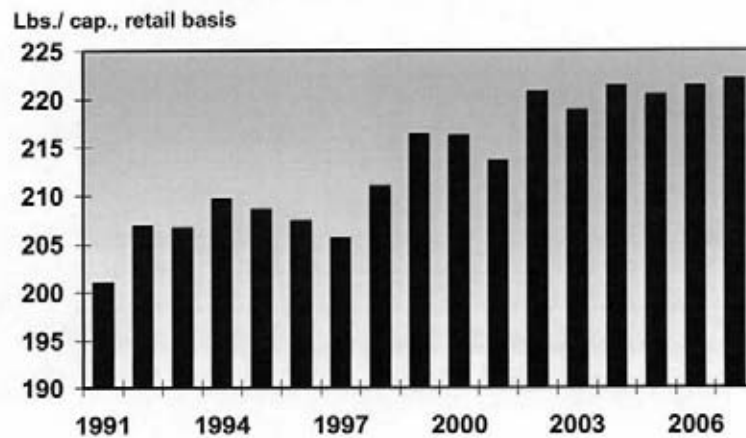
Cash Receipts



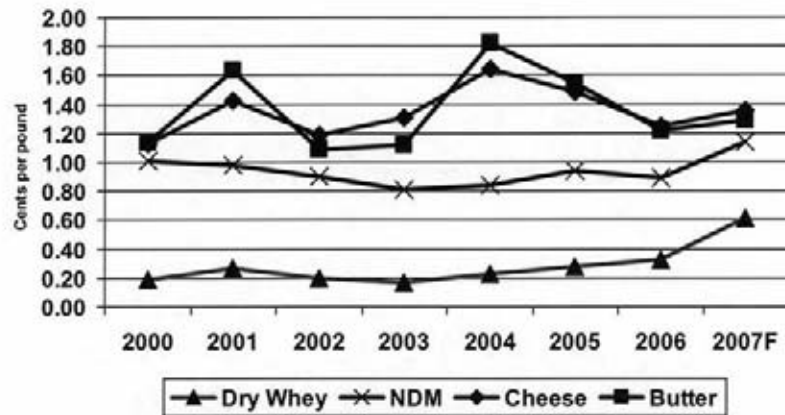
Meat & Poultry Exports



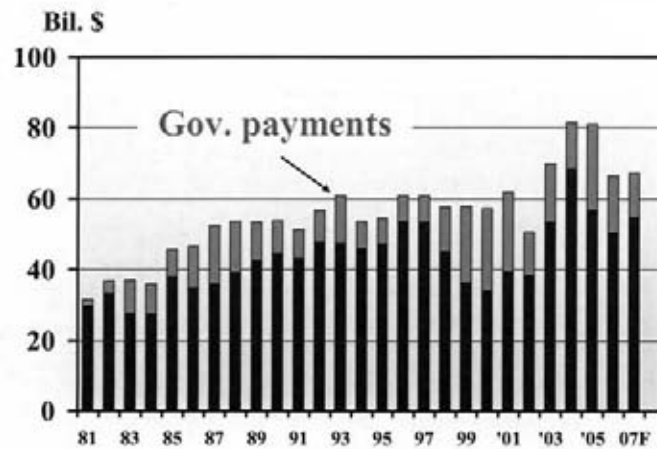
Retail Meat Consumption



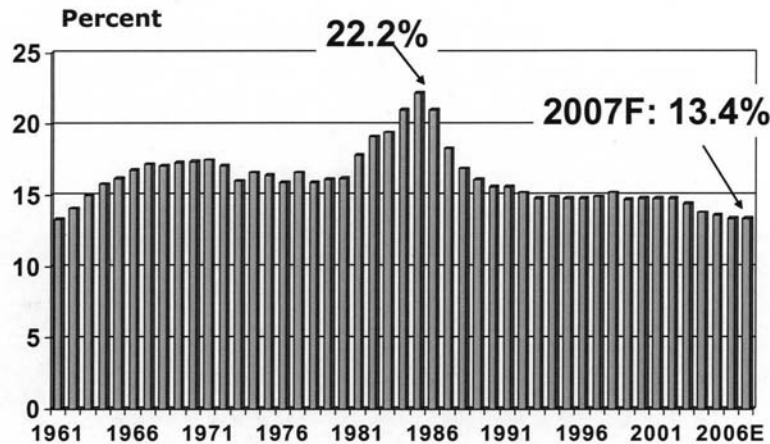
Dairy Product Prices



U.S. Net Cash Farm Income



Farm Debt-to-Equity Ratio



PREPARED STATEMENT OF PHYLLIS K. FONG, INSPECTOR GENERAL, OFFICE OF THE
INSPECTOR GENERAL

Thank you for the opportunity to submit testimony to the Subcommittee about the Office of Inspector General's (OIG) recent and ongoing audit and investigative work, and our fiscal year 2008 Budget Request.

My testimony presents the highlights of our audit and investigative work for the period of March 2006-March 2007. OIG conducted extensive work in 2006 on important issues and USDA activities regarding food safety, the risks posed by plant and animal-based diseases, fraud that impairs vital nutrition and hurricane-relief programs, and financial management accountability within USDA agencies.

To ensure that OIG devotes its resources to the most pressing issues and challenges facing USDA agencies, stakeholders, and consumers, we have formally prioritized our work and organized our resources according to three Strategic Goals. They are improving Safety, Security, and Public Health in USDA operations; enhancing Program Integrity in the many USDA benefit programs that touch the lives of your constituents; and oversight work regarding USDA's Management of Public Resources. This statement presents the key elements of our recent and current work to the Subcommittee under the framework of these three strategic priorities.

SAFETY, SECURITY, AND PUBLIC HEALTH

One of OIG's top priorities is conducting independent and professional audits and investigations to protect the safety and security of USDA entities and the many agricultural stakeholders and consumers who benefit from USDA operations each day. In fiscal year 2006, we issued 12 audit reports involving safety, security, and public health issues related to USDA programs and operations. During the fiscal year, OIG referred a total of 120 cases for prosecution.

Assessing the Performance of Consumer Safety Inspectors in Meat and Poultry Establishments

In our prior audits we determined that the Food Safety and Inspection Service's (FSIS) management control system needed strengthening to ensure accountability of consumer safety inspector performance. A key component of the FSIS management control system is the In-Plant Performance System (IPPS), which was estab-

lished to strengthen supervision and improve inspector accountability. In response to several OIG audits, FSIS has cited IPPS reviews as a critical measure to improve monitoring of food safety at meat and poultry establishments.

In our most recent audit of this area, issued in 2006, we evaluated the adequacy of agency policy and procedures related to preparing for, executing, and monitoring IPPS reviews. FSIS did not require supervisors to complete and/or document the completion of all IPPS review procedures when evaluating inspectors. In 84 percent of the inspector assessments OIG reviewed, certain elements of inspector duties—some of which could be considered critical¹—were not addressed. We found that FSIS did not have a system to schedule and track the completion of IPPS reviews and supervisors were not required to use the extensive guidance available to help them prepare for the reviews. As a result, supervisors had not used significant segments of the guidance to enhance their onsite review of consumer safety inspectors.

FSIS agreed to closely monitor field managers and supervisors involved in the IPPS process, analyze IPPS review data, and periodically evaluate the IPPS review process. FSIS also agreed to revise its guidance to require supervisors to examine specific data sources and system reports before performing an IPPS review and complete and provide narratives for all IPPS review elements during an inspector's performance rating period.

Improving Pathogen Reduction Testing in Meat and Poultry Establishments

The Pathogen Reduction Enforcement Program (PREP) is a system used to support FSIS' pathogen reduction efforts by scheduling microbiological product sampling at FSIS-inspected meat and poultry establishments and generating automated reports that allow FSIS managers to monitor both the sampling process and the results of laboratory tests.

OIG evaluated the effectiveness of FSIS' process for scheduling and conducting microbiological testing of meat and poultry products. We found that in the testing programs for the adulterants *E. coli* O157:H7 and *Listeria monocytogenes*, FSIS had developed procedures to transfer establishment data from the Performance Based Inspection System (PBIS) to the PREP (two separate systems) and was selecting the identified meat and poultry establishments for testing within reasonable timeframes.

However, we found that *Salmonella* testing program controls needed strengthening to ensure that all applicable establishments are included in the universe for microbiological testing. A significant number of establishments were excluded from *Salmonella* testing due to ineffective processes for identifying establishments eligible for testing. FSIS district office personnel did not fully understand the process for inserting/updating establishments into the testing database. In one district we visited, 28 percent of the establishments subject to *Salmonella* testing were excluded from testing. We also found that establishments whose slaughter or processing activity falls below a specific threshold or produces non-intact beef products (such as raw ground beef sausages and meatballs) were also excluded from the universe for testing.

We recommended that FSIS strengthen its procedures to ensure that all establishments subject to *Salmonella* testing are identified and modify PBIS to allow PREP to draw establishment information for testing from PBIS rather than depend on manual updates. The agency should develop a risk assessment to support its policy for excluding low-volume establishments from *Salmonella* testing or conduct testing in all plants. Further, FSIS should obtain scientific advice to evaluate whether its policy of not testing certain raw ground beef products for *E. coli* O157:H7 contamination should be continued. FSIS officials generally agreed with OIG's findings and recommendations.

Assessing FSIS Oversight of State Meat and Poultry Inspection Programs

FSIS has oversight responsibility for State meat and poultry inspection (MPI) programs to ensure that meat and poultry products sold intrastate meet inspection standards "at least equal to"² Federal laws and regulations. OIG initiated a review to examine the effectiveness of FSIS management controls and procedures to ensure that State MPI programs were "at least equal to" Federal inspection programs.

We determined that FSIS was not providing timely oversight of State MPI programs. From October 2003 through June 2005, FSIS had conducted only 8 initial onsite reviews from a total of 28 State MPI programs. After our fieldwork began and since July 2005, FSIS initiated reviews of 16 more State MPI programs and developed plans to conduct the 4 remaining reviews prior to the end of fiscal year

¹ Such as hazard analysis and critical control point system procedures.

² As established by the Federal Meat Inspection Act and the Poultry Products Inspection Act.

2006. Completing the review process is important, especially since four of the eight programs initially reviewed needed corrective actions to achieve “at least equal to” Federal standards.³

Moreover, FSIS had not performed timely onsite fiscal reviews and reviews of new programs and did not timely implement its year-end grant closeout procedures to ensure that State MPI programs promptly returned any excess Federal funds. FSIS had not recovered \$260,201 in excess Federal funds from one State for fiscal year 2004. In this State, during fiscal year 1997–2004, unnecessary interest costs of approximately \$100,000 were incurred by the Federal Government because the State retained unused Federal funds.

OIG made numerous program improvement recommendations based upon this audit. We recommended that FSIS establish criteria to determine how deficiencies in meat processing establishments affect State acceptability determinations. FSIS should analyze the staffing requirements of State MPI programs and confirm that laboratories adhere to standards “at least equal to” Federal requirements. The agency needs to eliminate the backlog of onsite fiscal reviews and perform timely, year-end grant closeouts of State MPI programs and seek prompt recovery of \$260,201 from the identified State MPI program. FSIS responded positively to OIG’s recommendations, and management decision was reached on 6 of the 12 recommendations.

The USDA Response to Avian Influenza

The emergence of highly pathogenic Avian Influenza (HPAI) as a potential pandemic has rapidly changed the environment in which the Animal and Plant Health Inspection Service (APHIS) operates. The November 1, 2005, issuance of the President’s strategy for the preparation, detection, and response to a pandemic accelerated APHIS’ actions in dealing with AI. The strategy recognizes roles for all segments of society, including Federal, State, local and Tribal governments, private industry, international trade partners, and individual citizens.

In our June 2006 review of APHIS’ oversight of Avian Influenza (AI), we concluded that APHIS has made commendable progress in developing plans and establishing the networks necessary to prepare for, and respond to, outbreaks of AI. However, APHIS had not yet developed a comprehensive approach for surveillance and monitoring of AI in domestic poultry. APHIS relies on a variety of voluntary State and commercial programs to monitor and test domestic poultry and wild birds. Because these programs are voluntary, APHIS did not know the extent of surveillance activity in place and was not gathering consistent data to properly detect changes in epidemiological parameters (e.g., subtype of AI or rate of prevalence) or to report incidents of AI in accordance with new international trade requirements.

In regard to USDA’s National AI Preparedness and Response Plan, OIG found that APHIS needed to provide additional guidance on preparing and responding to HPAI or notifiable AI outbreaks in live bird markets or other “off farm” environments.⁴ APHIS also needed to clarify actions that employees should take in obtaining and administering necessary vaccines and anti-virals in the event that a culling operation for HPAI occurs. Finally, APHIS needed to finalize interagency coordination on the process and procedures for notifying owners of susceptible animals of the current infectivity risks and the necessary protective actions they should take when an outbreak of AI occurs. In its response, APHIS described a number of initiatives planned and in process to address our concerns.

OIG currently has a related audit underway. We are evaluating the effectiveness of APHIS’ implementation of the Homeland Security Council’s National Strategy for Pandemic Influenza (issued May 2006). We will also follow up with the agency on its corrective actions responding to our prior audit.

Targeting the Smuggling of Animals and Plant Products

The smuggling of animals and animal/plant products into the United States is of significant concern. The smuggling of these products presents both a human health risk and a risk to the United States’ animal and plant populations because of the potential for the transmission of disease.

OIG works closely with USDA regulatory agencies such as APHIS and FSIS that enforce standards for the importation for meat, poultry, and live animals into the United States. As stated in our testimony before the Subcommittee last year, OIG

³ FSIS issued a report in January 2007 that contained the results of all 28 reviews.

⁴ The plan is intended to complement regional, State, and industry plans that are written to be more specific to local issues and needs. States should continue to develop plans that are specific to their poultry industries and requirements. The USDA/APHIS plan will evolve as additional information and experience is gained.

works with USDA agencies to achieve a balance among risk mitigation efforts, regulatory investigations, and criminal investigations when such products are smuggled into the United States. To achieve this goal, we have been working to establish protocols to clarify each USDA agency's role in response to smuggling. We anticipate the Department will issue these protocols this summer.

One of the groups in which OIG is participating is an interagency working group comprised of both regulatory and law enforcement agencies from the Department of Homeland Security (DHS), the Department of Justice, and the Department of Interior. While the initial objective of this working group was to improve smuggling investigations concerning HPAI, OIG's participation has also improved our investigative capabilities to respond to smuggling investigations involving any type of prohibited product. The inter-agency working group fostered productive relationships and communications between OIG and those departments and more clearly defined our respective roles.

OIG participated in a joint investigation at the Port of Newark known as "Operation Fowl Play." The investigation led to the seizure of approximately 1 million pounds of prohibited poultry, fowl, meat, pork, vegetables, fruit, and other merchandise over several months. The investigation, which began in 2005, involved several New York based companies responsible for importing these products from China.

Preparing for Agricultural Emergency Situations and Wildland Fire Fatalities

OIG's Emergency Response Team (ERT) and Wildland Fire Investigation Team (WFIT) engaged in training and were both actively deployed in fiscal year 2006. The ERT has the capability to safely and effectively respond to criminal acts that could threaten or compromise the United States' food supply, agricultural infrastructure, or USDA facilities. The WFIT is responsible for conducting an independent investigation into the deaths of any Forest Service (FS) firefighters who are killed as a result of a burnover or entrapment. We thank the Members of the Subcommittee for your continued support of these important programs.

During 2006, ERT members participated in several tabletop exercises concerning AI and Foot and Mouth Disease, attended Food Defense Exercises, and State and local emergency preparedness meetings. Our ERT works with various Federal, State, and local agencies to educate them about the assistance and resources OIG can provide when an agriculture-related incident occurs. Coordination with and outreach to our counterparts at the State and local level is vital to build the skills and partnerships necessary for effective, multilevel government responses to agricultural emergencies.

During the execution of a search warrant in one investigation in 2006, the ERT assisted with the identification and depopulation of game fowl at an illegal cock-fighting pit in Oklahoma. Birds utilized in animal fighting competitions present a health risk to humans and animals because the birds may carry infectious diseases such as Exotic Newcastle Disease and AI.

Our WFIT members undergo extensive training to gain the skills and experience necessary to conduct wildland fire-related investigations.⁵ The OIG agents comprising the WFIT attend the FS' Basic Fire Academy that incorporates training in Incident Command, Basic Wildfire Suppression Orientation, Firefighter Training, Introduction to Wildland Fire, and Interagency Serious Accident Investigation Training. In October 2006, WFIT members responded to the Esperanza Fire that claimed the lives of five FS fire engine crew members near Cabazon, California. WFIT members arrived at the site within 24 hours of the fatalities to begin organizing their investigation. OIG's investigation of the circumstances leading to the Esperanza Fire deaths is ongoing.

The Bovine Tuberculosis Eradication Program

APHIS administers the Bovine Tuberculosis Eradication Program (BTEP) that was established in 1917 to eliminate bovine tuberculosis (TB) in the United States. Because of concerns we previously identified regarding the agency's systemic classification and testing of relevant TB cases in one State, OIG conducted a more comprehensive audit of APHIS' administrative controls over BTEP. We found that APHIS had made improvements to BTEP since the Secretary's Emergency Declaration in October 2000,⁶ but weaknesses in oversight made it difficult for the agency to timely detect and eradicate the disease. APHIS' status system—important because it dictates the extent of Federal testing and movement controls for cattle in

⁵ Public Law 107-203, enacted July 24, 2002, established the statutory requirement for a USDA-OIG investigation of FS fatalities occurring due to wildland fires.

⁶ The emergency declaration authorized the transfer of \$44.1 million from emergency contingency funds to APHIS to expand the TB eradication program.

each State or zone—did not capture most TB cases. From fiscal year 2001 through 2005, 272 TB-infected cattle were detected through slaughter surveillance, but APHIS excluded 96 percent from the status system because it could not locate the source herd or find an additional infected animal in that herd. Approximately 75 percent of the TB-infected cattle detected through slaughter surveillance originated in Mexico, and these animals spent months at U.S. farms and feedlots with no restrictions to prevent commingling with domestic cattle. Mexican cattle are tested before entry, but APHIS had not established controls to compensate for the 3- to 2 month TB incubation period.

We recommended that APHIS perform program reviews periodically; review and approve States' annual and monthly reports and use them to assess/minimize areas of highest risk; enhance its two key BTEP control functions (the status classification and slaughter surveillance systems); and strengthen movement/testing controls to address the disease's incubation period. The agencies agreed to take corrective actions based on our findings and recommendations.

Agricultural Inspection Efforts on the U.S. Border

With the creation of DHS in March 2003, U.S. Customs and Border Protection (CBP) assumed responsibility to inspect agricultural goods arriving at U.S. ports while APHIS retained responsibility for agriculture related policies and procedures. We issued a report in February 2007 from our joint review with DHS–OIG of border inspection issues. We assessed selected agricultural inspection activities that were transferred to CBP.

Our joint review found that CBP generally complied with agricultural inspection requirements at the ports we visited. However, improvements are needed regarding risk identification activities. CBP's sampling for Agricultural Quarantine Inspection Monitoring (AQIM)—which helps USDA predict future risks to agriculture from pests/diseases—did not meet sampling requirements for 13 of 18 pathway activities at four ports.⁷ CBP also lacks a current staffing model for agriculture specialists and performance measures for many activities that would ensure personnel are used effectively.

APHIS officials agreed to develop a risk assessment process for incoming rail cargo. However, agency officials cite operational difficulties (such as obtaining timely cargo manifests) as a barrier to developing a workable system. APHIS has not yet issued policies and uniform procedures to clearly define how transportation/export shipments will be monitored. We also found that APHIS needs to issue instructions to CBP clarifying APHIS policy on labeling and packaging seized agricultural products.

PROTECTING AND IMPROVING THE INTEGRITY OF USDA PROGRAMS

OIG's second strategic priority is audit and investigative work to protect the integrity and efficiency of USDA programs and benefits. A substantial amount of OIG's audit and investigation resources in fiscal year 2006 were focused on Farm Service Agency (FSA) and Risk Management Agency (RMA) programs and operations. OIG continues to work to combat fraud and deter criminal activity in farm programs, such as payment limitations, crop insurance, and conversion of mortgaged property.

Food and Nutrition Service (FNS) programs providing food assistance to needy Americans is a major portion of USDA's annual budget—the Food Stamp Program helps over 26 million people each month, and 15.5 million children receive a free or reduced-price school lunch. Fraud in FNS programs such as the Women, Infants, and Children (WIC), Food Stamp, and the Children and Adult Care Feeding Programs remains a high priority for OIG.

USDA Compliance with the Improper Payments Information Act

Within USDA, the Office of the Chief Financial Officer (OCFO) is designated as the lead agency for coordinating and reporting on the Department's efforts to implement the Improper Payments Information Act (IPIA). OCFO has designated IPIA compliance as a top priority for fiscal year 2007.

To determine the Department's compliance with IPIA, OIG initiated audits of four USDA agencies in fiscal year 2006—FSA, FS, Rural Development's (RD) Rural Housing Service (RHS), and the Natural Resources Conservation Service (NRCS). Our objectives included reviewing agency efforts to quantify improper payments for high risk programs, assessing agency corrective actions related to our previous audits, and substantiating agency results reported in USDA's Performance and Accountability Report for fiscal year 2005.

⁷ Such as air passengers and truck cargo AQIM inspections.

Our audits revealed significant findings on agency compliance with IPIA. OIG found that valid statistical samples had not been performed for three of the four agencies reviewed. Improper payments reported in fiscal year 2005 were not properly calculated and the estimated improper payments reported in fiscal year 2005 did not always include payments made to ineligible recipients. We determined that corrective actions were too narrow in scope and ineffective in addressing our prior findings. OCFO generally agreed with our recommendations to correct these conditions and we are working with agencies to improve their implementation of IPIA requirements. OIG is currently auditing several USDA agencies to assess their efforts to quantify improper payment error rates for high risk programs.

Farm Programs—Improving Agency Controls to Prevent Loans to Ineligible Recipients

When farmers and ranchers are unable to repay their Farm Loan Programs (FLP) loans in full, Congress requires that FSA consider them ineligible for future loans. Using data-mining techniques, we reviewed the approximately 139,000 loans active in FSA's database (as of the beginning of fiscal year 2005) to isolate 239 borrowers who were potentially ineligible for having received prior debt forgiveness. Our detailed review of six potentially ineligible borrowers revealed that three were, in fact, ineligible and should not have received FLP loans. FSA subsequently reviewed all 239 borrowers and ultimately found 113 loans totaling over \$7.5 million, issued during 1999–2004, were ineligible. In general, we determined that the unauthorized assistance occurred because FLP loan officials did not follow established procedures for determining applicants' eligibility and FSA's automated management tools lacked the applicants' complete debt history.

FSA took action to collect the 113 ineligible loans as appropriate. Further, FSA issued guidance to help employees determine whether applicants have received prior FLP debt forgiveness and is developing a new automated system that will automatically display applicants' complete debt histories. FSA is currently pilot testing the new system at two State offices and plans to implement it nationwide.

Improving the Integrity of the Crop Insurance Program

Due to continuing concerns about costs incurred by the Federal crop insurance program, OIG conducted an overview of the program. In collaboration with FSA and RMA, OIG identified conditions that are often associated with fraud, abuse, and mismanagement.

We identified two major factors that must be in place to enhance the integrity of the crop insurance program: effective management controls to ensure program operations are meeting program objectives and aggressive enforcement through criminal investigations and agency compliance reviews.

Based on this overview and our discussions with FSA/RMA about the current state of the crop insurance program, we presented a series of recommendations that are consistent with OIG's prior work. Among other recommendations, we found that agency officials should accelerate plans to create a single comprehensive information system for crop insurance, conservation, and farm programs; increase coordination and communication between RMA and FSA to ensure more effective growing season inspections; and strengthen RMA's oversight and monitoring of the private sector's application of the quality control review system.

Investigating Fraud in USDA Farm Programs

A recent OIG investigation resulted in a Montana producer and a former loan officer being sentenced for a scheme in which the producer filed false claims with FSA in order to receive program payments. The producer circumvented program payment limitations to fraudulently receive \$1.4 million. The private loan officer provided false financial documents to FSA regarding the other partners' participation in the farming operation. In July 2006, the producer was sentenced to serve 10 months in Federal prison and ordered to pay \$226,035 in restitution. The former loan officer was sentenced the following month to a period of home confinement and probation.

Another OIG investigation into potential farm program fraud resulted in orders to repay the Government over \$1 million and the sentencing of two individuals and three corporations in 2006. Our investigation revealed that two individuals and three corporations in the Texas panhandle fraudulently obtained approximately \$400,000 in RMA crop insurance indemnity payments and FSA disaster program payments by shifting their unreported cotton production for program payment purposes. The producers assigned their hidden cotton production to other established accounts at a cotton gin owned by one of the individuals. A producer and two corporations were sentenced in August 2006. The producer was sentenced to 12 months' imprisonment, followed by 36 months' supervised release, and was ordered to pay approximately \$331,000 in restitution. The corporations each received sen-

tences of 60 months of probation and were ordered to pay restitution totaling approximately \$331,000. In September 2006, the second individual and the remaining corporation were both sentenced to 60 months of probation and were ordered to pay restitution of \$362,775, severally and jointly.

A third OIG investigation involving farm program fraud resulted in the repayment of \$1,085,000 to FSA. The Idaho producer involved received 3 years of probation and 80 hours of community service. The producer's son was also sentenced to 3 years probation and was fined \$4,000. The sentence included a joint restitution order of \$1,085,000 imposed on the two defendants. The OIG investigation disclosed that the mother and son converted 305 head of cattle pledged as collateral to FSA. They pled guilty in May 2006 to theft/conversion of FSA collateral. FSA also has a lien against their property that is valued at more than \$1 million.

USDA Food Programs—FNS Oversight of Electronic Benefits Transfer Operations

In fiscal year 2007, FNS estimates that Food Stamp benefits of about \$30 billion will be provided to over 25 million participants. State agencies now deliver Food Stamp Program (FSP) benefits almost entirely through Electronic Benefit Transfer (EBT) systems using EBT benefit cards issued to recipients. OIG has monitored and audited the implementation of EBT by FNS and States since the system's inception in the 1990s. We recently issued a follow-up audit to evaluate corrective actions FNS has taken in response to our prior audits and to ensure adequate agency oversight of EBT systems.

We concluded that FNS oversight of EBT operations was generally effective. However, despite FNS requirements to safeguard EBT systems, inadequate control over State agency access to the system remains a problem. Based on our earlier work, FNS had agreed to strengthen procedures for controlling access to State EBT systems and directed States to conduct semiannual reviews of employee access. However, FNS did not independently confirm that States adequately controlled access.

EBT trafficking through the illegal and unauthorized use of Point of Sale (POS) equipment is another system vulnerability. Unscrupulous retailers have circumvented the EBT security controls by fraudulently obtaining new equipment and/or illegally moving existing machines to unauthorized locations. Our September 2006 report found that in their contract proposals to acquire EBT systems, States were not required to consider equipment functionality and/or technological specifications that could prevent the illegal removal and unauthorized use of existing EBT POS equipment.

Based on our audit, FNS agreed to take steps to ensure that States limit unauthorized access to EBT systems and to require States to implement, via the EBT contract, formal processes during POS equipment replacement to prevent retailers from fraudulently obtaining equipment.

This year, we will conduct further audits regarding FNS oversight of EBT systems. Our work will include reviewing FNS oversight of the largest private EBT processor and two State agencies.

Investigations of EBT Trafficking

OIG devotes extensive resources to investigate unscrupulous retailers who circumvent EBT security controls by fraudulently obtaining new equipment and/or illegally moving existing machines to unauthorized locations. In our Food Stamp Program investigative work, we focus our resources on high impact cases, such as those involving large-scale traffickers, those with potential connections to terrorist activity, and cases involving additional types of criminal activities beyond benefit fraud.⁸ Comparing our final fiscal year 2006 investigative statistics to the prior fiscal year, the number of food stamp trafficking investigations we opened increased from 77 to 84; the number we referred to DOJ increased from 21 to 31; and the number of indictments resulting from OIG food stamp investigations increased from 70 to 146.

EBT fraud cases are very complex investigations, so OIG worked in 2006 to develop and conduct training focused on improving methods to detect and analyze trends indicating fraud. OIG is creating a database that will capture vital information regarding EBT trafficking investigations to identify large scale fraud networks.

OIG has initiated numerous investigations as a result of our collaborative efforts with multiple Federal and local law enforcement agencies. A major OIG food stamp fraud investigation resulted in a Chicago grocery store owner being sentenced in August 2006 to 51 months in prison and ordered to pay \$1.4 million in restitution. The store owner pled guilty to wire fraud and money laundering. Two months earlier, the store owner pled guilty in Federal court in Florida to conspiracy for providing

⁸Examples would be food safety concerns affecting public health, such as contaminated food or black-market WIC products.

funding to the Palestinian Islamic Jihad, in violation of the International Emergency Economic Powers Act. The store owner had conspired with other persons and unauthorized stores to conduct thousands of illegal electronic food stamp benefit transactions.

Expanding Efforts to Deter WIC Fraud

WIC is a vital Federal program to provide supplemental foods and nutrition education to lower-income pregnant, breast-feeding, and postpartum women, and infants and children who are at nutritional risk.

The main product purchased with WIC vouchers is infant formula. Theft rings around the country are stealing, re-labeling, and reselling infant formula. When infant formula is stolen, it is taken out of the regulated retail system, and there can be no guarantee the formula is safe and wholesome. In response to this growing concern, OIG is expanding alliances with State and local law enforcement agencies to better coordinate jurisdictional investigative efforts into broader regional efforts. Our ultimate objective is to develop a national initiative that will enable OIG to track and maintain records of stolen infant formula incidents across the United States.

A recent OIG infant formula investigation involved an Ohio furniture store owner who led a nationwide network that trafficked in stolen merchandise and food stamps through inner-city markets. The stolen merchandise included infant formula, diabetic blood glucose test strips, and over-the-counter medications. The stolen merchandise was transported to wholesalers and warehouses in States including Indiana, Illinois, Wisconsin, New York, Florida, and California. The store owner and 24 other individuals were charged with crimes ranging from food stamp trafficking to transportation of stolen property and money laundering. During 2005–2006, 21 individuals have pled guilty or were found guilty, including the leader of the criminal organization. Sentences imposed on the defendants ranged from 8 months to 11 years, and monetary judgments and restitutions totaled over \$2.7 million. On February 20, 2007, two of the three store owners involved in the scheme in Wisconsin pled guilty to false statements and conspiracy; the third is awaiting trial. This was a joint investigation with the FBI and the Ohio Organized Crime Investigations Commission.

A second OIG infant formula investigation determined that a Pennsylvania convenience store owner was trafficking in food stamps and operating and engaging in an unlicensed money transmitting business. From 2001 to May 2006, the store owner transmitted more than \$7 million without the license required by Federal and State law. The store owner bought and sold stolen goods such as infant formula, drug paraphernalia, and counterfeit cigarettes and music CDs. The store owner pled guilty in Federal court in November 2006 to operating an unlicensed money transmitting business and agreed to forfeit over \$252,000. This investigation was part of a taskforce that included OIG agents and several other Federal and State enforcement agencies (FBI, Immigration and Customs Enforcement, Secret Service, IRS, and the Pennsylvania Department of Revenue).

The OIG Response to Hurricanes Katrina and Rita: Audit Oversight and Investigative Support

During last year's testimony, we discussed USDA's role in the Federal recovery efforts related to Hurricanes Katrina and Rita. OIG continues to work with the President's Council on Integrity and Efficiency (PCIE) and DHS working groups to coordinate related investigative efforts and thereby maximize Federal investigative resources and prevent duplicative efforts. We coordinated efforts with both the Department of Housing and Urban Development's (HUD) OIG and DHS–OIG to develop computer matching agreements with RHS. These agreements facilitate the ability of the participants to identify improper and fraudulent disaster assistance payments. Data matching is a highly effective tool in disaster assistance payment investigations for all of the agencies involved.

OIG special agents are working Hurricane Katrina Fraud Task Force investigations in the Gulf Coast region. We continue to receive referrals throughout the country on individuals who have submitted false claims or provided false statements to obtain Federal benefits for which they were not entitled. At this time, as hurricane reconstruction efforts in the Gulf Coast region continue, OIG has begun receiving investigative referrals from FSA and RD that involve larger monetary amounts of fraud or theft and more complex fraud cases.

A recent example of our hurricane relief investigative work involved an Illinois woman who obtained at least \$23,000 in Hurricane Katrina housing, food stamps, and cash assistance for which she was not entitled. OIG worked with the Postal Service's OIG to determine that the individual never resided in Louisiana or Mis-

Mississippi and thus would not have been affected by Hurricane Katrina. The individual sought benefits for non-existent family members. She pled guilty in October 2006 to mail fraud and false statements and was sentenced in January 2007 to 48 months in Federal prison, followed by 36 months of supervised release, and was ordered to pay \$23,982 in restitution.

We have also committed significant audit resources to conduct reviews of the Department's hurricane relief efforts. In view of the substantial Federal funds appropriated for hurricane disaster relief, a continuing concern for both program managers and the Congress is the potential for excessive or duplicative payments to individuals in hurricane-affected communities.

In the aftermath of Hurricanes Katrina and Rita, RD—through RHS—placed 11,000 evacuees into 4,100 Rural Rental Housing (RRH) apartment units in 45 States and provided \$2.6 million in emergency rental assistance. OIG evaluated RHS management controls for multifamily housing funds targeted for disaster assistance. We found that most residents placed in RRH apartments needed only adequate housing and not rental assistance because the Federal Emergency Management Agency (FEMA) was already providing financial assistance. As a result, much of the \$2.6 million provided by RHS duplicated FEMA assistance.

Specifically, our review determined that RHS' database system contained generally inaccurate/incomplete information on hurricane victims and the amount of rental assistance they received. Some property owners required tenants to pay rent even though the owner had already received rental assistance directly from RHS. The agency was also not able to identify victims who used the FEMA identifying numbers of other individuals to obtain housing assistance. OIG found that some property owners had reclassified existing tenants as hurricane victims even though the tenants had no change in income or other circumstances. This resulted in unnecessary RRH rental assistance to the tenants.

RHS agreed to improve its information system and related management controls. To better prepare for future disaster situations, the agency is implementing corrective actions regarding coordinating its actions and information with other Federal agencies providing housing assistance.

This year, we will continue our oversight work regarding USDA's response to major hurricanes. OIG currently has 11 audits in process pertaining to the Department's hurricane relief operations, including reviews of FNS' Disaster Food Stamp Program payments in five hurricane-affected States and RMA controls to provide hurricane victims in Florida with timely and accurate indemnity payments.

Assessing USDA Trade Programs and Operations

In 2002, the Farm Bill and the President's Management Agenda (PMA) established a number of new goals and requirements for the Foreign Agricultural Service (FAS), the agency charged with coordinating USDA's international activities. The 2002 Farm Bill's trade section contained 13 provisions affecting FAS programs, including export credit guarantees, market development, export enhancement, food aid development, and technical barriers to trade. OIG initiated a review to determine the status of FAS' efforts to implement the 2002 Farm Bill's trade and food aid programs and to evaluate the agency's efforts to address problems that the PMA identified in food aid programs.

We found that FAS took prompt action to implement 10 out of the 13 Farm Bill trade provisions within 1 year of enactment. However, FAS has not developed a business process to ensure that the Farm Bill's global market strategy requirements—coordinating USDA resources and programs with other Federal agencies to identify export opportunities and remove trade barriers—are being met on a global basis. FAS managers have followed a strategy of supporting agricultural exporters (referred to as "cooperators") when implementing their individual country and regional market strategies. In our view, such efforts have not been sufficiently integrated to produce a focused, global strategy that would allow FAS to effectively identify and react to changing trends in global markets. The U.S. share of global agricultural exports declined from 22 percent to 9.7 percent during 1984–2005, yet FAS officials do not believe that a central planning process or formal global marketing strategy is necessary.

The PMA cited several problems in U.S. food aid programs, including program duplication between FAS and the U.S. Agency for International Development (USAID) that wasted donated food supplies and excessive administrative/transportation costs. OIG found that FAS has strengthened its program planning and improved consultation and coordination with USAID, USDA's Economic Research Service, and other organizations to develop better outcome-oriented performance measures and reporting. However, we recommended that FAS develop outcome-based performance measures to more accurately reflect program accomplishments in recipient countries. OIG

is assessing the agency's response to our draft report and we anticipate issuing a final report in April 2007.

Identifying Barriers to U.S. Agricultural Exports

OIG received a congressional request in 2006 to review certain aspects of FAS market development programs in fostering expanded trade activities for U.S. agricultural exports. We initiated an audit to examine the extent to which FAS conducts outreach to U.S. agricultural interests to identify trade constraints and foreign agricultural business opportunities; determine if the agency is presenting information on identified trade barriers to the U.S. Trade Representative (USTR) and FAS' private sector cooperators; and review whether USDA efforts to promote U.S. agricultural exports are being presented, with measurable benchmarks, in the National Export Strategy. OIG's report was issued in February 2007. We found that FAS does not formally track its efforts to expand trade activities or conduct outreach to U.S. exporters and does not have a formal process for summarizing and presenting trade barriers to the USTR.

Ensuring Accountability in Foreign Food Aid Programs

FAS administers foreign food aid programs, largely through grants to intermediaries known as private voluntary organizations (PVOs), the charitable, non-profit organizations responsible for implementing program objectives abroad. FAS expended approximately \$400 million for its food aid programs in fiscal year 2006. In March 2006, we issued a report assessing FAS' progress in addressing management control weaknesses regarding the Food for Progress program identified in an earlier OIG audit. Our latest report also reviewed eight judgmentally selected PVOs, three of which were the subjects of a hotline complaint. The audit evaluated issues such as internal agency controls/processes for evaluating grant proposals and awarding grant agreements, monitoring compliance with grant terms and conditions, and determining program results.

OIG found that many of the recommendations from our prior audit report had not been implemented, and therefore FAS could not provide reasonable assurance that PVOs were meeting their program objectives or spending funds appropriately. FAS lacked procedures to confirm that PVOs were recognized by their host governments and were able to operate effectively in-country. FAS did not pursue grant funds lost due to PVO mismanagement. Due to these internal control weaknesses, we concluded that FAS did not adequately follow up and determine whether there was mismanagement of \$2.2 million in grant funds.

We recommended that FAS strengthen its ability to monitor food aid agreements by implementing procedures to review PVOs' semiannual reports, conduct onsite reviews, and complete closeout reviews of food aid agreements. The agency should confirm that PVOs are viable agents in their host countries before shipping donated commodities to these private groups and aggressively seek recovery of grant funds lost due to PVO mismanagement. Generally, FAS agreed with our recommendations and stated that agency efforts were underway to implement several of them.

Oversight of Farm, Conservation, and Research Programs in 2007

OIG has initiated or plans to conduct several audits to review USDA farm and conservation programs. Work is underway to examine RMA's effectiveness in monitoring private insurance providers and determine if its compliance activities are adequate to improve the crop insurance program and reduce fraud, waste, and abuse. We are planning to review FSA's management controls in 2007 to assess their effectiveness to prevent farm program payments being made to producers who have been disqualified due to civil, criminal, or administrative actions.

There is considerable congressional interest in expanding USDA's role in our nation's efforts to develop a viable renewable energy program. The Department's activities include financial incentives (loans, loan guarantees, grants for capital equipment) for farmers to grow crops that can produce renewable energy products such as ethanol. USDA research agencies are engaged in developing and improving methods to produce renewable energy. In 2007, OIG will evaluate the Department's efforts to foster renewable energy technologies as well as the coordination between USDA agencies and other Federal agencies. These audits are currently underway.

NRCS' Wetlands Reserve Program (WRP) is a voluntary program offering landowners the opportunity to protect, restore, and enhance wetlands on their property. NRCS provides technical and financial support to help landowners with their wetland restoration efforts. We are reviewing the legitimacy of restoration costs and the agency's ability to monitor restoration efforts. A related voluntary agency program is the Conservation Security Program (CSP), in which payments are provided to landowners to maintain and enhance natural resources. CSP identifies and rewards those farmers and ranchers who are meeting the highest standards of conservation

and environmental management on their operations. The Government Accountability Office reported that NRCS lacked adequate controls to prevent participants from receiving financial assistance from multiple programs for the same conservation practice. OIG has initiated an audit to determine whether NRCS has adequately implemented provisions of CSP. We are focusing on whether the agency has properly handled key issues such as program eligibility, the calculation of program payments, and the detection of improper payments.

OIG also has an audit underway to review the agency's procedures to assess and prioritize the rehabilitation of dams constructed with NRCS funding. Many of these dams are nearing the end of their 50-year design life. A recent survey of known rehabilitation needs in 22 States revealed that more than 2,200 dams need rehabilitation at an estimated cost of more than \$540 million. The cost of rehabilitation will only increase with time as deterioration increases, construction costs rise, and more rehabilitation needs are identified. The Watershed Rehabilitation Program budget reported in the USDA fiscal year 2008 Budget Summary and Annual Performance Plan is \$6 million. Our primary objective is to review the adequacy of NRCS program controls for the rehabilitation of flood control dams to mitigate potential threat or danger to life and property.

Congress has provided substantial resources to support Agricultural Research Service (ARS) research regarding a wide array of food quality and safety issues, nutritional needs, and our environment's natural resource base. ARS spends approximately \$1.1 billion annually on 1,200 research projects organized into 22 national program areas at 100 locations and 4 overseas laboratories. We are currently evaluating the efficacy of ARS management controls over its intramural and extramural research agreements to ensure they are properly implemented. Our audit is examining ARS procedures to ensure that research funding is used for its intended purposes, research projects are adequately monitored, and project milestones are properly managed.

THE MANAGEMENT OF USDA'S PUBLIC RESOURCES

Information Technology Security in USDA

In recent years, USDA's Office of the Chief Information Officer (OCIO) and OIG have placed a major emphasis on the need to plan and implement effective information technology (IT) security for the Department. OIG continues to conduct various audits and reviews of the Department's IT security systems to assess and improve their performance.

Based on our reviews in 2006, the National Information Technology Center (NITC) in Kansas City, Missouri, sustained its unqualified opinion on its general control structure, and OCFO's National Finance Center (NFC) in New Orleans, Louisiana, received its first unqualified opinion on its design of its general control structure. However, we issued a qualified opinion on the effectiveness of NFC's controls because the controls were not operating during the entire year. This effectiveness qualification was primarily attributed to the disruptive effects of Hurricane Katrina on NFC's normal operating procedures. When our review determined that certain controls were not adequately designed, OCFO NFC updated its procedures to address our concerns.

As required by the Federal Information Security Management Act of 2002, our annual audit of the Department's IT security program continued to find significant weaknesses. These included needed improvement in contingency planning and testing, annual risk assessments, and configuration management. Due to the significance of the issues identified in our reviews, we continue to classify IT security as a material internal control weakness for USDA.

USDA's Universal Telecommunications Network (UTN) is the critical general support system serving the Department's data network backbone for telecommunications and network support services. We identified weaknesses in OCIO's ability to effectively manage and secure the UTN. OCIO had not completed required system testing, security control testing, and certification/accreditation of the UTN network prior to implementation. OCIO concurred with our recommendations and has taken significant actions to address identified weaknesses.

Reducing Risks From Stolen USDA Computer Equipment

In light of the disclosure or theft of Privacy Act/sensitive information from several Federal agencies in 2006 and OMB's recent mandates on securing such information, OIG is assessing potential risks at USDA. We issued a report on February 27, 2007, from our review of stolen equipment within USDA.

To the extent possible, we identified the information maintained on the stolen computers as well as sensitive information currently maintained on computers with-

in the Department. OIG found that controls over stolen computer equipment were lacking in the four USDA agencies reviewed.⁹ Specifically, we found Privacy Act/sensitive information was stored on computers that were stolen and the agencies did not notify the individuals whose information may have been compromised. Additionally, these agencies lacked policies and procedures to adequately notify proper authorities and affected parties when thefts of computer equipment occurred. The agencies agreed with OIG's recommendations.

To date, OCIO has provided agencies with limited guidance on what actions to take if computers are lost or stolen. OIG recommended that OCIO implement Departmentwide guidance regarding tracking and reporting requirements for lost/stolen computer equipment. This should include procedures for determining whether the subject equipment may have contained Privacy Act or sensitive information.

USDA Procedures to Assess Employee Civil Rights Complaints

We have previously presented testimony to the Subcommittee about our audit work focusing on the Department's processes and performance in handling allegations of discrimination against USDA employees or in USDA programs. Our most recent civil rights audit¹⁰ assessed the Office of the Assistant Secretary for Civil Rights (ASCR) implementation of prior OIG recommendations that focused on the agency's management and oversight of program and employment complaints. In response to a 2006 congressional request, we initiated an audit to evaluate the Department's progress in addressing employee civil rights complaints and employee accountability for acts of discrimination. OIG will identify and evaluate the adequacy of the Department's controls to properly process employee civil rights complaints and its processes to hold employees accountable for discrimination towards employees or in USDA programs. We anticipate issuing this report by the end of March 2007.

The National Computer Forensic Division: Advanced Investigative and Evidentiary Support

As an authoritative resource in the investigation and analysis of network intrusions and attacks on USDA networks, OIG's National Computer Forensic Division (NCFD) conducts thorough and accurate analyses of any IT network compromise by analyzing compromised servers, firewall logs, Intrusion Detection System logs, and Internet Protocol traffic logs. The NCFD continues to provide support, training, and advice on evidence collection and analysis to USDA agencies. During the past year, the NCFD provided onsite search warrant assistance for 12 warrants and analysis for 38 cases involving criminal activity, employee misconduct, and network intrusions.

An example of NCFD's work includes an investigation that was requested by the Department relating to a network intrusion and two servers that were compromised. NCFD determined that while two computer servers had been compromised multiple times by hackers in June 2006, the database containing personal identity information for 26,000 USDA employees had not been compromised or transferred from USDA computers. OIG is working with OCIO to ensure that all USDA networks and employee personal information are secure.

Another recent investigation involved a woman employed as a Geographic Information Systems (GIS) technician with FSA. The woman reproduced and sold 41 pirated copies of USDA-licensed software on two Internet auction websites. The woman received \$7,120 from the sales of the pirated software although its retail value exceeded \$326,000. In June 2006, the woman pled guilty in a Federal court in Indiana to copyright infringement and was sentenced to 5 years of probation, restitution of \$7,120 to the company owning the software copyright, and forfeiture of all computer-related equipment seized at her residence. This case resulted in the first Federal criminal conviction in Indiana involving the illegal sale of copyrighted materials over the Internet.

NCFD forensically imaged and analyzed the hard drives of eight computers in the GIS lab of FSA's Indiana State office for evidence that the software was copied utilizing one of the FSA computers. The forensic analysis produced evidence that was utilized in negotiating a guilty plea.

USDA Financial Management

As defined by the Government Accountability Office (GAO), success in Federal financial management is an unqualified audit opinion with no reportable conditions

⁹ FSA, NRCS, RD, and OCIO.

¹⁰ "Follow-up on Prior Recommendations for Civil Rights Program and Employee Complaints," issued September 2005.

and no instances of noncompliance with laws and regulations. In 2006, the Department's financial statements received unqualified audit opinions, as did six USDA entities.¹¹ This is an improvement from previous years. However, the Department and three agencies had material weaknesses and reportable conditions. The Department and four agencies also had instances of noncompliance with laws and regulations.

Specifically, the Department's material weaknesses related to improvements needed in overall financial management across USDA and IT security and controls. A reportable condition existed related to improvements needed in certain financial management practices and processes. Three instances of noncompliance were identified relating to the Federal Financial Management Improvement Act, the Improper Payments Information Act, and Managerial Cost Accounting practices. OIG continues to work with OCFO to ensure effective financial management throughout USDA.

The Role of USDA and Agriculture in Protecting the Chesapeake Bay Watershed

The Chesapeake Bay Program, which is administered by the U.S. Environmental Protection Agency (EPA), is mandated to direct restoration of the Chesapeake Bay through a regional partnership of Federal, State, and local agencies, academic institutions, and non-government organizations. OIG participated in a joint review of the program with EPA's OIG that concentrated on the agricultural best management practices used to address non-point nutrient and sediment loading to the Chesapeake Bay watershed.

Despite significant efforts to improve water quality in the Chesapeake Bay watershed, excess nutrients and sediment continue to impair the Bay's water quality. Our joint review found that few of the agricultural practices in the State tributary strategies have been implemented because the agricultural community considers many of these practices to be either unprofitable or to require significant changes in farming techniques. We found that EPA must improve its collaboration with its Bay partners and the agricultural community to reduce the agricultural nutrients and sediments entering the Chesapeake Bay watershed. Members of the agricultural community have been reluctant to participate in this endeavor with EPA because of its regulatory enforcement role.

We recommended that the Secretary or Deputy Secretary assign a senior-level official with commensurate authority to coordinate relevant USDA goals and programs with EPA and the Chesapeake Bay Program. USDA should consider the feasibility of targeting USDA funds on a regional and/or geographical basis to assist the Bay's environmental restoration. The Department should also direct USDA agencies to expedite the establishment of outcome-based performance measurements to properly evaluate their conservation activities. USDA generally agreed with our recommendations.

Evaluating Forest Service Use of Private Wildland Firefighting Crews

As wildfire activity on National Forests (NF) has become more intense, FS has made increasing use of contract suppression crews to supplement agency resources. FS incident management personnel had previously noted numerous performance problems with poorly trained and inexperienced crews. Other reports (GAO, incident management personnel) have indicated similar problems. We evaluated FS' administration of these contracts and its coordination with other parties¹² that also use these contracts.

We determined that FS needed to improve its contract oversight to ensure that contract employees had met both the training and experience requirements for the positions they held on fire fighting crews. Our review found that a significant number of contract firefighters may not have been qualified to perform the duties required under the contract. FS needed to address control weaknesses with wildfire suppression associations¹³ that provide training to contract employees. Language proficiency assessments should be improved to ensure contract crew personnel can communicate adequately with FS incident management personnel. Finally, we recommended that FS coordinate with other Federal agencies to identify undocumented workers on contracted crews. FS officials agreed with all of OIG's recommendations and established timeframes for corrective actions.

¹¹ Federal Crop Insurance Corporation, Commodity Credit Corporation, FS, Rural Telephone Bank, FNS, and RD.

¹² Primarily State and local governments. The crews at issue in this report were obtained from the Oregon Department of Forestry's list.

¹³ Private organizations that represent wildlife suppression contractors and provide training to their employees.

Reducing Forest Service's Large Fire Suppression Costs: Shared Responsibilities

FS' wildfire suppression costs have exceeded \$1 billion in 4 of the past 7 years. Our audit focused on the most significant "cost drivers" that were impacting fire suppression costs. We determined that the majority of FS' large fire suppression costs are directly linked to protecting private property—as opposed to National Forest System land—in the wildland urban interface (WUI). FS managers need to evaluate their agreements with State and local governments to ensure the costs of protecting the WUI are appropriately apportioned. A significant portion of these costs can be avoided and the safety of firefighters improved if the Federal Government can proactively work with State and local governments regarding prudent "Firewise" zoning and building codes.

In another report focusing on wildland fire issues and the Healthy Forest Initiative, we determined that FS needs to change some policies regarding wildland fire use (WFU). Hazardous fuels such as dead vegetation and undergrowth in our national forests are increasing the size and complexity of wildland fires. FS needs to reduce these fuels, increase the number of qualified personnel, and expand WFU to help control the costs of future fires. OIG further recommended that the agency implement improved processes to more effectively hold managers accountable for the financial impact of their decisions.

FS agreed with our findings and recommendations and initiated corrective actions. These include working with OIG to jointly develop training for FS personnel conducting reviews of large fire operations. FS and OIG will jointly conduct the training prior to the 2007 fire season.

OIG'S FISCAL YEAR 2008 BUDGET REQUEST

Before concluding, I would like to briefly comment on OIG's fiscal year 2008 Budget Request. With your assistance and support, we are pleased to have built a solid record of constructive audit oversight and investigative accomplishment. Over the last 4 years we have produced a return on investment of \$5.34 for each dollar of appropriated funds you have provided. During that period, our work has produced over \$1.65 billion in monetary recoveries and cost avoidances, 1,449 indictments and 1,358 convictions. In addition to our monetary results, we have made numerous recommendations that resulted in substantive management and program improvements. For example, in fiscal year 2006 we issued 425 program improvement recommendations and USDA managers agreed to implement 384 of them. These recommendations involved issues of congressional and public concern such as improving surveillance and monitoring of AI in domestic poultry, strengthening USDA's food inspection operations, and improving the collection of unauthorized farm program payments.

In addition to the statistical accomplishments mentioned above, fiscal year 2006 and the first few months of fiscal year 2007 have been a particularly productive time for OIG in other ways as well. The following activities may be of particular interest to the Subcommittee.

- OIG has devoted over \$2 million and several staff years to providing oversight to USDA programs supporting the Gulf Coast region devastated during the 2005 hurricane season in order to increase accountability in these programs and avoid waste and fraud in the distribution of benefits. The \$445,000 Congress authorized in the fiscal year 2006 emergency supplemental to support these efforts was of great assistance. Currently, we have 11 audits and 11 investigations underway pertaining to USDA hurricane recovery assistance programs.
- We also directed resources to review Departmental plans to deal with the threatened avian influenza pandemic, by advising the Department on how it could improve its plans and programs.
- OIG took prompt and comprehensive action to evaluate the implementation of the Department's IT security system. Through a coordinated program of audits, investigations, and other reviews, USDA OIG is addressing the areas of highest risk and providing insight and support to USDA program agencies.
- We formed an Office of Inspections and Research (OIR) to address emerging issues that may require scientific, legal, statistical, or other expert competencies. Generally, OIR will conduct short-term, focused reviews and inspections of USDA's programs and operations. OIR projects completed in the last year and currently underway include:
 - A review of the Federal crop insurance program that, in collaboration with FSA and RMA, identified a number of fraud indicators or conditions that are often associated with fraud, waste, and mismanagement.
 - An inspection regarding the coordination of the Department's international activities and agreements.

An inspection of the security practices at a USDA laboratory that found the laboratory had made many improvements, both physical and through extensive training of personnel.

- With the support of our congressional appropriators, we were able to strengthen our ability to support USDA programs through effective audits and investigations. Five years ago our information technology systems were inadequate to support our audit and investigative program. Thanks to your continued support, our IT environment is current and able to support sophisticated audit and investigative techniques. From fiscal year 1996 to fiscal year 2006, OIG's staff level fell a total of 21 percent—which directly translates into a commensurate reduction in our audit and investigative capacity. With your support, we were able to arrest that trend in fiscal year 2006 and have begun—in a very small way—to strengthen our capacity.

We respectfully request your support in continuing our efforts to maintain, and in some areas even improve, OIG effectiveness in fiscal year 2008. The President's request asks for the minimum necessary to support our staffing level and advance our ability to safely and effectively respond to emerging public health and agriculture security threats. Specifically, the President's fiscal year 2008 request of \$84 million for OIG provides for:

- \$1.9 million for 2008 mandatory pay costs.
- \$994,000 for 2007 pay costs.
- \$340,000 to fund five staff to reinforce our audit, investigation, and inspection programs focusing on the approximately \$20 billion spent annually on USDA farm programs.
- \$757,000 for necessary equipment and training updates to the Computer Forensics Unit and the Emergency Response Team, and implementation of an automated audit workpaper system that will improve the timeliness of our audits and ensure that audit evidence is kept in accordance with Department of Justice standards.

This concludes my testimony statement. I thank the Members of the Subcommittee for the opportunity to present information about OIG's activities and our fiscal year 2008 Budget Request.

PREPARED STATEMENT OF NANCY C. PELLETT, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, FARM CREDIT ADMINISTRATION

Mr. Chairman, Members of the Subcommittee, I am Nancy C. Pellett, Chairman and Chief Executive Officer of the Farm Credit Administration (FCA or Agency). On behalf of my colleagues on the FCA Board, Leland Strom of Illinois and Dallas Tonsager of South Dakota, and all the dedicated men and women of the Agency, I am pleased and honored to provide this testimony to the Subcommittee.

I would like to thank the Subcommittee staff for its ongoing assistance during the budget process, and before I discuss the role and responsibility of the Farm Credit Administration and our budget request, I would respectfully bring to the Subcommittee's attention that FCA's administrative expenses are paid for by the institutions that we regulate and examine. In other words, FCA does not receive a Federal appropriation but is funded through annual assessments of Farm Credit System (System) institutions and the Federal Agricultural Mortgage Corporation (Farmer Mac). We fully support the proposed 2008 Budget Submission of the President.

Mission of the Farm Credit Administration

As directed by Congress, FCA's mission is to ensure a safe, sound, and dependable source of credit and related services for agriculture and rural America. The Agency accomplishes its mission in two important ways.

First, FCA ensures that the System and Farmer Mac remain safe and sound and comply with the applicable law and regulations. Specifically, our risk-based examinations and oversight strategies focus on an institution's financial condition and any material existing or potential risk, as well as on the ability of its board and management to direct its operations. Our oversight and examination strategies also evaluate each institution's efforts to serve all eligible borrowers, including young, beginning, and small farmers and ranchers.

Secondly, FCA approves corporate charter changes, and researches, develops, and adopts regulations and policies that govern how System institutions conduct their business and interact with their customers and provides other necessary guidance. If a System institution violates a law or regulation, or operates in an unsafe or un-

sound manner, we use our supervisory and enforcement authorities to ensure appropriate corrective action.

Fiscal Year 2006 Accomplishments

In 2006 we continued our efforts to achieve our Agency's strategic goals through (1) responsible regulation and public policymaking and (2) effective risk identification and corrective action. FCA has worked hard to maintain the System's safety and soundness. We also continually explore ways to reduce regulatory burden on the FCS and to ensure that all System institutions are able to provide agriculture and rural America with continuous access to credit and related services.

EXAMINATION PROGRAMS FOR FCS BANKS AND ASSOCIATIONS

One of the Agency's highest priorities is the development and implementation of efficient and effective risk-based oversight and examination programs that meet the high standards and expectations of the Congress; investors in System debt obligations; the farmers, ranchers, and cooperatives that own System banks and associations; and the public at large. Our examination programs and practices have worked well over the years and have contributed to the present safe and sound overall condition of the System, but we must continue to evolve and prepare for the increasingly complex nature of financing agriculture and rural America.

With the changes in the System and our human capital challenges within the Agency (i.e., pending retirements, normal attrition of staff, and the ever-increasing need for more sophisticated skills in the financial sector), we have undertaken a number of initiatives to enhance our skills and level of expertise in key functional examination areas. We have also realigned our organizational structure to make the best use of our resources. The evolving nature of agriculture and the Farm Credit System necessitates a flexible organizational structure at FCA. At the present time, the sound financial condition of the System also provides us a unique opportunity to prepare for the future. In 2006 our Office of Examination completed its transition from a regionally based field office structure to division examination teams that are organized on a national basis. Office locations have been retained, but the examination programs are now managed nationally to better match examiner skills to material and strategic risks faced by the FCS institutions.

On a national level, we actively monitor risks that may affect groups of System institutions or the entire System, including risks that may arise from the agricultural, financial, and economic environment in which the System institutions operate. Our job is not to forecast specific events but to understand the environment so that we can take steps to help System institutions take pre-emptive actions before adverse trends develop.

Examiners also use a risk-based examination and supervision program to differentiate the risks and develop individualized oversight plans for each FCS institution. We set the scope and frequency of each examination based on the level of risk in the institution. In addition, we continually identify, evaluate, and proactively address risks within each institution. Examiners base the scope of their oversight and examination activities on their assessment of an institution's internal control environments and the ability of the institution's board and management to manage risks, both present and future. The frequency and depth of our examination activities may vary, but each institution is provided a summary of our activities and a report on its overall condition every 18 months as required by the Farm Credit Act.

As part of our ongoing efforts, we monitor each institution's risk profile. The Financial Institution Rating System (FIRS) is the primary risk categorization and rating tool used by examiners to indicate the safety and soundness of an institution. The rating system is similar to other Federal financial regulators' CAMELS (capital adequacy, asset quality, management performance, earnings, liquidity, and sensitivity to interest rate risk) rating scale. FIRS ratings range from 1 (for a sound institution) to 5 (for an institution that is likely to fail). Throughout fiscal year 2006, FIRS ratings as a whole continued to reflect the stable financial condition of the FCS. The overall trend in FIRS ratings continues to be positive, with eighty-three 1-rated institutions and seventeen 2-rated institutions, and one 3-rated institution. Importantly, there were no 4- or 5-rated institutions. In addition, no FCS institutions were under enforcement action and no FCS institutions were in receivership. The overall financial strength maintained by the System remains strong and does not pose material risk to investors in FCS debt, the Farm Credit System Insurance Corporation (FCSIC), and FCS institution stockholders.

During fiscal year 2006, FCA also performed various examination and other services for the Small Business Administration, the U.S. Department of Agriculture, FCSIC, and the National Cooperative Bank. Each of these entities reimburses FCA for its services. The safety and soundness of the System and Farmer Mac remains

our primary objective. However, we believe the continuing use of FCA examination resources by other agencies is a positive reflection on the expertise of FCA examiners and serves to broaden their examination skills while increasing job satisfaction and employee retention. It also helps us defray some of the costs of our operations while providing a valuable service.

REGULATORY ACTIVITY

Congress has given the FCA Board statutory authority to establish policy and prescribe regulations necessary to ensure that FCS institutions comply with the law and operate in a safe and sound manner. The Agency's regulatory philosophy articulates our commitment to establishing a flexible regulatory environment that enables the System, consistent with statutory authority, to offer high-quality, reasonably priced credit to farmers and ranchers, their cooperatives, rural residents, and other entities on which farming operations depend. This translates into developing balanced, well-reasoned, flexible, and legally sound regulations. We strive to ensure that the benefits of regulations outweigh the costs; to maintain the System's relevance in the marketplace and rural America; and to ensure that FCA's policy actions encourage member-borrowers to participate in the management, control, and ownership of their Government-sponsored enterprise (GSE) institutions.

For 2006 and early 2007, the Agency's regulatory and policy projects included the following:

- A final rule on governance of FCS institutions that provided enhanced oversight of management and operations by strengthening the independence of System institution boards and by incorporating best governance practices.
- A final rule that amended and updated the regulations governing the termination of System status by a System institution.
- A final rule to improve the transparency of public disclosures, strengthen board and management accountability and auditor independence, and increase shareholder and investor confidence in the System.

In addition, relative to Farmer Mac, the Agency finalized a rule updating the Farmer Mac Risk-Based Capital (RBC) Stress Test. We amended the RBC regulations in response to changing financial markets, new business practices, and the evolution of the loan portfolio at Farmer Mac, as well as continued development of industry best practices among leading financial institutions. The rule is intended to more accurately reflect risk in the model in order to improve the model's output—Farmer Mac's regulatory minimum risk-based capital level.

The Agency has also adopted an ambitious regulatory and policy agenda for 2007. The agenda includes the following goals:

- Evaluating comments received on a proposed rule to change the ownership requirement for the eligibility of processing and marketing entities.
- Continuing to evaluate how System partnerships and investments can increase the availability of funds to help stimulate economic growth and development in rural America under a pilot program initiated during fiscal year 2005.
- Continuing to review current regulatory requirements governing eligibility and scope of lending to determine if these requirements are reasonable in light of agriculture's changing landscape. Agency staff will identify issues and explore options for the Board's consideration.
- Developing and issuing an Advance Notice of Proposed Rulemaking to solicit public input on appropriate changes to FCA's capital adequacy requirements for the System in light of Basel II and IA proposals by the other Federal banking agencies.

CORPORATE ACTIVITIES

The pace of System restructuring remained slow in fiscal year 2006. Only one corporate application was submitted for FCA Board review and approval during fiscal year 2006, compared with four applications the prior year. As of January 1, 2007, the System had 95 direct-lender associations and five banks for a total of 100 banks and associations. Seven service corporations and special-purpose entities brought the total number of FCS institutions to 107 entities. Through mergers, the number of FCS associations has declined from 172 to 95 since 2000, and the number of FCS banks has dropped from seven to five.

Condition of the Farm Credit System

I will now turn to the condition of the Farm Credit System. I am pleased to report that the System's overall condition and performance remained strong throughout 2006. The FCS is fundamentally sound in all material aspects, and it continues to be a financially strong, reliable source of affordable credit to agriculture and rural

America. Capital levels continued to be strong, especially in consideration of the System's risk profile. Asset quality remained high, loan volume growth was strong, and favorable credit conditions enabled the System to achieve almost \$2.4 billion in earnings for the 12 months ended December 31, 2006.

Loan volume continued to grow at a strong pace during 2006 while loan quality remained high. Gross loans increased by 16.2 percent to 123.4 billion. The level of nonperforming loans, including nonaccrual loans, decreased to 0.50 percent of gross loans outstanding. Delinquencies also remained minimal. The System has earned more than \$1 billion consistently since the early 1990s; as a result, capital remains strong and is made up largely of earned surplus, the most stable form of capital. A strong capital position will help the System remain a viable, dependable, and competitive lender to agriculture and rural America during any near-term downturns in the agricultural economy.

Federal Agricultural Mortgage Corporation

FCA also has oversight, examination, and regulatory responsibility for the Federal Agricultural Mortgage Corporation, which is commonly known as Farmer Mac.

Congress established Farmer Mac in 1988 to provide secondary market arrangements for agricultural mortgage and rural home loans. In this capacity, Farmer Mac creates and guarantees securities and other secondary market products that are backed by mortgages on farms and rural homes. Through a separate office required by statute (Office of Secondary Market Oversight), the Agency examines, regulates, and monitors Farmer Mac's disclosures, financial condition, and operations on an ongoing basis and provides periodic reports to Congress.

Like the Farm Credit System, Farmer Mac is a GSE devoted to agriculture and rural America. FCA and the financial markets recognize Farmer Mac as a separate GSE from the System's banks and associations. Farmer Mac is not subject to any intra-System agreements or to the joint and several liability of the FCS banks, nor does the Farm Credit System Insurance Fund back Farmer Mac's securities. However, by statute, in extreme circumstances Farmer Mac may issue obligations to the U.S. Treasury Department to fulfill the guarantee obligations of Farmer Mac Guaranteed Securities.

In conclusion, we at FCA remain vigilant in our efforts to ensure that the Farm Credit System and Farmer Mac remain financially strong and focused on serving agriculture and rural America.

Fiscal Year 2008 Budget Request

Earlier this fiscal year, the Agency submitted a proposed total budget request of \$47,482,520 for fiscal year 2008. The Agency's proposed budget includes an assessment on System institutions for fiscal year 2008 of \$42,550,000. The total amount of assessments collected from the FCS and Farmer Mac with carryover funds equals \$46,000,000. Since approximately 82 percent of the Agency's budget goes for salaries, wages, and related costs, almost all of the total budget amount will be used for these purposes.

It is our intent to stay within the constraints of our fiscal year 2008 budget as presented, and we continue our efforts to be good stewards of the resources entrusted to us in order to meet our responsibilities. The Agency has worked hard to hold down the assessment to the System for our operations, and I believe we have achieved that objective over the past several years. While we are proud of our record and accomplishments, I assure you that the Agency will continue its commitment to excellence, effectiveness, and cost efficiency and will remain focused on our mission of ensuring a safe, sound, and dependable source of credit for agriculture and rural America. On behalf of my colleagues on the FCA Board and at the Agency, this concludes my statement and I thank you for the opportunity to share this information.

Senator KOHL. Thank you very much, Mr. Secretary. We'll now begin our rounds of questions.

FSIS FUNDING LEVEL

Mr. Secretary, I was pleased to see an increase in the budget for the Food Safety and Inspection Service of approximately \$100 million over the level provided in fiscal year 2006, but as you know, Mr. Secretary, there were some very serious budget problems last year, even though we provided the requested funding. Can you commit that this funding level will be adequate, in light of increas-

ing workload and industry growth, for FSIS to maintain the proper amount of staff with the ability to do the proper testing and the work throughout the country?

Secretary JOHANNIS. Yes, we believe it will. And you're absolutely right, last year we were in a very tough situation with the budget, and about 80 percent of this area is staffing, so if you get in a tough situation there's not much you can do. It's just a very, very difficult situation. But with the increased funding we have requested, we believe we can cover the anticipated need out there and meet the needs of this inspection area. So we appreciate your understanding of the situation, but we believe this will get us there.

Senator KOHL. All right. Mr. Secretary, the problems faced in fiscal year 2006 and fiscal year 2007 were the result of several years of FSIS being shortchanged in their pay costs, although Congress has always provided the full amount requested. We seem to have dug ourselves out of that hole. Will this funding level keep us above board, or is FSIS going to have to dig into their program levels to fully fund pay costs?

Secretary JOHANNIS. Well, I'll ask Scott to talk about pay costs, but again I think we're in good shape with this funding request to get the job done. But, Scott, talk about pay costs, if you will.

Mr. STEELE. Thank you. Yes, Senator, we have fully funded the on line inspection staff. We're anticipating the growth in the industry in terms of meat and poultry inspection requirements. Of course there is some uncertainty with that, in terms of how much demand for inspection will be out there in the meat industry, but this is our best estimate right now. Based on that, we have fully funded all the inspection requirements, on line inspectors, that we need.

And of course, as the Secretary pointed out, a large part of the budget is for wages and benefits, so there is a limited amount of flexibility. But we are doing audits on the agency right now. We've had people come in and look at that, outside auditors to look at the financial balance sheets of the organization. We're doing a better job of tracking the expenditures in the agency. I think we're at this point in time on top of the workload and funding requirements, but we will keep the committee and staff informed as we move through the year and report to you if there are any changes to our estimates.

Senator KOHL. That's good.

AVIAN INFLUENZA (AI)

Mr. Secretary, the problem of avian flu, as we all know, has not gone away. In fact, there have been recent reports of an outbreak in England, and with spring weather around the corner there will be a lot of activity in migratory bird flyways. Can you tell us the total amount within APHIS that will be spent on avian flu activities this year, and tell us what this money will buy?

Secretary JOHANNIS. Yes. The 2008 budget requests a total of \$82 million for avian influenza. This will continue efforts initiated with the supplemental funding, which if you'll remember was \$91 million. \$57 million of that is specifically designated for APHIS highly pathogenic AI activities.

Funding will be used to continue our surveillance, diagnostics, preparedness and response efforts, and then a piece of that is for international veterinary capacity-building. Of the total requested, \$3.2 million is to develop methods to detect AI in the environment and over \$5 million is for further AI research, including development of poultry vaccines.

The 2008 budget also includes about \$17 million for the APHIS ongoing low pathogenic program. Low path AI is a concern for its potential cost to the poultry industry, but it's also a concern to us because of the potential that it might mutate into the highly pathogenic variety, so we also pay attention to that. So that details what we're doing with the AI funding.

Senator KOHL. Mr. Secretary, can we expect more outbreaks of avian flu this spring? And if we can, what precautions do you have in place?

Secretary JOHANNES. Low pathogenic AI is common in the United States, so to address low path first, it's been around about 100 years. Birds go through a flu season much like humans go through a flu season. It's typically not fatal to birds, and it's not a problem to human consumption of poultry. You cook the bird and you kill the virus. And that would be true of both low and high path. But we will see low path. We have strategies in place to deal with that, but again, it's fairly common.

We've only had high path avian influenza in the United States on three occasions. The most recent was in 2004. And so far in this most recent international outbreak of high path avian influenza, we have not detected it.

And we have been doing aggressive testing, in cooperation with the Department of the Interior, of wild birds and in Alaska, birds that would come down through the United States, through the flyway. In fact, we've done 79,000 wild bird samples to date. We haven't detected it, which is good news. We will continue our efforts to monitor and detect, will continue to do environmental samples, but so far, so good, on the high path.

EMERALD ASH BORER

Senator KOHL. Good. I'd like to ask you about emerald ash borer. Would you speak to the efforts of APHIS in undertaking to control and eradicate emerald ash borer where it has been found, and also please say a word about the surveys that the budget requests funding for in order to prevent the spread of emerald ash borer in States like my own of Wisconsin?

Secretary JOHANNES. The budget includes \$30.7 million, an increase of about \$21 million over the 2007 Continuing Resolution, for emerald ash borer efforts. The funding will support survey efforts and regulatory activities to prevent additional spread of the pest. The budget also requests \$2 million in APHIS plant methods development, a line item to develop control methods to do a better job of managing EAB.

The program's immediate goal is to protect infested areas by containing the current infestation—mainly that would be in Michigan, Ohio, and Indiana—and eliminate isolated outbreaks, such as those detected in States like yours or Illinois or Maryland, and develop a long term control and eradication strategy. So we've boosted our

request for funding here by about \$21 million over where we were with the Continuing Resolution.

Senator KOHL. I thank you very much. I'd like to call on Senator Bennett.

Senator BENNETT. Thank you, Mr. Chairman.

FSA COMPUTER SYSTEM

Mr. Secretary, we're becoming increasingly aware of the situation regarding the computer system in the Farm Service Agency. I'm sure you're familiar with that. I understand it has gotten so bad that direction has been given to State and county officers as to what times of day they could use the system because it's not up in a uniform fashion.

Can you walk us through the issues in relation to that and what you're doing? The funding request did not appear in this year's budget, so I assume you have a strategy for dealing with it. Just talk us through that one.

Secretary JOHANNES. Well, we are working with staff. In fact, I think it was yesterday we gave an extensive briefing with our computer experts on some of the problems we are facing. And I'll just be very candid with you. This is an area where we're going to need some help.

Senator BENNETT. Does "help" mean money?

Secretary JOHANNES. It always does in government, doesn't it?

Senator BENNETT. Yes.

Secretary JOHANNES. Here is the challenge we face. Beginning in November 2006, FSA experienced performance problems in its web-based software for programs such as the MILC program, Direct and Counter-Cyclical Payments, and the 2007 crop year farm reconstitutions. The amount of time systems were off line, in other words, dark, became progressively longer. A number of corrective actions were put in place, but again, the problem just continued to worsen.

So FSA did what you said, they rationed web access time to try to alleviate that overloading of computing resources, as a means to try to continue serving producers while other steps were put in place to aggressively diagnose the problem we're facing. That policy was suspended on February 9.

A team was put together of USDA and private sector experts to observe the Kansas City Web Farm under a load situation. The team's recommendations to optimize the performance of the computing environment in applications systems are being implemented, and service has been restored at a pre-November level. That's my understanding. But I will tell you that I don't believe, in fact, no doubt about it, the problem is not solved.

FSA and the department's OCIO have compiled a comprehensive list of investments in managed services that are needed to stabilize the infrastructure used by FSA to deliver program benefits. There's dozens of reasons as to why this is happening now, but suffice it to say that over time a lot has been added to this system, and maybe at times not enough money to deal with the issues that the system was asked to face.

So what happens now, as it has been explained to me, and this is very nontechnical language, but let's say a farmer shows up and

we put that farmer's information into the system to assist that farmer in some way. That is routed to our Kansas City facility, where that request works its way through a very complex system of lap and overlap and overlays, and quite honestly patched-together systems over a period of years. And as it's working its way through all of that and trying to make this work, a period of time elapses, and if you don't get your request met within that period of time, it will just kick you out.

Senator BENNETT. Yes. I don't want to go that deep into it because I want to hang onto my time, but I'm glad to know you're on top of it to that degree. Can we expect a request for reprogramming or a supplemental or something?

Secretary JOHANNIS. In the next 3 weeks we hope to have in front of you, your staff, a business case for what's going to be involved in this system. Here is what I will tell you, Senator, just to cut to the chase.

I think there's going to be a short term response to this, because building a new system takes time and it's very expensive. It takes time. It could take 3 years plus. And so because of a new farm bill, because of a whole bunch of other things that just come along, I think there will be a short term response that we're going to have to deal with and then a long term approach to a system.

Senator BENNETT. I see. Well, thank you.

INTERNATIONAL TRADE

Let's talk about international trade. You mentioned exports being up, record levels. Trade Promotion Authority is set to expire this year. How much of the increase that we've seen in farm exports can be attributed to TPA, and also Trade Adjustment Assistance, or TAA, for farmers? How effective has all of this been with respect to that, and what would be the effect if TPA expired without being renewed?

Secretary JOHANNIS. Personally, I think it would be a very bad situation for farmers. Our exports have been growing. There are better experts here on the panel that can tell you or offer thoughts about what is related to Trade Promotion Authority or what is not, but here is the bottom line.

I don't think you will see another trade agreement negotiated or approved without Trade Promotion Authority. I think the trade initiative will just stop. It will just stop. Why? Why would a country negotiate with us, if the end result is there really is no agreement? There really is no end to the negotiations, and the possibilities for shaking on the deal and then the deal not really being a deal. So I personally believe it's critically important.

I will also offer this, because I've said it publicly. To me it doesn't matter who is in the White House, it doesn't matter if it's one party or another party, I would have the same argument for Trade Promotion Authority no matter who was in the White House. I believe it's just an important part of what we do.

Now, I think there's always an opportunity for discussion and analysis and debate about are we doing it well enough, are we not doing it well enough, what should we be doing, are we taking care of labor issues, environmental issues, trade issues, all of that. I think that's a very, very appropriate discussion. But I think with-

out Trade Promotion Authority we disarm whoever is in the White House to negotiate trade agreements and bring those to the Senate and the House for approval.

Senator BENNETT. Thank you. I was going to discuss ag disaster assistance, but I think Senator Dorgan has signaled that he is going to deal with that.

NATIONAL ANIMAL IDENTIFICATION SYSTEM (NAIS)

Let me ask you one last question quickly about the National Animal Identification System. There is some confusion about that. We have given you some money in the past. You have asked for some more money. But can you help us understand exactly where that is and where you see it going in the coming year?

Secretary JOHANNIS. The first thing I want to tell you is that it is a voluntary system. The system that we have designed and articulated basically says to the producer, "this is for you to make a decision as to whether this is the best approach for what you're doing in your operation." It is a voluntary system.

The first piece of funding, if you will, actually predates me, but it was funding designed to put in place the structure necessary to do premises identification and lay the groundwork for the next steps. I can tell you that we had a goal at the end of January of having 25 percent of our premises registered, and we met that goal. We were right there. It was about 24.6 percent, so we have met that goal, and we continue to work with States across the country.

The bottom line is this, Senator. Some States are really doing well. They're doing great. They're registering premises. People believe in it. Other States are not doing as well. They are behind. They are not registering premises as aggressively. There is a debate in the country as to how important this might be, but I think we're overcoming that. We're working to get good information out there.

Ultimately, I think it has to happen. I was an advocate when I was Governor. I'm an advocate now as Secretary. I do believe the voluntary approach beats the mandatory approach. I think that's where we need to be now. So I personally believe it is where we need to be headed.

Senator BENNETT. Thank you very much, Mr. Chairman.

Secretary JOHANNIS. Thank you, Senator.

Senator KOHL. Thank you very much, Senator Bennett.

Senator Dorgan.

Senator DORGAN. Mr. Chairman, thank you very much.

DISASTER AID

Mr. Secretary, welcome. I intend to try to offer a disaster aid provision to the emergency supplemental bill. I mentioned to you that I've done that three times. Twice it got through the full Senate, got to conference, and was blocked by the administration. If I am successful in getting a disaster aid bill through the Senate on this supplemental, I'm wondering whether the administration will continue to want to block it or whether you'll be working with us to try to pass it.

Secretary JOHANNIS. As you know, the administration's historic position is to require offsets to find a way to pay for disaster aid,

and I don't see anything that would indicate a change in that historic position.

Senator DORGAN. Well, the President doesn't request any offsets for any emergency supplemental bills.

Secretary JOHANNES. In this area, the administration's position, though, has been to require offsets. Here is what I would say, Senator, and you know I went through this when I was governor, and it hasn't changed. On an annual basis we talk about disaster, and there will be disasters. This is a very, very large country. Weather patterns are different north to south and east to west. Probably the one guarantee I can make you each year is that somewhere in the United States there will be a disaster.

It's just a big country. Somewhere there's going to be drought. Somewhere there's probably going to be hurricane and tornado and hail damage and all of the things that farmers and ranchers deal with. And yet in other parts of the country they oftentimes experience historically best years. I won't go through the figures. You know the figures. But I could cite figures about corn production this year and soybean production, etcetera.

I personally believe that the long term answer to this is to look at what we're doing here in terms of the policy and try to figure out, is there a solution? I would love to sit down with you and talk to you about some of the proposals we've made in the farm bill, because I believe they'll make a big difference. I believe they will help this situation. Revenue countercyclical does work better—

Senator DORGAN. Mr. Secretary, I only have 5½ minutes of it is now gone. I'm very interested in what you are saying, but that—I'm interested in a response to the question of will the administration attempt to block a disaster piece that I put in the emergency supplemental.

Secretary JOHANNES. I can tell you, Senator, today the administration's position has been and will be that offsets will be required to finance that.

Senator DORGAN. Mr. Secretary, did the administration request offsets when we provided farm disaster aid for farmers who lost everything during Hurricane Katrina?

Secretary JOHANNES. We have programs for disaster aid that we administer, and we administered some of those programs there that were funded and we literally could identify some funding and go out there and try to help in the Katrina situation.

Senator DORGAN. Mr. Secretary, with respect to Katrina, that disaster had a name. Last year's drought, the epicenter of which was in North and South Dakota, but it spread substantially, had no name. But the farmers in the Gulf region, as a result of Hurricane Katrina, did get disaster relief. A significant portion of that was declared emergency, signed by the President.

I think it is unfair to suggest somehow that other farmers who lost everything, and there are others that did, should be subject to a different standard. And I just would say to you that I'm going to attempt once again to put a disaster provision in the emergency supplemental, and my hope is that this time the administration will not block it.

COUNTRY-OF-ORIGIN LABELING

I want to ask—again, we have such limited time—I want to ask about Canadian beef. I don't understand why the administration is so anxious to almost have a cattle drive from Canada coming to this country. One-third of the cattle that have been identified with BSE in Canada were born after the feed ban, and yet the administration tells us because of the imposition of a feed ban that we won't have any risk associated with this.

It seems to me, Mr. Secretary, if you're at least considering, as you are, bringing in substantial additional animals from Canada, who just recently discovered their ninth case—or tenth, if you consider the American cow—of BSE, that before you would do that you would agree to implement country-of-origin labeling and be aggressively interested in country-of-origin labeling, after which we then have a discussion about whether it is protective of this country's economic interests and this country's beef industry to bring in additional cattle from Canada in the shadow of their ninth case of BSE. Would you respond?

Secretary JOHANNES. I'd be happy to. In reference to the question about country-of-origin labeling, let there be no mistake. Country-of-origin labeling is the law, effective October 1, 2008. I want you to understand that although I may have personal feelings about it and desire to have a great debate about it, those personal feelings aren't important at this point. We will administer the law that Congress has put in place.

In reference to the minimal risk rule that you referred to, that is in the rulemaking process at this point in time. We have sought comments. The deadline for that is coming up pretty quickly. We will very carefully review those comments and then make a decision about the appropriate course of action.

We oftentimes say, and you've heard me say it, and probably read my comments when I speak of Japan and South Korea, that they must live by international standards. It's not fair to have a personal country standard. And so I will endeavor to do everything I can to make sure we live by those standards, and that not only do I preach them, but I'm willing to recognize those standards in this country. So that's kind of how we approach it.

Senator DORGAN. Mr. Chairman, first of all, thank you. I would like to submit additional questions, and I'd like the record to show my great personal restraint in not responding to the cheerleading about Fast Track.

Senator KOHL. Thank you, Senator Dorgan.

Senator CRAIG.

Senator CRAIG. Byron, message received.

USDA LOAN GUARANTEE AUTHORITY

Mr. Secretary, I have twice passed legislation seeking to increase USDA loan guarantee authority from the \$40 million it is now to about \$100 million. Your lawyers said then that they couldn't handle the logistics for projects this size. Now the President has proposed in his fiscal year 2008 budget a USDA loan guarantee package much larger than I ever tried to pass, as you know, to get into the ag portfolio new technologies. We must go beyond where we

have been. I sensed that some years ago with anaerobic digestion and a combination of other things, not only to solve waste problems but to enhance energy production.

Question: Since we are now talking in the backdrop of a new farm bill that will likely increase the energy title and therefore the loan guarantee authority for USDA, could you talk about the process of the USDA's loan guarantee program and your opinion as to how the department will handle this new loan guarantee authority?

Secretary JOHANNIS. Well, we do loan guarantees. They're not new to us, as you know, Senator, and they are something we're familiar with. In the farm bill proposal that we have submitted, we are proposing, for example, \$2.1 billion in loan guarantees targeted at cellulosic ethanol.

Senator CRAIG. Right.

Secretary JOHANNIS. And I guess probably the best way of answering your question is that the process that we have in place, we really envision as the process that would move us through those loan guarantees. So, again, it's not new for us. It's something we have done in the past. We feel confident that we can do it for what we're proposing in the future.

Senator CRAIG. Okay. Well, we'll work with you on it. We're glad that USDA is moving more aggressively in that direction. That's certainly part of the solution of getting us over the hump in some of these changes necessary in technology, cellulosic being one of them.

THE NATIONAL VETERINARIAN MEDICAL SERVICE ACT

In December 2003 the President signed into law a USDA program called National Veterinarian Medical Service Act that provides incentive to bolster the number of veterinarians in the field who would serve as first responders in emergency situations. Now, we're primarily talking about large animal industry type veterinarians in rural areas.

As I said in my opening statement, we are dumping millions of dollars into livestock disease research, and this panel helped provide hundreds of millions of dollars to create a National Animal Disease Lab in Ames, Iowa. I find it ironic that after spending all this money, we find ourselves in a crisis situation where we have a shortage of livestock veterinarians whose sole purpose is to intercept and defend this country against catastrophic animal diseases.

Congress provided \$500,000 in 2006, \$750,000 in the 2007 budget bill, to implement a pilot program, but your fiscal year 2008 budget still does not support this program. Now I'm hearing from veterinarians that your department has no plan to implement the rules and regulations for the law passed over 3 years ago to reverse the spiraling reduction in our first responders, i.e. large animal veterinarians. Your response to that?

Secretary JOHANNIS. You are right, there was \$500,000 worth of funding in 2006. Here's what it boiled down to. By national standards, in trying to pull off a national program, it wasn't a huge amount of money, I think we would both agree. It turned out to be a rather complex program. It was a program that took some effort, if you will, to get together.

I will assure you, Senator, it's not a program that we are opposed to, not at all. We see the need out there. Vets are educated and only a few of them decide to go with large animals versus the small animal practice. You see that in your State, we saw it in our State.

Senator CRAIG. It's where the money is.

Secretary JOHANNIS. Yes. Well, and you know, there's just a certain difference in the kind of work that is performed, too.

Senator CRAIG. Sure.

Secretary JOHANNIS. But we believe in the program. The only defense I can offer, and I don't want to sound defensive because we do like the program, is it just turned out to be more complicated than what it would appear.

Senator CRAIG. Then my question is, is there a process of rules and regulations that will be implemented? Is this program something that will come into function, or is it at idle?

Secretary JOHANNIS. We are moving ahead with the design and the implementation of the program, so the answer to your question is yes.

Senator CRAIG. Thank you. Thank you, Mr. Chairman.

Senator KOHL. Thank you very much.

Senator NELSON.

Senator NELSON. Thank you, Mr. Chairman.

ADMINISTRATIVE EXPENSES FOR EARMARKS

Mr. Secretary, as you know, during recent months there has been a great deal of attention drawn to earmarks, and we can certainly agree that transparency, accountability, and disclosure is extremely important on this topic. With that in mind, and this is sort of—it's a budget issue and question—can you tell me if 100 percent of the congressionally-directed earmarks that go through USDA are actually allocated to the congressionally-directed recipient?

Put another way, does USDA take some money, a certain percent of the earmark, for its own administrative expenses in connection with the earmark, both related and unrelated to the earmark? And would you support greater transparency, so that Congress and the public are aware of exactly how USDA directs this money? And it may be something you want to refer to somebody else, but—

Secretary JOHANNIS. I'll have Scott Steele offer a thought on that.

Mr. STEELE. Senator, yes, as I understand it, each of the agencies that pass through money through earmarks do take some administrative costs from that amount, and I think the percentages vary by agency. But yes, we think it should be transparent. I think that we do identify, and I'd have to check the records on this, and I can respond more for the record exactly what percentages agencies do take, but the Cooperative State Research, Education and Extension Service I know does take a certain percentage, and NRCS and the others do, but I think they do vary by agency.

Senator NELSON. But what is the authority to do that? Because I'm not sure that there's any mandated percentage that is part of the earmark, that directs the agency to be able to do this. And so is the amount determined within the agency? Why is that not included within the appropriations process for the agency's budget, so it doesn't become skimming?

Mr. STEELE. Well, I don't know if it's called skimming or not. I think it's an issue of the cost of doing business. There are some administrative costs in dealing with implementing programs, and they can't all be ignored.

Senator NELSON. Well, why wouldn't that be, without being argumentative, why wouldn't that be in the budget process, in the appropriations process we approve here?

Mr. STEELE. Well, the earmarks themselves, we have not requested earmarks in our budget request. We receive the earmarks from the Congress. So in our justification to the committees, we would not be justifying the earmark to the committee.

We receive the money. In turn, we make use of it and follow the legislative intent, and I think in that process certain agencies have taken a percentage of the earmark for their administrative costs of tracking the expenditures and making sure that the work is carried out properly and there is some overhead costs that have to be covered in this process.

Senator NELSON. But that's not an agency expenditure that's appropriated as part of the budgetary process.

Secretary JOHANNES. No. I think what's happening here, Senator, is this. Historically earmarks have not been included in the administration's budget request. Even before the discussion really heated up on earmarks, you could go and look at past budget requests and we don't include them, so therefore there would be no administrative costs to include.

But, as Scott indicates—and you probably have the numbers in front of you but we would be happy to supply them to the committee, too—there is a certain cost in just administering the earmark that has been established, and so that administrative cost has been covered by some piece of that, and I'm not even aware how much, for the program itself.

Senator NELSON. Well, some are 2.5 percent for expenses related to implementing the President's Management Agenda; agency assessment of about 8 percent to pay for administrative support; program assessment, 2.5 percent to 9 percent, to support overall program direction. It means that the range could be from somewhere from 13 to 20.5 percent, or higher if the department charge is raised.

It is something I think we need to look into as part of the appropriations process, so that we don't end up with, in effect, off-budget, outside appropriation, taking of certain expenses to the agency for the process of doing that. Or at least it ought to be formalized in some uniform way, so that if an earmark is in fact directed to a certain agency, that you know in advance what it's going to be, so it doesn't erode the amount of the earmark that you're expecting to go to the recipient.

Secretary JOHANNES. We would be happy to work with you to find a very transparent approach, because I think the dilemma we find ourselves in is, we do have certain oversight responsibilities and so that's how this is coming about. But again, we want to be transparent about it. If we're doing something that you'd like to see different, we're open to—

Senator NELSON. As a matter of compliment, you were able to provide us some of this information when we requested it. Some other agencies told us it was none of our business.

Secretary JOHANNNS. No, we're happy to provide it and happy to work through the issue.

[The information follows:]

ADMINISTRATIVE COSTS FOR EARMARKS

Several USDA agencies administer funds as a result of Congressional earmarks. The amount of administrative costs withheld from an earmark differs based on the nature of the earmarked funds and the agency administering the particular earmark. There are some specific statutory set-asides that all agencies within USDA are required by law to apply against programs, including from earmarks. For example, all funding related to extramural research and development is subject to a requirement to set aside 2.5 percent of funds to be used for the Small Business Innovation Research Program (Small Business Research and Development Enhancement Act of 1992, Public Law 102-564, as amended). In addition, all biotechnology research projects are required to set aside 2.0 percent of funds to support the Biotechnology Risk Assessment program (Section 1668 of the Food, Agriculture, Conservation, and Trade Act of 1990, Public Law 101-624, as amended).

In addition to statutory set-asides, agencies also have authority to use a portion of the appropriated funds to pay for administrative costs. The portion of the appropriated funds used to pay for administration costs may differ for each agency and program. Specific examples include:

- The Cooperative State Research, Education and Extension Service (CSREES) has specific statutory authority (Section 1469 of National Agricultural Research, Extension and Teaching Policy Act of 1977, Public Law 95-113, as amended) to retain up to 4 percent of amounts appropriated for research, extension and teaching programs for administration of these programs.
- The Agricultural Research Service (ARS) assesses 10 percent of all appropriations to finance management costs associated with the conduct of their nationwide research programs. ARS does not have a separate budget line item to cover management support.
- The Animal and Plant Health Inspection Service (APHIS) assesses a rate between 2.5 percent to 9 percent depending upon the program. APHIS, like ARS, does not have a separate budget line item to cover management support.

Senator NELSON. My time has expired. Thank you, Mr. Chairman. Thank you, Mr. Secretary.

Secretary JOHANNNS. Yes.

Senator KOHL. Thank you, Senator Nelson. Senator Reed, then Senator Feinstein, then Senator Specter. Senator Reed?

Senator REED. Thank you very much, Mr. Chairman, and Mr. Secretary and gentlemen.

PROVINCIAL RECONSTRUCTION TEAMS (PRTS)

I understand that this budget for the first time includes \$12.5 million to support USDA personnel in provincial reconstruction teams in both Afghanistan and Iraq. Is that correct, Mr. Secretary?

Secretary JOHANNNS. That is correct, yes.

Senator REED. Any reason why this is the first time it's been in the budget? I can tell you they are really high valued items over there.

Secretary JOHANNNS. Scott tells me that it was actually in last year's budget at \$5 million, so maybe what caught your attention is that it's there this year at \$12 million. The reason why it's there is that we do have a presence. We think that presence is important. We think we can do some good things in those countries.

In fact, in one of the farm bill proposals we made, we identify a place for this kind of activity, whether it's Iraq or Afghanistan

or some other place. We have international expertise. We have offices in 75 foreign countries or 70 foreign countries. We are all over the world, and we think we can be very helpful.

Senator REED. Well, Mr. Secretary, I second that. I've been out visiting these PRT teams numerous times and talking to military leaders. I was up in Tikrit with General Nixon of the 25th Infantry Division, and he said he could use many more USDA experts.

Secretary JOHANNIS. Yes.

Senator REED. Will you be able to fill all the requirements that you've received with this money?

Secretary JOHANNIS. Yes, we believe we will. I can give you an update today, that we have staff in Iraq and we have had from the beginning. We have, on the PRTs I think we have six positions, five of which are already there, and I think the sixth one will be heading over there in April of this year. So this would fund what we've been asked to do.

Senator REED. Are these contract personnel or employees?

Secretary JOHANNIS. No, they're employees.

Senator REED. There are some non-DOD agencies that are having difficulty getting personnel to go over, for a couple of reasons. One is, they don't get all the benefits that DOD gets, but also there's a fear that if they leave their job in the United States or elsewhere, that they will suffer in terms of promotion or their management will suffer in terms of losing a key person without replacement.

How are you dealing with that? Say for example an expert from the Southeast of the United States goes overseas. Can you put a replacement in there, or does that agency or that unit have to get along without them?

Secretary JOHANNIS. I've never run into it, but I would tell you my personal approach would be that they not lose anything; that if they want to go over and do a period of time in Iraq, that is of real value, or Afghanistan, they should not be set back in their career pathway. But, like I said, I haven't run into it, so I'm hoping that's an indication that that has not been a problem. In fact, one of our personnel—he just refreshed my recollection—actually came back because they got a promotion, and so they came back to fill that promotion.

Senator REED. Well, I think this is a key area, and it's not just for the Department of Agriculture, it's for all the agencies that are complementing our military efforts, and I would ask you to go back and look seriously about the incentives or disincentives, about the ability to fill all of the requested slots and the sufficient funding to do that. But I note this is some progress. It's taken 4 years or so to finally gear up, but at least we've geared up.

LOCALLY PRODUCED FOOD TO SCHOOLS

Let me change topics quickly. In Rhode Island there's a number of organizations that are working with farmers in our State to bring locally produced food to schools, and I'm glad that one of the recent USDA farm bill proposals indicates support for fresh fruits and vegetables in schools. However, since the Farm-to-Cafeteria program was authorized in Section 122 of the 2004 child nutrition and WIC reauthorization, the program has received no funding in

the administration's budget. Why is that the case, if we're trying to get fresh food into the school cafeteria program?

Secretary JOHANNIS. Scott, do you know about past funding?

Mr. STEELE. Senator, I think that there was a pilot for the schools in prior years that we did fund, and we've been trying to get local sponsors to work and continue those pilots. But I think that the farm bill proposal is going to accelerate our efforts in dealing with this question.

Secretary JOHANNIS. Our farm bill proposals, and I'll turn to that, would dramatically boost our efforts here. We're proposing \$2.75 billion—and these are all scored in a 10-year basis—\$2.75 billion in funds to purchase fruits and vegetables for our food assistance programs, and an additional \$500 million to increase the purchase of fruits and vegetables in our school meals program. So over \$3 billion will go into fruits and vegetables purchases in nutrition or school lunch.

Senator REED. And just a final question because my time has expired, but there will be an emphasis on purchasing local produce from local farmers?

Secretary JOHANNIS. Absolutely. Wherever we can buy locally, we want to do that. And the other thing I would point out is that our proposals at least are for mandatory money, so again if Congress agrees with us, your fruit and vegetable producers, your specialty crop farmers, will see a pretty significant presence in the farm bill that they have never seen before.

Senator REED. Thank you. Thank you, Mr. Chairman.

Senator KOHL. Thank you, Senator Reed.

Senator FEINSTEIN.

Senator FEINSTEIN. Thank you very much, Mr. Chairman.

DHS AGRICULTURAL INSPECTIONS AT U.S. BORDERS

If I might, Mr. Secretary, why don't we go to this question that I had about DHS taking over ag inspections at the border. Just from the California experience, there is some indication to me that this may not be the best way to go. Could you comment?

Secretary JOHANNIS. We have a cooperative effort that goes on here with Homeland Security, and the USDA is a part of that. We can give you some numbers of things that we have done together. I can tell you from the USDA standpoint it is our goal to work as seamlessly as we possibly can with DHS in the administration of this program, and our attitude is, if we have resources that might be helpful, we want to provide those resources and be of assistance.

I think, Senator, part of what is maybe being experienced here, this was a change, and sometimes it just takes a while for the system to adjust to that change. Every time I go to California, and I'm there on a frequent basis, this issue does arise from the agricultural community, because they're worried about pests coming in and that sort of thing.

Senator FEINSTEIN. And they're coming in.

Secretary JOHANNIS. Well, and from the USDA standpoint, I want you to know that we're ready to do whatever we can to make the system work, and we'll work as seamlessly as we possibly can to do that.

Senator FEINSTEIN. Well, I am told that fewer ag inspections are being done since the transfer.

Secretary JOHANNIS. I don't have those numbers in front of me, but——

Senator FEINSTEIN. May I ask you to take a look at that?

Secretary JOHANNIS. I will.

Senator FEINSTEIN. And get back to me, because California's ag is so big and affects so many States, and the penalty that comes from having fruit fly and then you quarantine three counties, the penalty is enormous. The key has to be to keep contaminated fruit out. Right now there's a problem with avocados coming in with a pest attached, and it's not being caught.

Secretary JOHANNIS. I will be happy to dig into the numbers and we will provide you with that information.

[The information follows:]

AGRICULTURAL QUARANTINE INSPECTION

[Inspection Data]

Pathway	United States	California
Fiscal Year 2002:		
Air Passengers arrivals	55,220,906	10,728,329
Air Passengers inspected	10,521,155	1,560,235
Cargo inspections/clearances	2,821,221	518,040
Fiscal Year 2003:		
Air Passengers arrivals	56,690,220	10,584,656
Air Passengers inspected	9,814,540	1,789,183
Cargo inspections/clearances	3,208,140	544,973
Fiscal Year 2004:		
Air Passengers arrivals	57,204,756	11,354,159
Air Passengers inspected	11,757,977	1,551,359
Cargo inspections/clearances	2,544,184	644,893
Fiscal Year 2005:		
Air Passengers arrivals	66,254,784	12,538,889
Air Passengers inspected	10,092,452	1,384,565
Cargo inspections/clearances	2,316,903	724,088
Fiscal Year 2006:		
Air Passengers arrivals	68,457,060	12,832,403
Air Passengers inspected	8,523,178	1,437,212
Cargo inspections/clearances	2,110,075	752,715

One of the major benefits of transferring all port of entry inspections to one agency is a front line inspection for all types of contraband by one individual. As a result, the front line inspectors today are not solely agricultural, narcotics, or weapons inspectors, but rather they have been trained to detect any and all contraband. This system allows for an efficient use of resources without compromising protection. However, having the front line inspectors trained to detect multiple forms of contraband does not allow for a direct comparison with the inspection regime prior to the transfer. For example, all international air passengers must be cleared through the Department of Homeland Security's Customs and Border Protection's (CBP) primary inspection. They may be directed to undergo a secondary agricultural inspection for a variety of reasons. While the actual number of secondary agricultural inspections of air passengers has decreased since the transfer, the primary inspection now includes a much stronger agriculture component because APHIS provides basic agricultural training to all CBP inspectors. Additionally, CBP has a more sophisticated risk identification system and database that allows for more targeted inspections.

AGRICULTURAL QUARANTINE INSPECTION (AQI) FEES

Senator FEINSTEIN. All right, because don't you have \$133 million for administrative expenses? Is that for new ag inspectors, or is that something else?

Secretary JOHANNIS. Scott, do you know?

Mr. STEELE. Senator, this is the Agricultural Quarantine Inspection fee program that we carry out. We collect these fees from airline passengers, and that money is collected and those fees do change periodically in terms of how much money we recover from them. Then some of that money is transferred over to DHS from the Department. At this point in time for the 2008 budget, it looks like we have estimated obligations in this program of about \$482 million, and about \$299 million, almost \$300 million, of that would be transferred to the Department of Homeland Security to carry out the inspections you're talking about.

Now, APHIS does keep some of those fees for their own internal use in helping DHS carry out its responsibility, but DHS is now in charge of the front line inspectors. They would be the one checking the baggage and those kinds of things. APHIS would be called in if there needed to be fumigation, training, and other things, sort of a secondary back-up role to the DHS people. Now, those DHS people, they were transferred from APHIS over to DHS. They originally worked for USDA, and they are now working for DHS, and they are being assigned and managed by DHS.

NUMBER OF AQI INSPECTORS

Senator FEINSTEIN. How many of them are there?

Secretary JOHANNIS. I don't have an exact number, of the total number of inspectors, but we can provide that for the record and tell you exactly who is doing what.

Senator FEINSTEIN. Well, for the record, this is one Senator—

Secretary JOHANNIS. Yes, and how many are in California.

Senator FEINSTEIN [continuing]. That doesn't really like that transfer. I don't think that inspections are well served by taking agricultural people and putting them under DHS, where the mission is totally different, and I don't want to see my State suffer because of it, either. So I'm going to watch carefully, and I hope you will as well.

Secretary JOHANNIS. We will, and we'll get you that information you have requested.

[The information follows:]

AGRICULTURAL QUARANTINE INSPECTION POSITIONS TRANSFERRED TO DHS

In fiscal year 2002, the Animal and Health Inspection Service (APHIS) had 3,484 Agricultural Quarantine Inspection (AQI) full time equivalents (FTEs). Of these FTEs, 2,515 were inspection personnel.

In fiscal year 2003, APHIS transferred 2,655 positions (529 of those positions were in California with 75 vacant positions) to the Department of Homeland Security. Of these 2,655 positions, 2,407 were inspection positions (including Plant Protection and Quarantine Inspectors and Technicians). Of the inspection positions, 346 were vacant at the time of the transfer (accordingly, 2,061 inspection personnel were transferred). Of the total 2,655 positions, 387 were vacant.

In fiscal year 2007, DHS informs the Department that they have 2,188 agricultural specialist positions, including 130 vacancies. DHS also indicates that there are 337 inspectors currently located in California.

E. COLI IN SPECIALTY CROPS

Senator FEINSTEIN. Thank you. Let me go to E. coli. The outbreak of E. coli that essentially came from California products, at least the spinach, I mean, 90 percent of the United States is fed with that spinach, and I note that the budget increases by \$4 million food safety research, but you also discontinue the food safety project at the Albany station in California which specifically targets E. coli, and so my question is, why?

Secretary JOHANNIS. This is one of the things that I mentioned in my opening statement. We did a farm bill proposal on kind of a parallel track with the budget, but eventually these two have to marry together because in 2008 we have a new farm bill.

When it comes to specialty crops, I think you're going to like the proposals we have made. We are proposing not only that increase of additional fruit and vegetable purchases, which of course would be really good for California, but we're also proposing to increase research in that area by \$1 billion—and again, these numbers are all on a 10-year score—because one of the things that we heard from our specialty crop farmers was, we need assistance in this area of research and phytosanitary/sanitary issues.

So we heard them, and again, never, I promise you, never in the history of farm bills have we had such a significant presence for specialty crop producers as what we are proposing. So if these proposals were to be adopted, there would be a major step forward for research in this area. It would be very significant.

Senator FEINSTEIN. My time is up, Mr. Chairman, but if I might just say—and you don't have to answer it, we can talk about this later—the time has perhaps come for some regulations from your department with respect to the phytosanitary handling of crops, to prevent this from happening again, instead of leaving it up to each State.

Secretary JOHANNIS. California has a very, very mature ag industry, as you know. They do good work. Some of their counties actually produce more agricultural products in value than some States. And so I guess what I would say to you is, we like what we're seeing there. They really do seem to be aggressively addressing this issue. Any time you go to a national phenomenon, it becomes that. I mean, it tends to be uniform, one-size-fits-all. I really want to talk to you about that before maybe any of us reach some conclusions on that.

I would also mention that APHIS does work with California, and the FDA, in this area. But again, I think this would really warrant some serious thought and discussion, and I would really want to consult with our producers across the country, especially in California. They do some good work, as you know.

Senator FEINSTEIN. Thank you. Thank you, Mr. Secretary. Thank you, Mr. Chairman.

Senator KOHL. Thank you, Senator Feinstein.

Senator SPECTER.

Senator SPECTER. Thank you, Mr. Chairman.

COMMODITY SUPPLEMENTAL FOOD PROGRAM (CSFP)

Mr. Secretary, I am concerned about the budget request which is \$4 billion lower than the 2006–2007 level, and the termination of the Commodity Supplemental Food Program which provided some 6.4 million food packages to over 500,000 people in low income brackets, also seniors. I know that the projection is that the WIC program and food stamps will meet the needs, but that really isn't applicable when the seniors are not included in those programs.

So my question, how can your department really keep up with the demands for very important services, and have a budget cut and not have even an inflationary increase, and continue to provide important programs like the Commodity Supplemental Food Program?

Secretary JOHANNIS. Overall, our nutrition programs are fully funded—not only funded for what we have today but the anticipated need. They're fully funded for the inflationary increase we anticipate, and they're even fully funded in terms of a contingency amount of money for WIC and food stamps. So we believe that we will meet the needs that are out there, and if we don't, if we have underestimated those, we have a contingency program that is available.

Senator SPECTER. What is the contingency program?

Secretary JOHANNIS. It's a large amount of money. Scott, how much?

Mr. STEELE. Senator, yes, we have set aside additional money in a contingency fund if we would need to use it. It's \$3 billion for the Food Stamp Program. If our estimates are wrong on participation, we could then go to that contingency fund to make up the difference, the shortfall.

In the WIC program it's \$200 million. If we miss the estimate that we have now for 8.3 million women, infants and children, we would be able to tap into that \$200 million if our estimate is wrong. So we have asked for that additional amount of money in the budget request.

Secretary JOHANNIS. Here is the situation on CSFP, and it is a popular program. It's certainly well received out there. Here is why it keeps popping up. The administrative costs get people's attention. They are about 46 percent of the food that is purchased. It is not a nationwide program. It's in 32 out of the 50 States, and I think we have it on some Indian reservations.

And, again, we just believe—and we have monies in the budget for outreach—that if we can identify the people and move them to one of our other programs, it will work better for them. So that's why it keeps popping up every year.

Senator SPECTER. Mr. Secretary, let me thank Keith Collins, your chief economist, for substantial help he has given us in the past when we've had some tough milk issues in Pennsylvania. I recall one incident where he came to the State and was enormously helpful.

I'm not going to be able to stay for Commissioner von Eschenbach's testimony. I want to note with approval his confirmation. Good to see him on the job, past that hurdle.

And one question which I would like him to answer for the record. It involves the—I note an increase in user fees, \$15.7 billion, on some of the drug review programs. We hear comments from time to time that the people who are awaiting those programs would be glad to increase their user fees if we could have more expeditious treatment. I'd like him to take a look at that question and give us a response in writing.

Thank you very much, Mr. Chairman.

Senator KOHL. Thank you, Senator Specter.

Senator Harkin.

Senator HARKIN. Well, thank you very much, Mr. Chairman. Thank you, Mr. Secretary, Mr. Deputy Secretary, and all of you who are here. I just had a couple of questions.

ORGANIC FARMING

Again, we tried in the last farm bill, Mr. Secretary, to put in some funds and different programs to help organic farmers. There has always been this sort of "valley of death" as they call it, when a farmer wants to transition to become an organic. Well, you take 3 years. You've got to have 3 years. Well, during those 3 years you can't really say it's organic, so how do you get through that sort of "valley of death" from being nonorganic to being organic?

So we put funds in the bill and we put a couple of programs in there to help farmers do this. I see that the budget now zeros this out, zeros this out. Let's see, where was it? Yes, we had \$1.8 million, very small, in discretionary funds last year, and the budget would provide no funds at all.

Now, we do have some money that we put in there, mandatory money. We do have some of the mandatory money in there, that's true, but that's sort of on research and stuff. But the transition funds—we do the research, and that money is there, Mr. Chairman, for research in organics and what farmers might do and how they set up marketing things and stuff like that. That's that research, but the transition funds were extremely important, and they're just zeroed out at a time when consumers can't get enough organics.

The fastest growing part of the food industry in America is organics, 20 percent a year. People at Whole Foods say they can't get enough organics. They can't even keep up with it. So people want it. The producers can't keep up. It seems to me a great opportunity, and I just want to know what kind of justification there is, because I'm looking at the farm bill this year, and if nothing else, I'd like to actually beef that up and do more in that area, Mr. Secretary.

Secretary JOHANNES. I was just looking at our proposals that we submitted to your Agriculture Committee, Mr. Chairman, relative to organic farming, and we're doing a number of things here that I think would be helpful. I don't pick up that proposal in what we've put here, though, I don't think.

So I guess what I would offer to you, I'd be anxious to sit down with you and see if there's something we can do there, because you're right, there is a period of time where you transition. We do have some money in this year's budget, some mandatory funding,

as you point out, but in the next farm bill there's probably an opportunity here to take a look at this issue again.

Senator HARKIN. I'm open for any suggestions you've got on things where we can work together and how we focus on this.

And the other thing that I heard, Mr. Secretary, was that we just had a meeting with some of these farmers in Iowa recently, sometime in January, I think it was, and the problem seems to be in terms of marketing, regional kinds of processing facilities and stuff, where a small farmer could take this in and get it processed and packaged and sent out, someplace like that, so I would like to visit with you about that.

Secretary JOHANNIS. Okay.

DHS AQI INSPECTORS

Senator HARKIN. I am told that in my absence Senator Feinstein covered the problems with the inspectors coming in. I think we've got a real problem there, and we're going to have to think about whether or not, Mr. Chairman, whether or not these inspectors ought to be brought back under USDA or should they stay under DHS. And quite frankly, everything I have heard is that they were doing their job under Ag, they had a good structure for it, and now they have been shifted and it's sort of the tail end of everything out there under DHS. I just wonder if we shouldn't somehow bring them back in under USDA. I assume you spoke about that in my absence.

Secretary JOHANNIS. Yes. Senator Feinstein has asked for some information on where we were on inspections before the change, where are we at now, and we'll provide that.

FOOD AID

Senator HARKIN. Okay. The last thing I just want to cover is food aid. Because of the continuing crisis in Africa and everywhere else, we have been obligated to provide additional emergency funding for Title II international food aid above and beyond the appropriated levels, and this goes back for the last several years.

Again, the administration—we're talking about a budget here, now—the administration has been unwilling to acknowledge that increased demand. They have not requested any funding above the recent level of \$1.2 billion for Title II, and I'm wondering why, since we know we're going to have to provide more, why there isn't more of a budget thing and why there isn't some justification in the budget for this food aid? It just makes it tough on us when it's not in that budget.

Now, if you don't have the answer now, if you could submit it in writing, that would be fine with me.

Secretary JOHANNIS. Okay. We'll submit it in writing.

Senator HARKIN. That's fine. Just look at that.

Secretary JOHANNIS. Okay.

Senator HARKIN. Same level it has always been every year. We've got to come in and get more and more every year. And I think as you look around the world now, we're going to be asked to do that again, so it should be part of the budget.

Secretary JOHANNIS. Okay.

[The information follows:]

2008 BUDGET REQUEST FOR PUBLIC LAW 480 TITLE II DONATIONS

The 2008 budget requests just over \$1.2 billion of appropriated funding for Public Law 480 Title II donations; this is a slight increase above the level provided in 2007. The requested funding will be supplemented by reimbursements from the Maritime Administration for prior year cargo preference costs, which are expected to total just over \$120 million in 2008.

The appropriations request reflects a careful prioritization among the competing demands for international humanitarian assistance. The United States has a number of different programs and authorities for responding to humanitarian needs overseas, each of which is important and makes a unique contribution to our humanitarian response efforts.

In addition, it is important to understand that emergency food needs are difficult to predict in advance, especially given the complex nature of evolving, rapidly changing conflicts and the unpredictability of rainy seasons in drought-prone areas. However, should unanticipated and extraordinary emergencies arise during the course of the year, the Administration has a number of options for responding, including a supplemental appropriations request and a release of commodities from the Bill Emerson Humanitarian Trust. At present, the Trust holds 915,000 metric tons of wheat and \$107 million of cash. The wheat tonnage equivalent of that cash is approximately 500,000 metric tons, so in total the Trust has resources equal to about 1.4 million metric tons of wheat.

In view of these considerations, the Administration believes the 2008 budget continues our commitment to addressing the most severe and critical emergency food aid needs.

Senator HARKIN. Thank you very much, Mr. Chairman.

Senator KOHL. Thank you, Senator Harkin.

Senator NELSON, do you want to make comments?

Senator NELSON. Thank you, Mr. Chairman.

CONTINGENCY FUNDING

One quick item: Mr. Chairman, I commend the contingency fund to deal with the challenges of food stamps and making sure that the numbers match with the requirements. I wonder if it's possible to do a similar thing with mitigation funding, with a contingency fund.

We know every year we're going to have disasters that will relate to agriculture, whether it's hurricanes or whether it's continuing drought. In the past they've been offset typically from some program within the previous farm bill, 2002. I remember Nebraska being a beneficiary of that when you were Governor. It's an ongoing situation. We don't know where it's going to happen, but we know that it will happen.

Why aren't we in a position to set aside a contingency? If we're going to take \$18 billion, roughly, out of the farm bill, why don't we preserve some of that to deal with the fact that disasters will occur that are not going to be adequately covered by crop insurance?

There isn't any way an 8-year continuing drought can be covered by crop insurance. We went over that, I think, in the Senate Ag Committee, in talking about how we will balance that all out. But isn't it possible to set aside \$5 billion or \$6 billion? If we can set aside \$3 billion for food stamps, it would seem to me that we ought to be able to hedge our bet a bit on natural disasters for crop coverage.

CROP INSURANCE GAP COVERAGE

Secretary JOHANNIS. Here is the challenge you will face if you want to establish a fund and just have money in it, whatever that

amount would be. Keep in mind during the last farm bill, notwithstanding the attempts to pass recent disaster relief, we spent about \$8 billion on disaster relief programs, and the current discussion is somewhere along the lines of \$3 or \$4 additional billion, so you could be up to around \$12 billion. And you're going to start with a baseline just like we did, and everything outside of that is above the baseline, and you know the drill on amounts above the baseline.

Here is what I would offer to you, though. I do believe that this crop insurance approach is worth looking at. One of the big criticisms with crop insurance today is, you can't cover the gap, so we're proposing a gap coverage be made available to cover that typically 30 percent gap in coverage between 70 percent and 100 percent.

And then the second thing is the revenue-based countercyclical program just will work better. We can't talk about the specific product, we're forbidden, but there is some effort to look at this issue of ongoing disaster and its impact on crop insurance and—

Senator NELSON. Well, you just reach the base, so that ultimately you're out of business unintentionally.

Secretary JOHANNNS. Exactly. Dr. Collins can give you a great briefing on that. But we're looking at some of the very issues you're talking about, and this actually might—I would respectfully suggest—be a better model than just the fund.

Senator NELSON. Well, I would agree with you for the occasional loss. I don't think that you can rely on crop insurance to cover a disaster that continues for 8 years. It's not designed to do that. That's like insuring your house and having it burn down every year for 8 years. The mechanism just doesn't presuppose that in the actuarial computations.

But statistically I'm sure Mr. Steele could calculate over the last 20 years what, adjusted for current dollar value, what the crop losses have been that would be disaster occurrences, so that you could calculate highs and lows and treat it as, if you will, a contingency fund on an actuarial or statistical basis within the budget, and have it covered.

Now, it's true, sometimes it's better to cover that 30 percent. I understand that difference. But I don't think your crop insurance is going to work for a multiyear drought that goes on and on and on and on. For occasional losses, I think that's the way to go for 2 or 3 years, but not an 8- or 9-year loss as you know we're experiencing in southwest Nebraska.

Something for you to consider, and I hope that you will take a close look at it, and I hope as we put together the appropriations package, we can work in that direction.

Secretary JOHANNNS. Okay. We would be anxious to sit down with you, and we'll consider your comments.

Senator NELSON. Thank you.

ADDITIONAL COMMITTEE QUESTIONS

Senator KOHL. Thank you very much, Senator Nelson.

And we would like to thank you, Secretary Johannns, along with Mr. Conner, Mr. Steele, Mr. Collins. Your testimony and your re-

sponse to our questions has been really good, and we look forward to continuing to work with you as the process unfolds.

Secretary JOHANNIS. Mr. Chairman, thank you.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR HERB KOHL

VEAL

Question. Mr. Secretary, I am very concerned that we have some serious trade distortions with Canada which disadvantage U.S. veal producers.

Wisconsin veal producers believe that Canadian policies, particularly access to low-priced feed coupled with support from the Quebec production price insurance program, give their competitors in Canada an unfair economic advantage in the form of lower production cost which encourage over production. Some of the increased production is exported to the U.S. market where it is further processed and sold as U.S. produced product. The relatively low cost of production in Canada also encourages many Canadian producers to purchase replacement calves in the United States which drives up prices for U.S. producers.

I would like the USDA's Economic Research Service to review this topic and provide some updated data on this matter. I'm particularly interested in an updated comparison of subsidies which apply to U.S. veal producers and their counterparts in Canada.

Answer. The information is submitted for the record.

[The information follows:]

In 2005 the cost of production for a milk- or formula-fed veal calf raised to about 450 pounds in the United States was \$682.50 versus a net cost of \$699.97 in Canada, which includes a payment from the Canadian Agricultural Income Stabilization (CAIS) program.

Exports of veal meat from Canada to the United States in the carcass, cuts-bone-in, and cuts boneless categories (assumed to be available for further processing in the United States) have increased from 2000 to 2005.

Carcass exports to the United States have risen rapidly due to increased slaughter capacity in Canada and restrictions on live animal trade as a result of BSE-related border measures. U.S. cattle export data to Canada do not provide breakouts by size so we cannot readily determine how many calves are really being shipped to Canada for veal. A category in USDA export statistics that includes these calves is Cattle not for Breeding which we show here for 2002 to 2006.

Exports fell with the onset of BSE-related border measures, dropping from about 133,500 animals in 2002 to a low of 14,200 in 2004 and rebounding slowly afterward. Exports reached 36,050 animals in 2006. Purchases of veal calves by Canadians make up some unknown share of these exports.

Veal market data reports show the following calf slaughter numbers in Canada and the United States in recent years.

	Canada	U.S.
2003	251,309	971,459
2004	284,334	838,405
2005	267,900	717,338
2006	245,341	698,618

Question. I would also like to receive a summary of steps you have taken in conjunction with the U.S. Trade Representative to resolve this dispute.

Answer. USDA, along with the Office of the United States Trade Representative (USTR), is aware of the concerns that have been identified and has examined Canadian Federal and provincial policies regarding support provided to Canadian veal producers. To date, USDA has not identified components of the Quebec Income Stabilization Program that are inconsistent with Canada's international obligations but remains open to additional information and assessment. There are several recent factors that have changed the dynamics of the United States and Canadian veal and veal calf markets, including the imposition of U.S. BSE restrictions on Canadian cattle. USDA will continue to monitor the situation closely. If new information indicates that Canada is not fully meeting its international obligations, USDA and USTR will take prompt action to address the matter.

AFGHANISTAN/IRAQ PROVINCIAL RECONSTRUCTION ACTIVITIES

Question. Last August, we received notification from the U.S. Department of State that \$7.8 million of the Iraq Relief and Reconstruction Fund was being transferred to USDA to restore and expand a sustainable agriculture sector in Iraq. Your request for 2008 includes \$12.5 million for Provincial Reconstruction Teams to restore and stabilize the agricultural economies in Afghanistan and Iraq.

Please tell us the amount of funds that USDA has used for these activities since the beginning of fiscal year 2006, including funds directly appropriated to USDA or transferred from other Departments. Also tell us what specific activities were carried out with these funds.

Answer. Since the beginning of fiscal year 2006 through March 2007, USDA has expended approximately \$3.39 million in Afghanistan (\$2.45 million transferred from USAID, \$140,000 from the CCC-funded Emerging Markets Program, and \$800,000 from USDA appropriated funding) to support USDA participation in the Provincial Reconstruction Teams (PRTs); to provide technical assistance and capacity building to the Ministry of Agriculture; and to support development of agriculture and trade programs at institutions of higher education. This amount will grow as additional expenses are incurred during fiscal year 2007.

Since the beginning of fiscal year 2006 through March 2007, USDA has used approximately \$6.56 million in Iraq (\$5.3 million transferred from the State Department to support revitalization of Iraqi agricultural extension programs; \$260,000 transferred from USAID to support USDA participation in the PRTs; and \$1 million from USDA appropriated funding) to provide both agricultural advisors to the PRTs and Ministry of Agriculture, and public affairs specialist to work with the Iraq Reconstruction Management Office (IRMO). This amount will also increase as we move through fiscal year 2007.

Question. What specific outcomes have been realized by the expenditure of these funds and are these consistent (and on schedule) with the original objectives of the allocations?

Answer. With this funding, USDA has been an active participant in the ongoing reconstruction initiatives in both Afghanistan and Iraq. In the case of Afghanistan, USDA has been able to introduce modern agriculture production and marketing techniques to the rural provinces. Among other things, efforts have been focused on irrigation system rehabilitation, post-harvest loss reduction, marketing system improvements and livestock health.

In Iraq, USDA's Agricultural Extension Revitalization Program is on schedule to provide the first training of Iraqi extension agents in June 2007. In addition, USDA has deployed PRT and ministry advisors as well as public affairs specialists who are now embedded into the Iraqi and U.S. institutions to which they were assigned. Recruitment for additional advisors is ongoing. USDA is cooperating with other U.S. Government agencies to continue identifying appropriate assignments.

The outcomes that have been achieved through these activities have been consistent with the purposes for which the funding was originally allocated.

Question. How do you recruit people to take assignments in locations such as Iraq and Afghanistan, and how do you assure their security?

Answer. The Foreign Agricultural Service coordinates the recruitment and selection of USDA agricultural advisors, drawing upon the expertise of the Department's agencies such as the Natural Resources Conservation Service, the Animal and Plant Health Inspection Service, and the Agricultural Marketing Service, as well as the Land Grant Universities and 1890 colleges. A panel from USDA interviews and selects candidates, matching their technical skills, as well as their anticipated ability to operate in an insecure area, to skills needed in the PRTs. Recommendations are sent to the Secretary for final approval.

Prior to deployment, all advisors attend a two-week security training program. Once deployed, each advisor is embedded with the U.S. military to ensure personal security.

Question. In Afghanistan, there had been hopes that poppy production could be replaced with food crops that could help sustain their people. Yet we hear that poppy production there is still their leading crop and that the World Food Program considers that country in serious need of humanitarian food assistance.

Explain what has been done to try and move Afghan farmers away from poppy production and why does it not seem to be working?

Answer. USDA's role in support of the Administration's efforts to promote alternative livelihoods includes providing expertise to the Afghanistan Ministry of Agriculture to strengthen programs in agricultural extension, animal health, plant protection, and natural resources, and helps the Ministry extend its programs to all

provinces and districts of the country. USDA's advisors on the PRTs work with their ministry counterparts to build capacity and develop programs at the local level.

USDA helped to establish and continues to support the Afghan Conservation Corps which has employed thousands of Afghans in projects for reforestation, soil and water conservation, and conservation education. With local sales proceeds derived from the monetization of USDA food aid commodities, USDA has supported the renovation of agricultural and veterinary teaching facilities at Kabul University and the training of faculty. USDA also is working to build the capacity of five agricultural universities in Afghanistan, through faculty training, construction, and renovation of laboratories and classrooms.

Finally, because livestock is vitally important to the Afghan economy, USDA is training Afghan veterinarians in the recognition, diagnosis, and control of animal diseases.

CCE AND INFORMATION TECHNOLOGY

Question. Mr. Secretary, the budget for the Common Computing Environment is spread to the 3 agencies it serves this year—Rural Development, the Natural Resources Conservation Services, and Farm Service Agency. However, total funding for CCE decreases by nearly \$30 million.

It is not my understanding that information technology needs at USDA have decreased—in fact, at the Farm Service Agency—the opposite is true. We have all heard about the problems and delays at the county offices—when the East Coast is working, the West Coast can't work, and vice versa, or FSA risks overloading the system. This is clearly unacceptable, and although the Farm Bill is scheduled to be reauthorized this year, which will obviously increase FSA's workload, funding increases in their budget for IT will only maintain the antiquated system in place now. It's like trying to stop a dam from bursting with duct tape.

Why is the budget for CCE decreasing this year, when needs are certainly not?

Answer. Funding for the CCE has been comprised of Service Center Agency (FSA, NRCS, RD) information technology (IT) purchases through their own appropriations, in addition to funding provided through the CCE direct appropriation. This funding has been used to develop an infrastructure to support the business delivery functions of the Service Center Agency (SCA) field offices located across the country. The 2008 budget requests that \$78.5 million with an additional \$12 million for CCE activities specific to FSA be included in the SCA salaries and expenses appropriations to meet the ongoing business delivery needs. This funding will support the continued IT activities of the SCAs as they jointly maintain the CCE infrastructure. In addition, the SCAs will continue to work with the Information Technology Services (ITS) division of the Office of the Chief Information Officer in USDA. ITS is funded through reimbursable agreements with the SCAs and delivers staffing and services to the agencies in support of the CCE. In coordination with ITS, the agencies will be able to ensure that the necessary services and staffing are available to maintain the infrastructure and program delivery.

Question. Does the USDA have a solid budget estimate of the cost to replace the current outdated FSA computer system?

Answer. FSA is planning to implement a long-term modernization effort known as MIDAS to replace its obsolete equipment. At this time, FSA anticipates submitting a business case for this investment to the Office of Management and Budget during March 2007. Preliminary cost estimates indicate that this planned transition would require about \$278 million over fiscal years 2007 through 2009. It would also have a total 10-year lifecycle cost of \$463 million unadjusted for risk and an estimated cost of \$617 million when adjusted for risk.

In addition to this modernization effort, further costs must be incurred to stabilize the FSA IT system components at field offices in the short term. These additional costs are estimated to be about \$150 million to bring the Kansas City web-based system up to at least moderate reliability; about \$97 million to implement likely disaster assistance and Farm Bill legislation; and nearly \$29 million to replace obsolete field office components. Thus, estimated total costs of nearly \$553 million over fiscal years 2007 through 2010 will be required to bring the current system up reasonable operating capability and to transition to a modernized system. However, the actual modernization component as noted above is estimated to cost about \$278 million.

Question. Is this part of the Farm Bill proposals submitted? If not, where will this funding come from, since it is not in the President's budget?

Answer. Funding for modernization of FSA's information technology systems is not included in the Administration's Farm Bill proposal. USDA is working with the Office of Management and Budget to identify an appropriate funding source for this investment.

AGRICULTURAL RESEARCH

Question. Federal support for agricultural research is one of the most important contributions we make to support productivity for our farmers, ranchers, and all parts of our rural economy. A very good case can be made that this type of research is not getting the full support it needs in terms of funding, but the results have been impressive.

What, if anything, is broke about the current agricultural research programs? If there is a need to combine agencies like ARS and CSREES, isn't that just a matter of coordination? Isn't that the role of the Under Secretary now?

Answer. While current agricultural research programs are functioning well, they can be strengthened. Currently, both ARS and CSREES support basic and applied research spanning the full spectrum of agriculture related issues including plant and animal systems, food and nutrition, and natural resources.

Our proposal will greatly facilitate closer collaboration by establishing a single National Program Staff (NPS) to manage programs and resources across all areas of research, both intramural and extramural, as well as extension and education. This will help ensure that resources will be maximized and that the comparative strengths of our intramural and extramural system are better utilized to address critical problems facing agriculture.

While the Under Secretary has a role in coordinating programs between the REE agencies, it is important that this coordination be institutionalized. This can best be accomplished by merging the agencies.

Question. Can you please give us your view on how Federal support for agricultural research should be administered? For example, what is the role of the State/Federal partnerships that have worked so well over the past?

Answer. Continued Federal support for agricultural research is critical to the future of American agriculture. It is important to maintain both strong intramural and extramural research programs. Central to USDA's extramural efforts is the State/Federal partnership with the Land Grant Universities and other cooperators. These efforts should be maintained and strengthened.

Question. Do you think that USDA should have its own in-house research agency? As you know, there are proposals under consideration that would remove agricultural research from the jurisdiction of USDA and place it with an independent agency. How do you feel about that?

Answer. Agricultural research and education is a core mission of USDA and it is important to maintain a strong intramural research capacity. The Administration strongly supports keeping intramural research efforts within the jurisdiction of USDA and does not support moving these efforts into an independent agency.

One of the Administration's farm bill proposals would make significant changes to the Research, Education, and Economics mission area within USDA. Specifically, CSREES and ARS would be folded into one agency. The thrust of the argument for this change is that it will provide better coordination and allow for enhanced efficiency and effectiveness of program implementation and resource allocation.

Question. How do you think we best meet the needs for long-term research that can be well served by long-term formula funds and competitive grants and the short term problem solving needs that can perhaps be best served by use of your special grant authorities? Do you think we need to maintain a balance to meet both these type of research needs?

Answer. Our experience is that a mixed portfolio of formula funds and competitive grant programs allows us to address the needs of research for American agriculture. Our programs support the goals and objectives of USDA, and incorporate stakeholder input on a continuing basis. Formula funds ensure that each State has an immediate response capacity to address emerging issues and problems. When an issue arises, existing resources can be mobilized quickly to begin to deal with the problem.

For those areas of longer-term concern, competitive programs are able to lay the scientific groundwork needed to address specific problems. Because these programs are designed at the Federal level, with stakeholder input, and take into account the needs of the entire nation, they apply available resources to America's highest agricultural research priorities. In our experience, well developed and logically structured competitive programs take no longer and can be as responsive to solving science based issues as legislatively mandated special research grants.

NATIONAL VETERINARY MEDICAL SERVICES ACT

Question. Please provide an update on the implementation of the National Veterinary Services Act.

Answer. We plan to publish a Final Rule delegating the National Veterinary Medical Services Act program to CSREES in the Federal Register on March 19, 2007. Although there are additional administrative steps that must be completed prior to the distribution of funds, a framework for the program has been developed by CSREES. The Department recognizes the importance of this Act to the veterinary community and those that they serve and is moving forward in the implementation of this program as quickly as possible.

AVIAN FLU

Question. Secretary Johanns, as you are aware, we provided in the Joint Resolution we recently passed more than \$47 million to annualize funding provided in an fiscal year 2006 supplemental bill for avian flu activities in APHIS. Further increases are included in the budget, although we understand that this may change some based on passage of the joint resolution. Although it may seem that there was certainly a few months where we didn't hear about too many avian flu outbreaks, very recently there has been a new outbreak in Britain, and we are headed into the spring, when the birds will be migrating and we know their migratory patterns must be monitored closely. I know that you are aware of the importance of staying ahead of this situation—this is evidenced by your budget request.

What is the total amount within APHIS that will be spent on avian flu activities this year? What will this money buy?

Answer. APHIS is planning to spend \$107.7 million (\$30 million in 2006 supplemental funding, \$16.8 million carryover from Low Pathogenic Avian Influenza (LPAI), \$47.2 million for highly pathogenic avian influenza (HPAI) appropriated funding and \$13.7 million for LPAI appropriated funding) during fiscal year 2007. The use of these funds will increase surveillance in wildlife, domestic poultry, and game birds; increase and enhance existing preparedness; and provide capacity building for highly pathogenic avian influenza (HPAI) in the international community. Additionally, APHIS is increasing its interdiction activities to reduce the threat of an HPAI introduction through smuggling.

Question. Can we expect more outbreaks of avian flu as we enter Spring?

Answer. The United States has not experienced any introductions of the Asian strain of highly pathogenic avian influenza. APHIS is confident that the current surveillance activities in wildlife, domestic poultry, as well as smuggling interdictions provide an ample early warning solution that will enable Federal, State, and local resources to rapidly respond to an incursion of the virus, and thereby limit its potential for spread.

EMERGING PESTS

Question. Secretary Johanns, I was pleased to see an increase of \$20.5 million in the Emerging Plant Pests program for Emerald Ash Borer, bringing total funding to respond to this pest to more than \$30 million. I was also pleased to see that a portion of this increase is going to support surveys in States where EAB is most likely to occur next, one of which is my home State of Wisconsin. USDA estimates, as you know, that if EAB is not contained and eradicated, it could cost State and local governments and landowners \$7 billion over the next 25 years for tree removal and replacement. It has already devastated areas where it has shown up.

Could you please speak to the efforts APHIS is undertaking to control and eradicate Emerald Ash Borer where it has been found? Also, please talk about the surveys the budget requests funding for in order to prevent the spread of EAB. What do you do if you find it in a new place?

Answer. APHIS and USDA's Forest Service have been cooperating with affected States since 2002 to address EAB. The program uses a management strategy with survey, regulatory, outreach, and control components designed to contain the general EAB infestation and find any isolated infestations and take appropriate action to contain or eradicate them. In December 2006, APHIS expanded its EAB quarantine regulations to cover the entire States of Illinois, Indiana, and Ohio, more than tripling the existing regulated area to prevent additional spread of EAB.

Regulatory activities include monitoring high-risk businesses and ensuring that they move regulated articles only under compliance agreement with the EAB program as well as working to identify pathways for the potential movement of regulated articles and conducting special operations such as weigh station blitzes. The regulatory program also includes a strong outreach component to ensure that businesses and residents in quarantined areas are aware of the risk of moving items.

Survey activities, including visual surveys and the use of detection trees, which are trees that have been stressed to release volatile chemicals attractive to the beetle, are used to detect the presence of EAB in new areas and delimit the extent of

known infestations. If the program detects EAB outside of the known infested areas, delimiting surveys are conducted to determine how old and how large the infestation is and what action would be appropriate. The only available eradication method requires the removal of all ash trees within a half-mile radius of a young infestation. Such activities take place only at small, truly isolated infestations.

APHIS is also investing in methods development projects for EAB, including more accurate survey methods and control options. The fiscal year 2008 Budget also requests funds to expand survey efforts into States near currently infested areas, including Wisconsin, Minnesota, Iowa, Missouri, Kentucky, Tennessee, West Virginia, Virginia, Pennsylvania, and New York. These States have risk factors based on the movement of EAB host materials.

Question. How does APHIS work to prevent things such as Emerald Ash Borers (EAB) and the Asian Longhorn Beetles from entering the United States? What improvements need to be made at the borders to prevent these incredibly expensive pests from entering and causing these problems?

Answer. The Agriculture Quarantine and Inspection program protects the United States from the risks associated with the introduction of invasive agricultural pests and diseases. APHIS and the Department of Homeland Security cooperate to carry out this program, and fund the programs through a combination of appropriations and user fees. The Pest Detection program supports APHIS' goal of safeguarding U.S. agricultural and environmental resources by ensuring that new introductions of harmful plant pests and diseases are detected as soon as possible, before they cause significant damage. USDA is requesting a \$15 million increase in the Pest Detection program for fiscal year 2008.

Exotic wood boring and bark beetles such as EAB and Asian longhorned beetle (ALB) likely entered the United States through infested solid wood packing materials such as pallets, crates, and other materials used in international shipping. These materials are often reused and reshipped many times throughout the world. Many countries have recognized the need to deal with the pest risk. APHIS worked with its international counterparts to develop standards for safely moving solid wood packing materials and implemented regulations based on the developed standards. While APHIS and affected States are still dealing with the effects of EAB and ALB and several other exotic forest pests already in the United States, we believe that the new regulation of wood packaging materials should help prevent future infestations of this type.

ERADICATION VERSUS MANAGEMENT

Question. At what point do you make a determination that the eradication of a disease isn't possible, such as in the case of citrus canker? What are the next steps once that determination has been made.

Answer. Although each pest or disease situation must be analyzed separately, there are several factors we consider when determining whether or not eradication is feasible. Among these are: the availability of adequate funding and active participation from Federal, State, and industry cooperators; weather and any other environmental constraints; the potential of the pest to do significant economic damage to agricultural or forest resources; the extent to which the pest or disease has spread; the availability of effective detection, diagnostic, and control technology; the availability of acceptable alternatives to eradication; public support for an eradication program; the disease's public health significance; and the vectors associated with a disease (e.g., mosquitoes, ticks, etc.).

Federal officials take all of these and other factors into consideration as they determine whether the eradication of a pest or disease is possible. If one or more of these factors change considerably during the course of an eradication effort, the planned course of action will be reevaluated. Prior to making any major decisions about discontinuing an eradication effort, Federal officials will consult with their State and industry cooperators, then update policies and regulations as appropriate.

INVASIVE SPECIES

Question. Please provide a list of current plant and animal invasive species, ranked by their threat level. What is APHIS' short and long-term plans to deal with these?

Answer. The Administration has not ranked invasive species by threat level. Invasive species that APHIS addresses include, but are not limited to, the programs focused on cattle fever tick, Mediterranean fruit fly, emerald ash borer, potato cyst nematode, sudden oak death, citrus diseases, brucellosis, pseudorabies, and chronic wasting disease. APHIS addresses each of these threats as resources allow.

Over the long term, APHIS develops response plans for exotic pests and diseases that have the potential to cause significant economic or environmental damage and uses its safeguarding system, which involves prevention, detection, and management components, to protect U.S. agriculture. Under the Pest and Disease Exclusion mission area, APHIS works to prevent exotic pests such as cattle fever tick and Mediterranean fruit fly from entering the United States. These and other pests have direct pathways into the United States. APHIS takes action at U.S. borders or in other countries to mitigate the risks associated with them.

Under the Monitoring and Surveillance mission area, APHIS conducts plant pest surveys, animal health surveillance, and other activities designed to detect exotic plant pests and foreign animal diseases if they are present so that we can deal with them quickly if needed. These programs target a changing list of high-risk plant pests depending on trade and travel pattern and outbreaks in other countries. These programs also conduct intensive monitoring and emergency preparedness efforts. APHIS analysts follow animal and plant health situations around the world and frequently adjust monitoring and surveillance efforts and pest and disease exclusion priorities to safeguard U.S. agriculture and natural resources from high-risk pests and diseases.

APHIS also works to control or eradicate high priority invasive species through programs in the Pest and Disease Management area, including, but not limited to, emerald ash borer, potato cyst nematode, sudden oak death, several citrus diseases, brucellosis, pseudorabies, and chronic wasting disease.

CHRONIC WASTING DISEASE/STATE MATCH

Question. The budget request includes a decrease of over \$6 million for activities related to chronic wasting disease. One of the justifications for this decrease is a match in which the Federal Government will pay for 60 percent of anticipated program needs, and the State will fund the rest. Similar proposals for State match are mentioned throughout the APHIS budget.

Specifically for Chronic Wasting Disease, how will the requirements for the States change with this proposal? Will their funding level need to increase?

Answer. The 2008 budget proposes a reduction of about \$4 million. The program requirements for the chronic wasting disease (CWD) herd certification program (HCP) will not change with the funding reduction. At the requested funding level, USDA anticipates the States and cooperators would contribute additional resources to support the efforts at current levels.

Question. More broadly, what amount does APHIS anticipate saving by requiring increased State matches for APHIS activities? Is there currently a mandated match level for States, or is this an entirely new proposal? If a State can't or does not provide the requested match amount, what will APHIS do then?

Answer. The following table is provided for the record.

[The information follows:]

Line Item	Savings
Chronic Wasting Disease	\$4,400
Emerging Plant Pests—Citrus Health Response Program (Florida)	2,300
Emerging Plant Pests—Asian Longhorned Beetle (NJ & NY)	1,691
Emerging Plant Pests—Glassy-Winged Sharp Shooter (California)	1,001
Johne's Disease	5,005
Noxious Weeds	300
Total	14,697

There is currently no mandated match level for States, nor is USDA proposing a mandated level. It is our goal to leverage increased participation from the States to maximize the benefits received from Federal dollars.

If a State is unable to contribute the estimated amount for a particular program, USDA will evaluate the overall impact to program efforts and adjust future funding requests accordingly.

JOHNE'S DISEASE

Question. Mr. Secretary, the APHIS budget for Johne's disease includes a decrease of nearly \$10 million approximately 75 percent. One of the reasons for this justification is the supposition that States, universities, and producers, would be responsible for testing, herd clean-up, risk assessments and disease management, as well as the continuation of the national Johne's demonstration herd project.

Was there any input gathered from those whose responsibilities will be increased before this proposal was put forth? Are these activities that the States, etc. are currently undertaking, or would have to pick up?

Answer. USDA has consulted with our partners in the Voluntary Bovine Johne's Disease Control Program (VBJDCP), and they are aware of our request. From its inception, the VBJDCP has been a cooperative effort among APHIS, State departments of agriculture, and industry. States have been the main driving force of the VBJDCP. A large part of the Johne's disease funds not requested in the President's Budget has been used by the States to pay for producer testing and risk assessment fees. With a reduction in Federal funding, these costs will need to be covered by producers who benefit from this program. In addition, State and University partners would assume responsibility for continuation of the Johne's disease demonstration herd projects implemented in each region. These projects focus on new and current testing schemes and control methods to determine the most effective cost management practice options.

APHIS will continue to provide oversight to the VBJDCP and support analysis of the national demonstration projects, along with continuing laboratory approval and licensing diagnostic tests and vaccines for commercial use.

NATIONAL ANIMAL IDENTIFICATION SYSTEM

Question. What is the status of the development of a National Animal Identification System?

Answer. The National Animal Identification System is composed of three components: premises registration, animal identification, and animal tracing. Premises registration is the foundation of the program. As of March 12, 2007, all 50 States, 60 Tribes, and 2 U.S. Territories are capable of registering premises according to USDA standards, and approximately 378,000 locations have been registered.

Significant progress has also been made on the second component of NAIS, animal identification. As of March 12, 2007, approximately 1 million Animal Identification Number devices have been distributed.

The third component of the NAIS, animal tracing, is currently under development with the help of USDA's industry and State partners. Industry, through private systems, and States will manage the animal tracing databases that maintain the movement records of animals. Full deployment of the Animal Trace Processing System is planned for the near future.

Question. If such an animal identification system is made voluntary, what effect does APHIS anticipate that will have on participation? What efforts will be made to encourage participation?

Answer. Participation in the NAIS is voluntary. The USDA remains committed to building upon our strong partnership with the States and industry to meet producers' needs and establish a versatile system that makes sense for everyone.

Moving forward with this voluntary approach has allowed producers the opportunity to test the program and recommend the most practical solutions for a more effective system. In this sense, producers themselves are playing an active role in helping to shape the NAIS program so that it works well for their particular needs. Additionally, a voluntary NAIS allows for the best price competition between service providers (identification device manufacturers, database providers, etc.) and leaves room for market applications (such as age/source/process verification) to help drive the system.

To encourage participation, USDA has provided funding to facilitate development and implementation of an efficient system, and flexibility to adapt to producers' operations and needs. On February 2, 2007, USDA published a request for proposals from nonprofit organizations that wish to enter into cooperative agreements with USDA to advance premises registration. USDA will make up to \$6 million available, subject to the availability of funding, for the cooperative agreements. These cooperative agreements will support the efforts of such organizations to promote the NAIS and, specifically, increase participation in premises registration—the foundation of the program.

SMALL FARM/ORGANICS/AMS SEED MISLABELING

Question. We continue to hear reports that the number of farmers in the United States is getting smaller and the farms are getting larger. Still, we have a responsibility to promote programs and policies to help small and beginning farmers be productive and able to maintain a reasonable life style. After all, these small independent farmers are truly small business entrepreneurs who need the government to be their friend, not their obstacle. I fear that in too many cases, government is their obstacle.

Last year I asked you a question about how USDA can help these small farmers. What have you done since then to improve their opportunities?

Answer. Through a number of different programs, USDA helps operators of small and medium-size farms. For example, the Farm Service Agency (FSA) provides a variety of farm loan programs, including traditional operating loans, beginning farmer and youth programs. The Agricultural Marketing Service (AMS) helps small producers obtain greater access to marketing channels and engage in more profitable farm marketing activities through research, alternative market development, and grant programs. Additional information will be provided for the record.

[The information follows:]

FSA offers direct and guaranteed farm ownership and operating loans to family-size farmers and ranchers who cannot obtain commercial credit from a bank, Farm Credit System institution, or other lender. Borrowers include beginning farmers who do not qualify for conventional loans because they have insufficient financial resources, as well as established farmers who have suffered financial setbacks from natural disasters, or whose resources are too limited to maintain profitable farming operations. FSA loans can be used to purchase land, livestock, equipment, feed, seed, and supplies; they can also be used for building construction and improvements. FSA guaranteed loans provide conventional agricultural lenders with up to a 95 percent guarantee of the principal loan amount. The lender is responsible for servicing a borrower's account, including the collection of payments, for the life of the loan. All loans must meet certain qualifying criteria to be eligible for guarantees. Farmers interested in these loans must apply to a conventional lender, which then arranges for the FSA guarantee.

AMS conducts or supports applied research to help small and medium-sized farm producers and processors make better informed business decisions in the face of changing marketing conditions and practices; maintains a centralized information clearinghouse of agricultural marketing research materials and resources on the agency's website and disseminates research results, technical assistance, and data via internet, publications, conference presentations, and outreach efforts; administers the Farmers Market Promotion and Federal-State Marketing Improvement grant programs; and collaborates with other agencies that support small farm marketing, including State departments of agriculture, land-grant universities, Tribal governments, trade associations, non-profit organizations and private foundations.

During fiscal year 2006 and early 2007 AMS supported four national and four regional farmers market and direct marketing workshops, and AMS personnel presented or trained at nineteen conferences and meetings that support small farms, farmers markets, and agricultural community outreach to improve food marketing practices among small-scale and socially disadvantaged farmers, and expand awareness of available marketing services and resources. Further, AMS created a regularly updated Farmers Market Resource Guide in March 2006 that provides a one-stop information source about available financial and technical assistance for farmers market and direct farm marketing activities.

AMS also provides specific funding assistance. AMS awarded \$1 million through 20 Farmers Market Promotion Program (FMPP) grants for 2006. Agricultural cooperatives; local and Tribal governments; non-profit, public benefit and economic development corporations; and regional farmers' market authorities are eligible for FMPP grants. The Federal-State Marketing Improvement Program (FSMIP) funded 27 competitive matching grants worth \$1.334 million to State Departments of Agriculture and other appropriate State agencies to assist in exploring new market opportunities for U.S. food and agricultural products and to encourage research and innovation aimed at improving the efficiency and performance of the U.S. marketing system. The majority of FSMIP projects are geared toward small to medium sized producers. In addition, the Specialty Crop Block Grant Program makes funds available to State departments of agriculture to enhance the competitiveness of specialty crops. It has made \$6.58 million available to 50 States (and to Puerto Rico and the District of Columbia).

Question. When we see problems like the mis-labeling of GM grain that gets into the market place, that sends a very troubling message to our trade partners and can create problems that small operators can't absorb.

We have heard several reports of genetically modified material getting into crops intended for commercial sales, the most well-known being rice. What has the economic effect been of instances such as this?

Answer. The economic effect can be reductions in seed available for planting and potential trade restrictions. For example, two popular long grain rice varieties can no longer be planted for commercial production due to the presence of genetically modified material. The value of certified seed of these varieties produced in 2006 for planting in 2007 is estimated to be \$39 million.

Question. What programs does USDA have in place to make sure those sort of labeling problems don't happen?

Answer. The Agricultural Marketing Service administers the interstate labeling provisions of the Federal Seed Act, a truth-in-labeling law that regulates the interstate shipment of agricultural and vegetable seeds. Enforcement of the Act by AMS helps ensure that seed purchased by small independent farmers is of high quality and truthfully labeled. However, the Act does not regulate biotechnology traits or biotechnologically derived seeds. Instead, the Act considers biotechnology derived seeds found in traditional varieties as "other" crop seeds and they have to be labeled as such. If the biotechnology derived seeds exceed 5 percent, they have to be listed as a separate component on the seed label.

Question. As you know, the organics label is a very important label, what are you doing to protect the integrity of that label?

Answer. USDA's National Organic Program (NOP) is responsible for administering the organic regulations and ensuring that all requirements are met to protect the integrity of the organic label. The 2008 budget includes an increase of about \$1 million above the 2007 level of \$2 million to ensure that the NOP can meet the needs of the rapidly growing organic industry. The increase will support, among other efforts, development of standards requested by the industry and regulatory enforcement to maintain labeling credibility. To ensure compliance with the regulations, the NOP directly oversees its accredited certifying agents to monitor organic producers and processors, conducts retail surveillance, conducts investigations, takes action on complaints, and imposes penalties where appropriate.

GENETICALLY MODIFIED MATERIALS IN COMMERCIAL CROPS

Question. How is AMS, and USDA overall, working to prevent the introduction of genetically modified materials into crops intended for commercial sales?

Answer. The Animal and Plant Health Inspection Service (APHIS) is involved in regulation of the biotechnology industry. Various measures are used in authorized field tests to ensure that genetically engineered organisms are confined to the test site. The measures include isolation distances to mitigate cross pollination with other crops and weedy relatives, cleaning of farm equipment to mitigate the inadvertent spread of seed, timely disposition of the field test, and post-harvest monitoring for volunteers. To ensure compliance, inspections of the test site, facilities, and records are conducted. Once a crop is deregulated, that crop is considered no different than conventional crops and may be planted without restrictions from APHIS.

For organic products, regulations of AMS' National Organic Program prohibit the use of genetically modified organisms in organic production. Accredited certifying agents review organic production and handling plans before certified organic production begins to ensure that no genetically modified organisms are used in production and that handling procedures protect organic products from contact with genetically engineered materials. Penalties are in place for intentional disregard of the regulations.

COUNTRY OF ORIGIN LABELING (COOL)

Question. Please provide an update on plans to implement COOL.

Answer. AMS has entered into cooperative agreements with 14 States for the purpose of conducting audits of retail establishments to enforce the COOL regulations for fish and shellfish. Audits in States without cooperative agreements were conducted by USDA personnel. In fiscal year 2006 1,159 retail stores were audited; the number of audits in fiscal year 2007 will increase slightly.

For the remaining covered commodities, AMS will issue proposed regulations for public comment and issue final regulatory actions to implement COOL by the statutorily established effective date.

Question. If language was enacted that would move the current implementation date for COOL forward to sometime during fiscal year 2008, please explain what steps would be required to implement it on an accelerated schedule. What funds would be required to implement COOL during fiscal year 2008?

Answer. To implement COOL for the remaining covered commodities on an accelerated schedule, it could be necessary for AMS to issue final regulatory actions without the benefit of a public comment process.

Given the current implementation date, AMS will not need additional funding in fiscal year 2008. To include the additional commodities, the program needs to develop the necessary regulations. Once regulations are established, the program must expand retail and supplier enforcement through adequate Federal staffing and by establishing additional cooperative agreements with State agencies and U.S. terri-

tories to conduct retail surveillance audits. The program would focus on training and educating Federal and State employees on their enforcement responsibilities; overseeing the uniform application of the requirements from the Federal level; conducting educational and outreach activities with interested parties; conducting routine surveillance and product trace-back audits throughout the supply chain to ensure proper labeling and enforcement; responding to formal complaints; and initiating enforcement actions against violators. Since expanding the current program to all commodities in the statute will constitute an increase in program activity, implementation will require an increase in funding.

RISK MANAGEMENT AGENCY

Question. Is RMA developing any new products to serve regions of the country that currently have few, if any, options for risk management? If so, please explain them.

Answer. The Risk Management Agency (RMA) has undertaken an evaluation of its product portfolio to identify gaps in availability, particularly with respect to underserved crops and/or regions. This evaluation found that, with few exceptions, crop insurance coverage is generally available for the most economically significant crops in the underserved regions. This result is consistent with the conclusions of a recent independent evaluation of RMA's product portfolio. This suggests that RMA should place greater emphasis on improving currently available products to provide more effective risk management protection, and target efforts on the development of new products towards filling the few remaining gaps. RMA is currently conducting comprehensive evaluations of several crop programs to identify areas for improvement, particularly among underserved regions.

In addition, RMA has implemented several new products, most notably Adjusted Gross Revenue (AGR), Adjusted Gross Revenue-Lite (AGR-Lite), and two Pasture, Rangeland and Forage (PRF) pilot programs. The AGR, AGR-Lite and PRF programs are particularly oriented to producers for whom traditional crop insurance products were either impractical, or did not provide effective risk management protection. In addition, over twenty pilot programs are currently active that pertain to specialty crops, including pilot programs for processing chili peppers, Hawaii Tropical Fruit, and Florida Fruit Trees. RMA also has ongoing development efforts for a revenue insurance product for certain specialty crops, as well as an umbrella weather-peril product that could provide effective coverage for certain crops with relatively limited market value. Additional risk management tools are developed through partnership agreements that impact underserved producers. These partnership agreements deal with a wide range of topics including the development and understanding of markets, pest and disease control, and water management.

The Crop Insurance Board also accepts private sector submissions that allows persons to develop and submit for approval their own products targeted to specific risk management needs.

GLOBAL WARMING

Question. USDA conservation programs provide a model for natural resources protection on a vast scale. Today, there is much discussion about the issue of global climate change.

Please describe any current agricultural activities that may contribute to global climate change.

Answer. Through a portfolio of beneficial conservation programs and energy conservation practices Producers have opportunities to save money and time while reducing greenhouse gas emissions. There are several agricultural and forestry production systems that can be implemented to reduce GHG emissions and increase carbon storage, called sequestration, in soils and vegetation. Many conservation practices used by agricultural producers can mitigate negative effects attributed to climate change. One example of a specific practice is Conservation tillage. Residues and tillage can be managed to build organic matter and to sequester carbon while also reducing energy requirements and soil erosion. Another example is Comprehensive Nutrient Management systems. These systems can capture methane for energy production while also reducing negative water quality impacts.

Question. Please describe any changes in agricultural production or conservation practices that might better mitigate against the threat of global climate change. For example, what are the benefits of carbon sequestration as a means to reduce greenhouse gasses or other potential contributors to global warming?

Answer. USDA is providing incentives and supporting voluntary actions by private landowners in targeting efficiency improvements through the USDA/Department of Energy (DOE)/Environmental Protection Agency (EPA) AgSTAR, as well as

many other programs. USDA has instituted new standards and is targeting specific incentives that encourage carbon sequestration and greenhouse gas (GHG) emission reduction efforts. USDA also is sponsoring improved monitoring and reporting guidelines for voluntary initiatives. USDA agencies and their partners are developing tools to estimate the amount of carbon stored and GHG emissions reduced at the field and producer level. Such tools will make it easier for producers to estimate carbon storage and GHG emissions reductions.

The Agricultural Research Service conducts global climate change research under the Global Change National Program. This research focuses on four aspects of global change: Carbon Cycle and Carbon Storage; Trace Gases; Agricultural Ecosystem Impacts; and Changes in Weather and the Water Cycle at Farm, Ranch, and Regional Scales. These factors may significantly affect agricultural productivity and are not addressed specifically by other ARS National Programs. Recently, in response to concerns about global climate change, a strong interest has developed in determining how agricultural activities and practices can be used to store carbon, particularly in soil. A Federal multi-agency research initiative on the carbon cycle, the U.S. Global Change Research Program Carbon Cycle Initiative, is under development to address carbon cycle science.

VALUE-ADDED GRANTS

Question. Funding has been provided for Value-Added Agricultural Product Market Development Grants since the Agricultural Risk Protection Act of 2000. Ample time has elapsed to evaluate the effectiveness of this program.

Please describe the types of products that have been funded.

Answer. A wide variety of projects are funded, including value added products made from meat, dairy products, grains, fruits and vegetables, oilseeds, and renewable energy sources. Grant funds totaling \$150,000 were used as working capital for the start up phase of a new tilapia production facility where the fish will be raised and processed into fillets. Other types of products include wine, compost made from dairy waste, wind energy, soy-flour, identity-preserved yogurt, dehydrated apple slices, and branded cuts of beef.

Question. Are these products becoming marketable and sustainable?

Answer. Information about the long-term sustainability became available early this year from a study that the University of Missouri has done. The study indicates that approximately 60 percent of the projects funded resulted in a marketable product.

Question. What are the outcome measures that are being used to determine the success of this program?

Answer. Several measures evaluating the program are in place, including the number of jobs created, the increase in producer revenue due to the project, the increase in customer base due to the project, and the sustainability of the business receiving the grant.

Question. How many grants and how much funding has been provided to energy-related projects?

Answer. Since 2001, 155 grants have been made for energy-related projects, totaling \$25.2 million.

Question. How successful are these energy-related projects and how do you define success?

Answer. We define the success of energy-related projects in the same way as for other project types—we consider any project that resulted in a marketable product to be successful. We estimate that approximately 48 percent of energy related projects resulted in a marketable product. This compares to 60 percent success in projects over all for the value added program.

SINGLE FAMILY HOUSING LOAN PROGRAMS

Question. Mr. Secretary, the Budget terminates the direct single family housing loan program that has served very low and low income rural households well for over 40 years. The 2000 Census reveals that 7.8 million of the non-metropolitan population is poor, 5.5 million face housing cost overburden, and 1.6 million non-metro housing units are either moderately or severely substandard.

While the direct loan program is terminated, funding for the guaranteed loan program is given a concomitant increase. However, this increase comes with a 50 percent rise in the fee to participate. Average incomes of households in the guaranteed program are about twice as high as in the direct program, and this fee increase will force those incomes higher.

The Administration proposes to submit legislation for subsidized guaranteed options, but no language has been provided and no funding is requested in 2008.

Given the large income differential between direct and guaranteed program participants, how will very low income households gain assistance for homeownership loans?

Answer. We anticipate that many very-low income families will be able to participate in our guaranteed homeownership program. Currently about 30 percent of those families who have received guaranteed loans have very low and low incomes.

Question. When does the Administration expect to send up legislation on subsidized guarantees?

Answer. We anticipate the legislative package will be delivered soon.

Question. The current direct program can provide mortgage interest rates as low as 1 percent for very low income households. How deeply subsidized do you expect the proposed guaranteed program to be?

Answer. We are currently developing options to assist very low and lower income families through the subsidized guaranteed program. Our goal is to help more lower income families to achieve homeownership through a guaranteed loan originated and serviced by private sector lenders. Currently interest rate reduction provisions have not been developed.

Question. Do you expect the guarantee fee increase to result in a deterioration in the credit quality of the guaranteed portfolio?

Answer. No, all applicants will be required to meet current credit quality standards. The proposed fee increase, which can be financed as part of the loan, will only increase the average customer's loan payment by about \$7 per month.

Question. How much do you expect the average income of guaranteed program participants to rise as a result of raising the fee?

Answer. We do not expect to see an increase in the income of our guarantee program participants.

OFFICE CONSOLIDATIONS

Question. Mr. Secretary, delivering a direct single family housing program is clearly much more labor intensive than a guaranteed program. In conjunction with refocusing housing lending from direct to guaranteed loans, Rural Development is proposing to reduce staff somewhat and consolidate its field office structure.

What is the proposed magnitude of staff reductions, and extent of field office consolidations?

Answer. Any office consolidations that may occur will be done so as recommended by each Rural Development State Director in order to accommodate a reduction of management levels in each State while recognizing population shifts, the need to improve delivery systems in order to deliver all programs in all locations and to accommodate enhancements in technology enabling us to do business in new ways.

Since the State plans are currently being reviewed, we do not know the number of offices to be closed or that will operate on a part-time basis. RD will keep the Committee informed of its plans. It is RD's intent that the realignment be completed by March, 2008.

Rural Development operated with 6,475 FTE's in fiscal year 2006, and expects to operate with 6,300 FTE's in fiscal year 2007. Rural Development is not proposing a Reduction-in-Force and all employees will be offered a position at their current grade and pay level. We are also seeking Voluntary Early Retirement Authority which could be of interest to those employees who are several years short of being eligible for regular retirement.

COMMUNITY FACILITIES GRANTS

Question. Rural Development's Community Facilities program includes direct loans, guaranteed loans, and grants to support essential community facilities in poor, remote rural communities. Through this program communities can finance rural hospitals, health clinics, day care centers, libraries, town halls, fire trucks and other first responder vehicles and equipment, and a myriad of other essential community facilities. This has been one of the most successful programs in Rural Development's portfolio.

Budget authority may be transferred among the loan and grant programs. However, this Budget appears to eliminate the grant programs, leaving only direct and guaranteed loans to meet needs of small rural communities.

What is the back-log of applications and pre-applications for loans and grants?

Answer. As of March 13, 2007, there were 667 applications and pre-applications totaling \$955,581,290 for the Community Facilities direct loan program, 48 applications and pre-applications totaling \$176,316,844 for the guaranteed loan program, and 757 applications and pre-applications totaling \$62,511,425 for the grant program.

Question. Will the aggregate requested program level be adequate for the fiscal year 2008 demand?

Answer. The aggregated requested program level will be adequate to meet our highest priorities in fiscal year 2008.

Question. How will small, low income communities, who in the past relied on grant assistance, finance the community infrastructure they need?

Answer. There are a number of Federal community development programs and State and local economic development agencies designed to serve low-income and rural communities. A recent GAO report highlighted 73 Federal agencies which serve the purpose of economic development, with several of these specifically supporting the construction of facilities in low-income rural communities.

Question. Has Rural Development estimated the impacts of this proposal on communities by size, region and income level? What are the results of that study?

Answer. No, RD has not estimated the impacts by size, region and income level. However, as there are other Federal agencies providing grant funding for low-income rural communities, the impacts of the proposal will be ameliorated.

MUTUAL AND SELF-HELP HOUSING

Question. The Self Help Housing Program has been hugely successful in assisting very low income households become successful homeowners. With technical assistance provided by grantees, program participants jointly contribute sweat equity as they construct their new homes. Long term financing has been provided by the Sec. 502 direct program. However, this Budget terminates the direct program, terminates the Sec. 523 Self-Help Land Development loan program, and reduces Self-Help grants by 72 percent.

In the face of the success and long term support for the Self-Help program, why is the Administration taking this action at this time?

Answer. Increasing cost in other Rural Housing Programs and fiscal year 2008 budget constraints require program reductions. Rural residents participating in the Self Help Housing program are encouraged to seek financing using the Section 502 guaranteed program or obtain financing from the private sector.

Question. What are the private sector funding sources that will replace this program, and provide homeownership opportunities for these very low income households?

Answer. Most Self-Help Housing grantees have been successful in securing other financial assistance to operate their programs. We anticipate that grantees can seek further funds from outside sources and use the Habitat for Humanity model which does not rely upon Federal financing.

RURAL RENTAL HOUSING

Question. Mr. Secretary, this Budget again proposes to terminate direct rural rental housing loans (Sec. 515), to rely solely on the Sec. 538 guaranteed loan program for affordable rural rental housing construction. The direct program provides subsidized mortgage loans and allows the opportunity for rental assistance for very low income tenants. Subsidized financing, coupled with rental assistance that caps certain tenants' rent payments at 30 percent of income, allows the program to serve tenants with mean incomes under \$10,000.

The bulk of Sec. 515 tenants are very low income, with a majority female headed households, elderly and/or handicapped. Without the Sec. 515 program, what will be the source of new affordable rental housing for these, most vulnerable, rural residents?

Answer. Section 538 guaranteed multi family rural rental housing program has experienced great success and will be the primary source of multi family units without Section 515 funding.

Question. Rental assistance is not available in Sec. 538 projects. Without rental assistance, how can the Sec. 538 program reach the very low income rural population now being served?

Answer. The section 538 program reaches very low income rural population in two ways. Leveraged tax credit financing is present in nearly 80 percent of section 538 projects. Nearly 7,000 units currently enjoy tax credits. Additionally, savings incurred from interest credit subsidies are passed on to the tenants through lower required rent payments.

Question. Are there areas of the country where the Sec. 515 program, even without new rental assistance, could reach very low income households that would not be served through the Sec. 538 program?

Answer. The section 538 program can provide rents that are comparable to the rents created by the section 515 program without rental assistance. This is because

the section 538 is eligible to be combined with 9 percent tax credits, as well as other affordable funding sources. The 538 program also offers an interest credit which buys down the interest rate of up to \$1.5 million of the lender's loan to the Applicable Federal Rate for the entire term of the loan and loan amortizations of up to 40 years. These factors all aid in the creation of units with affordable rents.

MULTI-FAMILY HOUSING REVITALIZATION

Question. Mr. Secretary, Rural Development has a direct loan portfolio reflecting over 17,000 properties, containing over 460,000 affordable rental units. Many of these properties are in excess of 20 years old, in need of substantial repair and rehabilitation. A recent study indicated that the portfolio could be segmented into three components: 10 percent are in growing markets in which it is economically feasible for owners to prepay, leave the program, and raise rents; 10 percent are in declining markets where the costs of maintaining the properties exceed the foreseeable benefits and need; and the 80 percent balance of the portfolio that is appropriate for revitalization and retention in the affordable housing program. Last year the Administration proposed revitalization legislation, including restructuring tools such as interest rate reductions, loan deferrals, reamortizations, subordination, debt forgiveness, etc. Funds were provided in fiscal year 2006 for a demonstration revitalization program for rural rental housing properties.

Please provide a summary of actions taken under the fiscal year 2006 revitalization demonstration program.

Answer. Last year we were able to approve and obligate funding to revitalize 78 properties with over 2,300 apartment units in 16 States, using \$8.9 million in budget authority provided to the demonstration program.

Question. How much of the funds were utilized and in what manner?

Answer. We were able to obligate the following program level amounts: \$48 million in debt deferral, \$4.5 million in soft "bullet" (any loan that requires a generous repayment term usually at the end of the life of the loan and it is anticipated that the loan will be refinanced) loans, \$.28 million in zero percent loans and \$.21 million in grants.

Question. What is the status of a demonstration for fiscal year 2007?

Answer. With a similar level of budget authority this year, we anticipate that the funding NOFA will be released during the month of April. Our key demonstration goals this year are to fund revitalization transactions in every State, fund an increased number of portfolio level transactions and increase the use of leveraged funds.

Question. What is the status of the Administration's revitalization legislation proposal?

Answer. Our legislative proposal is currently in the final stages of review. We expect to transmit it to Congress shortly.

Question. What were the lessons learned under the fiscal year 2006 demonstration and have you revised the legislative proposal accordingly?

Answer. We found last year that by using debt deferral and carefully underwriting revitalization transactions, we were able to approve transactions with very limited rent increases. We also found last year that applications were received from approximately 4,100 properties or a quarter of the Section 515 properties in our portfolio. The large number of applicants reflects the clear need to have new cost effective revitalization tools to help preserve this valuable portfolio.

MULTI-FAMILY HOUSING VOUCHERS

Question. In the face of loan prepayment demands by multi-family housing property owners, raising the specter of increased rents for very low income rural tenants, \$16 million was provided in fiscal year 2006 for rental housing vouchers.

How many properties, containing how many units, prepaid in fiscal year 2006?

Answer. In fiscal year 2006, owners of 151 properties containing 2,330 units went through the Rural Development prepayment process. In addition, 58 properties containing about 1,000 units completed the foreclosure process. This was a total of 209 properties containing 3,330 units.

Question. How many properties and units do you expect to prepay in fiscal year 2007 and in fiscal year 2008?

Answer. We are currently forecasting a total of 225 properties containing about 3,600 units to prepay or complete foreclosure proceedings in fiscal year 2007. We are currently forecasting a total of 275 properties containing about 4,400 units to prepay or complete foreclosure proceedings in fiscal year 2008.

Question. How many vouchers, using how much of the funds, were obligated in fiscal year 2006?

Answer. In fiscal year 2006, we offered vouchers to all tenants in properties where the mortgage was prepaid after September 30, 2005. The first voucher was issued in April, 2006. Three hundred and eight one-year vouchers were obligated for a total of \$601,000 which represents 12 months of payment.

Question. What are your forecasts for voucher utilization in fiscal year 2007 and fiscal year 2008?

Answer. In the first 6 months of fiscal year 2007, approximately 600 vouchers were obligated for a total of \$1.5 million. We are estimating to obligate a total of 1,800 vouchers this fiscal year and we estimate obligating about 2,200 vouchers in fiscal year 2008. Our experience, somewhat limited at this point, is that about half of a property's tenants accept the offer of a voucher, and of those about half utilize the voucher. The majority of the tenants utilize the voucher in the property where they were living at the time of prepayment or foreclosure, although the voucher can be used in any property where the owner will accept it.

RURAL BUSINESS DEVELOPMENT GRANTS

Question. Mr. Secretary, this Budget, again, terminates successful grant programs that promote economic development and job creation in rural America. Rural Business Enterprise Grants (RBEG) facilitate development of small and emerging business enterprises, while Rural Business Opportunity Grants (RBOG) provide technical assistance for business development planning. Current funding levels would create or save about 24,500 jobs, through 560 recipients, in rural areas desperately needing development assistance.

On a cost per job basis, these grant programs are probably the most effective in the Rural Development portfolio. Why is the Administration proposing to terminate such successful programs?

Answer. Funding can be provided by other business loan and grant programs within the Federal Government and rural development.

Question. This proposal was soundly rejected last year. What has changed in the rural economy to make this proposal now more palatable?

Answer. Limited discretionary funding, higher priorities, and the need to support other Departmental priorities all played into the Administration's proposal. Rural Development intends to focus its resources on programs with higher potential for encouraging private-sector investments, and that would reach a broader range of rural communities.

FINANCING NEW ELECTRIC GENERATION FACILITIES

Question. Mr. Secretary, we understand that there are about 66 electric Generation and Transmission (G&T) cooperatives and 864 distributional cooperatives, many of which rely on the Rural Utilities Service (RUS) electric loan program for financing. These cooperatives serve about 13 percent of U.S. electric customers, provide 11 percent of electric sales, and own about 4 percent of total U.S. operational capacity.

Cooperatives are entering a new wave of power plant investment to increase capacity and replace aging infrastructure that dates from the mid-1970's to mid 1980's. Planning for new construction takes several years, followed by construction periods that can span 5 years or longer. Cooperatives depend on the Federal Government for adequate, low cost financing to accommodate the Nation's growing energy needs. Financing is principally provided by Federal Financing Bank (FFB) loans guaranteed by RUS, which is offered at Treasury interest rates plus $\frac{1}{8}$ percent.

We are concerned that this Budget will not meet capital needs of rural electric cooperatives. RUS currently has applications exceeding \$10 billion for generation and transmission purposes, scheduled for funding in fiscal year 2007 and fiscal year 2008. About 80 percent of this total is for construction of new baseload generation. This Budget seeks only \$4.1 billion in fiscal year 2008 funding, and, for the first time, bars funding for new baseload generation.

Prohibiting new baseload generation will make many of these plants less feasible economically at a time when electricity demand is growing rapidly. Rural consumers already pay an average of 12 percent higher electric rates than neighboring utilities. Terminating Federal funding will force rural electric cooperatives to face higher interest rates, shorter loan terms, and raise rates charged to rural customers.

In the face of demonstrated needs for extensive infrastructure replacement and expansion, why is the Administration barring access to financing for new baseload generation?

Answer. There are significant demands on RUS electric loan resources. Needs for transmission and plant upgrades, including environmental upgrades, as well as the

need for new generation plans are high. Due to the inherent risks associated with construction of baseload generation, other significant demands on loan resources and the ability to obtain commercial financing, the Administration determined that restricting the use of electric loan funds made the best use of taxpayer funds while still providing significant support for rural electric needs.

However, understanding the concerns of Congress, the Administration has committed to providing a generation only subsidy rate.

Question. What studies has the Administration performed that indicate sufficient private financing is available to meet this immediate need for baseload generation?

Answer. Though no studies have been conducted by the Administration, there is significant liquidity in the capital markets to absorb demand for this segment of the energy sector.

Question. Has the RUS estimated the impacts of this policy change on electricity costs of rural consumers? What are the impacts?

Answer. The Administration has not estimated the impacts of this proposal on electricity costs.

WATER AND WASTE PROGRAM

Question. Mr. Secretary, Rural Development's Water and Waste Water program has provided loan and grant funds for years to small rural communities to ensure adequate clean water and sanitary waste disposal systems. This Budget again proposes to alter the method to determine borrower interest rates. Poverty and intermediate interest rates would float such that the poverty rate would be 60 percent of the market rate and the intermediate rate would be 80 percent of market. In the current interest rate environment, poverty and intermediate interest rates would substantially fall. Projects would be financed with substantially more debt and reduced grant funds, but with little change in communities' debt burdens due to the dramatic interest rate reductions.

Will you provide assurance that small, poor communities will not be left out of the program, and that debt burdens will not increase and raise water and sewer rates?

Answer. The lower interest rate would allow a small community to borrow more loan funds without an increase in their annual debt repayment. While a community's total debt may increase, their annual debt burden should not increase and will not raise water and sewer rates. Our objective is to provide a funding mix of low interest loan and grant funds to keep user rates reasonable and consistent with the cost of similar systems in the area. It is still anticipated that grant funds would be focused on helping the neediest communities. With lower interest rates, we would be able to increase our reach to more communities with lower incomes.

Question. Do regulations still allow borrowers with loan funds obligated but not closed to receive the interest rate in effect at the time of obligation or closing?

Answer. Yes.

Question. What is the magnitude of loan funds currently obligated but not closed?

Answer. As of March 13, 2007, there were \$2,482,693,545 in loan funds obligated but not closed. This represents 1,813 unclosed loan obligations.

Question. Please provide a distribution of unclosed obligations, by year.

Answer. As of March 13, 2007, the unclosed obligations by year were:

[The information follows:]

Fiscal year	No.	Amount
2007	209	\$270,506,775
2006	655	845,439,746
2005	399	569,531,323
2004	226	328,100,059
2003	116	164,029,838
2002	113	172,123,226
2001	25	37,473,080
2000	24	39,727,518
1999	19	21,932,140
1998	15	23,712,840
1997	5	4,201,300
1996	4	4,260,700
1995		
1994	1	300,000
1993	2	1,355,000

Fiscal year	No.	Amount
Total	1,813	2,482,693,545

INFORMATION TECHNOLOGY (IT) ISSUES

Question. Mr. Secretary, it appears that automated systems for the Farm Service Agency (FSA) are currently in an untenable situation. The current spate of severe access and response problems emerged last November, peaking in January with field offices experiencing only sporadic, random access to program software. FSA program participants faced substantial delays while FSA field staff endured long, erratic periods of unresponsive software.

Please describe how this Budget addresses FSA IT needs.

Answer. The fiscal year 2008 President's Budget provides sufficient funding to maintain the IT system at its current level of operation. USDA is working with the Office of Management and Budget to identify an appropriate funding source for stabilization and modernization.

Question. Our understanding is that it will take hundreds of millions to fully resolve the unstable IT situation. Please provide a detailed plan, with associated costs, that generates a long-term, sustainable, solution to this problem.

Answer. A business plan is being prepared to address the requirements and resources necessary to stabilize the current system, prepare it for implementation of a potential disaster bill and the new farm bill, and replace the current system with a fully modernized and integrated new system.

FSA's business plan includes the following major components:

- Network Stabilization (e.g., expand equipment capacity, purchase monitoring tools and hire personnel to monitor the system)
- Stabilize Databases and Farm Program Payment Applications (e.g., establish proper test environment; employee training and consultants to address database design, configuration and problems; update applications; establish data warehouse for queries and reporting)
- Disaster Bill (e.g., hardware, software development and testing)
- Farm Bill (e.g., hardware, software development and testing)
- Modernization (e.g., capital investments and incremental operating costs)
- Field office system replacement (e.g. replacement of field office servers)

The following table summarizes the estimated costs.

[The information follows:]

FSA IT SYSTEM STABILIZATION AND MODERNIZATION

[Preliminary Cost Estimate]

	Fiscal Year				Total Cost Requirement
	2007	2008	2009	2010	
Capital Requirements:					
Network Stabilization	11,467,850	12,966,667	12,548,750	36,983,267
Database/Application Stabilization	12,983,000	44,047,100	12,067,100	69,097,200
Disaster Bill	8,500,000	8,500,000
Farm Bill ¹	16,000,000	42,000,000	58,000,000
Modernization	675,521	132,154,811	120,572,189	253,402,521
Total	49,626,371	231,168,578	145,188,039	425,982,988
Incremental Operating Requirements:					
Network Stabilization	4,949,286	5,307,077	6,798,435	1,556,275	18,611,072
Database/Application Stabilization	8,120,857	7,245,800	8,864,800	24,231,457
Disaster Bill	5,080,000	25,420,000	30,500,000
Farm Bill ¹
Modernization	12,118,000	12,364,000	24,482,000
Field Office System Replacement ²	19,200,000	9,600,000	28,800,000
Total	13,070,143	48,950,877	63,047,235	1,556,275	126,624,530

FSA IT SYSTEM STABILIZATION AND MODERNIZATION—Continued

[Preliminary Cost Estimate]

	Fiscal Year				Total Cost Requirement
	2007	2008	2009	2010	
Total Cost:					
Network Stabilization	16,417,136	18,273,743	19,347,185	1,556,275	55,594,339
Database/Application Stabilization	21,103,857	51,292,900	20,931,900	93,328,657
Disaster Bill	8,500,000	5,080,000	25,420,000	39,000,000
Farm Bill ¹	16,000,000	42,000,000	58,000,000
Modernization	675,521	144,272,811	132,936,189	277,884,521
Field Office System Replacement ²	19,200,000	9,600,000	28,800,000
Total	62,696,514	280,119,454	208,235,274	1,556,275	552,607,517

¹ Farm Bill estimate includes only IT-related costs. Additional expenditures to deliver the 2007 Farm Bill will be required. For example, temporary employee cost for the 2002 Farm Bill was approximately \$26 million for 1,100 temporary employees.

² Includes only those costs necessary to upgrade network servers located in field office locations. Estimate does not include normal replacement costs for other field office equipment (e.g. phone systems, printers, workstations, mobile devices, GPS systems, etc.) which may also be approaching the end of their expected useful life.

FSA FIELD STAFF AND OFFICE STRUCTURE

Question. Mr. Secretary, adequate FSA field staffing and office locations have been issues for some time. Substantial concerns were raised in the recent past in response to FSA plans to restructure.

What are current plans for altering FSA field staffing levels and field office locations?

Answer. FSA has asked each State Executive Director (SED) to conduct an independent local-level review of the efficiency and effectiveness of FSA offices in their respective State. There is no national plan or formula for closing or consolidating offices. SEDs and State committees have been directed by the FSA Administrator to form a review committee to identify what the optimum network of FSA facilities, staffing, training and technology should be for their State. Efficiencies will be based on each State's individual needs and will be within existing budgetary resources and staffing ceilings. FSA is also committed to coordinating with Congress, stakeholders, local groups and customers to ensure the agency offers the best service possible.

FINANCIAL MANAGEMENT SYSTEM

Question. The budget request includes an increase of \$24.8 million for the financial management system of the Chief Financial Officer.

What will the total cost for completion of this system be?

Answer. The estimated cost for implementation of USDA's new financial management system is approximately \$90 million.

Question. How many years will it take for this system to be completed?

Answer. Our preliminary schedule shows completion of implementation at the end of fiscal year 2011. USDA is presently in the acquisition phase and has yet to award a contract for services or hosting.

Question. If no funds are provided for this, will work continue?

Answer. If appropriated funding is not provided, the project will continue, but will do so at a pace that reflects the funding that would be available, and this is likely to be at a much slower pace than projected. Funding would be sought from other sources—the Working Capital Fund, reimbursements from customer agencies, purchase card rebate proceeds, and/or any funds that might be made available under authority to transfer unobligated balances. By relying upon these alternative sources, implementation timing will be affected as these resources may also be needed for other important corporate investments. To the extent that implementation is delayed, USDA will need to maintain operation of the legacy financial system, adding additional costs.

CAPITAL SECURITY COST SHARING PROGRAM

Question. The budget includes an increase of \$5,241,000 under the Foreign Agricultural Service for the Capital Security Cost Sharing Program. Since fiscal year 2005, this program has increased substantially.

When do you expect funding for this to plateau and then start to decline?

Answer. The Capital Security Cost Sharing (CSCS) program is designed to generate a total of \$17.5 billion to fund 150 new diplomatic facilities over a 14-year period. The FAS assessment comprises approximately 70 percent of USDA's total annual contribution to the program. In the case of FAS, its assessment started at \$0.6 million in 2005 and increased to over \$5.5 million in 2007. It is estimated to increase annually until 2009, at which time the estimated annual assessed level will total approximately \$9 million. This level is assumed to remain constant at that point for the next 9 years with FAS payments totaling as much as \$140 million over the life of the program.

Question. What assurance have you received from the State Department that FAS is paying for space that they actually occupy?

Answer. FAS Washington staff have worked closely with our field offices and with the State Department's Office of Building Operations to correctly identify positions that should be billed to FAS. Also, according to Section 604 of the Secure Embassy Construction and Counterterrorism Act of 1999, the funds collected under the CSCS program are devoted entirely to the construction of new embassy and consular compounds worldwide, regardless of presence.

Question. Is the agency currently paying for space in facilities where they do not have a presence?

Answer. The CSCS program funds construction of new U.S. embassy compounds by contributions from all agencies in proportion to their overseas presence. Of the 80 planned security projects in the next seven years, FAS will occupy space in 27 of the new facilities.

Question. Which agencies at USDA contribute to the Capital Security Cost Share Program?

Answer. Other USDA agencies that contribute to the CSCS program include the Animal and Plant Health Inspection Service, Agricultural Research Service, Rural Development, Natural Resources Conservation Service, and Grain Inspection, Packers and Stockyards Administration.

Question. Is this reflected in all of their budget justifications? If not, why?

Answer. Like FAS, APHIS and ARS display their contributions to the CSCS program in their explanatory notes. In the case of the other agencies, the amounts involved are less than \$60,000 for 2008, and the agencies have not displayed them separately from other administrative funding.

PUBLIC LAW 480 TITLES I AND II AND FOOD FOR PROGRESS

Question. Over the past several years, funds have been transferred from Public Law 480 Title I to carry out activities under the Food for Progress program. Please explain the impact of your request to eliminate the Title I program will have on the Food for Progress program.

Answer. Food for Progress programming in 2008 will continue to be carried out through Commodity Credit Corporation funding. The 2008 President's budget projects that CCC-funded Food for Progress programming will total approximately \$163 million.

Public Law 480 Title I funding to carry out Food for Progress will no longer be available in 2008. Although no funding was appropriated for Public Law 480 Title I for 2007, approximately \$39 million of Title I funding that was carried over from prior years is being used to support Food for Progress programs this year. No similar carry over balances are expected to be available during 2008.

Question. Is it your anticipation that there will be increased availability of funds in fiscal year 2008 for non-emergency programs under Title II? If not, is the Title I elimination another overall reduction in non-emergency food aid programs?

Answer. It is difficult to predict with certainty what the level of emergency needs will be in 2008 and, therefore, difficult to state whether funding for non-emergency programs will increase above this year's level. When the 2007 budget recommended no further funding for Public Law 480 Title I, a corresponding increase of \$80 million was requested for Public Law 480 Title II donations. That increase was approved and remains in the base funding level for Title II and can, therefore, be used to support either emergency or non-emergency Title II programming.

AGRICULTURAL RECONSTRUCTION ACTIVITIES

Question. The Department supports the use of Provincial Reconstruction Teams as a way to assist, re-stabilize, and promote agricultural production in certain areas of the world, such as Iraq and Afghanistan. However, it seems that many of the developmental aspects of these teams could also serve in developing countries, such as in sub-Saharan Africa, where the ability to promote food security is crucial.

Do you think that the use of a mechanism similar to the Provincial Reconstruction Teams could serve a useful purpose as part of an overall global food security strategy?

Answer. The PRTs were first established in Afghanistan for the international community to provide improved security and to facilitate reconstruction, along with economic development, throughout the country. The PRTs are seen as transitional structures and operate in high risk, unstable and difficult situations. The PRTs have a broad mandate in bringing reconstruction to the local people and allow the U.S. Government to engage with key government, military, tribal, village, and religious leaders in the provinces, while monitoring and reporting on important political, military and reconstruction developments. They also provide protective services to experts providing assistance.

USDA has found PRTs to be effective in allowing USDA agricultural advisors to work and directly affect agriculture on a local level in Afghanistan and Iraq. PRTs could serve a useful purpose as part of an overall global food security strategy, especially in reconstruction and stabilization situations. In other situations they might have usefulness but, as transitional structures, they would need to be modified considerably to make them relevant and cost effective.

Question. If not, then why do you think they will be successful in Afghanistan and Iraq?

Answer. USDA believes that PRTs in Afghanistan and Iraq are effective platforms from which our specialists can operate. USDA's PRT advisors continue to make significant contributions to the training of Ministry of Agriculture staff at the local level, and they provide valuable expertise to local and international non-governmental organizations, donors, and others working in agricultural development. PRTs allow USDA to work in close collaboration with other agencies to plan and implement projects that utilize a combination of resources. Many of these projects would be beyond the capacity of USDA alone.

CONSERVATION OPERATIONS

Question. For Conservation Technical Assistance, there is an increase of \$1,000,000 for a stand-alone financial audit.

Why is this audit necessary?

Answer. The Conservation Technical Assistance program is the foundation for all of USDA's conservation efforts. This makes it vital for policy officials to have the most accurate information possible in order to make the best programmatic and management decisions. An independent financial audit will help the agency identify weaknesses in program implementation and help institute improvements for program management and accountability.

Question. What concerns were raised in order for these funds to be needed?

Answer. During preparation of the 2008 President's budget request, issues of program management and accountability were closely looked at. It was determined that an independent financial audit would help identify steps needed to address concerns regarding improper or duplicate payments; large number of up(down)ward adjustments, proper use of commitments and obligations; and validity of open obligations and reimbursable accounts.

Question. The budget includes a decrease of \$17,225,000 for the Grazing Lands Conservation Initiative but retains \$10,000,000 for a competitive grants program.

Please explain the purpose and aspects of this program.

Answer. By Congressional directive in recent years, NRCS provided technical assistance to owners and managers of private grazing lands to improve long-term productivity and ecological health. In fiscal year 2006, Congress directed that \$4,188,000 (of the \$27,500,000 GLCI earmark) be used on efforts to manage the spread of invasive species. A nationwide competitive grants process was used to carry out the fiscal year 2006 Congressional directive. The President's 2008 budget proposes to continue the competitive grants program to control invasive species. It is estimated that invasive plants infest over 100 million acres of grazing land in the United States.

Question. How will these funds be awarded?

Answer. A nationwide announcement would be issued to attract viable applications from eligible government and non-government organizations and individuals to compete for the available funding. The grants would be awarded based on various elements in the applications including purpose and goals, soundness of approach, proposed project management, and transferability (technology transfer). A matching contribution would be required of the applicant. A portion of the funds would be set aside for competition among limited resource farmers and ranchers and Tribes.

Question. What are the goals and expected outcomes of this program?

Answer. The objective of the invasive species grants would be to encourage and support the management and control of invasive species affecting grazing lands. We will use the “cooperative conservation” approach to address invasive species concerns on a local, statewide, or regional basis. The use of Integrated Pest Management techniques and biological pest control methods would be encouraged.

RESOURCE CONSERVATION AND DEVELOPMENT

Question. The budget includes a decrease of \$37,717,000 for Resource Conservation and Development program activities. Included in this is a proposed consolidation of RC&D Coordinators, reducing the number from 375 to 50.

Why is this consolidation necessary?

Answer. The Program Assessment Rating Tool (PART) analysis found the program to be duplicative of other conservation and rural development programs and the program does not prioritize or target funding effectively. Specifically, the purposes and services provided by the RC&D program overlap with other similar resource conservation planning, rural economic development, and community facilities/amenities development services provided by other USDA agencies (such as the Forest Service and Rural Development) and other Federal departments (such as the Department of Commerce’s Economic Development Administration).

Question. What plans are currently in place should the Committee decide to decrease funding for RC&D?

Answer. While the overall program budget will decrease, NRCS will continue to provide support through a state-wide RC&D coordinator. The coordinator’s role will focus more on coordinating USDA assistance toward the implementation of RC&D Area Plans rather than day-to-day operations of RC&D councils. For several years, USDA has partnered with the National Association of RC&D Councils, Inc. to increase the capacity and sustainability of RC&D councils across the country. Many councils have increased their partnerships and financial portfolios so they are less reliant on NRCS direct technical and financial assistance. The budget proposal reflects an expectation that more councils will be able to take on the additional responsibility.

Question. Will staff be folded into other agencies within the Department?

Answer. The majority of RC&D coordinators are classified in such a way that they will fit well within other jobs and activities of NRCS. Most RC&D Coordinators were previously NRCS Soil Conservationists prior to becoming RC&D Coordinators. The majority would easily adjust to soil conservationist type work at the field level.

AGRICULTURAL MARKETING SERVICE

Question. How does AMS intend to protect the organic standard in light of current FDA proposals to approve food from cloned animals, with no requirement for labeling?

Answer. In response to the FDA announcement regarding cloned animals, AMS issued a notice to the industry that, pursuant to the National Organic Program (NOP) regulations, cloning is a prohibited practice in organic production. AMS also consulted the National Organic Standards Board (NOSB) and received a recommendation to prohibit not only cloning as a production method, but the use of their progeny in organic production as well. AMS intends to develop rulemaking or guidance related to clones and their progeny in organic production.

Question. What actions has AMS taken in response to the audits performed by the American National Standards Institute in 2004 and by the USDA Office of Inspector General in 2005, which made strong recommendations about changes needed in the administration of the National Organic Program?

Answer. The audit conducted by the American National Standards Institute (ANSI) found that there were many procedures, required by an ISO Guide 61 system (since revised by ISO and reissued as ISO 17011), that the ANSI auditors were not able to identify during the onsite audit. In response, AMS assigned a task force of experienced quality system specialists to work on the NOP quality management system. Those processes were completed by the September 2005 target date agreed to by AMS. Some processes that require participation by certifying agents or certified operations, such as our reinstatement procedures, have been posted on the NOP website. Some additional procedures have been posted as they were approved by the Office of the Inspector General, who conducted a separate but similar review at about the same time. The OIG audit found similar deficiencies as the ANSI audit and identified 10 action items to be completed by the NOP. All of the OIG action items have been completed.

NATIONAL ORGANIC CERTIFICATION COST SHARE PROGRAM

Question. Of the \$5 million provided in the fiscal year 2002 Farm Bill for the National Organic Certification Cost Share Program, how much remains unobligated and/or unspent? Please provide a breakdown of the States with remaining unobligated and/or unspent funds, as well as a list of States that have spent all of their funds.

Answer. The information is provided for the record. As of March 20, 2007, \$148,340 is unobligated and unspent funds total \$247,100 for the 24 States with funds remaining.

Eighteen States have exhausted all of their allotted funds: Arkansas, Colorado, Florida, Georgia, Illinois, Iowa, Massachusetts, Minnesota, Montana, New Hampshire, New York, North Carolina, Oklahoma, Pennsylvania, Tennessee, Virginia, Washington, and Wisconsin.

Seven States that have spent more than 90 percent of program allotted funds: California, Maine, Michigan, North Dakota, Oregon, South Dakota, and Vermont.

Seventeen States have more than 10 percent of program allotted funds remaining: Alaska, Hawaii, Idaho, Indiana, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, New Jersey, New Mexico, Ohio, South Carolina, Texas, Utah, and Wyoming.

Eight States chose not to participate in this program: Alabama, Arizona, Connecticut, Delaware, Louisiana, Nevada, Rhode Island, and West Virginia.

Question. If funding for the National Organic Certification Cost Share Program remains unobligated and/or unspent in some States at the end of fiscal year 2007, does USDA have the authority to make that funding available to other States? Does USDA plan to do so?

Answer. Within each AMS-State cooperative agreement, there is a provision that gives AMS the authority to terminate agreements and redistribute unspent funds to other States that have exhausted funds. If States are not actively obligating funds and large balances remain unspent at the end of fiscal year 2007, AMS will exercise this authority.

Question. What is the total funding provided in the fiscal year 2008 budget for the National Organic Program?

Answer. The fiscal year 2008 request for Organic Standards is \$3.18 million.

EMERGING PESTS

Question. How does APHIS work to prevent things such as Emerald Ash Borers and Asian Longhorn Beetles from entering the United States? What improvements need to be made at the borders to prevent these incredibly expensive pests from entering and causing these problems?

Answer. The Agriculture Quarantine and Inspection program protects the United States from the risks associated with the introduction of invasive agricultural pests and diseases. APHIS and the Department of Homeland Security cooperate to carry out this program, and fund the programs through a combination of appropriations and user fees. The Pest Detection program supports APHIS' goal of safeguarding U.S. agricultural and environmental resources by ensuring that new introductions of harmful plant pests and diseases are detected as soon as possible, before they cause significant damage. USDA is requesting a \$15 million increase in the Pest Detection program for fiscal year 2008.

Exotic wood boring and bark beetles such as EAB and Asian longhorned beetle (ALB) likely entered the United States through infested solid wood packing materials such as pallets, crates, and other materials used in international shipping. These materials are often reused and reshipped many times throughout the world. Many countries have recognized the need to deal with the pest risk. APHIS worked with its international counterparts to develop standards for safely moving solid wood packing materials and implemented regulations based on the developed standards. While APHIS and affected States are still dealing with the effects of EAB and ALB and several other exotic forest pests already in the United States, we believe that the new regulation of wood packaging materials should help prevent future infestations of this type.

Question. At what point do you make a determination that the eradication of a disease isn't possible, such as in the case of citrus canker? What are the next steps once that determination has been made?

Answer. Although each pest or disease situation must be analyzed separately, there are several factors we consider when determining whether or not eradication is feasible. Among these are: the availability of adequate funding and active participation from Federal, State, and industry cooperators; weather and any other environmental constraints; the potential of the pest to do significant economic damage

to agricultural or forest resources; the extent to which the pest or disease has spread; the availability of effective detection, diagnostic, and control technology; the availability of acceptable alternatives to eradication; public support for an eradication program; the disease's public health significance; and the vectors associated with a disease (e.g., mosquitoes, ticks, etc.).

Federal officials take all of these and other factors into consideration as they determine whether the eradication of a pest or disease is possible. If one or more of these factors change considerably during the course of an eradication effort, the planned course of action will be reevaluated. Prior to making any major decisions about discontinuing an eradication effort, Federal officials will consult with their State and industry cooperators, then update policies and regulations as appropriate.

Question. Specifically for Chronic Wasting Disease, how will the requirements for the States change with the proposal for a match in which the Federal Government will pay for 60 percent of anticipated program needs, and the State will fund the rest? Will the State funding level need to increase?

Answer. The 2008 budget proposes a reduction of about \$4 million. The program requirements for the chronic wasting disease (CWD) herd certification program (HCP) will not change with the funding reduction. At the requested funding level, USDA anticipates the States and cooperators would contribute additional resources to support the efforts at current levels.

Question. More broadly, what amount does APHIS anticipate saving by requiring increased State matches for APHIS activities? Is there currently a mandated match level for States, or is this an entirely new proposal? If a State can't or does not provide the requested match amount, what will APHIS do then?

Answer. The following table is provided for the record.
[The information follows:]

Line Item	Savings
Chronic Wasting Disease	\$4,400
Emerging Plant Pests—Citrus Health Response Program (Florida)	2,300
Emerging Plant Pests—Asian Longhorned Beetle (NJ & NY)	1,691
Emerging Plant Pests—Glassy-Winged Sharp Shooter (California)	1,001
Johne's Disease	5,005
Noxious Weeds	300
Total	14,697

There is currently no mandated match level for States, nor is USDA proposing a mandated level. It is our goal to leverage increased participation from the States to maximize the benefits received from Federal dollars.

If a State is unable to contribute the estimated amount for a particular program, USDA will evaluate the overall impact to program efforts and adjust future funding requests accordingly.

APHIS COOPERATIVE AGREEMENTS

Question. Please provide a chart showing all cooperative agreements with States and other organizations to be carried out in fiscal year 2007, including total funding provided by Congress, and funding retained by APHIS.

Answer. Given the timing of the full-year fiscal year 2007 appropriation, APHIS is currently in the process of negotiating with States and other organizations in the development of work plans and agreements for this year. Therefore, the requested information is not available at this time. This information will be provided when available, but not later than August 1, 2007.

Question. Was there any input gathered from those whose responsibilities will be increased before this proposal was put forth to decrease funding for Johne's disease? Are these activities that the States, etc. are currently undertaking, or would have to pick up?

Answer. USDA has consulted with our partners in the Voluntary Bovine Johne's Disease Control Program (VBJDCP), and they are aware of our request. From its inception, the VBJDCP has been a cooperative effort among APHIS, State departments of agriculture, and industry. States have been the main driving force of the VBJDCP. A large part of the Johne's disease funds not requested in the President's Budget has been used by the States to pay for producer testing and risk assessment fees. With a reduction in Federal funding, these costs will need to be covered by producers who benefit from this program. In addition, State and University partners would assume responsibility for continuation of the Johne's disease demonstration herd projects implemented in each region. These projects focus on new and current

testing schemes and control methods to determine the most effective cost management practice options.

APHIS will continue to provide oversight to the VBJDCP and support analysis of the national demonstration projects, along with continuing laboratory approval and licensing diagnostic tests and vaccines for commercial use.

COMMON COMPUTING ENVIRONMENT

Question. Why is the budget for CCE decreasing this year, when needs are certainly not?

Answer. Funding for the CCE has been comprised of Service Center Agency (FSA, NRCS, RD) information technology (IT) purchases through their own appropriations, in addition to funding provided through the CCE direct appropriation. This funding has been used to develop an infrastructure to support the business delivery functions of the Service Center Agency (SCA) field offices located across the country. The 2008 budget requests that \$78.5 million with an additional \$12 million for CCE activities that are specific to FSA be included in the SCA salaries and expenses appropriations to meet the ongoing business delivery needs. This funding will support the continued IT activities of the SCAs as they jointly maintain the CCE infrastructure. In addition, the SCAs will continue to work with the Information Technology Services (ITS) division of the Office of the Chief Information Officer in USDA. ITS is funded through reimbursable agreements with the SCAs and delivers staffing and services to the agencies in support of the CCE. In coordination with ITS, the agencies will be able to ensure that the necessary services and staffing are available to maintain the infrastructure and program delivery.

Question. Please provide a chart showing the total CCE funding, either within the CCE account or at the Agencies, over the past 5 years.

Answer. A chart has been provided for the record showing the funding for the CCE for fiscal year 2002 through fiscal year 2006. This chart includes funding from the CCE direct appropriation, agency direct purchases of IT equipment and services for the CCE, and agency reimbursements of the OCIO-Information Technology Services (ITS) through the Working Capital Fund (WCF). These amounts paid for ITS operating expenses for the CCE and other IT activities, such as Geographic Information Systems (GIS).

[The information follows:]

CCE FUNDING

	Fiscal year				
	2002	2003	2004	2005	2006
Funding Source:					
CCE Direct Appropriation	\$59,369,000	\$133,155,000	\$118,585,000	\$121,577,300	\$108,971,000
Service Center Agency IT purchases for CCE (paid directly to vendors; did not go through WCF)	29,174,241	30,924,733	30,748,000	55,413,000	30,265,009
Total	88,543,241	164,079,733	149,333,000	176,990,300	139,236,009

Question. Does the USDA have a solid budget estimate of the cost to replace the current outdated FSA computer system?

Answer. FSA is planning to implement a long-term modernization effort known as MIDAS to replace its obsolete equipment. FSA anticipates submitting a business case for this investment to the Office of Management and Budget during March 2007. Preliminary cost estimates indicate that this planned transition would require about \$278 million over fiscal years 2007 through 2009. It would also have a total 10-year lifecycle cost of \$463 million unadjusted for risk and an estimated cost of \$617 million when adjusted for risk.

In addition to this modernization effort, further costs must be incurred to stabilize the FSA IT system components at field offices in the short term. These additional costs are estimated to be about \$150 million to bring the Kansas City web-based system up to at least moderate reliability; about \$97 million to implement likely disaster assistance and Farm Bill legislation; and nearly \$29 million to replace obsolete field office components. Thus, estimated total costs of nearly \$553 million over fiscal years 2007 through 2010 will be required to bring the current system up reasonable operating capability and to transition to a modernized system. However, the actual modernization component as noted above is estimated to cost about \$278 million.

Question. Is an FSA replacement system part of the Farm Bill proposals submitted? If not, where will this funding come from, since it is not in the President's budget?

Answer. Funding for modernization of FSA's information technology systems is not included in the Administration's Farm Bill proposal. USDA is working with the Office of Management and Budget to identify an appropriate funding source for this investment.

COMMODITY SUPPLEMENTAL FOOD PROGRAM

Question. How many people currently on CSFP do you estimate will lose all benefits, either by not deciding to participate in Food Stamps, or receiving fewer benefits under Food Stamps?

Answer. We do not know how many current CSFP participants would not participate or potentially receive a food stamp benefit lower than the value of the CSFP package. We estimate that CSFP participants who opt to transition to food stamps will receive an average monthly benefit of \$54 per person. In contrast, we project that the average CSFP food package for elderly people would have a retail value of about \$44 in fiscal year 2007.

PROPOSED LIMIT ON WIC ADMINISTRATIVE FUNDING

Question. Please explain how the proposed limit on WIC administrative funding will affect the activities that WIC providers are required to carry out, including nutrition education, referral services, and other important services?

Answer. We appreciate the hard work that WIC professionals have done to create and operate one of our premier nutrition assistance programs. However, nutrition services and administration (NSA) funding continues to require a greater and greater proportion of the annual WIC appropriation. In every other sector of government—Federal, State and local—we have all had to learn to become more efficient within tighter administrative budgets. We believe WIC can, too. WIC State agencies have achieved remarkable success in controlling food costs; we have no doubt that the same creativity can be applied to the NSA costs without compromising important client services and program operations.

Our proposal would provide NSA funds at the fiscal year 2006 per-person level. This would allow for a greater proportion of appropriated funds to be used for food benefits and to ensure that funding continues to be adequate to serve all eligible individuals who wish to participate. It is anticipated that the total appropriation needed for fiscal year 2008 would be reduced by approximately \$145 million through this redirection of NSA funds to food funds.

Question. Please outline how this proposal is different from the fiscal year 2007 budget request.

Answer. The current proposal is intended to provide a reduction in WIC NSA funding to slow its growth rather than to "cap" the funds available for NSA at 25 percent as proposed in the fiscal year 2007 budget.

Current legislation provides an amount for State agency NSA grants sufficient to guarantee a national administrative grant per participant (AGP). The guaranteed national AGP for each fiscal year is based on the prior year's AGP, inflated by the State and Local Purchase Index, as required by legislation. The WIC AGP inflation rate from fiscal year 2006 to fiscal year 2007 was 6 percent.

Our current proposal would reduce the AGP used to determine the proportion of funds made available for NSA in fiscal year 2008 rather than using the inflated fiscal year 2007 AGP level.

Question. If this proposal is not adopted, will your request level for WIC still be adequate?

Answer. USDA estimates that setting the fiscal year 2008 administrative grant per participant at the fiscal year 2006 level will save approximately \$145 million through redirection of NSA funds to food funds. If this proposal is not adopted, then an additional \$145 million would be needed in the fiscal year 2008 appropriation for the WIC Program in order to support average monthly participation at the anticipated level of 8.28 million.

Question. Will the proposal regarding income limits actually save any money? Will this proposal, if included, require States to re-check the eligibility of all of their participants?

Answer. USDA estimates that approximately \$2 million per year will be saved by the proposal to limit income eligibility based on participation in Medicaid to those individuals whose incomes are below 250 percent of the Federal poverty guidelines. This will help ensure that WIC benefits are targeted to those most in need. The proposal would not require States to re-check the eligibility of all of their current par-

ticipants. Rather, affected States will need to ask new WIC applicants and applicants whose prior certification has expired to show documentation of eligibility in a means-tested program other than Medicaid, such as the Food Stamp Program or Temporary Assistance for Needy Families, or to show documentation of their income to determine eligibility.

Question. How many States will be affected by the income eligibility proposal, and how much will it cost them to re-certify all WIC participants? How many people do you think will have to be re-certified, and how many ineligible participants will be identified?

Answer. Based on current Medicaid income eligibility levels, seven States would be affected: Hawaii, Maryland, Minnesota, Missouri, New Hampshire, Rhode Island and Vermont. The proposal would not require these States to re-certify current participants. Rather, these seven States will need to ask new WIC applicants and applicants whose prior certification has expired to show documentation of eligibility in a means-tested program other than Medicaid, such as the Food Stamp Program or Temporary Assistance for Needy Families, or to show documentation of their income to determine eligibility. We estimate that approximately 3,000 applicants who are on Medicaid in these States will have incomes above the 250 percent threshold and therefore no longer be eligible for benefits.

FOOD STAMP PROGRAM LEGISLATIVE PROPOSALS

Question. How does the legislative proposal in the Food Stamp Program work to streamline Federal assistance programs?

Answer. Many of the proposals work together to streamline the administration of the Food Stamp Program by simplifying complex policies, while at the same time supporting low-income working families. For example, we are proposing to exclude all retirement accounts and certain educational savings accounts from resources when determining eligibility. This simplifies the eligibility determination on the part of the State agencies while encouraging low-income families to save for retirement and their children's future even if they experience a temporary need for food stamps. We are proposing to exclude combat related pay for military personnel. This proposal would make permanent a policy that has been enacted on a yearly basis through the budget process. This proposal makes it easier for State agencies to determine eligibility while supporting the families of service personnel fighting overseas by ensuring that they do not lose food stamps as a result of the additional deployment income. Taken as a whole, these proposals would have a significant affect on streamlining the administration of the Food Stamp Program.

CENTER FOR NUTRITION POLICY AND PROMOTION

Question. Please list all cooperative agreements or contracts entered into by CNPP in regard to My Pyramid, including funding levels and recipients.

Answer. Current contracts are for hosting and maintenance operations, evaluation, customer service, and refinement of tools already developed for the MyPyramid.gov Web site. Three cooperative agreements exist for educational purposes in support of MyPyramid and the 2005 Dietary Guidelines for Americans. No funds are exchanged between parties for these cooperative agreements. A list will be provided for the record.

[The information follows:]

Hosting and Maintenance Contracts (for support of website and associated databases):	
National Information Technology Center, Kansas City, KS	\$181,000
American Systems Corporation, Chantilly, VA	90,000
Akamai Technologies, Cambridge, MA	120,000
Evaluation (for 12 month American Customer Satisfaction Index):	
ForSee Results, Ann Arbor, MI	25,000
Customer Service (for customer support specialist):	
Network Management Resources Consulting, Inc., Annapolis, MD	79,451
Refinement of Tools (to increase usability of existing interactive tools):	
Porter Novelli, Washington, DC	102,052
Cooperative Agreements (To promote MyPyramid and the 2005 Dietary Guidelines for Americans):	
Tufts University, Boston, MA and Safeway, Inc., Pleasanton, CA	(¹)
Naturally Nutrient Rich Coalition (NNRC), Chicago, IL	(¹)
Hispanic Communication Network (HNC), Washington, DC	(¹)

¹ No funds were exchanged for Cooperative Agreements.

FOOD SAFETY AND INSPECTION SERVICE

Question. Will States receive the full funding level they requested in fiscal year 2007 with the additional funding that we provided in the Joint Resolution?

Answer. Funding levels for the States are reviewed in order to determine the amounts they require to perform their inspection tasks and may at times vary from the amount requested. However, adequate funds are available for States.

Question. Is the President's budget for fiscal year 2008 sufficient to provide the States with their full funding request in fiscal year 2008 for their State meat inspection programs?

Answer. FSIS requests an increase of nearly \$1 million for State MPI programs in fiscal year 2008, as stated in the amended budget explanatory notes. The fiscal year 2008 President's Budget provides full funding for the State MPI programs based on estimated needs when the budget was proposed. FSIS will know the funding request from the States sometime after August 2007, when the States provide updated funding needs.

Question. Please provide information regarding any long-term contracts FSIS has regarding public meeting space, including funding spent on these contracts.

Answer. The Food Safety and Inspection Service has no long-term contracts for public meeting space.

Question. Please provide information on employee performance bonuses at FSIS in fiscal year 2006, including the total amount of bonuses provided to GS employees, and the total amount of bonuses provided to SES employees.

Answer. The Food Safety and Inspection Service's Senior Executive Service (SES) performance awards for fiscal year 2006 totaled \$269,362, and were paid in fiscal year 2007 using fiscal year 2007 funds. For fiscal year 2006, all other employees received a total of \$2,774,926 in bonuses.

Question. How often do processing inspectors working in combination slaughter/processing plants have to perform slaughter duties because of an absence of a slaughter inspector due to vacancies, illness, vacations, etc.? Please describe the type of records the Agency keeps in such instances provide those records for the past 2 years.

Answer. The Food Safety and Inspection Service utilizes a variety of strategies to staff critical slaughter positions when absences occur due to vacancies, illnesses, and vacations. These strategies include utilization of relief inspectors and relief public health veterinarians, other-than-permanent employees, higher graded slaughter inspection personnel, and processing inspection personnel. The use of processing inspectors to cover the absence of slaughter inspectors has been policy for several decades, and is the best use of staff, as the presence of inspectors at slaughter facilities must be continuous. Documentation of the daily staffing strategies utilized at each plant is not maintained. Thus, records on the use of these staffing strategies are not available.

Question. What is the current career ladder for FSIS inspection personnel? For the years 1996–2006, please identify the number of Agency employees by GS level that worked in Agency headquarters; that worked in field locations. How will the Agency's implementation of RBI affect the numbers of employees in each GS level?

Answer. FSIS' inspection program personnel include the following primary occupations:

- Food Inspection (slaughter), GS–5, career ladder GS–7
- Consumer Safety Inspectors (processing), GS–8, career ladder GS–9
- Consumer Safety Inspectors (relief positions), GS–10
- Public Health Veterinary Medical Officers, GS–11, career ladder GS–12

Under a more robust risk-based inspection system for meat and poultry processing, USDA will continue using the same number of inspection program personnel, spending the same amount of overall time conducting inspections. Risk-based inspection is about working smarter to protect public health by having inspection personnel spend more time in the processing plants that need assistance and expertise.

A chart identifying the number of Food Safety and Inspection Service positions at headquarters and in field positions (1996–2006) follows:

[The information follows:]

FOOD SAFETY AND INSPECTION SERVICE

Actual Headquarters and Field Positions for 1996–2006

Grade	1996		1997		1998		1999		2000		2001		2002		2003		2004		2005		2006	
	Wash DC	Field	Wash DC	Field	Wash DC	Field	Wash DC	Field	Wash DC	Field	Wash DC	Field	Wash DC	Field	Wash DC	Field	Wash DC	Field	Wash DC	Field	Wash DC	Field
Senior Executive Service ...	16	5	23	1	20	1	21	21	19	2	19	2	21	26	25	1	25	1
GS-15	44	9	45	30	45	30	57	25	51	25	52	25	51	26	59	27	60	26	59	32	58	32
GS-14	89	44	100	48	100	48	102	49	93	46	94	46	103	58	107	72	98	72	130	87	128	85
GS-13	212	246	215	347	215	347	248	297	232	283	248	301	221	331	228	351	208	369	293	406	240	394
GS-12	91	956	148	939	148	939	106	935	81	874	91	883	93	889	108	960	97	1,027	117	1,058	97	1,027
GS-11	67	387	28	463	28	463	36	406	35	345	42	329	34	384	44	304	32	280	53	260	45	253
GS-10	176	195	1	345	471	2	510	515	1	516	1	494	2	459	1	409	1	403
GS-9	60	2,195	104	264	109	2168	42	2,017	41	1,826	45	1,859	49	1,951	43	1,878	57	1,971	49	1,959	42	1,892
GS-8	25	1,235	8	1,220	8	1,171	13	986	11	1,023	12	1,046	11	1,068	14	1,101	31	965	14	959	12	930
GS-7	86	3,492	84	3,265	84	3,267	75	3,551	70	3,647	64	3,630	54	3,348	57	3,234	74	3,278	60	3,223	55	3,120
GS-6	73	63	38	70	38	70	34	55	37	47	27	47	17	43	14	42	11	50	14	48	11	46
GS-5	68	460	46	341	44	341	16	284	18	656	19	676	11	317	12	401	14	313	11	240	8	232
GS-4	20	84	38	49	38	49	7	54	2	34	36	1	32	3	24	3	51	8	38	6	36
GS-3	2	17	3	6	3	6	1	21	1	20	2	19	1
GS-2	2	2	1
GS-1	2	1
Ungraded Positions	2	19	2	24	1	22	1	23	23
Total Permanent Positions	859	9,391	882	9,262	882	9,267	759	9,153	694	9,339	713	9,417	666	8,985	713	8,907	720	8,863	834	8,720	728	8,451

Question. In late October 2006, 493 beef carcasses at the Swift & Company plant located in Grand Island, Nebraska were inadvertently sprayed with sewage water. Instead of condemning the carcasses according to the provisions of 9 CFR 318.14, FSIS management officials instead approved a “rework” of the contaminated carcasses. Please explain the justification for this action.

Answer. Under 9 CFR 318.2(d), USDA’s Food Safety and Inspection Service (FSIS) has historically considered offers to recondition product if it believes that an establishment can make the product safe for human consumption. I will provide more information on this particular action for the record.

[The information follows:]

In this case, the establishment developed an aggressive reconditioning plan based on relevant science, in close consultation with FSIS officials, and approved by FSIS. After reconditioning, extensive testing showed that, microbiologically, these carcasses had testing results equal to or better than carcasses normally processed at the facility.

Question. The fiscal year 2008 budget proposal calls for the imposition of a licensing fee on all meat, poultry and egg production facilities within FSIS jurisdiction. Will the approximately 1000 foreign establishments that are eligible to export to the United States also be subject to such a licensing fee?

Answer. No, foreign establishments eligible to export to the United States would not be subject to the proposed fee. USDA is recommending a fee for each Federally inspected establishment or official plant to partially cover the costs of USDA inspection services.

Question. The fiscal year 2008 calls for the imposition of reinspection fees for all firms that are subject to failure of performance standards and/or recalls. Will foreign establishments that export to the United States be subject to reinspection fees when FSIS auditors find violations of U.S. standards?

Answer. No. The proposal would not provide for charging fees to foreign establishments that export meat, poultry or egg products to the United States. FSIS may decertify foreign establishments, i.e., prohibit them from exporting meat, poultry or egg products to the United States, if it finds that they do not meet the requirements set forth in its regulations for imports.

Question. What is the status of the study being conducted in Canada to justify less than daily inspection of processed meat and poultry products that are exported to the United States?

Answer. The Canadians are continuing their study of less-than-daily inspection, and nothing has been submitted to USDA at this time. Once a study is completed, it will need to be peer reviewed and the data assessed by USDA. The Canadians will maintain daily inspection for any product exported to the United States until the study is completed and reviewed and a decision is made on how to proceed.

Question. What is the Meat Safety Enhancement Program as it applies to meat imports from Australia? How does it differ from traditional inspection procedures? Have there been any Australian establishments approved to export meat products to the United States using MSEP? Are there any pending applications from any Australian meat establishments to use MSEP to export to the United States? If there are, what is the status of those applications? What criteria will FSIS use to make its final determination on the viability of those applications?

Answer. Australia’s Meat Safety Enhancement Program (MSEP) is an alternative inspection program to Australia’s traditional slaughter inspection procedures, which rely solely on government-paid inspectors. MSEP differs from Australia’s traditional inspection approach by using both company inspectors and government-paid inspectors. It was developed by the Australian government patterned after the United States’ HACCP-Based Inspection Model Project (HIMP). USDA’s Food Safety and Inspection Service determined MSEP to be equivalent in 1999. While one MSEP establishment in Australia has applied for the ability to export its product to the United States, FSIS has not given approval until it completes its assessment of a pilot study carried out by the establishment and the Australian government and concurs that the food safety conditions established as part of the 1999 equivalence decision are being achieved.

FSIS RISK BASED INSPECTION

Question. Please provide us an update on the FSIS announcement regarding its change to risk-based inspection. What is the ultimate goal of this change, and do you believe that FSIS has the right science and testing capabilities at this time, to do this safely?

Answer. A risk-based inspection system will help USDA improve the safety of meat and poultry products from USDA-inspected processing establishments, and

therefore decrease the incidence of illness and deaths caused by foodborne pathogens.

Since USDA's Food Safety and Inspection Service (FSIS) inspection program personnel are in each plant every day, FSIS has the necessary scientific and testing data to institute a risk-based inspection system in processing establishments. In addition to considering the inherent risk of product, as well as its volume, FSIS will use seven key factors to specifically determine a plant's ability to control risk: food safety recalls; verified food safety consumer complaints; noncompliance records that are significant to public health, enforcement actions FSIS has taken against establishments, ready-to-eat and *E. coli* O157:H7 sampling results, ready-to-eat *Listeria monocytogenes* control alternatives, and a plant's *Salmonella* verification category. For more information on how FSIS will measure risk in 30 prototype processing establishments, visit the agency's Web site at: http://www.fsis.usda.gov/Regulations_Policies/RBI_Meeting_040207/index.asp.

Question. Do you currently have enough data on *E. coli*, *Salmonella* and *Listeria* testing, for example, to make sure that you are targeting the right plants, or are you still collecting it?

Answer. The USDA's Food Safety and Inspection Service (FSIS) has sufficient data to establish the plants' ability to control risk, but the agency will continue to collect data on a daily basis. The data already on hand is historical, and the last 12 months data can be used to calculate ability to control risk. The data the agency will collect in the future will give FSIS a snapshot of current conditions in establishments, as well as provide the agency with a measure of establishments' ability to control risk that particular day. The data will allow FSIS to adjust plant inspection intensity in real-time, based on current data, thereby being more proactive instead of reactive by, for instance, increasing intensity after a recall.

Specifically with regard to *E. coli* O157:H7, *Listeria monocytogenes*, and *Salmonella* sampling analysis, in calendar year 2003, FSIS conducted over 80,000 analyses of samples, and that number grew to almost 100,000 in CY 2006. These sampling data, particularly when combined with the other risk-based factors, provide FSIS with a very good picture of the food safety controls within regulated establishments.

Question. Will risk-based inspection result in fewer food inspectors at processing facilities?

Answer. Under a more robust risk-based inspection system for meat and poultry processing, USDA will continue using the same number of inspection program personnel, spending the same amount of overall time conducting inspections. Risk-based inspection is about working smarter to protect public health by having inspection personnel spend more time in the processing plants that need assistance and expertise.

Question. What level of funding has been used so far to develop this program?

Answer. FSIS has not dedicated a specific funding level for the risk-based inspection initiative. However, some of the recent expenditures for this effort include public meetings and technical summits, employee meetings, meetings with the National Advisory Committee on Meat and Poultry Inspection, a contract with Resolve Inc., and other miscellaneous items.

Question. Please provide a detailed explanation of the evaluation FSIS will undertake of the pilot risk-based inspection program before expanding it to further plants. How will you measure success or failure, and what are the parameters of that determination?

Answer. USDA's Food Safety and Inspection Service (FSIS) intends to implement and review risk-based inspection for processing in a careful and deliberative manner. The perfect report card for the long-term would be a measured decrease of food borne disease and death. While FSIS is still in the process of developing how we intend to evaluate RBIS, in the near-term, FSIS will compare such measures as verified consumer food safety complaints, product recalls, and changes in the effectiveness of establishment risk controls between RBIS and traditionally-inspected establishments. In addition, FSIS will be interviewing inspection program personnel, and the USDA's Office of Inspector General will be continuing to audit the development and implementation of RBIS.

Question. What role is turning off the PBIS inspection task scheduler playing in risk-based inspection in processing? Have there been circumstances when the PBIS scheduler has been turned off within the past 5 years, and if so, please identify those circumstances and the reasons for them.

Answer. The Food Safety and Inspection Service (FSIS) will no longer use the Performance Based Inspection System (PBIS) database scheduler in the initial 30 prototype processing locations under risk-based inspection. However, at that time, the agency will not discontinue the use of PBIS as a whole—only the scheduler. Proc-

essing inspectors at the prototype processing locations will continue to report their findings into the PBIS system, and these data will be analyzed on an on-going basis.

In 2000, FSIS allowed District Offices the option of not scheduling the inspection procedures to be performed in a plant on a specific day. This change recognized that some establishments operate seasonally, such as plants that specialize in seasonal or holiday meats; some operate infrequently, such as one day per week; and some prepare products for inspection by FSIS and by the Department of Health and Human Services' Food and Drug Administration on different days. This policy saves inspection program personnel time, since they do not have to check a "not performed" box for a day when an establishment is simply not producing FSIS-inspected product.

Question. The fiscal year 2008 budget proposal calls for the expenditure of funds during the last quarter of the fiscal year to cover the costs of training and relocation of staff when risk-based inspection in slaughter is implemented. How did the Agency arrive at those figures? Does the Agency anticipate reductions in staff when risk-based inspection in slaughter is implemented?

Answer. The agency's goal is to begin to implement risk-based inspection for young chickens at slaughter plants during the last quarter of fiscal year 2008. For that to happen, FSIS will need to have a final rule in place.

Implementation of risk-based inspection in slaughter facilities is projected to require two weeks of training for Food Inspectors and one week for Consumer Safety Inspectors. Cost considerations include travel, per diem, supplies, and materials as well as backfill of frontline inspection personnel while employees are in training. These costs also include post-training meetings conducted by FSIS' Technical Service Center employees to ensure consistent policy application. Other cost considerations include employee relocation expenses in accordance with Federal travel regulations.

Risk-based inspection in processing establishments will not lead to reductions in the inspection program personnel workforce. Once it is implemented in the future, risk-based inspection for slaughter may result in a redistribution of the inspection workforce.

Question. Does the Agency anticipate reductions in the overall inspection workforce as it implements both risk-based inspection in processing and slaughter? If it does, what role will attrition play in those reductions? Will the Agency be forced to reduce staffing through layoffs?

Answer. Under a more robust risk-based inspection system for meat and poultry processing, USDA will continue using the same number of inspection program personnel, spending the same amount of overall time conducting inspections.

Risk-based inspection for slaughter will likely result in a redistribution of the inspection workforce. Anyone who is employed by FSIS when risk-based inspection for slaughter is implemented and desires to keep working for the agency will continue to do so. Risk-based inspection is about working smarter to protect public health by having inspection personnel spend more time in the plants that need assistance and expertise.

Question. What Notices and Directives has the Agency issued in preparation for the implementation of risk-based inspection in processing? What is the legal justification for implementing risk-based inspection in processing without the need for formal rulemaking or a change in existing statutes?

Answer. As of February 27, 2007, USDA's Food Safety and Inspection Service (FSIS) has not issued any directives, but will issue a directive to personnel regarding the implementation of risk-based inspection at the thirty prototype processing locations in order to instruct employees on how they are to perform daily tasks. In addition, before implementing the nationwide risk-based inspection system for processing, the agency will issue either an updated or new directive for personnel. I will have FSIS provide additional information explaining this rationale more thoroughly.

[The information follows:]

The Administrative Procedure Act (APA) (5 U.S.C. 511–599) is the law under which regulatory agencies, including FSIS create the rules and regulations necessary to implement and enforce the statute such as the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act. Section 553 of the APA, titled "Rule making" defines the procedures and specifies exemptions from rulemaking. Section 553(a) of the APA States that matters relating to agency management or personnel are not subject to rule making. Risk-based inspection does not place new regulatory requirements on establishments that will be subject to this new inspection management strategy. What risk-based inspection does is determine which inspection tasks are to be completed by FSIS inspectors for specific establishments. This is a matter of agency management, and so is not subject to rule making.

Even though rule making is not required, FSIS has engaged in, and plans to continue to engage in, a public, transparent development process in devising its new management strategy. The agency believes that public involvement by its stakeholders will yield the best results and the best positive effects on public health in the end. As FSIS gains practical insights from prototyping risk-based inspection, the agency plans to adapt the system to changing circumstances and its evolving understanding as to how best to manage inspection staff.

Some of FSIS' public participation activities used in the development of risk-based inspection include a two-day public listening session in October 2006, and three public sessions with the National Advisory Committee on Meat and Poultry Inspection to gather input. In addition, on April 2, 2007, FSIS will hold a public meeting to gather feedback on the proposed methodology to determine plant ability to control risk, and specifically how best to utilize noncompliance records. The agency will also hold another public meeting on April 5, 2007, to determine to how to improve attribution data. Public meetings are scheduled for April 25 and 30, 2007, to discuss how best to use establishment volume and establishment reported data, respectively, in the formulas for risk determination.

Question. What is the status of the installation of the FSIS Automated Technology Suite (FACTS)? How is FACTS being used in the data collection for plants involved in the risk-based inspection in processing program? Please specify all the types of recorded data available to the Agency that will be considered in making decisions for risk-based inspection. For example, the Agency plans to use information on Non-compliance Records (NRs)—what specific information is available on a NR that will be factored into RBI decisions?

Answer. The Food Safety and Inspection Service's (FSIS) Automated Technology Suite (FACTS) applications have been incorporated into the Public Health Data Consolidation business case. When fully funded, this will allow FSIS to continue building an information technology system that is modernized to consolidate data into one data warehouse system and process and analyze this data through transactional systems. With this initiative FSIS will be able to gather data efficiently, increase data integrity and security, and expedite analysis of all FSIS data.

The data from the processing plants that has already been gathered, along with risk-based inspection data to be gathered, will be stored and utilized through the data warehouse system described above.

Since FSIS inspection program personnel are in each plant every day, the agency has the necessary data to institute an enhanced risk-based inspection system in processing establishments. In addition to considering the inherent risk of product, as well as its volume, FSIS will use seven key factors to specifically determine a plant's ability to control risk: food safety recalls; verified food safety consumer complaints; noncompliance records that are significant to public health, enforcement actions FSIS has taken against establishments, ready-to-eat and *E. coli* O157:H7 sampling results, ready-to-eat *Listeria monocytogenes* control alternatives, and a plant's *Salmonella* verification category. For more information on how FSIS will measure risk in 30 prototype processing establishments, visit the agency's Web site at http://www.fsis.usda.gov/Regulations_and_Policies/RBI_Meeting_040207/index.asp.

FSIS FOOD INSPECTORS

Question. Please provide vacancy rates for food inspectors by district. Please provide a breakdown of FSIS inspectors and plant responsibility over the past 5 years.

Answer. As of February 27, 2007, the inspection work force has increased by 139 positions since the end of fiscal year 2006. These are potential new employees who have passed background checks, had satisfactory interviews, and have agreed to a start date. At any given time, the Food Safety and Inspection Service (FSIS) shows a vacancy rate due to a lag in hiring, attrition, difficulty in recruiting in some remote areas, difficulty in recruiting in some high income locations, and retirement. To meet current demand, FSIS projects that we would have 7,500 in-plant personnel by the end of the fiscal year. The information is provided for the record.

[The information follows:]

IN-PLANT OFF-LINE VACANCY DATA ¹

[As of February 27, 2007]

District	Positions	Employment	Current Value Rate (percent)
Alameda	275.00	229.00	16.73
Denver	278.00	253.00	8.99

IN-PLANT OFF-LINE VACANCY DATA ¹—Continued

[As of February 27, 2007]

District	Positions	Employment	Current Value Rate (percent)
Minneapolis	185.00	167.00	9.730
Des Moines	259.00	236.00	8.88
Lawrence	227.00	206.00	9.25
Springdale	313.00	286.00	8.63
Dallas	229.00	183.00	20.09
Madison	148.00	140.00	5.41
Chicago	278.00	234.00	15.83
Philadelphia	281.00	259.00	7.83
Albany	254.00	214.00	15.75
Beltsville	190.00	170.00	10.53
Raleigh	261.00	233.00	10.73
Atlanta	333.00	297.00	10.81
Jackson	317.00	296.00	6.6296
Total	3,828.00	3,403.00	11.10

¹ Talmadge/Aiken (T/A) plants are not included.

ON-LINE (SLAUGHTER) VACANCY DATA

[As of February 27, 2007]

District	Positions	Employment	Current Vacancy Rate
Alameda	209.00	175.00	16.27
Denver	220.00	187.00	15.00
Minneapolis	164.00	141.00	14.02
Des Moines	413.00	373.00	9.69
Lawrence	334.00	313.00	6.29
Springdale	453.00	431.00	4.86
Dallas	337.00	309.00	8.31
Madison	104.00	90.00	13.46
Chicago	169.00	141.00	16.57
Philadelphia	142.00	126.00	11.27
Albany	33.00	25.00	24.24
Beltsville	275.00	255.00	7.270
Raleigh	504.00	456.00	9.52
Atlanta	509.00	450.00	11.59
Jackson	612.00	576.00	5.88
Total	4,478.00	4,048.00	9.60

Note: It is important to note that the total number of field inspection staff identified above cannot be compared with the total number of "field staff" in an exhibit of FSIS' fiscal year 2008 Explanatory Notes entitled: "Permanent Positions by Grade and Staff Year Summary—2006 Actual and Estimated 2007 and 2008." The field staff identified above relate to the inspection personnel whereas the "field staff" in the "Permanent Positions by Grade and Staff Year Summary—2006 Actual and Estimated 2007 and 2008" exhibit relate to all FSIS staff outside of the Washington, D.C. area (e.g., Technical Service Center staff in Omaha, Nebraska, Financial Processing Center in Urbandale, IA, lab personnel in the three FSIS laboratories, etc.)

INPLANT POSITION AND EMPLOYMENT FIVE YEAR HISTORY ¹

	On-Line	Off-Line	Enforcement, Investigation Analysis Officer/Compliance Officer	Public Health Veterinarian/Veterinarian Medical Officer ²	Total
	Sla-07	CSI 08-10			
			GS 12-13	GS 11-13	
Available Positions					
Fiscal Year 03	3,952	3,491	189	992	8,624
Fiscal Year 2004	3,652	3,749	195	983	8,579
Fiscal Year 05	3,547	3,608	212	995	8,362
Fiscal Year 06	3,509	3,556	215	966	8,246
Fiscal Year 07 ²	3,518	3,610	202	964	8,294

INPLANT POSITION AND EMPLOYMENT FIVE YEAR HISTORY ¹—Continued

	On-Line	Off-Line	Enforcement, In- vestigation Anal- ysis Officer/Com- pliance Officer	Public Health Veterinarian/Vet- erinarian Medical Officer ²	Total
	Sla-07	CSI 08-10			
				GS 12-13	
Employment					
Fiscal Year 03	3,310	3,226	189	838	7,563
Fiscal Year 2004	3,302	3,090	195	850	7,437
Fiscal Year 2005	3,217	3,150	188	831	7,386
Fiscal Year 2006	3,158	3,183	185	793	7,319
Fiscal Year 20071A ³	3,147	3,181	183	772	7,283

¹ T/Apositions are not included.² Includes VMS.³ Current as of 2/27/2007. The end of fiscal year projected employment is 7,500.

OTHER THAN PERMANENT—STAFF YEARS

Years	Usage
2003	438
2004	377
2005	310
2006	298
¹ 2007	360

¹ Planned OTP usage.

RISK MANAGEMENT AGENCY

Question. Is RMA developing any new products to serve regions of the country that currently have few, if any, options for risk management? If so, please explain them.

Answer. The Risk Management Agency (RMA) has undertaken an evaluation of its product portfolio to identify gaps in availability, particularly with respect to underserved crops and/or regions. This evaluation found that, with few exceptions, crop insurance coverage is generally available for the most economically significant crops in the underserved regions. This result is consistent with the conclusions of a recent independent evaluation of RMA's product portfolio. This suggests that RMA should place greater emphasis on improving currently available products to provide more effective risk management protection, and target efforts on the development of new products towards filling the few remaining gaps. RMA is currently conducting comprehensive evaluations of several crop programs to identify areas for improvement, particularly among underserved regions.

In addition, RMA has implemented several new products, most notably Adjusted Gross Revenue (AGR), Adjusted Gross Revenue-Lite (AGR-Lite), and two Pasture, Rangeland and Forage (PRF) pilot programs. The AGR, AGR-Lite and PRF programs are particularly oriented to producers for whom traditional crop insurance products were either impractical, or did not provide effective risk management protection. In addition, over twenty pilot programs are currently active that pertain to specialty crops, including pilot programs for processing chili peppers, Hawaii Tropical Fruit, and Florida Fruit Trees. RMA also has ongoing development efforts for a revenue insurance product for certain specialty crops, as well as an umbrella weather-peril product that could provide effective coverage for certain crops with relatively limited market value. Additional risk management tools are developed through partnership agreements that impact underserved producers. These partnership agreements deal with a wide range of topics including the development and understanding of markets, pest and disease control, and water management.

The Crop Insurance Board also accepts private sector submissions that allows persons to develop and submit for approval their own products targeted to specific risk management needs.

NATIONAL ANIMAL IDENTIFICATION SYSTEM

Question. What is the status of the development of a National Animal Identification System?

Answer. The National Animal Identification System is composed of three components: premises registration, animal identification, and animal tracing. Premises registration is the foundation of the program. As of March 12, 2007, all 50 States, 60 Tribes, and 2 U.S. Territories are capable of registering premises according to USDA standards, and approximately 378,000 locations have been registered.

Significant progress has also been made on the second component of NAIS, animal identification. As of March 12, 2007, approximately 1 million Animal Identification Number devices have been distributed.

The third component of the NAIS, animal tracing, is currently under development with the help of USDA's industry and State partners. Industry, through private systems, and States will manage the animal tracing databases that maintain the movement records of animals. Full deployment of the Animal Trace Processing System is planned for the near future.

Question. If such an animal identification system is made voluntary, what effect does APHIS anticipate that will have on participation? What efforts will be made to encourage participation?

Answer. Participation in the NAIS is voluntary. The USDA remains committed to building upon our strong partnership with the States and industry to meet producers' needs and establish a versatile system that makes sense for everyone.

Moving forward with this voluntary approach has allowed producers the opportunity to test the program and recommend the most practical solutions for a more effective system. In this sense, producers themselves are playing an active role in helping to shape the NAIS program so that it works well for their particular needs. Additionally, a voluntary NAIS allows for the best price competition between service providers (identification device manufacturers, database providers, etc.) and leaves room for market applications (such as age/source/process verification) to help drive the system.

To encourage participation, USDA has provided funding to facilitate development and implementation of an efficient system, and flexibility to adapt to producers' operations and needs. On February 2, 2007, USDA published a request for proposals from nonprofit organizations that wish to enter into cooperative agreements with USDA to advance premises registration. USDA will make up to \$6 million available, subject to the availability of funding, for the cooperative agreements. These cooperative agreements will support the efforts of such organizations to promote the NAIS and, specifically, increase participation in premises registration—the foundation of the program.

INVASIVE SPECIES

Question. Please provide a list of current plant and animal invasive species, ranked by their threat level. What is APHIS' short and long-term plans to deal with these?

Answer. The Administration has not ranked invasive species by threat level. Invasive species that APHIS addresses include, but are not limited to, the programs focused on cattle fever tick, Mediterranean fruit fly, emerald ash borer, potato cyst nematode, sudden oak death, citrus diseases, brucellosis, pseudorabies, and chronic wasting disease. APHIS addresses each of these threats as resources allow.

Over the long term, APHIS develops response plans for exotic pests and diseases that have the potential to cause significant economic or environmental damage and uses its safeguarding system, which involves prevention, detection, and management components, to protect U.S. agriculture. Under the Pest and Disease Exclusion mission area, APHIS works to prevent exotic pests such as cattle fever tick and Mediterranean fruit fly from entering the United States. These and other pests have direct pathways into the United States. APHIS takes action at U.S. borders or in other countries to mitigate the risks associated with them.

Under the Monitoring and Surveillance mission area, APHIS conducts plant pest surveys, animal health surveillance, and other activities designed to detect exotic plant pests and foreign animal diseases if they are present so that we can deal with them quickly if needed. These programs target a changing list of high-risk plant pests depending on trade and travel pattern and outbreaks in other countries. These programs also conduct intensive monitoring and emergency preparedness efforts. APHIS analysts follow animal and plant health situations around the world and frequently adjust monitoring and surveillance efforts and pest and disease exclusion priorities to safeguard U.S. agriculture and natural resources from high-risk pests and diseases.

APHIS also works to control or eradicate high priority invasive species through programs in the Pest and Disease Management area, including, but not limited to,

emerald ash borer, potato cyst nematode, sudden oak death, several citrus diseases, brucellosis, pseudorabies, and chronic wasting disease.

AGRICULTURAL MARKETING SERVICE

Question. We have heard several reports of genetically modified material getting into crops intended for commercial sales, the most well-known being rice. What has the economic effect been of instances such as this?

Answer. The economic effect can be reductions in seed available for planting and potential trade restrictions. For example, two popular long grain rice varieties can no longer be planted for commercial production due to the presence of genetically modified material. The value of certified seed of these varieties produced in 2006 for planting in 2007 is estimated to be \$39 million.

GENETICALLY MODIFIED MATERIALS IN COMMERCIAL CROPS

Question. How is AMS, and USDA overall, working to prevent the introduction of genetically modified materials into crops intended for commercial sales?

Answer. The Animal and Plant Health Inspection Service (APHIS) is involved in regulation of the biotechnology industry. Various measures are used in authorized field tests to ensure that genetically engineered organisms are confined to the test site. The measures include isolation distances to mitigate cross pollination with other crops and weedy relatives, cleaning of farm equipment to mitigate the inadvertent spread of seed, timely disposition of the field test, and post-harvest monitoring for volunteers. To ensure compliance, inspections of the test site, facilities, and records are conducted. Once a crop is deregulated, that crop is considered no different than conventional crops and may be planted without restrictions from APHIS.

For organic products, regulations of AMS' National Organic Program prohibit the use of genetically modified organisms in organic production. Accredited certifying agents review organic production and handling plans before certified organic production begins to ensure that no genetically modified organisms are used in production and that handling procedures protect organic products from contact with genetically engineered materials. Penalties are in place for intentional disregard of the regulations.

VALUE-ADDED GRANTS

Question. Funding has been provided for Value-Added Agricultural Product Market Development Grants since the Agricultural Risk Protection Act of 2000. Ample time has elapsed to evaluate the effectiveness of this program.

Please describe the types of products that have been funded.

Answer. A wide variety of projects are funded, including value added products made from meat, dairy products, grains, fruits and vegetables, oilseeds, and renewable energy sources. Grant funds totaling \$150,000 were used as working capital for the start up phase of a new tilapia production facility where the fish will be raised and processed into fillets. Other types of products include wine, compost made from dairy waste, wind energy, soy-flour, identity-preserved yogurt, dehydrated apple slices, and branded cuts of beef.

Question. Are these products becoming marketable and sustainable?

Answer. Information about the long-term sustainability became available early this year from a study that the University of Missouri has done. The study indicates that approximately 60 percent of the projects funded resulted in a marketable product.

Question. What are the outcome measures that are being used to determine the success of this program?

Answer. Several measures evaluating the program are in place, including the number of jobs created, the increase in producer revenue due to the project, the increase in customer base due to the project, and the sustainability of the business receiving the grant.

Question. How many grants and how much funding has been provided to energy-related projects?

Answer. Since 2001, 155 grants have been made for energy-related projects, totaling \$25.2 million.

Question. How successful are these energy-related projects and how do you define success?

Answer. We define the success of energy-related projects in the same way as for other project types—we consider any project that resulted in a marketable product to be successful. We estimate that approximately 48 percent of energy related

projects resulted in a marketable product. This compares to 60 percent success in projects over all for the value added program.

QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

AGRICULTURE QUARANTINE AND INSPECTION

Question. In 2002, agriculture inspectors who protect our Nation from invasive species and pests at ports of entry were transferred from USDA to the Department of Homeland Security (DHS). Consequently, now USDA is responsible for creating the policy for agriculture inspections at ports of entry but DHS is responsible for the implementation of that policy.

Secretary Johanns, can you tell me how much control USDA still has over the agriculture inspectors at ports of entry?

Answer. In order to fulfill the requirements of the Homeland Security Act of 2002, USDA and DHS entered into a memorandum of agreement (MOA) which specified the roles of the Animal and Plant Health Inspection Service (APHIS) and the Customs and Border Protection (CBP). Through this MOA, CBP conducts the majority of the front line activities. APHIS provides training, risk assessment, and technical support.

Question. A Government Accountability Office (GAO) report that came out last year noted that agriculture inspectors' morale is low, their rates of interception of potentially harmful material is low, and that there are fewer canine units performing inspections. Can USDA do anything to improve these problems, or is this responsibility now entirely in the hands of DHS?

Answer. After the issues were highlighted by GAO, the Animal and Plant Health Inspection Service within USDA and the Customs and Border Protection within DHS instituted quarterly face-to-face meetings. These meetings occur at both the technical level and managerial level. These meetings ensure transparency and are a forum for addressing present and future issues.

Question. What would be the positive and negative impacts in transferring these inspectors back to USDA from DHS?

Answer. The USDA supports the President's decision to transfer inspectors from the USDA to DHS. This decision allowed for the creation of a consolidated border inspection organization which provides information sharing, streamlined services, cross-training among specialists, and innovative techniques that were not possible when border inspection was the responsibility of three separate agencies. Rather than limiting agricultural inspection to a relatively small cadre of specialized inspectors, DHS greatly expanded the number of inspectors who can screen air passengers and vehicles at land border crossings for prohibited agricultural products.

U.S. FOREIGN FOOD ASSISTANCE

Question. As a result of continuing food crises in Africa and elsewhere, Congress has been obliged to provide additional emergency funding for Title II international food aid above and beyond appropriated levels for the last several years.

Why has the Administration been unwilling to acknowledge that increased demand for emergency food assistance has persisted, and not requested funding above the recent levels of \$1.2 billion for Title II in the fiscal 2008 budget proposal?

Answer. The 2008 budget request reflects a careful prioritization among the competing demands for international humanitarian assistance. It is also important to understand that emergency food needs are difficult to predict in advance, especially given the complex nature of evolving, rapidly changing conflicts and the unpredictability of rainy seasons in drought-prone areas.

Nevertheless, the 2008 budget does support our commitment to addressing the most severe and critical emergency food aid needs. And should unanticipated needs arise, the Bill Emerson Humanitarian Trust is available to ensure we can respond to them.

Question. The USDA policy with respect to the Bill Emerson Humanitarian Trust, at least as indicated in the budget summary document for fiscal 2008, is that up to 500,000 tons of food is available annually for unanticipated emergency food assistance. Since the Emerson Trust now has commodity reserves of about 800,000 tons, that would last less than 2 years. When does the Administration plan to ask for funds to replenish the Trust?

Answer. The Trust currently holds 915,000 metric tons of wheat and \$107 million of cash. Based on a current price of hard red winter wheat of about \$216 per metric ton, that cash equates to approximately 495,000 metric tons of wheat. That amount, combined with the 915,000 metric tons of wheat held in the Trust, provides a total

tonnage of just over 1.4 million metric tons. Wheat is not the only commodity that might be needed in an emergency, of course, but because it is used so frequently in overseas feeding programs, it provides a good illustration of the level of the Trust's resources.

At this time, the Administration is not planning to request funds to replenish the Trust. However, in 2 recent years, \$20 million was transferred annually from the Public Law 480 program to the Commodity Credit Corporation as reimbursement for commodities previously released from the Trust, and those funds were, in turn, assigned to the Trust. The Administration may consider future transfers of Public Law 480 funds that can be used to replenish the Trust, but current statutory authorities preclude annual reimbursement and replenishment above the \$20 million level.

CROP INSURANCE

Question. Wouldn't the Department's request to utilize mandatory funds to cover data mining and computer hardware costs cover some of the same costs that the user fee proposal would pay for?

Answer. No. The data mining operation is conducted on separate IT systems than those that would be funded through the user fee proposal. The existing IT system used by the Risk Management Agency (RMA) is outdated and is not capable of conducting the data mining activities. Consequently, RMA contracts with Tarleton State University to perform the data warehousing and data mining activities mandated by Congress.

NATIONAL VETERINARY MEDICAL SERVICES ACT

Question. In 2003 Congress passed the National Veterinary Medical Services Act to address the shortage of large animal veterinarians across the country. Four years later the regulations have yet to be issued for this program even though Congress has appropriated \$1 million for the program. At last year's agriculture appropriations hearing, you said the regulations would be done in 18 months.

When can we expect to see USDA release the regulations for this program?

Answer. We plan to publish a Final Rule delegating the National Veterinary Medical Services Act program to CSREES in the Federal Register on March 19, 2007. Although there are additional administrative steps that must be completed prior to the distribution of funds, a framework for the program has been developed by CSREES.

CONSERVATION SECURITY PROGRAM

Question. As part of the Continuing Resolution for fiscal year 2007, it is my understanding that the CSP includes a funding cap that will result in farmers and ranchers receiving a pro-rated reduced payment for contract modifications, which they are required to complete despite reduced payment.

How much of a reduction from the contract level will producers have to accept? Is there consideration of giving farmers the option of delaying their compliance with the modified contract if the Federal Government is not living up to its side of the bargain to make payment? If a farmer receives a partial CSP payment this year, will USDA pay the rest of the balance next year (or out of any supplemental funding provided in fiscal year 2007)?

Answer. Unmodified contracts and those that were modified but did not exceed their 2006 payment level, are fully funded in 2007. Participants with 2007 contract obligations that exceeded their 2006 level will receive just over half of the amount above what they received in 2006.

If the producer is not in compliance with the modified contract, the State Conservationist has the flexibility, on a case by case basis, to make adjustments to the participant's contract.

CSP is annually funded and payments will be made up to the level of funding made available by Congress.

APPROPRIATE TECHNOLOGY TRANSFER FOR RURAL AREAS

Question. In 1985, Congress authorized the implementation of a sustainable agriculture information service, Appropriate Technology Transfer for Rural Areas (ATTRA), to provide technical assistance and information to farmers, ranchers, extension agents, educators and others involved in sustainable agriculture. ATTRA now supports more than 20 agricultural specialists working in six locations across the Nation. I strongly urge USDA to not consider ATTRA an earmark given it was authorized in the 1985 farm bill.

What will USDA do to ensure ATTRA's funding level remains intact for fiscal year 2007?

Answer. Under the first Continuing Resolution \$936,000 was obligated in 2007 for ATTRA compared to about \$2.5 million that was provided in 2006. The revised Continuing Resolution reduced funding for rural cooperative development grants and no further funding was provided for ATTRA. No funding is included in the 2008 budget request for ATTRA, although the budget request does include funding for similar competitive grants.

QUESTIONS SUBMITTED BY SENATOR BYRON L. DORGAN

ARS RESEARCH FUNDING

Question. Secretary Johanns, in your statement you describe how the President's fiscal year 2008 budget request for USDA meets the challenges of the agricultural community by "funding our highest, most important priorities." That is why I was disappointed to see harsh cuts to important agricultural research across the country, particularly in North Dakota.

The President's fiscal year 2008 budget cuts research at the Fargo and Mandan ARS Centers. These cuts include research into wheat and barley scab, sclerotinia—a white mold disease that wilts or rots broadleaf crops, and precision agriculture.

Can you please explain why these research programs are singled out for cuts in the fiscal year 2008 budget?

Answer. The 2008 Budget for ARS proposes to discontinue funding for a number of research projects added by Congress that provide mostly localized benefits and do not have a nationwide impact. Doing so will enable the Department to focus limited resources on higher priority research and on addressing important national goals such as emerging and exotic diseases of plants and animals, renewable energy and obesity.

NATIONAL ANIMAL HEALTH LABORATORY NETWORK FUNDING

Question. The National Animal Health Laboratory Network (NAHLN) was established to create a greater infrastructure that enabled a rapid and adequate response to animal health emergencies. In addition to protecting animal health and the agriculture industries, these labs also play an important role in protecting public health.

The Network was started with 12 "pilot labs" around the country, and has since been expanded to include diagnostic labs from virtually every State. My State of North Dakota is a full partner in the network and is certified to respond in four areas, including avian influenza (AI), exotic Newcastle disease (END), foot and mouth disease (FMD), and classical swine fever (CSF).

Of the funding provided for the NAHLN, some goes to maintain the 12 pilot labs, and the rest is distributed to some of the remaining diagnostic labs. It appears that there are inadequate resources going into the NAHLN to adequately fund all participating labs or support the infrastructure that was created.

Will the President's fiscal year 2008 budget request for NAHLN support some operating or structural costs of each participating diagnostic lab (as supported by the American Veterinary Medical Association, the American Association of Veterinary Laboratory Diagnosticians, and the National Institute for Animal Agriculture)?

Answer. The NAHLN is a cooperative effort between the Animal and Plant Health Inspection Service (APHIS) and the Cooperative State Research, Education, and Extension Service (CSREES). CSREES provides infrastructure support to the 12 NAHLN pilot labs, while APHIS provides infrastructure support to other laboratories in the network as funds become available.

APHIS' fiscal year 2008 budget request will support upgrading three laboratories to biosafety level (BSL)-3 requirements. The agency is currently conducting disease risk assessments to determine the highest priority labs for the upgrade. The assessment will determine those areas that have the greatest risk of the introduction of a disease for which diagnostics would require this level of bio-security.

QUESTIONS SUBMITTED BY SENATOR RICHARD J. DURBIN

FRESH FRUIT AND VEGETABLE PROGRAM IN SCHOOLS

Question. With the President's Budget request, how many new States will be able to join the Fresh Fruit and Vegetable Snack Program this year?

Answer. The Department is not proposing to expand the Fresh Fruit and Vegetable Program. Instead, our Farm Bill proposal would increase mandatory spending

for fruits and vegetables in the National School Lunch and School Breakfast Programs by \$500 million over 10 years. In addition, the Farm Bill proposal would increase section 32 spending on fruits and vegetables by \$2.75 billion over 10 years, some of which would likely go to schools. The Department considered a range of approaches to increase the availability of fruits and vegetables in schools, and ultimately selected this approach because it has the potential to increase fruit and vegetable access to the greatest number of school children.

The Administration is committed to increasing fruit and vegetable consumption, given their importance to health and the specific recommendations of the Dietary Guidelines for Americans. Increased funding for fruits and vegetables in the school programs will help support the Administration's implementation of the 2005 Dietary Guidelines for Americans in the more than 31 million lunches served every school day.

Question. Is there a set of selection criteria at USDA for admittance to the program?

Answer. Almost all of the States currently participating in the Fresh Fruit and Vegetable Program were designated by Congress. Since the Department is not proposing to expand the Fresh Fruit and Vegetable Program, we have not developed selection criteria for additional States.

Question. Which States are poised to be accepted to the program soonest?

Answer. The Department is aware that a number of additional States have expressed interest in participating in the Fresh Fruit and Vegetable Program. The program has been well received by students and by State and local school administrators in those places where it currently operates. However, we believe that the policy emphasis is best placed on our Farm Bill proposals. The Administration's Farm Bill proposals have the potential to increase fruit and vegetable access to school children in every State.

BROADBAND AND DISTANCE LEARNING AND TELEMEDICINE FUNDING

Question. The President's Budget decreases funding for the set of broadband programs housed at USDA Rural Utilities Service (RUS). The budget proposes to cut the Distance Learning, Telemedicine, and Broadband Program from \$85 million in 2006 (actual) to \$31 million (fiscal year 2008 Budget). Grants are cut from \$70 million in fiscal year 2006 (actual) to \$25 million (fiscal year 2008 Budget). Total direct loan levels are decreased from \$1.155 billion in fiscal year 2007 (estimated) to \$300 million (fiscal year 2008 Budget). Direct loans for distance learning and telemedicine are eliminated entirely, from a level of \$156 million in fiscal year 2007 (estimated).

Can you explain the reasons why funding levels for these programs were decreased?

Answer. The distance learning and telemedicine program has received only a few applications for loans since the program was established a number of years ago. The 2008 budget maintains the grant portion of the program at its current level of about \$25 million although it does not include funding for other broadband grant programs for which about \$20 million is available for 2007. The 2008 budget also includes funding for \$300 million in broadband loans which is expected to be enough to meet the needs of those rural communities that have no or only limited access to broadband services.

Question. How do these decreases fit within the President's stated policy objective of making broadband universal and affordable by 2007?

Answer. USDA is providing a sufficient level of funding to meet the expected demand for loans. Moreover, program regulations are being revised to focus on areas that do not already have existing broadband providers. These revisions are expected to improve the performance of meeting the President's goal of universal and affordable service budget.

Question. Are there alternative funding streams or mechanisms in the President's Budget that make up for these decreased funding levels?

Answer. Currently the USDA's telecommunication loan programs finance technology that supports Broadband ready capabilities. Further, the Administration's 2007 Farm Bill proposal addresses the need for enhancing rural infrastructure by providing an additional \$500 million over 10 years. Both the broadband access and the distance learning and telemedicine programs are included among the programs that would be eligible for this funding.

Question. Last, have you heard of Connect Kentucky's work mapping broadband networks and increasing build out and demand in rural areas, and would you be interested in looking at ways the Department could work to facilitate similar work in other States and regions?

Answer. I understand that Connect Kentucky was recently recognized by the Economic Development Agency for excellence in innovation. It is a model for State-wide commitment for using technology to address economic opportunities and quality of life. Most importantly, it has an advisory board consisting of a wide range of public and private sector partners. I would encourage anyone with an interest in rural development to visit its website for more information.

RURAL DEVELOPMENT HOUSING PROGRAMS

Question. The President's Budget contains significant modifications to the rural housing programs run through USDA Rural Development (RD).

Can you please provide detailed information to assure me that USDA RD's overall loan activity in the area of housing would not decrease if these policy proposals were enacted into law?

Answer. The 2008 budget provides for over \$5 billion in housing loans, which is slightly higher than the amount available for 2007. In 2007 the total single family housing homeownership lending available was \$4.7 billion (\$1.1 billion for direct loans and \$3.6 billion for guarantees). Historically, RHS has offered both direct and guaranteed homeownership loans. Beginning in 2008 however, RHS will only offer guaranteed loans. The budget provides no funding for the 502 direct single family housing loan program, but total lending for single family housing homeownership loans will be \$1 million higher than in 2007 at \$4.8 billion. The direction of Rural Development's single family housing mortgage assistance over the last two decades has been towards guaranteed loans. Solely utilizing guarantees for single family housing mortgage is consistent with the other Federal homeownership programs. In fact, there are no Federal single family direct loan homeownership programs for urban areas.

Furthermore, financial markets have become more efficient and increased the reach of mortgage credit to lower credit qualities and incomes. While there are still rural areas with "pockets of need", these areas are shrinking as improvements and innovations in the banking industry take hold, use of Fannie Mae and Freddie Mac grows, and lending through the internet have become more prevalent. Therefore, utilizing the private banking industry to provide this service, with a guarantee from the Federal Government, is a more efficient way to deliver that assistance.

The demand for Rural Development's single family housing guaranteed loan program has been consistently strong both among borrowers and private lenders. We have no reason to expect a change to this in 2008 and are confident that with the requested level of funding for guaranteed loans, RHS will be able to facilitate the dream of homeownership to more rural residents than we did in 2007.

Question. What motivated the policy proposal of decreasing direct loan activity to the area of guaranteed loans—are there differentials in default rates or other operational aspects that inspired the policies?

Answer. No other Federal agency offers direct loans for single family housing. So the decision was made to conform to a consistent Federal policy on the type of assistance to provide in promoting homeownership. Further, guaranteed loans have accounted for almost all the growth in our program activity since the mid 1990's and borrowers with very low and low incomes account for 30 percent of this activity. Default rates for both direct and guaranteed loans have been relatively low, although this was not a factor in the decision.

Question. Currently, what is the difference in the terms and rates offered to applicants on average through the direct loan versus the loan guarantee program, and would the President's policies negatively affect RD housing loan applicants?

Answer. In short, the difference is that interest rates on direct loans may be subsidized down to 1 percent and there are no fees, while the interest rates on guaranteed loans reflect the market rate and there is a one-time fee which is currently set at 2 percent and proposed to be increased to 3 percent in the 2008 budget.

USDA recognizes that guaranteed loans are more costly to borrowers than direct loans and is examining alternatives for proposed legislation to provide a subsidy to soften the difference. Specifically to help replace the loss of assistance for mortgage credit from the direct loan program, the Administration expects to propose legislation to authorize a subsidized guaranteed single family housing program.

CONSERVATION RESERVE PROGRAM

Question. In terms of conservation, the Budget proposes to eliminate new enrollments in the Conservation Reserve Program (CRP) in 2007 and 2008. The economics of high commodity prices will play a significant role in landowner decisions to re-enroll in the program.

Given these higher prices and higher motivation not to participate in CRP as well as the Administration's 2007 Farm Bill conservation recommendations, why is the Administration proposing no new sign ups in 2007 and 2008?

Answer. As you point out, higher commodity prices will probably dissuade many landowners from participating in the CRP. For this reason, the Administration's budget baseline does not assume a general sign-up for 2007 or 2008. However, continuous sign-up of high-priority buffers, wetlands and other initiatives, as well as the Conservation Reserve Enhancement Program, will continue and USDA encourages farmers and ranchers to consider these opportunities. We are closely monitoring interest in CRP re-enrollment, planting projections, and supply-demand situations for various commodities to determine the most appropriate future actions in administering the CRP.

NRCS TECHNICAL ASSISTANCE FUNDING

Question. Also, I have been concerned to see USDA Natural Resources Conservation Service (NRCS) technical assistance (TA) funding decrease. The fiscal year 2008 Budget proposes to cut TA from \$708 million in fiscal year 2007 (estimated) and \$727 million in fiscal year 2006 (actual) to \$689 million in fiscal year 2008 (proposed).

How is NRCS supposed to support higher program activities when its TA allocation is being cut?

Answer. Higher priority program activities within NRCS will continue to be supported in 2008. The decrease in conservation technical assistance (CTA) that you reference in your question represents amounts for Congressional earmarks in the CTA account and reflects the realignment of the Administration's conservation priorities.

It should be noted that NRCS also provides technical assistance to producers through other discretionary programs as well as through mandatory programs authorized in the current Farm Bill. Our 2007 Farm Bill proposals significantly increase funding for conservation programs and include the technical assistance component needed to implement these programs.

BSE SURVEILLANCE

Question. In 2004, USDA boosted BSE testing. Over a period of 18-months, a total of 759,000 cattle were tested and two additional cases of BSE were detected. USDA has relied on this data to prove that BSE is rare in the United States; however, USDA's Inspector General criticized the expanded testing program. The IG noted that because the expanded program was voluntary, the testing might not have captured a representative sample of the Nation's herd.

Last year, USDA announced plans to scale back BSE testing by 90 percent and based its decision on the results of the expanded testing program.

With 35 million cattle slaughtered for the U.S. food supply each year, how can testing only 40,000 cattle each year be sufficient to detect BSE?

Answer. The expanded surveillance effort, which was biased toward finding the disease, was designed to estimate the level of disease presence in the United States and provide input for designing a long-term surveillance plan. USDA has now developed such a plan. USDA has the ability to detect BSE at 1 infected animal per 1,000,000 adult cattle with a high degree of confidence. This ability far exceeds the international standards set by the World Organization for Animal Health (OIE).

QUESTIONS SUBMITTED BY SENATOR BEN NELSON

DISASTER ASSISTANCE

Question. The Administration has worked to block each and every emergency disaster assistance funding legislation we have attempted in the Senate and it has consistently argued against the need for such assistance. As I look through the President's budget proposal and the USDA budget justifications I am struck by two things: first, that there is practically no funding for drought and disaster assistance; and second, there is no funding for efforts to mitigate the devastating impacts of droughts and disasters.

As such, I have to ask what the Administration proposes to do, or expects to see happen, with regard to the many farmers and ranchers that continue to suffer from drought?

Answer. The Federal crop insurance program is intended to be, and should remain, our foremost tool to assist farmers and ranchers impacted by natural disasters.

ters of all types. The Administration's budget request fully funds the Federal crop insurance program.

In addition, this Administration has responded, with appropriate forms of assistance, to mitigate losses resulting from drought and other forms of disaster. However, this assistance has been crafted to specifically target producers directly impacted by adverse weather conditions. For example, the Administration developed the Livestock Assistance Grant Program (LAGP) which provided \$50 million in State block grants to help livestock producers recover forage production losses due to drought conditions during 2006. Furthermore, I would note that the assistance provided by this Administration has been provided within our available resources. Accordingly, this Administration would strongly urge Congress to fully offset the cost of any ad hoc disaster assistance with commensurate reductions in other agricultural spending.

Question. And, if the Administration is so opposed to providing emergency disaster aid why does it completely fail to provide funding to help mitigate the impacts from droughts and natural disasters?

Answer. The President's budget request for 2008 was prepared on a parallel track with the Administration's 2007 Farm Bill proposals. Taken together, these two documents provide for both disaster assistance and disaster mitigation. The 2008 budget request fully funds the Federal crop insurance program which is intended to be the primary tool for providing disaster assistance. In addition, a key farm bill proposal would improve the counter-cyclical payment (CCP) program by basing payments on revenue rather than price. Crop prices tend to be at their highest following a disaster. Under the current design of the CCP program high commodity prices means that producers are not eligible to receive a CCP payment. However, this is precisely the time when producers need the payments the most. Producers cannot benefit from high commodity prices if they have no commodity to sell. Our farm bill proposal would correct this situation by providing an effective means of mitigating the financial effects of a disaster.

USDA RENEWABLE ENERGY AND BIOFUELS INVESTMENT

Question. I applaud the Administration's multiple investments in renewable fuels and biofuels in the fiscal year 2008 budget, but I am concerned that we are not doing enough to help this important industry progress as expeditiously as possible.

Can you explain what the goals are for the renewable energy and biofuels investments in this budget?

Answer. The energy goals of this budget are to expand research and development of potential bioenergy sources and to encourage commercialization of production facilities and infrastructure by increasing the production of renewable energy, particularly biofuels from cellulosic feedstocks. USDA will focus primarily on research and development of innovative processes that are cost-effective and energy efficient, and financial support aimed at advancing commercial applications to facilitate sufficient amounts of private sector investment.

Question. What achievements can we expect to see and when can we expect to see them?

Answer. Ultimately, we expect to develop and encourage the adoption of technologies for commercially viable, low cost and energy efficient production of cellulosic ethanol. This includes the development of commercially-viable, value-added co-products. This achievement will be reached when cellulosic energy is a vital component of the Nation's energy production as was highlighted by the "20 in 10" initiative in the President's State of the Union address. Even though commercial viability of cellulosic ethanol may be several years off, the Department has already achieved numerous advances that will contribute to this ultimate goal. Included in these advancements are innovations in cellulosic feedstock development and research into energy conversion techniques.

Question. In what ways do the various proposals for renewable fuels complement each other—both within the USDA budget and across budgets with other agencies such as the Department of Energy?

Answer. USDA has the scientific expertise for conducting and administering research programs relating to all aspects of crop production, including post harvest usage of crops. Consequently, it is ideally suited to address these aspects of advancing the Nation's biofuel industry. Moreover, USDA's Rural Development mission area has the experience and capacity to provide financial support for a wide range of business and infrastructure projects that will be needed to encourage private sector investments in the industry. There are a number of other Federal agencies that have expertise to offer, most notably the Department of Energy (DOE) for its research capacities. To avoid duplication and ensure coordination, USDA, DOE and

other Federal agencies are participating in the statutorily established Biomass Research and Development Board to coordinate activities.

Question. Can you further explain how the USDA and DOE budgets work together to make sure we are advancing our biofuels industry in the most efficient and timely manner, without unnecessary duplication or conflict?

Answer. USDA and DOE are working together through the Biomass Research and Development Board and the USDA Energy Council. The Administration's Farm Bill proposes that this relationship be strengthened by moving the authority for USDA's existing renewable energy and energy efficiency loan and grant program, which is a stand alone authority contained in the 2002 Farm Bill, into the Biomass Research and Development Act of 2000, which established the Biomass Research and Development Board and contains the authority for the Biomass Research and Development program that received funding under Section 9008 of the 2002 Farm Bill.

Additionally, DOE and USDA will lead an interagency effort to prepare a detailed multi-year interagency coordination plan (MYICP). The MYICP will aim to improve the efficient use of resources by minimizing duplication of effort and defining clear roles and responsibilities for each agency and program. The MYICP will define a realistic long-term vision for achieving public policy goals through biomass utilization.

Question. With regard to the production of cellulosic ethanol: do you feel that we (both Congress and the Administration) are doing enough to make sure that not only are we advancing the production of cellulosic ethanol, but that we are also keeping up on a parallel track the advancement of the on-farm production of a diverse range of biomass feedstocks—such as, developing the infrastructure and logistical components for harvesting, transporting, storing and handling these potentially bulky feedstocks?

Answer. Production of cellulosic ethanol is at an early stage of development. New technologies will have a significant influence on the types of infrastructure and other related needs for commercial production. These technologies will likely affect even the location of production facilities. Consequently, while USDA is aware of various infrastructure and environmental issues relating to ethanol production, it is too early to know what the funding needs to address these issues may be. However, USDA does have research activities underway that are looking into the issues of harvesting, transportation, and storage of the feedstocks.

Question. Where in this budget are the Administration's investments in this important part of the cellulosic ethanol production chain?

Answer. There are a number of USDA programs that are available to support a cellulosic energy industry. Possible programs include The Renewable Energy and Energy Efficient loan and grant program, Business and Industry guaranteed loan program, and the Value Added Producer Grant program can be used to finance renewable energy related activities. In most cases, these programs serve a multitude of purposes and funding for cellulosic industry needs is not specifically targeted for this purpose.

RURAL DEVELOPMENT GUARANTEED LENDING

Question. Can you further explain the Administration's focus for rural development funding on guaranteed business and industry loans versus other programs such as the rural business grants, etc.?

Answer. In general, loans and loan guarantees are effective in providing support for rural infrastructure and they are less costly to the Government than grants. Rural Development intends to re-focus its limited resources on programs that have more potential for encouraging private sector investments and that would reach a broader range of rural communities. However, there is a role for the limited use of grants for such things as market surveys and technical assistance as well as demonstration projects.

Question. Do you have any data or other information that supports concentrating funding on the loans instead of the grants?

Answer. The 2008 budget contains information on the Government's cost for various loan programs. For example, it shows that the \$43.2 million in budget authority for business and industry loan guarantees will support about \$1 billion in private sector financing. Further, the Administration's 2007 Farm Bill proposal indicates that \$210 million in budget authority will support \$2.17 billion in guaranteed loans. It also indicates that the Administration proposes that the loan limit for renewable energy loans for cellulosic facilities be increased to \$100 million. If the same amount of budget authority were used to finance such facilities, only a small fraction of projects could be financed unless the grant funds are used only for specific purposes that encourage private sector financing.

Question. Certainly many of the witnesses at a recent rural development hearing before the Senate Ag Committee raised concerns about an over-emphasis on loans instead of grants for rural communities, especially when compared with how we provide funding to urban communities. Do you have any information or explanation for this discrepancy?

Answer. There is no denying the fact that certain needs for both rural and urban communities require mostly Federal funding, for example roads or rental housing projects. Minimizing the use of grant funds allows Rural Development to provide funding to more communities. For example, the 2008 budget proposes to reduce the interest rate on Water and Waste Disposal loans and reducing the amount of grants. This proposal is expected to provide more assistance to most rural communities at no additional cost to the Government.

COMMODITY SUPPLEMENTAL FOOD PROGRAM

Question. The Administration again proposes cutting the Commodity Supplemental Food Program (CSFP) this year because it has concluded that the CSFP program is duplicative of other nutrition programs. This is the exact opposite of what I am hearing from folks in Nebraska, specifically as it relates to elderly recipients and the supplemental nature of the products this program provides.

What support do you have for the conclusion that this is a duplicative program?

Answer. The CSFP does not duplicate other programs in every respect. However, there is significant overlap between the CSFP eligible populations of women, infants and pre school children and those of the Special Supplemental Nutrition Program for Women, Infants and Children (WIC). There is also significant overlap between the CSFP eligible elderly population and that of the Food Stamp Program. In addition, low-income elderly persons have access to the Emergency Food Assistance Program and programs administered by the Administration on Aging. Our priority is to fund the Food Stamp Program, WIC, and the Emergency Food Assistance Program (TEFAP) because they are nationally available, including in the communities served by CSFP. I will ask the agency to provide some additional details on this.

[The information follows:]

CSFP was created in January 1969 to assist nutritionally at-risk women, infants, and pre school children by providing commodities in specific amounts judged necessary for their health. WIC was enacted in September 1972 serving a very similar purpose through provision of coupons that could be redeemed at food retailers for supplemental food. WIC soon became the preeminent program serving this population, currently reaching over 8 million participants in an average month in fiscal year 2006, while CSFP WIC-type participation is about 40,000. WIC provides eligible participants better nutrition education, more active referrals to needed health care resources, and higher supplemental food benefits than the CSFP.

The Food Stamp Program is the Nation's primary domestic nutrition assistance program for low-income households including the elderly. The Food Stamp Program is a mandatory program available in all jurisdictions. It is designed to provide low-income households with adequate resources to buy a nutritious, low-cost diet. Because the CSFP operates in limited areas, some low-income elderly have access to nutrition assistance through commodities and/or Food Stamps, while most others must rely on Food Stamps, TEFAP and Administration on Aging programs for such help.

Ensuring adequate funding for programs that have the scope and reach necessary to provide access to eligible people wherever they may reside is a better and more equitable use of scarce resources than to allocate them to programs that cannot provide access to many areas of the country. For this reason, the Administration has placed a priority on funding the Food Stamp Program, WIC, and other nationally-available programs, such as the Administration on Aging programs for seniors and the Emergency Food Assistance Program (TEFAP), which provide benefits to eligible people wherever they may live, including communities currently served by CSFP. All seniors over age 60 are eligible for both congregate and home-delivered nutrition assistance provided by one of 655 Area Agencies on Aging, which are funded through the Administration on Aging in the Department of Health and Human Services. In addition to the Administration on Aging programs for seniors, low-income individuals of any age have access to TEFAP.

Question. How is it duplicative, particularly with regard to the specific components of CSFP compared to Food Stamps and WIC; i.e. where do those programs provide the food packages and items to needy and elderly people?

Answer. It is duplicative in that there are other, nationally available nutrition assistance programs that serve the same or similar demographics. In the few areas where CSFP is available, there is significant overlap between the eligible popu-

lations and areas of operation of CSFP and the Special Supplemental Nutrition Program (WIC), and for elderly eligibles, CSFP and the Food Stamp Program. Both the Food Stamp Program and WIC are available nationwide. Benefits in the Food Stamp Program provide low-income households with adequate resources to buy a nutritious, low-cost diet.

Question. Does the Administration have any idea of how many people will not be served or by how much they will lose support?

Answer. Most of the current CSFP participants will be able to switch over to food stamps and/or WIC. Spending for WIC food benefits would be as much, or more, than CSFP benefits; and for the elderly, the average elderly food stamp benefit purchases about 50 percent more than the retail value of the CSFP benefit. There would be some current CSFP recipients who would not qualify for either of these programs and who would need to go to TEFAP and/or the Agency on Aging programs. I have asked staff to provide more specifics.

[The information follows:]

Recent program reporting data show that about 463,000 individuals participated in CSFP in 2006—40,000 women, infants, and pre school children, and 423,000 elderly, persons 60 years of age or older. The Department estimates that a substantial portion of the women, infants and children who participate in CSFP will be eligible for WIC. The two groups of CSFP participants that are not eligible for the WIC program are children between the ages of 5 and 6 and certain women who are 6 to 12 months post-partum.

Based on the circumstances and experiences of all low-income elderly, we believe about two-thirds of the projected 423,000 elderly CSFP participants will be eligible for food stamps. Compared to CSFP benefits, food stamp benefits are more advantageous for elderly persons because they often have medical conditions that limit their food choices. Also, food stamps allow them to select foods appropriate to their preparation abilities and cultural preferences, both a challenge to meet via commodity distribution, where food selection is more limited than at food stamp retailers.

In addition to food stamps, all seniors over age 60 are eligible for both congregate and home-delivered nutrition assistance provided by one of 655 Area Agencies on Aging, which are funded through the Administration on Aging in the Department of Health and Human Services. Low-income individuals of any age also have access to the Emergency Food Assistance Program and other government and private non-profit programs that offer nutrition assistance.

U.S. AGRICULTURAL TRADE

Question. Finally, below are two common assumptions or perceptions that many believe help drive farm policy development. I have a few questions that correspond to these assumptions, and I would welcome answers to the questions that include any information or compilation of information (reports, charts, graphs, etc.) that address each:

Increased net agricultural exports through trade agreements focusing on greater market access are assumed to have been successful and that they hold the greatest promise for U.S. agriculture.

Has USDA developed a year-by-year analysis for the U.S. agricultural net balance of trade for the years 1975–2006—including the trade balance in both nominal terms, and in inflation adjusted 2006 dollar terms, as well as highlighting specific years when significant agricultural trade agreements have been passed? Please provide.

Answer. A table showing the U.S. agricultural trade balance from fiscal year 1975 to fiscal year 2006 will be submitted for the record. The trade balance is shown in nominal terms and real terms, using the GDP deflator based on 2000, as reported in the 2007 Economic Report of the President. In general, the agricultural trade balance has reflected the U.S. exchange rate, growing when the dollar was weak, such as in the early 1980s and early 1990s, but shrinking when the dollar appreciated, such as in the mid-1980s and in the early 2000s. Imports have been growing rapidly over the past decade, and do not seem to be strongly influenced by the value of the dollar. Exports have increased significantly the past few years, reflecting higher commodity prices and a weaker dollar.

The change in the agricultural trade surplus does not correspond with the implementation of a particular free trade agreement (FTA) for several reasons. FTAs are, by design, implemented slowly over a transition period to expressly avoid major trade disruptions. The U.S.-Canada FTA began in 1989, and U.S. exports increased by \$4 billion that year. But the NAFTA with Mexico began in 1994, and U.S. exports stayed about the same as in 1993. However, when viewed over the longer

term, data show that the value of U.S. agricultural exports to Canada have increased by 119 percent and to Mexico by 181 percent since implementation of NAFTA. In addition, Canada and Mexico are now more important markets for U.S. agriculture than they were before NAFTA. In 1993, Canada and Mexico combined accounted for about 21 percent of total U.S. agricultural exports. By 2006, that percentage had risen to 32 percent.

Exports in any 1 year are more influenced by changes in world commodity prices and global economic growth than by FTAs. Imports are more influenced by economic growth in the United States, which translates into greater purchasing power for U.S. consumers and greater demand for imported goods.

[The information follows:]

VALUE OF U.S. AGRICULTURAL TRADE BY FISCAL YEAR

[In billions of dollars]

Year	Exports	Imports	Trade Balance	GDP deflator 2000=100	Trade Balance in 2000 \$
1975	21.82	9.44	12.38	38.0	32.58
1976	22.74	10.49	12.25	40.2	30.48
1977	23.97	13.36	10.61	42.8	24.80
1978	27.29	13.89	13.40	45.8	29.27
1979	31.98	16.19	15.79	49.5	31.91
1980	40.47	17.29	23.18	54.0	42.92
1981	43.78	17.34	26.44	59.1	44.75
1982	39.10	15.46	23.64	62.7	37.70
1983	34.77	16.28	18.49	65.2	28.36
1984	38.03	18.91	19.12	67.7	28.24
1985	31.20	19.74	11.46	69.7	16.44
1986	26.31	20.88	5.43	71.3	7.61
1987	27.88	20.65	7.23	73.2	9.87
1988	35.32	21.01	14.30	75.7	18.89
1989	39.67	21.57	18.10	78.6	23.03
1990	40.35	22.71	17.64	81.6	21.62
1991	37.86	22.74	15.13	84.4	17.93
1992	42.55	24.50	18.05	86.4	20.89
1993	43.06	24.60	18.46	88.4	20.88
1994	43.89	26.56	17.33	90.3	19.19
1995	54.61	29.79	24.82	92.1	26.95
1996	59.79	32.44	27.34	93.9	29.12
1997	57.31	35.65	21.65	95.4	22.70
1998	53.66	36.83	16.83	96.5	17.44
1999	49.12	37.29	11.83	97.9	12.08
2000	50.76	38.86	11.90	100.0	11.90
2001	52.72	39.03	13.69	102.4	13.37
2002	53.32	40.95	12.37	104.2	11.87
2003	56.01	45.68	10.33	106.4	9.71
2004	62.41	52.66	9.75	109.4	8.91
2005	62.52	57.74	4.78	112.7	4.24
2006	68.72	64.03	4.70	115.8	4.06

October-September fiscal year.

Source: U.S. Bureau of the Census; Economic Report of the President for GDP deflator

Question. Has USDA developed an equivalent analysis and graph for only the food portion of the U.S. agricultural balance of trade, since the commonly published agricultural trade balance includes forest and other non-food items. Please provide.

Answer. There is no commonly accepted definition of “food” for purposes of analyzing U.S. agricultural trade. For example, the Department of Commerce includes fish and fish products in its definition of food trade, but USDA does not include fish in its official U.S. agricultural trade figures.

Tables will be provided for the record that show one breakdown of food trade, including fish. In general, practically all U.S. agricultural imports are food, under this definition. The share of food in U.S. agricultural exports has been growing, as exports have diversified into many more products such as fruits, vegetables, meats, and processed foods.

[The information follows:]

U.S. AGRICULTURAL IMPORTS
[In billions of dollars]

	Cal. yrs									
	1989	1990	1991	1992	1993	1994	1995	1996		
All processed foods	19,304	20,399	20,426	21,557	21,630	23,588	24,768	27,556		
Grain mill products	1,217	1,240	1,328	1,658	1,608	1,962	2,194	2,666		
Sugar & confections	1,862	2,188	2,091	2,142	2,059	2,088	2,330	3,101		
Preserved fruits & vegetables	2,326	2,589	2,404	2,623	2,414	2,597	2,658	3,118		
Dairy products	740	783	702	782	768	855	1,060	1,227		
Meat products	2,597	3,016	2,999	2,758	2,915	2,799	2,486	2,474		
Fish and seafood	5381	5,169	5,604	5,617	5,761	6,545	6,691	6,607		
Bakery products	343	347	381	422	473	546	603	660		
Miscellaneous foods	1,337	1,358	1,488	1,622	1,781	1,967	2,150	2,395		
Beverages	3,501	3,708	3,429	3,934	3,852	4,229	4,595	5,308		
Unprocessed foods	2,843	3,341	3,472	3,449	3,795	4,027	4,460	5,032		
Fruits, nuts, vegetables	72,795	73,286	73,425	73,395	73,665	73,921	4,405	4,961		
Fish and seafood048	.055	.047	.054	.130	.106	.055	.072		
TOTAL FOOD IMPORTS	22,146	23,740	23,899	25,006	25,424	27,615	29,228	32,589		
TOTAL NONFOOD IMPORTS	5,161	4,403	4,628	5,458	5,598	6,060	7,773	7,602		

Source: U.S. Census Bureau.

U.S. AGRICULTURAL IMPORTS—CONTINUED
[In billions of dollars]

	Cal. yrs.									
	1997	1998	1999	2000	2001	2002	2003	2004	2005	
All processed foods	30,072	31,858	34,549	36,600	37,024	37,807	42,465	47,067	51,029	
Grain mill products	2,768	2,715	2,546	2,557	2,369	2,275	2,577	3,298	3,408	
Sugar & confections	3,119	3,189	2,947	2,818	2,982	3,378	4,283	4,450	5,027	
Preserved fruits & vegetables	3,279	3,250	3,852	3,834	3,624	3,740	4,068	4,487	4,487	
Dairy products	1,164	1,398	1,456	1,529	1,642	1,575	1,740	2,027	2,224	
Meat products	2,825	3,044	3,477	3,992	4,447	4,443	4,618	5,858	5,895	

Fish and seafood	7.626	8.025	8.872	9.593	9.268	9.356	9.914	10.056	10.625
Bakery products711	.799	.921	1.032	1.124	.821	.878	.929	1.007
Miscellaneous foods	2.650	2.998	3.160	3.189	3.098	3.295	3.521	4.114	4.578
Beverages	5.929	6.441	7.318	8.056	8.472	9.445	11.194	12.265	13.780
Unprocessed foods	5.173	5.878	6.289	6.631	7.351	8.775	9.968	11.235	12.444
Fruits, nuts, vegetables	5.093	5.808	6.239	6.279	6.880	8.074	8.928	10.070	11.097
Fish and seafood080	.071	.050	.351	.470	.700	1.040	1.165	1.347
TOTAL FOOD IMPORTS	35.246	37.737	40.838	43.231	44.375	46.581	52.433	58.302	63.473
TOTAL NONFOOD IMPORTS	8.609	7.254	5.756	5.688	4.730	5.384	5.897	6.895	7.780

Source: U.S. Census Bureau.

U.S. AGRICULTURAL EXPORTS

[In billions of Dollars]

	Cal.yrs							
	1989	1990	1991	1992	1993	1994	1995	1996
All processed foods	15.546	17.133	18.906	21.460	22.129	24.726	27.643	28.441
Grain mill products	5.163	4.782	5.081	5.633	5.724	6.101	6.775	6.930
Sugar & confections521	.649	.682	.726	.822	.871	.891	.890
Preserved fruits & vegetables	1.423	1.771	1.966	2.210	2.294	2.580	2.869	2.960
Dairy products493	.439	.553	.832	.951	.867	.872	.827
Meatproducts	2.864	3.270	3.780	4.376	4.504	5.315	6.572	7.067
Fish and seafood	2.288	2.785	3.041	3.358	2.964	3.010	3.145	2.909
Bakery products110	.190	.233	.306	.358	.389	.382	.407
Miscellaneous foods	1.684	1.912	2.167	2.470	2.762	3.318	3.590	3.935
Beverages	1.000	1.335	1.405	1.549	1.751	2.276	2.545	2.517
Unprocessed food	2.861	3.877	4.131	4.462	4.788	5.517	5.579	5.884
Fruits, nuts, vegetables	2.815	3.810	4.031	4.368	4.709	5.436	5.478	5.779
Fish and seafood047	.067	.100	.094	.080	.081	.101	.105
TOTAL FOOD EXPORTS	18.407	21.010	23.037	25.922	26.918	30.244	33.222	34.324
TOTAL NONFOOD EXPORTS	24.030	21.334	19.453	20.631	18.989	19.040	26.275	28.998

Source: U.S. Census Bureau.

U.S. AGRICULTURAL EXPORTS—CONTINUED
[In Billions of Dollars]

	Cal. yrs.									
	1997	1998	1999	2000	2001	2002	2003	2004	2005	
Ali processed foods	29,654	28,150	27,655	28,245	30,112	26,565	28,652	28,525	32,076	
Grain mill products	8,063	7,807	6,600	6,454	7,081	6,871	6,852	6,969	7,534	
Sugar & confections929	.849	.884	1,041	1,230	1,052	1,119	1,238	1,307	
Preserved fruits & vegetables	3,163	3,105	3,209	3,243	3,243	2,783	2,906	2,994	3,160	
Dairy products	1,048	1,008	1,029	1,076	1,192	1,047	1,131	1,642	1,788	
Meatproducts	7,021	6,552	6,644	7,202	7,533	5,096	6,034	3,937	5,400	
Fish and seafood	2,029	2,642	2,651	2,894	2,606	2,629	2,898	3,112	2,909	
Bakery products446	.459	.456	.466	.489	.386	.385	.429	.478	
Miscellaneous foods	3,762	3,912	3,799	3,662	3,717	4,018	4,501	5,111	6,029	
Beverages	2,613	2,429	2,394	2,451	2,732	2,705	3,097	3,306	3,270	
Unprocessed food	6,007	5,951	5,790	6,238	6,261	7,257	7,894	9,149	10,633	
Fruits, nuts, vegetables	5,878	5,676	5,544	5,984	5,973	6,763	7,328	8,405	9,744	
Fish and seafood130	.275	.246	.254	.288	.494	.566	.744	.889	
TOTAL FOOD EXPORTS	35,662	34,101	33,445	34,483	36,373	33,822	36,547	37,674	42,709	
TOTAL NONFOOD EXPORTS	24,228	19,956	17,821	19,668	20,467	22,392	26,012	27,352	24,249	

Source: U.S. Census Bureau.

Question. It is generally assumed that approximately one-third of all U.S. farm production is exported. According to some analysts, however, 8 percent of the farm value of U.S. agricultural production is exported, and the “one-third” figure is largely based on processed food value at the export/import points, not farm-gate value, which arguably skews the data.

Has USDA analyzed and tabulated data showing the proportion of total farm cash receipts (\$239.0 billion in 2005) that have been exported, based on farm value for the years 1975 to 2006? Please provide.

Answer. There are several ways to measure the importance of trade to the agricultural sector, and none is perfect. A typical approach is to compare the value of exports to the value of agricultural production, or to farm cash receipts. One shortcoming of this method is that exports are valued at the point of export, which includes the value of farm-to-port transportation and other costs. It is also difficult to measure the value of processed products at the farm gate, which account for a large share of U.S. agricultural exports. Another factor affecting export share that is not captured in this measure is the increasing amount of corn, soybeans, and other feeds that are exported indirectly in the form of meat rather than directly.

USDA’s Economic Research Service uses two methods to examine the share of production that is exported. One approach is based on volume weights, and the other is based on dollar values.

Information reported by ERS using these two methods, will be supplied for the record. Data are not available before 1980.

[The information follows:]

EXPORT SHARES OF U.S. AGRICULTURAL PRODUCTION

Measure	1980–84	1990–94	1999	2002
Percent of production:				
Volume-based	29.2	23.1	22.8	21.9
Value-based	21.9	16.8	16.7	17.7

Both the volume and value measures include primary livestock and crop commodities as well as major processed food products. Each measure has advantages. The volume-based measure reduces the variations due to product prices, while the value measure better reflects product quality, such as differences between a pound of steak and a pound of hamburger.

To make volume- and value-based export shares comparable, the measures include only products for which both production and export volumes are available. Products excluded for this reason are mostly minor and include greenhouse and nursery products, seeds, cattle, hides and skins, and animal fats.

The export share of U.S. agricultural production, based on volume, has averaged 22 percent since 1996, reflecting the high weight of exported food and feed grains, oilseeds and oilseed products, cotton, and tobacco relative to their total harvested weight. However, this overall export share masks differences in trends between livestock products and crops and crop products. The export share of U.S. livestock products rose from 3 percent in the 1980s to more than 10 percent in recent years, while the export share of crops and crop products fell from over 30 percent to 23 percent during the same period. Behind these contrasting trends has been the increase in U.S. livestock and poultry production and the corresponding feed requirements that have diminished feed grains available for export.

The export share of U.S. agricultural products, based on values, averaged 17 percent from 1998 to 2002, 5 percentage points lower than the volume-based average. The lower value-based measure reflects the lower aggregate value of livestock exports relative to their farm production value. The historical movement of the two export share measures shows no consistent pattern—about half the time they move in the same direction and the other half not. For example, the volume-based share declined from 23 percent in 2001 to 22 percent in 2002, while the value-based share rose from 17 to 18 percent.

QUESTIONS SUBMITTED BY SENATOR JACK REED

PROGRESS IMPLEMENTING LOCAL FOOD PURCHASE PROVISION

Question. Section 4303 of the 2002 Farm Bill allows school districts to pursue a local food purchasing preference.

Can you tell me about USDA’s progress in implementing the provision?

Answer. This Farm Bill provision authorized funds to be requested to encourage schools to purchase locally produced foods and to provide grants and technical assistance for projects that improve access to local foods from small farmers and support school garden programs. This provision has not been funded. Nonetheless, I know that the Food and Nutrition Service has done quite a bit to encourage local purchases anyway. I will ask staff to provide more details on this.

[The information follows:]

Regarding implementation of section 4303 of the 2002 Farm Bill, the Conference Report that accompanied the Farm Bill indicated that this provision was not intended to permit State or local geographic preferences, or to circumvent Federal procurement requirements. School districts participating in the National School Lunch and School Breakfast Programs are prohibited by government-wide regulation from applying a geographic preference in their procurements.

Although no funds have been appropriated to carry out Section 4303, USDA has supported farm to school initiatives. In 1997, the Food and Nutrition Service established a "farm to school" initiative which is based on the cooperation of Federal, State, and local governments, as well as local farm and educational organizations. The initiative encourages schools to purchase locally grown fruits and vegetables. As part of this initiative, USDA has created two publications, which are posted on our web site, called Eat Smart-Farm Fresh! A Guide to Buying and Serving Locally-Grown Produce in School Meals and Small Farms/School Meals Initiative: a Step-by-Step Guide on How to Bring Small Farms and Local Schools Together. These publications provide practical tips in a handbook format on how school food service personnel can purchase products from local farmers.

Questions. If it is USDA's position that Congress's guidance in Section 4303 is inadequate to authorize farm to school initiatives and other local food purchasing programs, what language would you recommend that Congress include in the next Farm Bill to make clear its intent to authorize and encourage programs?

Answer. Current statutory authority does not unduly restrict farm to school and local food purchasing initiatives. Although school districts participating in the National School Lunch and School Breakfast Programs are prohibited by government-wide regulation from applying a geographic preference in their procurements, school districts may tailor their procurement specifications to maximize full and open competition and obtain high quality fresh produce for their school meal programs, in many instances from local producers. Consequently, we do not believe any change to current law is necessary to further authorize or encourage farm to school initiatives.

The Department is supportive of farm to school initiatives, and believes that these initiatives can be successful within the framework of current law and regulations and free and open competition for contracts.

QUESTIONS SUBMITTED BY SENATOR ROBERT F. BENNETT

RENTAL ASSISTANCE

Question. Mr. Secretary, the budget proposes changing the length of rental assistance contracts to a term of 1 year. Prior to fiscal 2007, those contracts were generally longer in length. The fiscal 2007 budget proposed a reduction to 2 years, and now the fiscal 2008 budget proposes renewing contracts for 1 year.

Can you please explain the rationale behind this change?

Answer. Other Federal housing programs offering rental assistance provide annual renewals, for instance the Department is aware of similar assistance offered by the department of Housing and Urban Development. The budget change will not affect the cost of the program, but the change in contract terms will impact the distribution of budget authority during the transition period.

Question. Would this change improve the ability of USDA to estimate the number of contracts expiring in a given year?

Answer. USDA has several tools available to assist in estimating the number of contracts expiring in a given year. However, contract costs are subject to many variables, including tenant income variations, increases in operating costs (particularly insurance and energy costs) that result in rent increases that increase the use of rental assistance, and rental assistance utilization rates that vary by property. The effects of these variables may be more prominent on contracts with a one-year term than contracts with multiple years, which could spread the impact of such variables across a longer period of time. USDA intends to monitor closely the performance of these one-year contracts and is developing an analysis of these variables on rental assistance.

Question. If this proposal is adopted, there would be a significant amount of contracts expiring in 2008, ranging from 5-year contracts signed in 2003 to some one-year contracts signed in 2007.

How will this affect the budget for fiscal 2009?

Answer. Current estimates for fiscal year 2009 indicate approximately 231,000 rental assistance units will be up for renewal. This is 84 percent of all rental assistance units. These consist of units obligated prior to fiscal year 2004 and units obligated under contract term limits in fiscal year 2005, fiscal year 2007 and fiscal year 2008.

Question. Do you feel a significant amount of additional funding will be necessary to renew this extreme volume of contracts?

Answer. There would be additional costs of continuing the same terms and conditions of contracts.

Question. Do you feel that adequate funding to cover all of these contracts will appear in your budget proposal for next year?

Answer. No decisions have been made for the President's 2009 Budget.

Question. Do you feel that Rural Development has the staff and resources needed to renew such a high volume of contracts in 1 year?

Answer. The majority of the tasks associated with renewing contracts are already automated, and we are currently modifying documents to require minimal manual intervention for renewals. We believe that Rural Development has the staff and resources needed for this renewal process.

RURAL DEVELOPMENT—DIRECT LOANS

Question. Funding for both Single Family and Multi-Family Direct Loans has been eliminated in your budget proposal.

Can you please explain the basis for eliminating these programs?

Answer. The other major Federal single family housing guarantee programs, including those operated by HUD and VA, rely on guaranteed loans. Direct loan programs are more costly to taxpayers. Based upon the fiscal year 2008 budget, the taxpayer's cost for providing a direct subsidized housing loan of \$100,000 would be \$9,357. With a 3 percent guarantee fee, a guaranteed housing loan of \$100,000 costs the taxpayer only \$200. With the same cost, taxpayers can provide one direct housing loan or almost 50 guaranteed loans. For this reason, guaranteed loans have accounted for virtually all the growth in our Single Family Housing program since the mid 1990s.

With regard to Multifamily Housing program, the primary reason for not requesting funds for direct loans is to concentrate on revitalization of existing portfolio. Direct loans for section 515 new construction have a subsidy rate of 45.67 percent and these projects also regenerate additional costs for rental assistance payments.

Question. If adopted, what effect will these changes have on the make-up of the participants in single family and multi-family housing programs? Will there be people who participate in these programs now who will no longer be eligible?

Answer. We anticipate that many customers once served by the direct housing loan program will be able to be served by the guaranteed program. Moreover, directing resources to our existing multifamily portfolio will protect the rent of existing tenants.

RISK MANAGEMENT AGENCY CROP INSURANCE USER FEE

Question. The budget proposes the collection of a user fee from participants in the crop insurance program to fund the Risk Management Agency's IT modernization beginning in fiscal 2009.

Please explain how the user fee would function and who would pay the fee?

Answer. The fee would be payable by the private sector insurance companies who participate in the Federal crop insurance program. The fee would be capped at \$15 million annually and would be based on a percentage of the premium written by the companies during the prior crop year. In this way, the companies that are the primary beneficiaries of the IT system would pay the larger portion of the fee. Based on current projections of total premiums, the fee is expected to be about one-quarter cent per dollar of premium.

Question. How would this proposal, if adopted, affect future RMA IT appropriations requests? Did I understand your testimony correctly that this fee would replace the need for appropriated IT funds entirely?

Answer. It is anticipated that the fee would eventually replace the need for appropriated funding. However, the budget proposal is designed such that the fee would initially supplement the annual appropriation for information technology (IT). This funding would be used to modernize the IT system currently in use by the Risk

Management Agency (RMA). However, once modernization is complete, the funding would be used for IT maintenance and would replace the need for appropriated funding. We anticipate that the modernization process will take about 2 years to complete.

RENEWABLE ENERGY—COMMODITY PRICES

Question. The recent boom in biofuel production has caused some commodity prices to spike. While this has a positive effect on many agricultural economic aspects, such as farmers earning more of their income from the market, these price increases have also caused negative results for some. Livestock feed prices have climbed dramatically, putting a strain on many ranchers across the country. Also, higher commodity prices have had a negative impact on food aid, since fewer commodities can be purchased for the same dollar amount.

With such a strong focus on renewable energy in both this budget and your farm bill proposal, how do you propose to combat the negative aspects of these new policies?

Answer. The extraordinary price run-up that started last fall has raised costs for the livestock and poultry industry, along with other users of corn. The spillover has also led to higher prices for most other commodities and is straining fixed budgets for food aid. However, as often noted, the best cure for high prices is high prices. That is, the market is responding to the incentive of high prices by a dramatic expansion in corn acreage that will boost supplies and lead to substantial moderation in prices.

There is no denying that this transition period before adjustments have occurred will be painful, but it should also be noted that grain prices have been very low for many years. In real terms, these prices have been extremely low and have made it difficult for farmers to cover costs without support from the Government. Consumers pay a record low share of their incomes for food in this country. Because of the expansion of biofuels, we do not project grain prices to fall back to very low levels, like the \$2.00 per bushel corn of recent years. Rising productivity and response to market incentives will bring prices down in the next few years from the highs seen last winter. Any breakthroughs in the production of ethanol from cellulosic materials would also contribute to easing pressure on grain supplies. Given huge interest and new investments in research, the ability to use cellulosic feedstocks, in a cost-effective way, for ethanol production may not be far away.

In the current environment, there are other adjustments taking place to reduce pressure on the livestock industry. Cattle and dairy producers are increasingly feeding distillers grains, a by-product of ethanol production. Research is underway to make these by-products more useable to pork and poultry feeders, as only limited amounts can be fed to these animals given current formulations.

On the food aid side, higher prices are not all negative. Many, if not all, farmers in developing countries face low prices, frequently reflecting an urban bias. These farmers respond to market incentives too. The well publicized case of Mexico, where corn-based tortilla prices have risen sharply, also offers an encouraging lesson. Mexican farmers are expanding corn production, and this will help contribute greatly to rural development as much as to increasing local food supplies.

We will continue to coordinate closely with the program agencies, USAID, FAS, to review commodities requested and complete market research to identify the most economical and effective products. Contracts are awarded based on lowest landed cost, so FSA must evaluate the combined commodity cost and the freight cost. The new award system implemented in February 2007 should help achieve some cost savings in all international food aid purchases.

AGRICULTURAL DISASTER ASSISTANCE

Question. There have been many efforts in Congress to pass comprehensive disaster assistance for the nation's farmers and ranchers dating back to 2005. I fully expect attempts by Members to include an agriculture disaster package in the supplemental appropriations bill Congress will soon be considering.

In your opinion, is there a need for ag disaster, and if so, where is it needed the most?

Answer. This Administration does not deny there have been times it has been necessary to provide relief to farmers and ranchers harmed by natural disasters. In fact, since 2005, this Administration has developed numerous ad hoc disaster assistance programs to aid producers impacted by adverse weather. However, these programs have been targeted to producers directly impacted by these extraordinary weather events. What this Administration has not supported are Congressional efforts to provide a multi-billion dollar, broad based, non-targeted disaster assistance

package covering a time period when producers have seen record or near record production and/or farm income levels and crop insurance losses have been at record or near record lows. The Administration would not support a broad disaster bill unless it is fully offset from other agricultural spending.

While individual producers in certain regions of the nation have experienced crop losses due to adverse weather, the farm economy overall has been financially strong. For calendar year 2005, total crop cash receipts were \$114 billion, the second highest ever. Preliminary estimates for calendar year 2006 are that total crop cash receipts will reach a record \$122 billion. However, that record is expected to be short-lived as calendar year 2007 crop cash receipts are forecasted to reach nearly \$134 billion.

For the period 2003–2005 the crop insurance loss ratio has averaged just 0.77, including a record low of 0.60 in 2005. This means that, on average, only 77 cents have been paid out in indemnities for each \$1 of premium. And, while the loss ratio for the 2006 crop year is not yet finalized, current estimates place it at about 0.8. By comparison, during the early 1990's the loss ratio averaged nearly 1.5.

Question. What has USDA done to address disaster needs since the start of 2005? Has the money that has been obligated by the department actually made its way to producers?

Answer. Throughout this period, assistance has been available under Federal Crop Insurance and the Noninsured Crop Disaster Assistance Program.

In addition, in October 2005, USDA authorized the use of \$250 million from Section 32 funds for crop disaster, livestock, tree, and aquaculture assistance. These funds are being distributed by way of five new programs; the Tree Indemnity Program (TIP), the Hurricane Indemnity Program (HIP), the Livestock Indemnity Program (LIP), and the Feed Indemnity Program (FIP); and an Aquaculture Grant Program.

Producers in Alabama, Florida, Louisiana, Mississippi, North Carolina and Texas counties declared primary presidential or secretarial disaster areas in 2005 because of hurricanes were eligible to apply for assistance under the new programs. In general, funds under these programs have been distributed to producers. However, for some programs it has been necessary to delay payments until it could be determined if there would be a need to prorate the available funding.

I will provide a list of further measures taken by USDA to assist farmers and ranchers in 2006.

[The information follows:]

Sign-up for programs authorized by the Emergency Agricultural Disaster Assistance Act of 2006 began on December 11, 2006.

In August 2006, USDA authorized \$780 million in assistance to help farmers and ranchers manage drought and weather related production challenges. This funding included a \$50 million Livestock Assistance Grant Program for States which had counties which were designated as D3 or D4 on the Drought Monitor anytime between March 7 and August 31, 2006.

In fiscal year 2006, the Farm Service Agency (FSA) provided \$48 million in Emergency (EM) loan assistance.

On July 13, 2006, USDA announced the expansion of Conservation Reserve Program (CRP) acreage eligible for emergency haying and grazing for livestock producers hit hard by drought. The expansion allows livestock producers from eligible counties to obtain needed hay or forage. The expanded area radiates 150 miles out from any county approved for emergency haying and grazing.

USDA also reduced producers' CRP rental payments by 10 percent, instead of the standard 25 percent, on CRP lands that are hayed or grazed under emergency authority in 2006.

On July 14, 2006 USDA announced sign-up for the Emergency Forestry—Conservation Reserve Program.

On June 29, 2006, USDA announced \$11.8 million in Emergency Conservation Program (ECP) funding for 18 States to help producers rehabilitate land damaged by drought and other natural disasters.

On June 9, 2006, USDA announced the availability of \$75.7 million in Emergency Conservation Program (ECP) funds for victims of the 2005 hurricanes.

On March 24, 2006, USDA announced that agricultural producers in 16 Texas counties adversely affected by wildfires would be eligible to receive \$8.1 million in ECP funds.

On March 21 2006, USDA announced that agricultural producers in six Oklahoma counties and 27 north Texas counties affected by wildfires could remove dry grass on and move cattle to CRP acreage, without facing charges for grazing value or the baled value of removed forage.

On March 15, 2006, USDA announced the allocation of more than \$20 million in ECP funds to 26 states affected by drought, wildfires and other natural disasters.

On March 3, 2006, USDA announced the allocation of \$63 million in ECP funds to assist agricultural producers struck by hurricanes in the Gulf of Mexico region during calendar year 2005.

USER FEE PROPOSALS

Question. The budget proposes user fees totaling \$149 million for the Food Safety and Inspection Service, Animal and Plant Health Inspection Service, Grain Inspection, Packers, and Stockyards Administration and Risk Management Agency. In previous fiscal years, USDA assumed savings for these fee requests. I am pleased to see that this budget request does not assume savings. However, I understand that USDA expects to realize savings from these fees in fiscal 2009. Realizing this savings requires USDA to actively engage the Congress and affected industry to pass this legislation.

Please describe, in detail, USDA's plan for getting each user fee passed including discussions with industry and the authorizing committees.

Answer. Although the budgetary treatment of proposed user fees has changed this year, procedures for implementing new user fees would remain the same. Generally, the steps for user fee implementation consist of: submitting proposed legislation to Congress; participating in special hearings or answering Congressional inquiries about the proposed fees; and engaging in the Federal rule-making process after enactment. Statutory prohibitions prevent us from lobbying for passage of new user fee legislation outside our communication with Congress. The rule-making process provides an opportunity for public input on any proposed rule. All public comments are evaluated and considered before a final rule is promulgated.

GREENBOOK CHARGES

Question. I am concerned that the charges assessed to the agencies by USDA, known commonly as greenbook charges, have grown excessively over the last few years.

Please provide, for the record, greenbook charges by category for each agency for fiscal year 2006, 2007, and 2008. For each category, provide an explanation of how the charges were assessed.

Answer. The actual funding for fiscal year 2006 and estimated 2007 funding by category for greenbook charges, including an explanation of how the charges were assessed, is provided for the record. Estimates for fiscal year 2008 greenbook charges have not been decided.

The cost breakout by agency for the greenbook charges is also provided for the record. The actual costs by agency for fiscal year 2007 are not yet known.

[The information follows:]

Department Wide Reimbursable Programs

[USDA Agencies fiscal year 2006 Allowance and fiscal year 2007 Estimated Cost Shares]

	Fiscal year 2006 allowance	Fiscal year 2007 estimate
Agricultural Marketing Service	\$1,291,169	\$1,392,694
Agricultural Research Service	4,378,636	4,915,646
Animal and Plant Health Inspection Service	4,563,266	5,020,820
Cooperative State Research, Education and Extension Service	493,847	313,085
Departmental Administration	181,779	250,226
Economic Research Service	278,897	235,454
Farm Service Agency	5,293,884	8,175,512
Food and Nutrition Service	1,604,131	1,103,188
Food Safety and Inspection Service	4,584,996	4,890,378
Foreign Agricultural Service	1,125,309	993,690
Forest Service	20,141,973	21,221,635
Grain Inspection, Packers and Stockyards Administration	364,035	409,168
National Agricultural Statistics Service	789,616	632,371
National Appeals Division	80,711	49,284
Natural Resources Conservation Service	5,555,459	5,583,986
Office of Budget and Program Analysis	33,508	30,091
Office of Chief Economist	114,940	99,493
Office of Civil Rights	94,242	92,852
Office of Communications	66,883	49,916

Department Wide Reimbursable Programs—Continued

[USDA Agencies fiscal year 2006 Allowance and fiscal year 2007 Estimated Cost Shares]

	Fiscal year 2006 allowance	Fiscal year 2007 estimate
Office of Executive Secretariat	10,749	9,316
Office of General Counsel	151,143	164,899
Office of the Chief Financial Officer	735,596	1,096,120
Office of the Chief Information Officer	5,969,036	2,832,153
Office of the Inspector General	448,138	457,316
Office of the Secretary	65,775	13,314
Risk Management Agency	452,737	263,383
Rural Development	4,312,387	3,547,010
TOTAL	63,182,838	63,843,000

FINANCIAL MANAGEMENT SYSTEM

Question. The budget proposal requests an increase of almost \$25 million for the development of a new financial management system. Implementing new IT systems is often very costly, especially replacing a financial system as large as USDA's.

How much does USDA plan to spend on the financial system implementation in fiscal 2007? Did this funding come from annual appropriations or from the working capital fund?

Answer. USDA intends to spend \$4.5 million in fiscal year 2007 for implementation activities. These funds would come from reimbursements received from USDA customer agencies to continue the planning and initial implementation of the Financial Management Modernization Initiative.

Question. Does USDA plan to fund any part of the financial system in fiscal 2008 from the working capital fund?

Answer. The President's fiscal year 2008 budget includes an estimate of \$5.5 million in operating support for this project, to be recovered via reimbursements from USDA customer agencies under the Working Capital Fund. This estimate is subject to change as the implementation schedule and requirements gathering move forward.

Question. Does the fiscal 2008 budget request any funding for the financial system from the interior appropriations subcommittee for the Forest Service?

Answer. The fiscal year 2008 budget for the Forest Service does not request any funds for the financial system from the Interior Appropriations Subcommittee. We do not expect to begin implementation of the Forest Service into the new system until after fiscal year 2008.

Question. Has USDA entered into a contract with a private company for the implementation of the new financial system? If so, please explain the terms of the contract. For example, what constitutes satisfactory completion of the system implementation by the contractor?

Answer. USDA is currently in the acquisition process and has not entered into a contract.

Question. What is the estimated total cost for development and implementation of the new financial system?

Answer. The estimated cost for implementation of USDA's new financial management system is approximately \$90 million.

Question. How much of the total development and implementation costs will be requested through the agriculture appropriations subcommittee?

Answer. At this time, no final decision has been made as to the allocation of funding needed for Financial Management Modernization Initiative implementation between the Agriculture and Interior appropriations subcommittees.

Question. How much of the total development and implementation costs will be requested through the interior appropriations subcommittee for the Forest Service?

Answer. At this time, no final decision has been made as to the allocation of funding needed for Financial Management Modernization Initiative implementation between the Agriculture and Interior appropriations subcommittees.

Question. How much of the total development and implementation costs will be funded through the working capital fund?

Answer. We do not expect that development and implementation costs will be funded through the Working Capital Fund (WCF). We have a small amount of operating funds budgeted for the system through the WCF, but it is our aim that devel-

opment and implementation funds be made available through appropriations and Departmental Reimbursable Program authority, if appropriate.

Question. Once the system is implemented, how much will operations and maintenance of the financial system cost annually?

Answer. The estimated average annual operations and maintenance cost for the expected life of the system, for the period fiscal year 2012 through fiscal year 2021, is approximately \$50 million.

Question. Will annual appropriations or the working capital fund pay for operations and maintenance costs?

Answer. Historically USDA has used the working capital fund reimbursement mechanism to pay for USDA's financial management system operations and maintenance costs.

FSIS FUNDING

Question. The Food Safety and Inspection Service received a significant funding increase of more than \$57 million in the fiscal 2007 joint resolution. How does FSIS plan to spend the additional funding?

Answer. FSIS allocated the fiscal year 2007 increase of \$62.1 million by funding pay costs, employee benefits and activities to strengthen the Food and Agriculture Defense Initiative.

Question. How many staff will FSIS be able to hire as a result of the additional funding?

Answer. FSIS is actively recruiting and hiring for positions in all of its 15 Districts and intends on filling 98 positions for slaughter services and 86 positions for in-plant processing in fiscal year 2007. In addition, the agency is recruiting to fill new positions resulting from industry growth and vacancies resulting from attrition.

RISK BASED INSPECTION

Question. Mr. Secretary, recently the Food Safety and Inspection Service announced a plan and time table for implementing risk based inspection in meat and poultry plants.

Please explain this proposal.

Answer. Under a risk-based inspection system, the type and intensity of inspection activity at each establishment will be determined by the relative inherent risk of product, the volume processed, and the ability of each establishment to control risk. Risk-based inspection will allow USDA's Food Safety and Inspection Service (FSIS) to more effectively allocate inspection resources to those processing plants that need them the most and carry out less intense inspection at plants with better risk control, while continuing daily inspection at all processing facilities. The public health goal of risk-based inspection is to target FSIS resources more directly at the greatest risks and reduce overall risks found in meat, poultry and egg products under agency jurisdiction.

Question. How have industry and consumer groups reacted to this proposal?

Answer. Most of the industry and consumer groups with whom FSIS has met believe the concept of risk-based inspection can achieve the desired goal of using FSIS resources more effectively.

Question. Does FSIS have an IT system for collecting and analyzing data for risk based inspection? If not, why not?

Answer. In fiscal year 2008, FSIS will use base funds to help move forward with information technology hardware and software improvements. The improvements are necessary to build a public health data infrastructure that will allow for real-time data analysis—a key element of the enhanced risk-based inspection system. FSIS efforts to upgrade its information technology infrastructure are expected to be completed in the first quarter of fiscal year 2008. The IT system will improve data by incorporating new inspection data generated as a consequence of planned enhancements to inspection activity. In addition, the agency will design an external-USDA peer-reviewed, risk assessment to model the implementation of risk-based inspection in processing plants such that we can predict and respond to the public health outcomes of inspection activity nationwide.

Question. How does FSIS expect risk based inspection will make meat safer for consumers?

Answer. RBI will make meat safer for consumers by targeting inspection resources to high risk activities and establishments. This will help ensure that meat and poultry products are being more effectively inspected using state-of-the-art data collection techniques and analysis.

Question. How will FSIS measure the success of the program?

Answer. USDA's Food Safety and Inspection Service (FSIS) intends to implement and review risk-based inspection for processing in a careful and deliberative manner. The perfect report card for the long-term would be a measured decrease of food borne disease and death. While FSIS is still in the process of developing how we intend to evaluate RBIS, in the near-term, FSIS will compare such measures as verified consumer food safety complaints, product recalls, and changes in the effectiveness of establishment risk controls between RBIS and traditionally-inspected establishments. In addition, FSIS will be interviewing inspection program personnel, and the USDA's Office of Inspector General will be continuing to audit the development and implementation of RBIS.

Question. Will total inspection hours or inspection staff be reduced as a result of this proposal?

Answer. Under a more robust risk-based inspection system for meat and poultry processing, USDA will continue using the same number of inspection program personnel, spending the same amount of time conducting inspections. Risk-based inspection is about working smarter to protect public health by having inspection personnel spend more time in the processing plants that need assistance and expertise.

NATIONAL ANIMAL IDENTIFICATION SYSTEM

Question. Mr. Secretary, the Congress has provided over \$99 million for the implementation of an animal identification system. I understand that an additional \$18.7 million has been transferred from the Commodity Credit Corporation for this purpose as well. The fiscal 2008 budget request proposes an additional \$33 million to continue this project. If this funding is provided in fiscal 2008, the total amount spent on the animal identification system will be in excess of \$150 million by the end of 2008. Unfortunately, the direction USDA plans to go with this system is still not clear.

What has all this funding accomplished?

Answer. The National Animal Identification System is composed of three components: premises registration, animal identification, and animal tracing. Premises registration is the foundation of the program. As of March 12, 2007, all 50 States, 60 Tribes, and 2 U.S. Territories are capable of registering premises according to USDA standards, and approximately 378,000 locations have been registered.

Significant progress has also been made on the second component of NAIS, animal identification. As of March 12, 2007, approximately 1 million AIN devices have been distributed.

The third component of the NAIS, animal tracing, is currently under development with the help of USDA's industry and State partners. Industry, through private systems, and States will manage the animal tracing databases that maintain the movement records of animals. Full deployment of the Animal Trace Processing System is planned for the near future.

Question. In USDA's opinion, how does a comprehensive animal identification system work from identification of an animal disease outbreak to resolution of the problem?

Answer. The NAIS includes three components: premises registration, animal identification, and animal tracing. When the system is fully operational, all three of the NAIS components would be used together to provide a streamlined system of information in a disease situation. This information would be available to help investigate the source of a disease outbreak and identify any animals and/or locations in the United States that may be at risk of spreading disease.

An example will be provided for the record.

[The information follows:]

A diseased animal is detected at a slaughterhouse; authorized animal health officials enter the animal's identification number (AIN) into the National Animal Identification System (NAIS) Animal Trace Processing System (ATPS); the search will provide information on AIN devices distributed to a premises and animal movement records for that animal from the private/State animal tracing database; authorized animal health officials then have a listing of locations associated with the animal; the search will also provide the other animal identification numbers that were present on the premises during the time the animal in question was there. This helps officials identify animals that may have been exposed to the disease. Animal health officials can then begin an epidemiologic investigation and take precise actions to address the situation, minimize its impact on producers, and speed disease response efforts.

While NAIS will not "prevent" the initial occurrence of a disease, it can reduce or prevent the spread of disease. Without this system of information, it can take days, weeks, and too often, months of manual searching to complete a disease inves-

tigation. Moreover, the inability to quickly address an emerging animal disease can have negative economic and domestic/international trade implications for the livestock industry and governments. Having NAIS—a streamlined, modern information system—in place will not only speed up disease response but also ensure that these efforts are comprehensive and accurate.

Question. How much does USDA estimate the animal identification system will cost when completed? Is there an end in sight to continual \$33 million funding requests?

Answer. It is projected that, once NAIS has been fully implemented, the funding necessary to maintain the system will be less than the funding necessary to create the supporting infrastructure in all States, participating Tribes, and Territories. However, premises information will need to be updated as changes occur throughout the country. Participants in the private sector will require ongoing administrative support and the technologies that enhance NAIS. Therefore, funding will still be necessary to maintain the system, to preserve security, to make any necessary upgrades, and to ensure that producers are well-informed regarding the system.

COMMODITY SUPPLEMENTAL FOOD PROGRAM (CSFP) ELIMINATION

Question. Mr. Secretary, for the second year in a row the budget request eliminates the Commodity Supplemental Food Program, which serves the elderly and young women and their children in 32 States, 2 Indian reservations, and the District of Columbia. The elimination of this program results in a \$107 million reduction from the fiscal 2007 joint resolution rate. Please explain why USDA chose to eliminate this program.

Answer. In the Administration's view, ensuring adequate funding for programs that have the scope and reach necessary to provide access to eligible people wherever they may reside is a better and more equitable use of scarce resources than to allocate them to programs that cannot provide access to many areas of the country. For this reason, the Administration has placed a priority on funding the Food Stamp Program, WIC, and other nationally-available programs which provide benefits to eligible people wherever they may live, including communities currently served by CSFP.

Question. Does the budget proposal provide an alternative for all CSFP participants?

Answer. In the Administration's view, ensuring adequate funding for programs that have the scope and reach necessary to provide access to eligible people wherever they may reside is a better and more equitable use of scarce resources than to allocate them to programs that cannot provide access to many areas of the country. For this reason, the Administration has placed a priority on funding FSP, WIC, and other nationally-available programs which provide benefits to eligible people wherever they may live, including communities currently served by CSFP.

Included in these programs are Federal nutrition assistance programs targeted specifically to seniors. These programs, administered by the Administration on Aging and authorized by the Older Americans Act of 1965, include congregate nutrition services and home-delivered nutrition services and are available nationwide to all seniors aged 60 and older. The Administration's 2008 budget request includes \$383 million and \$181 million for these two programs, respectively. In addition, the 2008 budget request includes \$147 million for the Nutrition Services Incentive Program. Combined, the Older Americans Nutrition Programs serve about 250 million congregate and in-home meals to about 2.6 million older adults annually. In addition to the Administration on Aging programs for seniors, low-income individuals of any age have access to TEFAP.

Question. What percentage of elderly CSFP participants are currently enrolled in food stamps and receive CSFP as a supplement to their monthly food stamp allotment?

Answer. We estimate that about 20 percent of elderly CSFP participants are currently enrolled in food stamps, based on data on low-income elderly individuals we have used in our budget estimates.

WIC LEGISLATIVE PROPOSALS

Question. Mr. Secretary, the budget includes a proposal to reduce state nutrition services and administration grants in the WIC program. Specifically, the proposal reduces the per participant nutrition services and administration amount paid to states in fiscal 2008 back to the fiscal 2006 rate. The proposal is accompanied by a \$145 million reduction to the WIC program in the budget. Please explain why USDA chose to reduce the NSA grant to states.

Answer. The current proposal is intended to provide a reduction in WIC NSA funding to slow its growth. Further cost containment is needed to maintain the Program's ability to serve all eligible persons expected to seek services in fiscal year 2008, which is estimated to be approximately 8.28 million persons. WIC State agencies have been extremely successful in containing food costs. We therefore believe WIC State agencies can achieve similar success in containing NSA costs.

Question. Why did USDA choose to go back to 2006 as the base year instead of keeping costs flat at the 2007 rate?

Answer. The administrative expenditure per participant (AGP) is determined each year by inflating the prior year's AGP by the State and Local Expenditure Index (SLEI). From fiscal year 1999 through fiscal year 2006, the SLEI increased 32 percent, or an average of 4.5 percent per year. The SLEI increase from fiscal year 2006 to fiscal year 2007 is even higher at 6 percent. Over the same period, some broader measures of inflation (e.g., the Consumer Price Index for Urban Wage Earners and Clerical Workers and the Gross Domestic Product Price Index) have risen more slowly (21 percent and 18 percent respectively). Given that these other measures reflect a significantly lower rate of inflation than the SLEI, using 2006 as the base year will reduce the AGP so that it is more consistent with what would have occurred if it had grown at a rate comparable to those broader inflation indicators.

Question. Why did USDA choose to use the budget as a vehicle for changing the NSA grant amount instead of asking for the change as a part of farm bill discussions with the authorizing committees?

Answer. For the proposed NSA cost containment initiative to be effective for fiscal year 2008, the proposal had to be included in the fiscal year 2008 budget request.

Question. How will this reduction impact the states' ability to implement new WIC programs such as the revised food packages that are to be implemented at the end of this year?

Answer. State agencies will be encouraged to work with Federal program staff to seek efficiencies in the administration of the requirements so that the reduction in NSA funding does not negatively impact program operations. FNS does not believe that the food package rule will necessitate increased staff or any other action that would result in major, additional administrative expenditures over the long term. FNS does not expect the reduction in NSA will affect the States' ability to implement the revisions to the food packages.

WIC MANAGEMENT INFORMATION SYSTEM FUNDING

Question. The budget request does not include funding for Management Information Systems. Please describe the current state of Management Information Systems in the WIC program including a discussion of states that still use paper systems to manage WIC caseload.

Answer. Currently, all State agencies use automated systems to manage caseload and support daily operations. While the vast majority of WIC systems are electronic rather than paper-based, many clinics have insufficient computers to accommodate every workstation. Thus, in some cases participant data may be collected manually and later entered into a centralized system.

Question. Why does the budget not include funding for Management Information Systems?

Answer. The fiscal year 2008 budget does not request additional funding for implementation of WIC EBT. In fiscal years 2006 and 2007, \$19.8 million was available for management information systems and technology needs. Assuming these funds are not needed to support caseload in fiscal year 2007, current funding is sufficient through fiscal year 2008 for system development and EBT initiatives.

WIC \$200 MILLION CONTINGENCY FUND

Question. The budget request proposes to increase the WIC contingency fund to \$200 million from \$125 million. Why does the contingency fund need to be increased?

Answer. Increasing the amount of funds available in the contingency fund will allow the Department to ensure that adequate funds are available to support expected participation should food costs exceed projections. The Department is concerned about the potential of increased food costs in fiscal year 2008. Infant formula rebate savings are a significant and integral part of the WIC Program and are estimated to support the participation of over 2 million women, infants and children. Any erosion of these savings has serious implications for funding needs to support projected participation. In the past 2 to 3 years, the Department has observed a reduction in the percent discount on infant formula received by some WIC State agencies, which has led to increased formula costs. For example, twenty-seven geo-

graphic State agencies have recently awarded contracts that have started in fiscal year 2007 or fiscal year 2008 and all but one of these State agencies received a rebate that yields a significant decrease in the discount on the wholesale cost from that received in its prior contract.

WIC FOOD PACKAGE

Question. The updated WIC food package is supposed to be finalized and implemented at the end of this year. Is the Department on-time to implement the food package?

Answer. Over 46,000 comments that were received on the proposed changes to the WIC food packages published for comment August 7, 2006 and are currently being analyzed. We anticipate issuing an interim final rule updating the WIC food packages in September 2007.

RESEARCH, EDUCATION, AND ECONOMICS REORGANIZATION

Question. One of the administration's farm bill proposals would make significant changes to the Research, Education, and Economics mission area within USDA. Specifically, CSREES and ARS would be folded into one agency. The thrust of the argument for this change is that it will lead to better coordinated research and end redundancies.

Is that not the job of the Under Secretary?

Answer. While the Under Secretary has a role in coordinating the efforts of the four REE agencies, it is important to institutionalize this coordination within the agencies themselves. This can best be accomplished by merging ARS and CSREES into a single agency with a single national program staff.

This will help ensure that resources will be maximized and that the comparative strengths of our intramural and extramural system are better utilized to tackle critical problems facing agriculture. This merger will also strengthen the tie between USDA's intramural research programs and the extension service. This will facilitate a broader dissemination of science-based technologies to farmers and ranchers.

Question. Does he not have the authority to make ARS and CSREES operate more efficiently?

Answer. While the Under Secretary has the authority to help make REE agencies more efficient, the current organizational structure of the mission area is a limiting factor. By having separate agencies with separate national program staffs, there are some inefficiencies that cannot be fully addressed without bringing the agencies together. The merger of ARS and CSREES will better enable the Under Secretary to overcome these inefficiencies.

Question. Why don't you use the budget process to better coordinate research?

Answer. The REE budget process promotes research coordination across the REE agencies. As part of the budget formulation process, each year the Under Secretary, in consultation with the agency Administrators, identifies high priority issues for which coordinated budget requests are developed. The proposals take into consideration the current research program within each agency and identify program enhancements that are responsive to research needs and agency strengths. For example, the President's fiscal year 2008 budget proposes complementary budget increases in bioenergy for CSREES, ARS, and ERS. Merging ARS and CSREES would result in one National Program staff and a single planning process for each program that would result in an integrated plan for the core program that capitalizes on the strengths of intramural and extramural research and minimizes any undesirable redundancies.

Question. What steps have you taken in the fiscal 2008 budget to eliminate redundancies and better coordinate research among ARS and CSREES?

Answer. For the REE fiscal 2008 budget, similar to previous years, the Under Secretary, in consultations with the agency Administrators, identified high priority issues for which coordinated budget requests were developed, thus promoting cross-agency coordination. The Under Secretary also oversaw the development of the agency proposed budgets to ensure an appropriate balance across programs and agencies. In some cases, this involved reprogramming within the core budget.

Throughout the fiscal year, the agencies frequently coordinate efforts on a range of research issues. For example, ARS and CSREES have recently developed a joint plan to address the Colony Collapse Disorder threatening the honey bee industry and production of many crops. Were ARS and CSREES to merge, there would be one national program staff that would routinely develop integrated program plans with intramural and extramural components. Such plans would inherently promote coordination and avoid redundancy.

Question. What specific direction has been provided to Under Secretary Buchanan to make certain that redundancies are eliminated and research is better coordinated?

Answer. USDA is continually striving to maximize the efficiency and effectiveness of its programs. Likewise, Under Secretary Buchanan is looking for ways to make REE agencies more efficient and effective. Merging ARS and CSREES will help reduce redundancies and better coordinate research, thus furthering this objective.

APHIS PROGRAM COST SHARE

Question. The President's budget for the Animal and Plant Health Inspection Service requests decreases for numerous programs such as Agricultural Quarantine Inspection, Boll Weevil, Brucellosis, Chronic Wasting Disease, Asian Longhorned Beetle, Glassy-winged Sharpshooter, John's Disease, Pink Bollworm, Wildlife Services Operations and Wildlife Services Methods Development. The justification for the funding reductions is the assumption that States or other cooperators/beneficiaries will begin paying more toward efforts to fight such plant and animal pests and diseases. In some cases, specific cost-share rates are indicated.

For the record, please provide the funding contributions and cost-share rates for Federal vs. State/Local/Other for fiscal year 2006, and estimates for fiscal year 2007 and fiscal year 2008, for all programs in the budget that request decreases to allow others to assume a larger funding portion of the program. In addition, please indicate what process and/or policies the Department uses to determine appropriate cost-share rates for these programs, and provide information on what indication you have that other State/cooperator/beneficiaries will begin paying the additional costs when Federal contributions are reduced.

Answer. The following table depicts the funding contributions and cost-share rates for fiscal year 2006. In addition, we have provided estimates for fiscal year 2007 and fiscal year 2008.

[The information follows:]

TOTAL FUNDING: ALL SOURCES (ANNUAL)

[Dollars in Millions]

	Federal	Cooperator	Total	Percent Federal
Chronic Wasting Disease:				
Fiscal year 2006 actual	\$15.163	\$4.473	\$19.636	77.22
Fiscal year 2007 (estimated)	13.746	9.164	22.910	60.00
Fiscal year 2008 (estimated)	10.009	11.141	21.150	47.32
EPP-Asian Longhorned Beetle:				
Fiscal year 2006 actual	27.322	10.434	37.756	72.36
Fiscal year 2007 (estimated)	19.904	13.713	33.617	59.21
Fiscal year 2008 (estimated)	18.316	15.404	33.720	54.32
EPP-Citrus Health:				
Fiscal year 2006 actual	21.191	39.884	61.075	34.70
Fiscal year 2007 (estimated)	36.455	29.022	65.477	55.68
Fiscal year 2008 (estimated)	34.409	33.368	67.777	50.77
EPP-Glassy-Winged Sharpshooter:				
Fiscal year 2006 actual	27.311	25.443	52.754	51.77
Fiscal year 2007 (estimated)	24.130	25.000	49.130	49.11
Fiscal year 2008 (estimated)	23.174	27.133	50.307	46.07
John's Disease:				
Fiscal year 2006 actual	13.057	6.900	19.957	65.43
Fiscal year 2007 (estimated)	12.080	7.877	19.957	60.53
Fiscal year 2008 (estimated)	3.266	16.691	19.957	16.37
Noxious Weeds:				
Fiscal year 2006 actual	1.875	0.121	1.996	93.94
Fiscal year 2007 (estimated)	1.441	0.121	1.562	92.25
Fiscal year 2008 (estimated)	1.146	0.716	1.862	61.55

Emergency program costs generally have been shared by APHIS and the State(s). These arrangements may also include local governments, industries, organizations, and groups that benefit from or are affected by animal and plant protection.

Long-standing relationships between APHIS and State and industry cooperators usually enable an effective programmatic response to serious outbreaks. While cooperator contributions are frequently in-kind or intangible in the early stages of a program, after several years USDA expects that funding would be requested at both

the Federal and State levels, as appropriate, to ensure continued progress in controlling and/or managing the pest or disease. When requested funding is not provided, USDA evaluates the overall impact to program efforts and adjusts future funding requests accordingly.

USDA believes that increased participation by all parties will facilitate improved planning and funding decisions by the Federal Government and its cooperators regarding plant and animal pest and disease programs. However, USDA has no predetermined rates.

In planning with our partners, we consider factors such as the availability of funding to program participants; weather and any other environmental constraints; the potential of the pest to cause significant economic damage to agricultural or natural resources; the extent to which the pest or disease has spread; the availability of effective detection and control technology or availability of diagnostic tests; and, the availability of acceptable alternatives for controlling and managing the pest or disease.

CROSS-CUTTING TRADE NEGOTIATIONS AND BIOTECHNOLOGY RESOURCES

Question. What is the basis for the funding increase proposed for fiscal year 2008?

Answer. As the usage of biotechnology, both domestically and internationally, has expanded in recent years, the Department has recognized the need to increase its oversight and regulatory activities in this area. The requested funding increase would allow for the expansion of regulatory and trade strategies for specialty crops and transgenic animals, and improved communication materials for both domestic and international markets.

Question. Specifically, how will the funds for “cross-cutting trade negotiations and biotechnology resources” be used?

Answer. Cross-cutting trade and biotechnology funding would be used to conduct: quantitative analyses and studies needed to support increasingly complex compliance activities; expand a project to develop a regulatory and trade strategy for specialty crops; increase regulatory activity in the area of transgenic animals—domestically, in international markets, and in international standard setting organizations; and increase outreach activities for both domestic and international markets. These projects would involve multiple USDA agencies.

Question. Please discuss specific results achieved using these funds in the past?

Answer. The Foreign Agricultural Service has used this funding to support U.S. trade policy objectives for agricultural biotechnology that include expanding market access through negotiation and coalition building initiatives. The funds support USDA bilateral and multi-lateral negotiating efforts by providing the means to sponsor technical and policy level exchanges (e.g., during the Korea and Malaysia FTA negotiations, Vietnam WTO accession negotiations, etc.), and to support the U.S. WTO challenge of the EU moratorium on agricultural biotechnology approvals. The funds also have helped to support U.S. coalition building efforts to address overly restrictive interpretations of the Cartagena Protocol. U.S. outreach efforts center around an array of USDA sponsored workshops hosted in multiple foras, including the Asia Pacific Economic Council and North American Biotechnology Initiative, to raise awareness of the importance of sound regulatory systems. Initiatives undertaken using these funds are aimed at increasing market access for U.S. agricultural trade and fostering implementation of policies that are transparent and based on sound science through coalition building, global public diplomacy, the advancement of science-based regulation and in accordance with international obligations.

The Animal and Plant Health Inspection Service has used the funds to focus on two areas. First, to strengthen Federal-State partnerships, APHIS’ Biotechnology Regulatory Services supported the pilot State inspection project, designed and began developing an on-line biotechnology training module for State regulatory officials and others, and conducted outreach to State regulators. Second, APHIS implemented recommendations from the Office of the Inspector General to enhance compliance and inspection activities, and funded select biotechnology inspections.

The Cooperative State Research, Education, and Extension Service used the funds to support the initial phases of the Specialty Crops Regulatory Initiative (SCRI), an effort by a diverse group of public and private-sector stakeholders to establish an entity that can assist developers of biotechnology-derived specialty crops to complete the existing regulatory process. During 2006–2007, a consultant for the SCRI planning group began development of a business plan and structure for SCRI, as well as a roadmap for phased implementation of the SCRI program.

Question. Why should the funds be appropriated to the Office of the Secretary instead to specific agencies?

Answer. Because of the cross-cutting nature of these activities, which can involve a number of different USDA agencies, the Department proposed several years ago that the funding be provided to the Office of the Secretary. This approach allows the funding to be allocated in response to emerging issues to whatever agency or agencies have the appropriate expertise and knowledge to address them. In addition, having a central fund helps in the coordination of these activities within the Department and avoids duplication in agencies' efforts.

OFFICE OF THE SECRETARY, PROVINCIAL RECONSTRUCTION TEAMS

Question. How would the funding be allocated between Iraq and Afghanistan?

Answer. USDA estimates that \$5.3 million will be used to support PRT activities in Afghanistan and \$7.2 million will be used to support PRT activities and related technical assistance in Iraq. These estimates are subject to change as conditions and opportunities dictate.

Question. For each country, please explain what activities the members of the PRT will be involved in.

Answer. In Iraq, USDA's advisors serving with the PRTs will work to support a market-based approach to agribusiness; improve livestock health and animal production; improve the production of dryland agriculture, especially wheat yields and crop diversification; and increase the production and processing of horticultural crops.

In Afghanistan, USDA will address many of the same issues, and will also continue efforts to improve irrigation and farm water use efficiency; promote post-harvest storage for improved nutrition; stimulate tree production, reforestation, and revegetation; and reestablish production of high-value horticultural crops.

Question. How will you measure success?

Answer. USDA's PRT advisors rely on funding from USAID and the military to carry out specific reconstruction projects. In designing projects, each advisor will establish metrics to measure success. In the long-term, success will be evident in improved crop yields, increased irrigated land under cultivation, and greater food stores in periods of seasonal need.

Question. How will you ensure these funds are used effectively?

Answer. USDA has instituted programmatic and administrative controls in field offices as well as Washington-based offices. USDA coordinated closely with other U.S. Government, Iraqi, and Afghan agencies to ensure that programs are designed to meet the specific needs of the end users.

Question. How much of the requested funding will go into the field?

Answer. USDA estimates that of the \$12.5 million requested for these activities in Iraq and Afghanistan, 76 percent or approximately \$9.5 million will be used to cover in-country staff salaries, operations, and technical assistance/capacity building activities.

Funding that is not used in country covers items that are essential for the administration and conduct of these activities. They include the costs for such things as recruitment and selection, medical and security clearances, supplies and equipment (e.g., satellite phones), travel for both recruitment interviews and deployment to the countries, and associated administrative costs of FAS, which administers these activities on behalf of the Department.

Question. Will any of the requested funding go to the State Department and/or Defense Department? If so, for what?

Answer. USDA anticipates that approximately \$200,000 will be transferred to the State Department to cover fiscal year 2008 International Cooperative Administrative Support Services (ICASS) charges related to USDA activities in Afghanistan. However, we do not anticipate that USDA will be assessed fiscal year 2008 ICASS charges for USDA activities in Iraq.

AGRICULTURAL RESEARCH SERVICE, BUILDINGS AND FACILITIES

Question. How much will the new facility in Athens, Georgia cost to construct, furnish, and equip?

Answer. The latest design and construction estimate is \$207 million—\$16 million for design in fiscal year 2008 and \$191 million for construction. Equipment necessary for the facility is included in the total construction cost.

Question. Please describe the process used to determine that this facility is necessary?

Answer. Avian Influenza is a continuing problem in Asia where millions of poultry have been killed to protect both the industry and the consumers, and where over 150 humans have died from infection after direct contact with sick birds. Avian influenza and other viral diseases of poultry, such as Newcastle disease that recently

devastated the poultry industry in the Southwest require new technologies to understand the origin and spread of the disease, their rapid detection and their control through vaccines and novel management approaches. A leading laboratory in the world to conduct research on such poultry diseases is the USDA Southeast Poultry Research Laboratory in Athens, Georgia. The high containment laboratory is housed in outdated facilities that make it difficult to meet the needs of a modern bio-containment facility. Clearly, a new facility is critical to the protection of humans as well as poultry. The proposed new, modernized facility will meet the long term needs for bio-containment laboratory and animal space. It will enable scientists to more adequately address the emerging/exotic poultry diseases which threaten not only the Nation's poultry industry but potentially the health of hundreds of thousands of Americans. This new facility would consolidate existing facilities in Athens, Georgia, and East Lansing, Michigan, some of which were constructed as early as 1939.

Question. How will ARS manage this construction project to make sure it is on budget and on time?

Answer. ARS has experience managing projects of this complexity and scope as evidenced by the successful implementation of the Ames Modernization Project. The engineering and contract management responsibilities and oversight will be handled by the ARS Facilities Division (FD). All detailed planning, design, scheduling and day-to-day construction inspection will be achieved through contracts with architect-engineering firms with oversight provided by the FD. Rigorous quality assurance measures will be instituted and lessons learned from the Ames Modernization Project related to bio- containment construction will be incorporated into the management strategy to ensure budget, schedule, and quality issues are adequately addressed.

Question. Are all ARS facilities currently in good repair? Do they meet all applicable state and Federal codes? Do they pose any threat to human health or safety? Please provide information, including an estimated cost, for each location where repairs are necessary to bring the facility into compliance.

Answer. In response to Executive Order 13327, Real Property Asset Management, ARS is in the process of implementing a Facility Asset Management program that will capture accurate repair and modernization needs—information not currently available. A private firm specializing in documenting facility condition was hired to support our efforts by sampling facility condition, analyzing ARS replacement values, and providing estimates of repair needs based upon sampling results and industry metrics. Based upon this analysis it has been determined that the ARS facility portfolio is considered to be in “fair” condition with an average condition index of 0.90 out of 1.0, and total deferred maintenance needs estimated at \$317 million.

All human health or safety issues are handled immediately utilizing existing funding resources. All non-threatening code issues are addressed as funds become available.

Question. Please provide an update on the status of the Anacostia Waterfront Corporation's Riverwalk project along the perimeter of the U.S. National Arboretum.

Answer. The U.S. National Arboretum (USNA) has contracted with a landscape architecture firm to develop a conceptual plan for improvements to and development of the USNA property adjacent to the Anacostia River water front. The plan includes access to the Anacostia River, a tram stop on the flood plain area, and considerable improvements to the entire Asian Collections. Portions of this area will become accessible and a new parking lot, as well as orientation and restroom facilities are planned. The USNA has met with the National Park Service to coordinate long-range plans which were then incorporated into a revised USNA Master Plan that was approved by the National Capital Planning Commission and the U. S. Commission on Fine Arts.

USDA OVERSEAS ACTIVITIES

Question. Please provide information on the activities of USDA in the Middle East, Southwest Asia, India, Afghanistan, Pakistan, and East Africa.

Answer. The requested information will be provided for the record.

[The information follows:]

Middle East and Southwest Asia.—With funding from the Department of State under the Middle East Partnership Initiative (MEPI), USDA is implementing projects supporting Free Trade Agreements (FTAs), Trade and Investment Framework Agreements (TIFAs), and WTO Accession for selected countries in the North Africa and the Gulf Region. Activities include technical assistance in food safety and food defense, animal health, plant health, and environmental considerations in these areas.

In Egypt, USDA and USAID are actively engaged in capacity building programs in cooperation with Egyptian Ministries. A main effort is to develop a biosafety regulatory system. Other U.S.-Egyptian capacity building efforts include U.S. inter-agency and Egyptian science and technology collaboration and training on sanitary and phytosanitary (SPS) standards.

The Cochran Fellowship Program has trained 163 fellows from Southwest Asia and Middle Eastern countries since 1999. Recent programs include training in food safety, agricultural extension, grain procurement and poultry management. The Norman E. Borlaug International Agricultural Science and Technology Fellows Program (Borlaug Fellows Program) conducts faculty and scientist exchange programs with developing countries. During fiscal years 2004–2007, the Borlaug Fellows program included eight participants from the Middle East and 12 from Southwest Asia.

India.—USDA is the lead agency on the U.S.-India Agricultural Knowledge Initiative (AKI), a 3-year public/private sector Presidential Initiative. Support for this initiative comes from USDA and across the U.S. Government, resulting in a large number of successful activities in four focus areas: (1) university capacity building; (2) biotechnology; (3) food processing and marketing; and (4) water resource management. For example, USDA is currently supporting four Animal and Plant Health Inspection Service (APHIS) technicians in India working on pre-clearance of mangoes. USDA is hosting two workshops on food safety regulations in Mumbai and Bangalore, with an upcoming workshop on biotechnology for the public and private sector and scientists. In addition, USDA worked with the National Association of State Universities and Land Grant Colleges to fund small seed grants to foster university-to-university collaboration.

With funds from USAID, USDA is providing training and technical assistance to the Government of India on rural electrification and alternative financing models. The Cochran Fellowship Program has trained 97 Indians since 2000. Under the India-U.S. Agriculture Knowledge Initiative, the Cochran Program will train 12 individuals per year from 2006 through 2008.

Afghanistan.—USDA's primary technical assistance initiatives in Afghanistan address a range of issues, including livestock health, SPS standards, agricultural extension, conservation of biodiversity, rangelands and watersheds management, and capacity building in information technology and communications. Under the Provincial Reconstruction Team (PRT) program, USDA has deployed and supported 36 agricultural advisors from nine USDA agencies on 9-month assignments. The advisors' activities focus on projects that rehabilitate a province's agricultural infrastructure, both physical and institutional. In 2007, USDA is providing seven advisors for PRTs.

The Cochran Fellowship Program has trained 14 Afghans since 2004 in the areas of small business entrepreneurship and animal disease diagnosis. The Cochran Program is currently planning programs for fiscal year 2007 and fiscal year 2008 in the areas of animal health and agricultural extension.

Pakistan.—Under a reimbursable agreement, since 2006 USDA has had two staff members detailed to USAID/Pakistan, working on the 4-year, \$200 million Pakistan Earthquake Reconstruction Program. USDA staff lead a 10-person team spread across four locations in Pakistan. The teams focus on construction, training, capacity building, and the rehabilitation of livelihoods (agriculture and markets). The Cochran Program has trained 20 Fellows from Pakistan since 2000 in the areas of feed manufacturing, grain procurement, cotton classification, cooperative development, biotechnology and wheat milling.

East Africa.—In 2007, USDA led an Agribusiness Trade and Investment Mission to East Africa. Participant countries included Burundi, Ethiopia, Kenya, Rwanda, Tanzania, Uganda and Zambia. The Mission's objectives were to promote U.S.-Africa agribusiness cooperation, trade, and investment. Under the Africa Growth and Opportunities Act (AGOA) USDA is implementing an SPS program that includes capacity building in plant and animal health and food safety systems for the East Africa region. This program specifically helps the following East African countries: Kenya, Ethiopia, Rwanda, Uganda, and Tanzania. The Cochran Fellowship Program has trained 207 fellows from East Africa; Cochran expects to train a total of 20–25 participants from these countries in fiscal year 2007. The Borlaug Fellows program on Women in Science has supported six scholars from Kenya and five from Uganda.

USDA has also provided food assistance to various countries in these regions as follows:

USDA FOOD AID ACTIVITIES IN SELECTED COUNTRIES IN FISCAL YEAR 2006 AND FISCAL YEAR 2007

[Dollars in millions]

Country	Activity	Value
Afghanistan	School feeding	\$26.2
Afghanistan	Agricultural development	12.7
Afghanistan	Agricultural and rural development	10.4
Afghanistan	Agricultural and rural development	9.5
Bangladesh	School feeding and food processing improvements	4.4
Bangladesh	School feeding	7.4
Ethiopia	Support for poverty alleviation programs	6.3
Jordan	Agricultural development, natural resource management, and income supplements for the poor.	20.0
Kenya	School feeding	18.1
Kenya	Dairy development	7.8
Kenya	Rural development and improvement in financing system	9.1
Lebanon	Agricultural development and food security	9.2
Mozambique	Agricultural development	12.7
Mozambique	School feeding	4.4
Mozambique	Rural development and HIV/AIDS education and prevention	8.4
Pakistan	School feeding and food processing improvement	8.1
Pakistan	School feeding	7.0
Pakistan	Relief for earthquake victims	11.9
Sri Lanka	School feeding	0.2
Sri Lanka	Agricultural development and de-mining	10.7
Tanzania	Agricultural development	6.8
Yemen	Rural development	11.6

FOOD SAFETY RESEARCH

Question. Please provide an overview on all food safety research being conducted through ARS and CSREES.

Answer. The information is submitted for the record.

[The information follows:]

ARS food safety research focuses on finding ways to assess and control potentially harmful food contaminants. These activities are conducted through 4 program components: microbial pathogens; chemical contaminants; mycotoxins and plant toxins. Research is designed to yield science-based knowledge on the safe production, storage, processing and handling of plant and animal products, and on the detection and control of toxin-producing and/or pathogenic bacteria and fungi, parasites, chemical contaminants, mycotoxins, plant toxins and biosecurity. This knowledge will assist regulatory agencies and the food industry in reducing the incidence of foodborne illnesses. ARS research also assists defense related agencies.

The research program is directed towards improving public health, which is in-line with other countries. Research accomplishments are measured by the development, transfer and implementation of new technologies to Federal agencies and the private sector. Since food-safety and -security are global issues, research also involves both national and international collaborations.

The program's role in bioterrorism related research is to establish methods to protect "at-risk" foods; strengthen and expand laboratory preparedness; and develop rapid and confirmatory laboratory methods to analyze suspect foods for "select agents," toxins and chemical contaminants.

Research is coordinated to meet the needs of USDA-FSIS; DHHS-FDA and the CDC, EPA and the DHS. The Program collaborates with the FDA, CDC, DHS, and fellow USDA agencies CSREES, ERS and FSIS on a wide variety of issues.

A detailed 2006-2010 Action Plan outlining the ARS Food Safety Research Program is available at: http://www.ars.usda.gov/research/programs/programs.htm?np_code=108&docid=278

The Food Safety Program has a long history of accomplishments for its major stakeholders and customers. The 5-year Accomplishment Report is available at: http://www.ars.usda.gov/research/programs/programs.htm?np_code=108&docid=7589

Recent areas of accomplishment include:

—Sensing technologies that enable detection of fecal contamination on animal carcasses and produce, helping lower the incidence of E. coli 0157:H7.

- Giving cattle an oral dose of sodium chlorate prior to slaughter holds promise as an effective intervention to kill *E. coli* in live cattle.
 - Rapid, sensitive and inexpensive assays for detecting pathogens and chemical residues, for example dioxins in food.
- Among the food safety research goals for the coming 5-years are:
- Understanding the epidemiology and ecology of pathogens in the farm environment through production and processing.
 - Development of intervention strategies to control pathogens in animal and produce production and processing.
 - Identification of factors responsible for mediating antibiotic resistance in foodborne and other bacteria.
 - Genomics to understand the differences between pathogens and non-pathogens, and identify factors that encode for variations in virulence.
 - Development and validation of methodologies and rapid screening tests, including on-line methods, to detect fungal and plant toxins.

The Food Safety Program involves 10 major laboratories and approximately 250 scientists. The total budget for fiscal year 2007 is \$105.2 million.

CSREES' competitively funded food safety research programs are presently focusing on a few areas of interest to U.S. agriculture and consumers, including microbial contamination of fresh produce which is minimally processed prior to consumption. Bacterial pathogens *E. coli* and *Salmonella* are emphasized in this area as they have been particularly problematic. Contamination of seafood with viruses and *Vibrio* bacteria, *Campylobacter* and *Salmonella* bacteria in poultry and swine, and epidemiological approaches to development of on-farm mitigation measures and analysis of critical control points are also focus areas for the Agency this year. Also funded are competitively awarded projects which couple research, education, and extension activities with focus on education, certification, and training of industry, retail personnel, and consumers. Integrated food safety projects also include emphasis in analysis of microbial contamination of fruits, vegetables, dairy, meat and poultry with subsequent information exchange through formal and informal educational settings.

Funded projects cover a wide variety of food safety issues; however, all maintain a scope of funding that relies on producing real-world answers to problems facing the food production, processing, distribution and regulatory communities as well as consumers. Priority areas align with CSREES mission and relevant goals, and demonstrate relevance to U.S. agriculture. Priorities are assessed annually to ensure food safety programs are able to respond to emerging issues. It is estimated that \$23 million of CSREES funds in fiscal year 2006, fiscal year 2007, and fiscal year 2008 support food safety research.

QUESTIONS SUBMITTED BY SENATOR ROBERT C. BYRD

NATURAL RESOURCES CONSERVATION SERVICE

Question. Could you please provide the committee with information regarding plans by the Department to close agency field offices across the country, including the possible reorganization of these offices within each State? The committee is aware that some States are currently operating with a deficit in funding and one of the options apparently being discussed to address these deficits is the reorganization of field offices in these states. I have been informed that NRCS in West Virginia, for example, could have a loss in workforce to address the deficit in our state. I have heard concerns from my constituents that a NRCS office in Hamlin, West Virginia, could be closed which will result in a loss of services to constituents in southern West Virginia.

Answer. In the face of constrained discretionary funding levels, NRCS has taken appropriate management steps to ensure that NRCS operates within its budget. As part of this effort, a central point of focus has been to ensure that there is the right number of offices in the right places. NRCS has not prescribed specific office moves or consolidation from Washington, DC. Instead, NRCS leadership believes that local agency staff, including the State Conservationist, know the State and local needs better than anyone. State Conservationists have to manage and work within a budget allocation each year. As a result, states are working with local partners, stakeholders, and constituents to develop plans that work to the betterment of each locale. Consistent with the Department's policy of keeping Congress informed of its activities, NRCS will notify Congress of office closures as appropriate.

RURAL DEVELOPMENT

Question. Could you please provide the committee with information regarding plans by the Department to close agency field offices across the country, including the possible reorganization of these offices within each State? The committee is aware that some states are currently operating with a deficit in funding and one of the options apparently being discussed to address these deficits is the reorganization of field offices in these states. I have heard concerns from my constituents that it is possible that Rural Development offices could be closed or reorganized in West Virginia which will result in a loss of services to my constituents.

Answer. The Rural Development State Directors have developed their reorganization plans for National Office consideration. While some employees will be working at a different office location, we are making every effort to minimize the disruption to staff. Rural Development is not proposing a Reduction-in-Force and all employees will be offered a position at their current grade and pay level. We are also seeking Voluntary Early Retirement Authority which could be of interest to those employees who are several years short of being eligible for regular retirement.

Since the State plans are currently being reviewed, we do not know the number of offices to be closed or that will operate on a part-time basis. RD will keep the committee informed of its plans. It is RD's intent that the reorganization be completed by March, 2008.

Our intent is to train staff so that they are knowledgeable in all Rural Development programs in order to provide better customer. We anticipate no reduction in services and plan to continue to provide comprehensive access to our programs.

FARM SERVICE AGENCY

Question. Could you please provide the committee with information regarding plans by the Department to close agency field offices across the country, including the possible reorganization of these offices within each State? The committee is aware that some states are currently operating with a deficit in funding and one of the options apparently being discussed to address these deficits is the reorganization of field offices in these States. I have heard concerns from my constituents that it is possible that Farm Service Agency offices could be closed or reorganized in West Virginia which will result in a loss of services to my constituents.

Answer. As competition and accountability for limited resources continue to increase, we want to ensure we are still providing our customers with the efficient, accurate and timely service they deserve. Our FSA State Executive Directors (SEDs) are conducting independent, local-level reviews of the efficiency and effectiveness of the FSA office structure in their State. In each State, the SED and State Committee have formed a review committee to develop proposals for the optimum network of FSA facilities, staffing, training, and technology for their State within existing budgetary resources and staffing ceilings. FSA is committed to meeting the needs of farmers and ranchers in the 21st century, and our hope is to wisely invest in our employees, technology and equipment.

There is no comprehensive national plan or formula for identifying the optimum network of FSA offices. Each State will submit recommendations to FSA's Deputy Administrator for Field Operations for review. If a State's plan proposes office closures or consolidations, we will strictly and faithfully follow the congressional and public notification procedures as required and outlined in Public Law 110-5. If a State recommends that any of our offices be closed or consolidated, we will hold public meetings in that county with area farmers, ranchers, and stakeholders within 30 days of headquarters concurrence with the plan. We will notify Congress of the Agency's intent to close offices 120 days prior to closure.

QUESTION SUBMITTED BY SENATOR ARLEN SPECTER

COMMODITY SUPPLEMENTAL FOOD PROGRAM

Question. The Commodity Supplemental Food Program (CSFP) provides 6.4 million food packages to over 500,000 mothers, infants, children, and primarily low-income seniors—in fiscal year 2005, 15,575 households in PA received CSFP packages. CSFP food packages are delivered monthly, and provide \$20 worth of food including cheese, milk, and canned fruits and vegetables. In his fiscal year 2008 budget request, as in his fiscal year 2007 request, the President eliminated this program, stating that Food Stamps and the WIC program could meet the needs of CSFP recipients. Congress provided \$112 million in fiscal year 2006 and has maintained that level in the fiscal year 2007 Continuing Resolution. Seniors, who represent 90

percent of CSFP recipients, are not eligible for the WIC program, and many of these seniors are also not eligible for food stamps, or are only eligible to receive \$10 per month in food stamp benefits. Additionally, for seniors with disabilities, the CSFP program meets a vital need by bringing food directly to their homes. How does the Department plan to meet the needs of many of these seniors who depend on the CSFP program and who will not be eligible to receive any benefits, or will receive reduced benefits, from the Food Stamp program?

Answer. Elderly participants who are leaving the CSFP upon termination of its funding and who are not already receiving food stamp benefits would be eligible to receive a transitional benefit worth \$20 per month, ending in the first month following enrollment in the Food Stamp Program under normal program rules, or 6 months, whichever occurs first. Based on the information we have about the characteristics of all elderly food stamp participants, the average monthly food stamp benefit for an elderly person living alone was \$70 per month in 2005. The percentage of food stamp households with elderly that received the maximum benefit (14.1 percent) was nearly as large as the percentage that received the minimum benefit of \$10 (15.5 percent). Using information on the financial circumstances of low-income elderly, we estimate that CSFP participants transitioning to food stamps will receive an average monthly benefit of \$54 per person.

Elderly CSFP participants who are ineligible for food stamps will be treated no differently than anyone else living in similar circumstances who is currently unable to participate in the CSFP due to its limited availability. Former CSFP participants will have access to the Emergency Food Assistance Program and other government and private non-profit programs that offer community-based food assistance opportunities.

Included in these programs are Federal nutrition assistance programs targeted specifically to seniors. These programs, administered by the Administration on Aging and authorized by the Older Americans Act of 1965, include congregate nutrition services and home-delivered nutrition services. The Administration's 2008 budget request includes \$383 million and \$181 million for these two programs, respectively. In addition, the 2008 budget request includes \$147 million for the Nutrition Services Incentive Program. Combined, the Older Americans Nutrition Programs serve about 250 million congregate and in-home meals to about 2.6 million older adults annually.

FSIS IT INFRASTRUCTURE

Question. It is my understanding that USDA's Food Safety and Inspection Service is initiating a major change in its inspection program in order to allocate Agency resources according to risk. In order to determine risk on an ongoing basis, the Agency will need to analyze a significant amount of data from a wide variety of diverse sources. Please detail the level of funding for information technology infrastructure for FSIS for fiscal year 2008 and compare this funding to 1) previous funding for information technology for FSIS for the past 3 fiscal years, and 2) information technology infrastructure funding for other agencies in the Department.

Answer. A chart detailing the funding for information technology infrastructure for USDA by mission area, for the previous 3 fiscal years, is provided for the record. [The information follows:]

INFORMATION TECHNOLOGY INVESTMENTS BY AGENCY

[Dollars in Millions]

Agency	Fiscal Year			
	2002 Actual	2006 Actual	2007 Estimate	2008 Budget
Farm and Foreign Agricultural Services:				
Foreign Agricultural Service	\$23.3	\$23.1	\$29.9	\$26.2
Farm Service Agency	237.6	263.6	270.4	303.0
Risk Management Agency	17.6	20.4	21.7	30.7
Subtotal, FFAS	278.5	307.2	322.0	359.9
Food Nutrition and Consumer Services: Food and Nutrition Service	52.2	593.8	605.3	641.2
Food Safety: Food Safety and Inspection Service	39.6	43.4	40.2	38.2
Natural Resources and Environment:				
Natural Resources Conservation Service	71.8	102.3	104.4	71.6

INFORMATION TECHNOLOGY INVESTMENTS BY AGENCY—Continued

[Dollars in Millions]

Agency	Fiscal Year			
	2002 Actual	2006 Actual	2007 Estimate	2008 Budget
Forest Service	411.2	396.7	410.0	407.1
Subtotal, NRE	483.0	499.0	514.3	478.7
Research, Education and Economics:				
Agricultural Research Service	37.4	52.2	59.1	39.3
Cooperative State Research, Education & Extension Service	10.0	9.7	10.8	10.8
Economic Research Service	7.1	7.3	6.1	6.3
National Agricultural Statistics Service	23.5	24.1	24.3	24.8
Subtotal, REE	78.0	93.2	100.3	81.3
Rural Development: Rural Development	108.5	119.9	137.5	138.1
Marketing and Regulatory Programs:				
Agricultural Marketing Service	18.1	35.8	35.2	48.3
Animal and Plant Health Inspection Service	75.1	81.7	73.7	76.2
Grain Inspection, Packers & Stockyards Administration	6.9	12.6	12.3	10.7
Subtotal, MRP	100.0	130.0	121.2	135.2
Office of the Chief Financial Officer: Office of the Chief Financial Officer	83.4	99.5	188.7	118.8
Office of the Chief Information Officer:				
Office of the Chief Information Officer	145.0	62.2	54.0	30.2
Common Computing Environment	179.9	128.3	217.8	(/1/)
Subtotal, OCIO	324.9	190.4	271.8	30.2
Staff Offices	45.7	44.7	56.5	69.7
Total, Information Technology Investments	1,593.9	2,121.0	357.9	2,091.3

¹ Fiscal year 2008 President's Budget includes funding for CCE in FSA, RD, and NRCS.

Question. Is the current level of funding sufficient for FSIS' data analysis needs for the Agency's new risk-based inspection initiative?

Answer. The Food Safety and Inspection Service's fiscal year 2008 budget request includes sufficient funding for hardware and software application needs, which includes the agency's needs for risk-based inspection in processing.

QUESTIONS SUBMITTED BY SENATOR CHRISTOPHER S. BOND

LOAN PROGRAM DELINQUENCY RATES

Question. For the geopolitical districts (States, Congressional districts) involved in each Federally declared disaster during the past 5 years, please provide a table showing the delinquency rates of participants in all USDA loan programs for each of the past 5 years.

Please clearly indicate in which of the past 5 years the disaster affecting that district was declared and what the nature of the disaster was.

Answer. I have asked my staff to prepare the available data.

[The information follows:]

EMERGENCY DISASTER DESIGNATIONS APPROVED/PROCESSED BY EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH, PECD
 [Final totals for fiscal year 2002]

State Abbrev	Name	PRE-Primary	PRE-Contiguous	ADM-Primary	ADM-Contiguous	SEC-Primary	SEC-Contiguous	PRE	ADM	SEC
AL	Alabama	19	35				7	54		7
AK	Alaska	6	15					21		21
AZ	Arizona	4	11			20	10	15		30
AR	Arkansas	20	69	9	29	6	26	89	38	32
CA	California		1			10	49	1		59
CO	Colorado	59	9			62	61	68		123
CT	Connecticut						10			10
DE	Delaware						1			1
FL	Florida	4	3					7		
GA	Georgia		5	2	10	25	86	5	12	111
HI	Hawaii			1					1	
ID	Idaho					10	47			57
IL	Illinois	106	129				9	235		9
IN	Indiana	72	112	5	22	6	34	184	27	40
IA	Iowa	21	26			8	29	47		37
KS	Kansas	35	40		6	75	135	75	6	210
KY	Kentucky	86	157		2		19	243	2	19
LA	Louisiana	15	15		2	32	26	30	2	58
ME	Maine			1		27	5		1	32
MD	Maryland	3	7	1			8	10	1	8
MA	Massachusetts						12			19
MI	Michigan	7	14		1	107	59	21	1	166
MN	Minnesota	26	70			15	36	96		51
MS	Mississippi	21	38	6	15	21	43	59	21	64
MO	Missouri	142	283		1	14	51	425	1	65
MT	Montana	5	10			56	24	15		80
NE	Nebraska	1	5	9	35	104	125	6	44	229
NV	Nevada					1	15			16
NH	New Hampshire		2				11	2		11
NJ	New Jersey									
NM	New Mexico		10			38	24	10		62
NY	New York	56	15	1	4	54	106	71	5	160
NC	North Carolina		8			60	53	8		113
ND	North Dakota	10	35			83	39	45		122
OH	Ohio		10		2	43	95	10	2	138

EMERGENCY DISASTER DESIGNATIONS APPROVED/PROCESSED BY EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH, PECD—Continued
[Final totals for fiscal year 2002]

State Abbrev	Name	PRE-Primary	PRE-Contiguous	ADM-Primary	ADM-Contiguous	SEC-Primary	SEC-Contiguous	PRE	ADM	SEC
OK	Oklahoma	48	37	1	4	105	28	85	5	133
OR	Oregon	5	9			7	26	14		33
PA	Pennsylvania		7			46	36	7		82
RI	Rhode Island						4			4
SC	South Carolina					46	11			57
SD	South Dakota		1			55	54	1		109
TN	Tennessee	36	72	7	20	27	77	108	27	104
TX	Texas	67	215	6	34	282	300	282	40	369
UT	Utah		7			53	11	7		64
VT	Vermont	4	15			11	16	19		27
VA	Virginia	25	86			14	80	111		94
WA	Washington			1	6	17	43		7	60
WV	West Virginia	11	41				7	52		7
WI	Wisconsin	27	51	9	34		6	78	43	6
WY	Wyoming		4			29	41	4		70
TOTALS		941	1,679	59	227	1,363	1,995	2,620	286	3,358
TOTALS					6,264					

PRE=Presidential, ADM=FSA Administrator, SEC=Secretarial.

EMERGENCY DISASTER DESIGNATIONS APPROVED/PROCESSED BY EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH, PECD
[Preliminary totals for fiscal year 2003]

State Abbrev	Name	PRE-Primary	PRE-Contiguous	ADM-Primary	ADM-Contiguous	SEC-Primary	SEC-Contiguous	PRE	ADM	SEC
AL	Alabama	69	68		4	67	49	137	4	116
AK	Alaska	11	18					29		
AZ	Arizona	1	6			16	9	7		25
AR	Arkansas	41	75	28	72	93	48	116	100	141
CA	California					52	74			126
CO	Colorado	29	28		3	6	26	57	3	32
CT	Connecticut	8	7		8	8	13	15	8	21
DE	Delaware	7	8		1	3	7	15	1	10

FL	Florida	10	20	2	12	23	30	2	35
GA	Georgia	32	13	270	67	32	17	337
HI	Hawaii	1	1
ID	Idaho	46	4	24	35	59
IL	Illinois	16	87	65	66	62	4	131
IN	Indiana	67	74	51	154	125
IA	Iowa	4	2	21	34	4	13	55
KS	Kansas	15	50	63	66	65	5	129
KY	Kentucky	119	157	120	61	276	6	181
LA	Louisiana	86	118	2	63	51	204	13	114
ME	Maine	12	11	16	2	23	18
MD	Maryland	44	52	21	12	96	33
MA	Massachusetts	14	14	10	12	12	28	13	24
MI	Michigan	14	14	2	33	25	28	13	58
MN	Minnesota	10	6	22	41	28
MS	Mississippi	57	114	82	50	171	6	132
MO	Missouri	75	73	29	59	148	9	88
MT	Montana	2	3	5
NE	Nebraska	19	52	21	53	17	71	83	70
NV	Nevada	34	6	40
NH	New Hampshire	7	15	10	22	3	10
NY	New York	26	22	8	19	20	48	20	39
NM	New Mexico	3	17	3	17
NC	North Carolina	133	95	9	81	82	228	48	163
ND	North Dakota	76	76	1	44	79	152	6	123
OH	Ohio	1	6	7
OK	Oklahoma	76	181	21	158	24	257	49	182
OR	Oregon	41	77	1	75	47	118	6	122
PA	Pennsylvania	14	38	52
RI	Rhode Island	50	111	59	49	161	6	108
SC	South Carolina	2	6	5	8	3	5
SD	South Dakota	6	15	46	25	21	71
TN	Tennessee	5	8	31	5	27	39
TX	Texas	120	179	3	108	149	299	12	257
UT	Utah	91	212	1	163	222	303	10	385
VT	Vermont	29	8	37
VA	Virginia	4	16	6	20	20	2	26
WA	Washington	139	166	15	105	144	305	63	249
WV	West Virginia	34	86	120
		79	119	51	54	198	12	105

EMERGENCY DISASTER DESIGNATIONS APPROVED/PROCESSED BY EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH, PECD—Continued
[Preliminary totals for fiscal year 2003]

State Abbrev	Name	PRE-Primary	PRE-Contiguous	ADM-Primary	ADM-Contiguous	SEC-Primary	SEC-Contiguous	PRE	ADM	SEC
WI	Wisconsin			4	16	41	35		20	76
WY	Wyoming		3			7	11	3		18
TOTALS		1,565	2,361	151	477	2,309	2,029	3,926	628	4,338
GRAND TOTAL					8,892					

PRE=Presidential, ADM=FSA Administrator, SEC=Secretarial.

EMERGENCY DISASTER DESIGNATIONS APPROVED/PROCESSED BY EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH, PECD
[Preliminary totals for fiscal year 2004]

State Abbrev	Name	PRE-Primary	PRE-Contiguous	ADM-Primary	ADM-Contiguous	SEC-Primary	SEC-Contiguous	PRE	ADM	SEC
AL	Alabama	67	44					111		5
AK	Alaska									
AZ	Arizona		2				9	2		9
AR	Arkansas	28	35	14	29	55	83	63	43	138
CA	California	8	18			40	181	26		221
CO	Colorado		2		2	49	71	2	2	120
CT	Connecticut	7	8			8	9	15		17
DE	Delaware		2				3	2		3
FL	Florida	174	117				9	291		9
GA	Georgia	124	157			87	37	281		124
HI	Hawaii			3		7	2		3	9
ID	Idaho									
IL	Illinois	4	7			33	63	7		96
IN	Indiana	89	40		5	42	53	44	5	95
IA	Iowa	77	104			30	34	193		64
KS	Kansas	31	83		9	72	74	160	9	146
KY	Kentucky	105	77			129	103	108	2	232
LA	Louisiana	17	92	1	6		23	197	7	23
ME	Maine	25	30	1	6	49	38	47	7	87
MD	Maryland		23			4	9	48		13
MA	Massachusetts	17	15					11		
						10	13	32		23

MI	Michigan	23	31	1	5	126	90	54	6	216
MN	Minnesota	15	5	25	65	59	15	30	124
MS	Mississippi	23	35	3	10	11	58	13	11
MO	Missouri	37	43	5	78	81	80	5	159
MT	Montana	4	46	45	4	91
NE	Nebraska	39	61	17	50	61	99	100	67	160
NV	Nevada	1	7	17	13	8	30
NH	New Hampshire	8	15	6	23	6
NU	New Jersey	2	12	3	14	19
NM	New Mexico	16	20	52
NY	New York	18	62	7	20	32	101	80	27	156
NC	North Carolina	86	79	1	55	29	165	1	35
ND	North Dakota	27	32	4	82	44	59	4	126
OH	Ohio	72	130	46	77	202	123
OK	Oklahoma	7	1	34	7	1	34
OR	Oregon	30	10	12	44	40	56
PA	Pennsylvania	70	102	2	14	1	19	172	16	20
RI	Rhode Island	7	6	7	6
SC	South Carolina	22	57	8	20	79	28
SD	South Dakota	9	21	6	74	70	30	6	144
TN	Tennessee	35	12	32	35	44
TX	Texas	5	6	41	82	432	5	47	514
UT	Utah	20	30	50
VT	Vermont	7	17	4	24	4
VA	Virginia	22	64	2	6	9	50	86	8	59
WA	Washington	15	18	29	45	33	74
WV	West Virginia	84	124	2	4	208	2	4
WI	Wisconsin	44	44	39	161	59	38	88	200	97
WY	Wyoming	2	14	37	2	51
TOTALS	1,412	1,904	101	412	1,565	2,362	3,316	513	3,927
GRAND TOTAL	7,756								

PRE=Presidential, ADM=FSA Administrator, SEC=Secretarial.

EMERGENCY DISASTER DESIGNATIONS APPROVED/PROCESSED BY EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH, PECD
[Final totals for fiscal year 2005]

State Abbrev	Name	PRE-Primary	PRE-Contiguous	ADM-Primary	ADM-Contiguous	SEC-Primary	SEC-Contiguous	PRE	ADM	SEC
AL	Alabama	53	95	10	21	148	10	21
AK	Alaska	3	5	8
AZ	Arizona	15	18	3	6	3	33	9	3
AR	Arkansas	0	6	2	40	56	6	2	96
CA	California	15	18	1	5	49	146	33	6	195
CO	Colorado	0	5	5	23	5	28
CT	Connecticut	0	4	4	9	4	13
DE	Delaware	1	2	3
FL	Florida	30	62	1	4	92	1	4
GA	Georgia	0	27	22	77	32	49	27	99	81
HI	Hawaii	1	4	1	4
ID	Idaho	1	6	11	37	7	48
IL	Illinois	16	24	93	27	40	120
IN	Indiana	136	45	20	16	24	181	36	24
IA	Iowa	0	6	1	16	27	6	1	43
KS	Kansas	41	35	3	19	101	76	3	120
KY	Kentucky	30	82	10	24	112	10	24
LA	Louisiana	54	83	1	6	20	137	7	20
ME	Maine	13	11	2	6	24	8
MD	Maryland	0	2	2
MA	Massachusetts	0	3	3	5	2	8	3	8	10
MI	Michigan	0	3	27	25	94	41	3	52	135
MN	Minnesota	7	19	65	82	26	147
MS	Mississippi	74	70	11	44	69	49	144	55	118
MO	Missouri	0	13	1	112	20	13	1	132
MT	Montana	0	1	43	49	1	92
NE	Nebraska	11	26	12	32	30	54	37	44	84
NV	Nevada	2	12	3	19	13	14	3	32
NH	New Hampshire	0	5	2	5	2
NJ	New Jersey	14	30	4	11	44	15
NM	New Mexico	0	10	1	14	10	15
NY	New York	48	113	7	23	65	105	161	30	170
NC	North Carolina	0	26	7	26	7
ND	North Dakota	26	49	14	23	75	37
OH	Ohio	79	59	6	24	108	82	138	30	190

EMERGENCY DISASTER DESIGNATIONS APPROVED/PROCESSED BY THE DISASTER ASSISTANCE BRANCH/EMERGENCIES SECTION (DAB/ES), PECO—
Continued

[Final totals for fiscal year 2006]

State Abbrev	Name	PRE-Primary	PRE-Contiguous	ADM-Primary	ADM-Contiguous	SEC-Primary	SEC-Contiguous	PRE	ADM	SEC
IN	Indiana	2	5	5	15	24	47	7	20	71
IA	Iowa		2	2	12	24	68	2	14	92
KS	Kansas	24	48			12	109	72		121
KY	Kentucky	2	32			23	43	25		152
LA	Louisiana	8	32			40	41	40		81
ME	Maine	1	4				2	5		2
MD	Maryland	3	24				6	27		6
MA	Massachusetts	12	17	1	3	13	27	29	4	40
MI	Michigan		2			74	79	2		153
MN	Minnesota	18	40	1	6	36	37	58	7	73
MS	Mississippi		4			166	28	4		194
MO	Missouri	48	155		12		17	203	12	17
MT	Montana		7	4	18	3	25	7	22	28
NE	Nebraska	29	35			98	136	64		234
NV	Nevada	6	16				13	22		13
NH	New Hampshire	13	20			10	7	33		17
NJ	New Jersey	3	15			36	12	18		48
NM	New Mexico	15	34			31	31	49		62
NY	New York	21	59	3	18	93	267	80	21	360
NC	North Carolina	10	22				33	32		33
ND	North Dakota	35	50		4	90	38	85	4	128
OH	Ohio	9	24				19	33		19
OK	Oklahoma	29	73	1	11	154	55	102	12	209
OR	Oregon	20	26			10	61	46		71
PA	Pennsylvania	28	96			23	60	124		83
RI	Rhode Island		6			5	12	6		17
SC	South Carolina	7	7		4		18	14	4	18
SD	South Dakota	32	44	3	13	94	156	76	16	250
TN	Tennessee	15	51	2	15	42	153	66	17	195
TX	Texas	33	123	2	9	342	1,252	156	11	1,594
UT	Utah		1				12	1		13
VT	Vermont		12			14	25	12		39
VA	Virginia	37	68			51	142	105		193

WA	Washington	11	13	28	42	24	70
WV	West Virginia	5	29	30	5	59
WI	Wisconsin	3	12	46	98	15	144
WY	Wyoming	1	14	1	14
TOTALS	565	1,359	60	267	2,301	3,861	1,924	327	6,162
GRAND TOTAL	8,413								

PRE=Presidential, ADM=FSA Administrator, SEC=Secretarial.

This data represents the dollar delinquency rate for all geographic counties, whether or not there was any loan activity in those counties. Data is as of December 31 in order to correspond to calendar year Presidential and Secretarial disaster declarations. For the year of the disaster declaration, primary counties are highlighted in red and contiguous counties in yellow. This data represents a snapshot on a particular day. In some instances, the delinquencies identified may be resolved within days as producers sell their crop and apply the proceeds to their loans

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
ALABAMA	AUTAUGA				.01	.08
ALABAMA	BALDWIN		.36	2.89	3.02	.99
ALABAMA	BARBOUR				1.47	.04
ALABAMA	BIBB					13.38
ALABAMA	BLOUNT	2.55	1.47	1.65	1.15	9.29
ALABAMA	BULLOCK					12.85
ALABAMA	BUTLER		.76	5.90	3.25	.70
ALABAMA	CALHOUN				1.34	
ALABAMA	CHAMBERS			1.17	.92	
ALABAMA	CHEROKEE	.12	2.29	.84		1.04
ALABAMA	CHILTON			2.30	1.98	16.72
ALABAMA	CHOCTAW	100.00	62.66	33.12	25.45	8.34
ALABAMA	CLARKE					
ALABAMA	CLAY	.77	.98	2.99		
ALABAMA	CLEBURNE	36.33	4.77	7.68	4.76	2.88
ALABAMA	COFFEE		.68	1.35	.33	.27
ALABAMA	COLBERT	.28			3.50	2.42
ALABAMA	CONECUH	4.33	3.79	1.14	5.13	
ALABAMA	COOSA					
ALABAMA	COVINGTON				.29	
ALABAMA	CRENSHAW					
ALABAMA	CULLMAN		8.60	4.18	1.99	1.72
ALABAMA	DALE		2.96			
ALABAMA	DALLAS	1.01	1.05	4.01	.62	.65
ALABAMA	DE KALB	7.15	2.33	5.49	3.86	2.80
ALABAMA	ELMORE		10.38	1.49	1.20	.64
ALABAMA	ESCAMBIA	1.72	.38		4.17	4.00
ALABAMA	ETOWAH	2.22	2.18	.93	14.89	7.83
ALABAMA	FAYETTE				3.08	3.75
ALABAMA	FRANKLIN	1.01	.92	.84	.94	1.18
ALABAMA	GENEVA	2.81	4.15	3.73	3.77	3.58
ALABAMA	GREENE	1.86	.94	1.28	1.89	5.83
ALABAMA	HALE	7.16	15.01	7.92	6.29	.73
ALABAMA	HENRY			2.58	4.29	1.61
ALABAMA	HOUSTON		7.73	5.22	4.10	2.63

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELQ RATE 12/31/06	DELQ RATE 12/31/05	DELQ RATE 12/31/04	DELQ RATE 12/31/03	DELQ RATE 12/31/02
ALABAMA	JACKSON	5.22	7.37	9.79	8.19	5.49
ALABAMA	JEFFERSON			10.86		
ALABAMA	LAMAR				3.30	2.91
ALABAMA	LAUDERDALE	1.25	.81	12.12	11.75	8.91
ALABAMA	LAWRENCE	11.42	9.59	7.31	5.25	4.20
ALABAMA	LEE			15.54		
ALABAMA	LIMESTONE	2.51	1.05	.66	2.30	.10
ALABAMA	LOWNDES	15.00	17.36	16.71	14.30	14.66
ALABAMA	MACON	4.93		8.92		
ALABAMA	MADISON	2.39	.65	1.40	2.13	.17
ALABAMA	MARENGO	3.21	3.78	2.87	1.73	1.57
ALABAMA	MARION			5.36		.57
ALABAMA	MARSHALL	.02	.97	2.42	.03	8.02
ALABAMA	MOBILE		1.32		14.97	
ALABAMA	MONROE	1.49	1.39	2.23	1.49	1.13
ALABAMA	MONTGOMERY	.13	.20	2.30		4.37
ALABAMA	MORGAN					.29
ALABAMA	PERRY	11.51	10.92	3.92	5.46	1.29
ALABAMA	PICKENS	3.79	3.76	1.60	1.93	.59
ALABAMA	PIKE					18.73
ALABAMA	RANDOLPH	.28	.12	.33	.07	
ALABAMA	RUSSELL					
ALABAMA	SHELBY				8.48	6.54
ALABAMA	ST. CLAIR					
ALABAMA	SUMTER	10.43	4.20	4.93	8.01	8.21
ALABAMA	TALLADEGA	1.83				2.14
ALABAMA	TALAPPOOSA		2.24			2.44
ALABAMA	TUSCALOOSA	1.08	.62	3.82	.18	
ALABAMA	WALKER					
ALABAMA	WASHINGTON					
ALABAMA	WILCOX	2.12		1.93	.31	3.16
ALABAMA	WINSTON			.27	1.79	1.76
ALASKA	ALEUTIANS E BOROUGH					
ALASKA	ALEUTIANS W CENSUS A					
ALASKA	ANCHORAGE BOROUGH					

ALASKA	BETHEL CENSUS AREA
ALASKA	BRISTOL BAY BOROUGH
ALASKA	DENALI BOROUGH
ALASKA	DILLINGHAM CENSUS A
ALASKA	FAIRBANKS NORTH STAR	11.75	10.74	8.53	11.32	5.82
ALASKA	HAINES BOROUGH
ALASKA	JUNEAU17	1.33	1.40	8.95	5.50
ALASKA	KENAI PENINSULA	4.12	15.99
ALASKA	KETCHIKAN GATEWAY
ALASKA	KODIAK ISL. BOROUGH
ALASKA	LAKE & PENINSULA
ALASKA	MATANUSKA-SUSITNA	14.53	10.61	7.19	4.15	3.89
ALASKA	NOME CENSUS AREA
ALASKA	NORTH SLOPE BOROUGH
ALASKA	NORTHWEST ARCTIC
ALASKA	PRINCE OF WALES
ALASKA	SITKA BOROUGH
ALASKA	SKAGWAY-YAKUTAT-ANGO
ALASKA	SOUTHEAST FAIRBANKS
ALASKA	VALDEZ-CORDOVA
ALASKA	WADE-HAMPTON
ALASKA	WRANGELL-PETERSBURG
ALASKA	YAKUTAT
ALASKA	YUKON-KOYUKUK
ARIZONA	APACHE S	38.25	32.21	23.82	10.62	8.74
ARIZONA	COCHISE	19.73	20.85	20.15	14.46	22.17
ARIZONA	COCONINO	11.99	10.45	15.54
ARIZONA	GILA	86.80	72.30	63.01	44.74
ARIZONA	GRAHAM	18.78	8.77	5.11	33.36	31.82
ARIZONA	GREENLEE	19.31
ARIZONA	LA PAZ	4.61	19.71
ARIZONA	MARICOPA	21.63	48.43	39.07	66.94	62.73
ARIZONA	MOHAVE	9.17	1.49	9.28	8.05	9.44
ARIZONA	NAVAJO S	70.65	32.30	80.77	76.52	58.92
ARIZONA	PIMA	54.40	100.00	47.09	43.44	45.98
ARIZONA	PINAL	24.87	23.21	3.46	19.13	13.15
ARIZONA	SANTA CRUZ
ARIZONA	YAVAPAI	80.69	78.00	76.27	71.46
ARIZONA	YUMA	13	11.30
ARIZONA
ARKANSAS	ARKANSAS	6.38	8.46	5.92	7.33	8.45

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
ARKANSAS	ASHLEY	15.50	26.88	22.61	30.67	32.25
ARKANSAS	BAXTER	.04	.03	.18	.07
ARKANSAS	BENTON	5.16	9.05	6.22	4.90	8.93
ARKANSAS	BOONE10	.01	.03
ARKANSAS	BRADLEY	44.57	44.07	48.42	51.24	39.29
ARKANSAS	CALHOUN	57.07	53.37	46.60	38.11	23.28
ARKANSAS	CARROLL	1.74	1.67	1.52	.96	.50
ARKANSAS	CHICOT	30.48	25.83	24.66	20.40	26.57
ARKANSAS	CLARK	.14	15.56	14.32	1.39	3.03
ARKANSAS	CLAY	.57	7.53	2.66	3.22	.04
ARKANSAS	CLEBURNE	1.50	.83	.88	1.12	1.88
ARKANSAS	CLEVELAND
ARKANSAS	COLUMBIA	25.19	20.54
ARKANSAS	CONWAY	3.72	4.01	4.60	3.33	3.10
ARKANSAS	CRAIGHEAD	2.18	3.06	.88	6.90	4.34
ARKANSAS	CRAWFORD	2.36	.76	3.86	2.48	2.53
ARKANSAS	CRITTENDEN	25.94	35.00	37.17	30.91	31.61
ARKANSAS	CROSS	22.11	10.77	20.66	11.07	9.75
ARKANSAS	DALLAS	9.0938	6.19
ARKANSAS	DESHA	4.25	2.69	5.72	7.53	4.99
ARKANSAS	DREW	19.45	4.28	2.29	14.55	10.97
ARKANSAS	FAULKNER	26.65	20.50	14.94	1.10	4.57
ARKANSAS	FRANKLIN	.85	.76	.37	2.40	2.24
ARKANSAS	FULTON	4.65	1.70	2.57	1.38	1.41
ARKANSAS	GARLAND	19.4725
ARKANSAS	GRANT	6.00	57.29	57.50	59.97
ARKANSAS	GREENE18	3.20	9.74	16.34
ARKANSAS	HEMPSTEAD	.42	2.88	4.13	2.72	1.18
ARKANSAS	HOT SPRING	2.4521	.04
ARKANSAS	HOWARD	21.67	21.65	18.48	15.12	13.28
ARKANSAS	INDEPENDENCE	4.49	3.47	4.46	1.74	2.08
ARKANSAS	IZARD	.78	1.12	.89	8.44	7.17
ARKANSAS	JACKSON	8.03	5.39	4.12	12.11	18.23
ARKANSAS	JEFFERSON	17.66	17.57	18.59	20.55	15.71
ARKANSAS	JOHNSON	.73	.33	.34	.21	.22

ARKANSAS	LAFAYETTE	7.14	6.68	8.55	10.98	8.83
ARKANSAS	LAWRENCE27	.2502	13.38
ARKANSAS	LEE	21.15	21.84	20.10	24.83	25.61
ARKANSAS	LINCOLN	44.89	44.62	33.82	25.54	20.05
ARKANSAS	LITTLE RIVER	5.63	15.13	21.42	19.06	15.89
ARKANSAS	LOGAN	8.47	5.33	5.11	.29	1.15
ARKANSAS	LONKE	8.93	7.39	5.63	4.52	5.72
ARKANSAS	MADISON14	.13	5.67	13.10	10.00
ARKANSAS	MARION	10.70	11.33	9.53
ARKANSAS	MILLER	3.55	1.89	5.62	3.94	3.58
ARKANSAS	MISSISSIPPI	2.31	2.45	4.66	3.31	5.75
ARKANSAS	MONROE	12.17	11.97	20.02	22.42	29.36
ARKANSAS	MONTGOMERY	8.29	6.87	6.85	5.95	2.79
ARKANSAS	NEVADA	23.13	24.92	19.65	17.26	17.57
ARKANSAS	NEWTON
ARKANSAS	OUACHITA	1.26	41.07	19.28	10.29	5.70
ARKANSAS	PERRY93
ARKANSAS	PHILLIPS	36.77	35.21	33.13	34.06	33.43
ARKANSAS	PKE	1.71	12.05	11.79	6.83	12.35
ARKANSAS	POINSETT	2.14	3.80	7.08	10.69	10.39
ARKANSAS	POLK	2.38	1.79	1.26	.64	2.02
ARKANSAS	POPE	5.60	4.28	2.38	.69	.32
ARKANSAS	PRAIRIE	11.70	10.77	6.50	5.63	2.71
ARKANSAS	PULASKI	1.91	1.79	1.54	3.08	19.15
ARKANSAS	RANDOLPH	6.76	8.20	7.49	4.69	3.96
ARKANSAS	SALINE	5.45	2.74
ARKANSAS	SCOTT	2.38	1.68	.05
ARKANSAS	SEARCY	3.40	2.42	2.58	4.63	.22
ARKANSAS	SEBASTIAN	2.04	1.19	.24
ARKANSAS	SEVER	2.82	1.94	4.65	4.53	3.72
ARKANSAS	SHARP11	.87	1.43	1.45	1.39
ARKANSAS	ST. FRANCIS	15.12	5.17	5.64	5.14	5.17
ARKANSAS	STONE80	.60	1.78	1.56	.40
ARKANSAS	UNION	18.71	12.14	9.31	8.02	6.78
ARKANSAS	VAN BUREN	2.48	8.03	6.57	6.09	5.76
ARKANSAS	WASHINGTON	3.63	2.05	1.07	1.12	9.48
ARKANSAS	WHITE	4.47	4.63	7.18	9.68	9.84
ARKANSAS	WOODRUFF	21.91	21.26	21.96	18.11	17.66
ARKANSAS	YELL14	.16	.28	.11	.42
CALIFORNIA	ALAMEDA	12.00	53.62

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELQ RATE 12/31/06	DELQ RATE 12/31/05	DELQ RATE 12/31/04	DELQ RATE 12/31/03	DELQ RATE 12/31/02
CALIFORNIA	ALPINE	2.72	31	4.39
CALIFORNIA	AMADOR	2.63	18.08	12.49	17.14
CALIFORNIA	BUTTE	10.64	94.84	14.25	20.14
CALIFORNIA	CALAVERAS	63.73	4.66	4.29	5.74	6.96
CALIFORNIA	COLUSA	34.86	4.30
CALIFORNIA	CONTRA COSTA
CALIFORNIA	DEL NORTE	3.49	27	2.07	5.24
CALIFORNIA	EL DORADO	42.31	39.25	17.24	25.00
CALIFORNIA	FRESNO	17.78	15.64	28.52	26.82	24.26
CALIFORNIA	GLENN	3.77	5.26	8.07	9.15	7.96
CALIFORNIA	HUMBOLDT	5.93	6.53	13.11	21.56	35.17
CALIFORNIA	IMPERIAL	1.06	24.81	26.92	15.59
CALIFORNIA	INYO	60	91
CALIFORNIA	KERN	1.47	59.46	65.12	61.27	56.85
CALIFORNIA	KINGS12	11.20	7.33	4.63
CALIFORNIA	LAKE	8.81	6.83	15.08	22.35	29.56
CALIFORNIA	LASSEN	67.08	70.99	65.40	60.13	60.49
CALIFORNIA	LOS ANGELES	100.00	86.33
CALIFORNIA	MADERA	19.78	19.90	18.28	19.58	22.25
CALIFORNIA	MARIN	1.33	10.56	10.65	10.19	1.93
CALIFORNIA	MARIPOSA	4.80	41.10	37.81
CALIFORNIA	MENDOCINO	30.00	22.87	23.54	24.44	14.60
CALIFORNIA	MERCED	47.89	44.13	38.33	35.29	34.20
CALIFORNIA	MODOC	15.23	15.67	13.55	13.22	12.67
CALIFORNIA	MONO
CALIFORNIA	MONTEREY	17.58	10.66	8.86	23.70	25.28
CALIFORNIA	NAPA
CALIFORNIA	NEVADA	19.56	16.30	9.44	8.21
CALIFORNIA	ORANGE	88.96	77.59	18.78	17.18
CALIFORNIA	PLACER	7.03	15.72	19.99	23.63	21.49
CALIFORNIA	PLUMAS
CALIFORNIA	RIVERSIDE	6.20	2.32	3.89	21.51	54.80
CALIFORNIA	SACRAMENTO	37.68	32.57	23.28	21.42	12.25
CALIFORNIA	SAN BENITO	93.48	91.52	90.98	90.90	93.89
CALIFORNIA	SAN BERNARDINO	76.77	24.07	32.32	30.76	28.85

CALIFORNIA	SAN DIEGO	20.95	20.23	57.61	53.98	60.50
CALIFORNIA	SAN FRANCISCO					
CALIFORNIA	SAN JOAQUIN	12.16	13.75	18.73	18.16	20.46
CALIFORNIA	SAN LUIS OBISPO	45.47	42.65	29.58	27.78	25.90
CALIFORNIA	SAN MATEO					
CALIFORNIA	SANTA BARBARA	20.12	8.14	15.11		3.62
CALIFORNIA	SANTA CLARA	82.53	78.46	79.50	78.30	77.80
CALIFORNIA	SANTA CRUZ	7.83	13.98	9.94	9.32	7.10
CALIFORNIA	SHASTA			.70		.70
CALIFORNIA	SIERRA				.41	
CALIFORNIA	SISKIYOU	1.97	1.95	11.05	9.46	7.22
CALIFORNIA	SOLANO	6.57				1.64
CALIFORNIA	SONOMA	18.00	62.28	74.25	64.65	39.72
CALIFORNIA	STANISLAUS	2.20	2.66	6.76	6.08	5.67
CALIFORNIA	SUTTER	2.94	3.06	2.04	5.92	5.82
CALIFORNIA	TEHAMA	13.24	11.06	11.88	14.10	7.58
CALIFORNIA	TRINITY					
CALIFORNIA	TULARE	4.65	7.12	9.56	11.84	10.82
CALIFORNIA	TUOLUMNE					
CALIFORNIA	VENTURA	72.04	75.51	74.61	73.49	70.47
CALIFORNIA	YOLO	1.13	21	8.95	6.90	3.98
CALIFORNIA	YUBA	.45	.04	1.46	.77	2.28
COLORADO	ADAMS	4.76	6.91	11.81	3.56	3.57
COLORADO	ALAMOSA	1.75	2.68	3.68	9.87	6.29
COLORADO	ARAPAHOE	6.87	16.63	17.91	18.69	
COLORADO	ARCHULETA	4.05	1.60	2.45	1.05	.55
COLORADO	BACA	10.15	15.86	15.64	9.69	26.44
COLORADO	BENT	.32	19.41	23.31	14.88	11.26
COLORADO	BOULDER	3.87		1.43	7.54	
COLORADO	BROOMFIELD					
COLORADO	CHAFEE					
COLORADO	CHEYENNE					
COLORADO	CLEAR CREEK					
COLORADO	CONELOS	7.54	9.09	5.98	7.20	21.36
COLORADO	COSTILLA	3.35	3.33	2.12	1.07	7.88
COLORADO	CROWLEY					15.82
COLORADO	CUSTER					34.64
COLORADO	DELTA					
COLORADO	DENVER	99.61	99.81	100.00	3.88	
COLORADO	DOLORES		2.32	.26		

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
COLORADO	DOUGLAS	14.10	.80	2.25		
COLORADO	EAGLE					
COLORADO	EL PASO	18.70	15.84	12.11	9.83	12.27
COLORADO	ELBERT	.83	2.87	2.54	1.57	3.12
COLORADO	FREMONT					
COLORADO	GARFIELD					
COLORADO	GILPIN	9.61				
COLORADO	GRAND					
COLORADO	GUNNISON					
COLORADO	HINSDALE					
COLORADO	HUERFANO					
COLORADO	JACKSON					
COLORADO	JEFFERSON			15.04	7.82	8.57
COLORADO	KOWA	2.81	1.48			
COLORADO	KIT CARSON	.98	1.07	1.75		
COLORADO	LA PLATA	6.13	.31		.15	1.83
COLORADO	LAKE					
COLORADO	LARIMER				11.69	13.31
COLORADO	LAS ANIMAS	12.68	12.23	16.56	15.52	4.72
COLORADO	LINCOLN	1.43	.27	.49	.06	1.28
COLORADO	LOGAN	7.90	10.79	6.67	10.08	4.62
COLORADO	MESA	2.69		1.06	20.00	10.50
COLORADO	MINERAL					
COLORADO	MOFFAT					
COLORADO	MONTEZUMA	3.45	.89	.91	1.69	3.76
COLORADO	MONTEROSE				2.22	1.21
COLORADO	MORGAN	10.75	13.76	16.19	15.85	12.72
COLORADO	OTERO	3.49	.93	.94	37.90	39.62
COLORADO	OURAY					
COLORADO	PARK					.29
COLORADO	PHILLIPS					
COLORADO	PITKIN					
COLORADO	PROWERS					
COLORADO	PUEBLO	22.38	21.52	19.77	22.56	29.61
COLORADO	RIO BLANCO	.33			.01	5.74

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELQ RATE 12/31/06	DELQ RATE 12/31/05	DELQ RATE 12/31/04	DELQ RATE 12/31/03	DELQ RATE 12/31/02
FLORIDA	FRANKLIN					
FLORIDA	GADSDEN	25.89	.06			
FLORIDA	GILCHRIST					
FLORIDA	GLADES					
FLORIDA	GULF		.02			
FLORIDA	HAMILTON		2.61	22.96	24.19	30.87
FLORIDA	HARDEE			3.87	26.75	78.32
FLORIDA	HENDRY					100.00
FLORIDA	HERNANDO					
FLORIDA	HIGHLANDS	.50	8.05	.41	25.94	24.27
FLORIDA	HILLSBOROUGH	13.54	11.52	17.24	17.60	14.79
FLORIDA	HOLMES	.47	1.31	3.94	4.30	7.79
FLORIDA	INDIAN RIVER	8.04	6.59	7.15	32.98	21.50
FLORIDA	JACKSON	.40	.15	.95	16.95	45.45
FLORIDA	JEFFERSON				2.16	
FLORIDA	LAFAYETTE				.03	.03
FLORIDA	LAKE	2.34	.19	46.71	48.20	8.04
FLORIDA	LEE				30.00	34.64
FLORIDA	LEON		12.42			
FLORIDA	LEVY	6.22	6.20	4.54	1.84	2.12
FLORIDA	LIBERTY					
FLORIDA	MADISON	28.22	25.02	17.62	14.66	27.68
FLORIDA	MANATEE	10.77	9.21	67.33	31.69	18.33
FLORIDA	MARION		77.13	67.14	89.48	92.16
FLORIDA	MARTIN		7.94	15.46	6.03	
FLORIDA	MONROE					
FLORIDA	NASSAU			100.00	85.72	52.93
FLORIDA	OKALOOSA				9.41	8.85
FLORIDA	OKEECHOBEE	8.56	7.86	8.48	2.76	1.35
FLORIDA	ORANGE					
FLORIDA	OSCEOLA					
FLORIDA	PALM BEACH	45.43	38.52	44.41	38.49	31.62
FLORIDA	PASCO				51.76	48.64
FLORIDA	PINELLAS		14.34			
FLORIDA	POLK	9.55	15.82	15.42	15.47	10.72

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
GEORGIA	CHATTOOGA	1.14	6.12	14.44	5.96	6.46
GEORGIA	CHEROKEE	21.68				
GEORGIA	CLARKE					11.21
GEORGIA	CLAY	100.00	25.14	14.24	22.93	
GEORGIA	CLAYTON				100.00	
GEORGIA	CLINCH					
GEORGIA	COBB					
GEORGIA	COFFEE	15.54	12.15	8.45	6.68	5.46
GEORGIA	COLQUITT	16.99	10.43	17.56	13.89	22.68
GEORGIA	COLUMBIA			5.97	45	
GEORGIA	COOK	10.93	6.37	6.97	5.96	10.60
GEORGIA	COWETA					
GEORGIA	CRAWFORD					
GEORGIA	CRISP	2.38	3.56	1.82	.87	
GEORGIA	DADE					
GEORGIA	DAWSON					
GEORGIA	DECATUR	11.88	16.67	12.67	28.27	19.58
GEORGIA	DEKALB					
GEORGIA	DODGE					
GEORGIA	DOOLY	1.11	.72	4.03	5.44	3.53
GEORGIA	DOUGHERTY			45.24	28.54	
GEORGIA	DOUGLAS					
GEORGIA	EARLY	7.21	.06	.37		
GEORGIA	ECHOLS	6.03	2.84	11.93	9.51	
GEORGIA	EFFINGHAM			26.70	24.03	
GEORGIA	ELBERT				.03	5.38
GEORGIA	EMANUEL			.94	.79	.42
GEORGIA	EVANS			53.79	4.56	
GEORGIA	FANNIN		12.89	10.23	1.91	
GEORGIA	FAYETTE					
GEORGIA	FLOYD	3.62	3.27		8.99	3.27
GEORGIA	FORSYTH					
GEORGIA	FRANKLIN			.33	9.65	5.86
GEORGIA	FULTON	98.52	98.87	99.15	99.35	99.52
GEORGIA	GILMER	.63	.24	3.23	8.21	3.55

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
GEORGIA	MONROE		39.77	1.88		
GEORGIA	MONTGOMERY			.60	8.51	4.25
GEORGIA	MORGAN				.21	16.05
GEORGIA	MURRAY					
GEORGIA	MUSCOGEE					
GEORGIA	NEWTON			4.38		
GEORGIA	OCONEE	1.46	1.42	1.84	1.37	3.97
GEORGIA	OGLETHORPE				3.99	1.39
GEORGIA	PAULDING					
GEORGIA	PEACH			12.08	13.97	15.25
GEORGIA	PICKENS	53.92	64.55	61.68	46.72	44.07
GEORGIA	PIERCE	10.71	18.52	16.41	18.53	24.41
GEORGIA	PIKE	52.89	46.56	39.13	35.93	29.41
GEORGIA	POLK		33.01	24.02	24.27	15.33
GEORGIA	PULASKI	.87	2.81	7.25	6.21	8.12
GEORGIA	PUTNAM	7.54	5.69	3.44	3.77	10.80
GEORGIA	QUITMAN					
GEORGIA	RABUN		3.07	2.82		
GEORGIA	RANDOLPH	3.96				
GEORGIA	RICHMOND					
GEORGIA	ROCKDALE					100.00
GEORGIA	SCHLEY	42.67	64.10	46.02	39.05	32.36
GEORGIA	SCREVEN	9.25	15.38	14.77	14.02	9.09
GEORGIA	SEMINOLE	6.30	4.79	7.89	39.12	55.39
GEORGIA	SPALDING		.89	1.18	1.12	.93
GEORGIA	STEPHENS					
GEORGIA	STEWART					
GEORGIA	SUMTER	23.77	25.12	25.06	20.27	25.58
GEORGIA	TALBOT	76.12	51.52	24.65	22.57	
GEORGIA	TALIAFERRO					
GEORGIA	TATNALL	4.62	7.65	7.55	33.24	38.38
GEORGIA	TAYLOR	7.47	4.83	3.86	3.70	7.00
GEORGIA	TELFAIR	4.73	3.80	2.97	3.53	2.77
GEORGIA	TERRELL	8.93	6.81	3.29	6.10	3.62
GEORGIA	THOMAS	20.58	21.90	19.49	15.46	13.48

GEORGIA	TIFT	22.67	22.13	22.20	29.22	27.01
GEORGIA	TOOMBS				4.80	.19
GEORGIA	TOWNS				15.71	7.18
GEORGIA	TREUTLEN	35.50	22.44	22.01		3.03
GEORGIA	TROUP	6.91	8.24	8.16		11.82
GEORGIA	TURNER	1.13	1.19	8.89	11.63	4.41
GEORGIA	TWIGGS	1.14				8.67
GEORGIA	UNION	.10	8.36	.25	.17	
GEORGIA	UPSON			27.54	13.85	.10
GEORGIA	WALKER	7.39	3.42	9.45	1.22	40.38
GEORGIA	WALTON		8.54		39.05	5.60
GEORGIA	WARE	2.05	1.16	1.71	.07	
GEORGIA	WARREN					
GEORGIA	WASHINGTON					5.82
GEORGIA	WAYNE	12.41	9.07	9.21	8.38	
GEORGIA	WEBSTER					
GEORGIA	WHEELER	1.59				
GEORGIA	WHITE					
GEORGIA	WHITFIELD					
GEORGIA	WILCOX	5.39	2.20	.69	1.52	1.15
GEORGIA	WILKES	7.17	28.99	10.94	61.06	46.06
GEORGIA	WILKINSON		25.63			
GEORGIA	WORTH	36.87	33.03	29.62	25.26	23.94
GUAM	AGANA	3.27	2.16	14.54	20.50	21.57
HAWAII	AMERICAN SAMOA	2.10	1.23			
HAWAII	HAWAII, E. (HILO)	13.25	10.53	6.28	8.08	6.72
HAWAII	HONOLULU	39.48	32.20	30.25	29.07	23.75
HAWAII	KALAWAO					
HAWAII	KAUAI	4.93	8.88	7.60	9.31	7.30
HAWAII	MAUI	1.23	6.87	7.40	8.34	5.79
IDAHO	ADA	4.66	6.10	6.40	8.43	4.99
IDAHO	ADAMS	.73	.46	.52		2.72
IDAHO	BANNOCK	1.37	.42		.22	.25
IDAHO	BEAR LAKE	4.19				
IDAHO	BENEAH					
IDAHO	BINGHAM					
IDAHO	BLAINE				2.58	1.32
IDAHO	BOISE					
IDAHO	BONNER					2.59
IDAHO	BONNEVILLE	4.06	2.86	7.71	3.52	3.01

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
IDAHO	BOUNDARY			3.68	2.92	1.57
IDAHO	BUTTE	1.13	.33	5.69	6.95	3.78
IDAHO	CAMAS					
IDAHO	CANYON	3.74	8.78	5.06	7.86	8.69
IDAHO	CARBON	4.57	2.37	2.20	1.03	.18
IDAHO	CASSIA	4.37	2.29	1.62	1.89	4.03
IDAHO	CLARK				23.47	15.30
IDAHO	CLEARWATER					
IDAHO	ELMORE	1.43	.13	11.21	4.54	3.04
IDAHO	FRANKLIN		.39	.24	.65	.52
IDAHO	FREMONT	3.03	.33	33.61	22.54	48.12
IDAHO	GEM	.73	1.30	.87	6.40	4.53
IDAHO	GOODING	1.10	.77		14.49	13.69
IDAHO	IDAHO	30.46	28.86	12.02	9.75	6.98
IDAHO	JEFFERSON	3.56	1.16	2.08	1.24	1.84
IDAHO	JEROME	2.48		2.15	1.05	1.64
IDAHO	KOOTENAI	.01		3.74	.07	
IDAHO	LATAH	2.87		7.16	30.93	42.19
IDAHO	LEMHI	19.91	24.18	19.33	9.17	4.82
IDAHO	LEWIS	14.85	13.49	12.55	13.71	20.62
IDAHO	LINCOLN			.60	1.59	.88
IDAHO	MADISON	3.50	4.06	14.15	13.08	2.71
IDAHO	MINIDOKA	14.28	13.96	11.21	9.37	13.80
IDAHO	NEZ PERCE		2.00	.10	.48	.43
IDAHO	NORTH CUSTER		6.14	2.78	.58	1.23
IDAHO	ONEIDA	.73	.16	1.16	25.53	27.09
IDAHO	OWYHEE	11.47	7.72	8.11	12.97	8.28
IDAHO	PAYETTE		.52	32.41	24.66	8.36
IDAHO	POWER	.07	2.88	6.48	4.98	.51
IDAHO	SHOSHONE					
IDAHO	TETON	5.31				
IDAHO	TWIN FALLS	1.21	.63	.46	.13	.66
IDAHO	VALLEY				45.81	11.76
IDAHO	WASHINGTON	1.10	2.37	1.11	3.85	2.01
ILLINOIS	ADAMS	.28		1.13	3.86	2.99

ILLINOIS	ALEXANDER	.21	.14	.12			
ILLINOIS	BOND				7.32	6.91	
ILLINOIS	BOONE					4.03	
ILLINOIS	BROWN			.69	1.06		
ILLINOIS	BUREAU						
ILLINOIS	CALHOUN	6.44	6.02				
ILLINOIS	CARROLL				23.87	16.04	
ILLINOIS	CASS	5.16	4.73				
ILLINOIS	CHAMPAIGN						
ILLINOIS	CHRISTIAN						
ILLINOIS	CLARK	5.82	5.86	6.35	3.36	2.38	
ILLINOIS	CLAY				22		
ILLINOIS	CLINTON			.63	1.25	.92	
ILLINOIS	COLES						
ILLINOIS	COOK						
ILLINOIS	CRAWFORD				3.97	.96	
ILLINOIS	CUMBERLAND		6.31	4.95	4.01	1.27	
ILLINOIS	DEKALB						
ILLINOIS	DEWITT						
ILLINOIS	DOUGLAS						
ILLINOIS	DUPAGE						
ILLINOIS	EDGAR	.54	.51	.21	.17		
ILLINOIS	EDWARDS		.47	1.08	.79	.75	
ILLINOIS	EFFINGHAM	12.56	11.73	11.01	8.40	7.85	
ILLINOIS	FAYETTE	.26		.07	4.27	4.62	
ILLINOIS	FORD						
ILLINOIS	FRANKLIN		7.85	4.11	14.89	14.87	
ILLINOIS	FULTON	.72	2.98	12.62	13.09	9.99	
ILLINOIS	GALLATIN	10.00	8.92	6.84	8.97	8.50	
ILLINOIS	GREENE	2.46	2.53	2.83	.71	.91	
ILLINOIS	GRUNDY				.78		
ILLINOIS	HAMILTON	.89	.04	.22	.30	.31	
ILLINOIS	HANCOCK		.86	.33	.13	.03	
ILLINOIS	HARDIN	8.94		2.35	5.44	7.12	
ILLINOIS	HENDERSON				3.51	4.60	
ILLINOIS	HENRY					1.00	
ILLINOIS	IROQUOIS	1.44	.64	.87	.45	.48	
ILLINOIS	JACKSON						
ILLINOIS	JASPER						
ILLINOIS	JEFFERSON				3.12	2.52	

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
ILLINOIS	JERSEY	1.82	1.22	.15	4.64
ILLINOIS	JO DAVISS	.13
ILLINOIS	JOHNSON	.26	7.40	.56	.76	2.60
ILLINOIS	KANE
ILLINOIS	KANKAKEE	.86	.77	.16	.87	.14
ILLINOIS	KENDALL	4.32	.75	.40	4.94	13.20
ILLINOIS	KNOX	.56	.28	.85	.76	1.52
ILLINOIS	LA SALLE	.0307	.04	.05
ILLINOIS	LAKE
ILLINOIS	LAWRENCE	1.24	1.26	1.17	4.21	1.05
ILLINOIS	LEE	1.74	1.12	.42
ILLINOIS	LIVINGSTON	.22	.25	.47	.48	.40
ILLINOIS	LOGAN13	.18	1.46
ILLINOIS	MACON
ILLINOIS	MACOUPIN	.18	1.78	.60	.59	.92
ILLINOIS	MADISON
ILLINOIS	MARION	.37	1.80	1.52	1.32	1.00
ILLINOIS	MARSHALL
ILLINOIS	MASON63
ILLINOIS	MASSAC	4.13	8.45	5.32	3.19	9.47
ILLINOIS	MCDONOUGH	1.42	1.45	1.43	1.25	2.06
ILLINOIS	MC HENRY
ILLINOIS	MCLEAN
ILLINOIS	MENARD	14.57
ILLINOIS	MERCER
ILLINOIS	MONROE
ILLINOIS	MONTGOMERY	6.88	6.80	6.21	5.52	31.88
ILLINOIS	MORGAN34	.31
ILLINOIS	MOULTRIE
ILLINOIS	OGLE	8.25	7.11	6.97	11.93	10.32
ILLINOIS	PEORIA
ILLINOIS	PERRY	2.78	3.14	1.80
ILLINOIS	PIATT	4.38
ILLINOIS	PIKE	1.61	1.55
ILLINOIS	POPE

ILLINOIS	3.09	5.63	3.88	1.83	1.38
ILLINOIS47
ILLINOIS	2.40	2.04	4.51
ILLINOIS	1.05	.71	.76	.83	1.01
ILLINOIS
ILLINOIS	4.33	4.76	3.78	4.96	7.00
ILLINOIS	3.08	7.74	6.52
ILLINOIS	4.70
ILLINOIS	60.17	57.25	38.54	29.62
ILLINOIS
ILLINOIS	8.25	9.10
ILLINOIS
ILLINOIS23	.76	1.11	1.09	.70
ILLINOIS	1.21
ILLINOIS	10.11	11.83	7.76	4.80	3.67
ILLINOIS	2.04	1.96	1.80	1.33	1.24
ILLINOIS	1.66	1.43	1.59	.36
ILLINOIS05
ILLINOIS02
ILLINOIS46	.16	.06	1.41
ILLINOIS	3.41	5.02	3.51
ILLINOIS	2.29	1.70
ILLINOIS	10.67	8.83	7.84	7.21	6.62
ILLINOIS	3.67	.98	1.22
ILLINOIS	30.31
ILLINOIS
INDIANA	5.95
INDIANA	3.52	4.88	17.24
INDIANA79	.34	.4251
INDIANA	9.25	11.57
INDIANA
INDIANA19	8.48	11.60
INDIANA	9.82	7.19
INDIANA15
INDIANA0513	.49	.83
INDIANA13	.73
INDIANA
INDIANA
INDIANA
INDIANA	2.71	5.09	3.25	8.94	33.67
INDIANA	71.69
INDIANA06

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
INDIANA	DEARBORN			8.39	60.49	57.14
INDIANA	DECATUR	.81	2.79	2.65	1.41	1.87
INDIANA	DEKALB	.25	.13	3.63	.33	9.60
INDIANA	DELAWARE	1.69				
INDIANA	DUBOIS					13.21
INDIANA	ELKHART	2.05		21.49	20.58	19.71
INDIANA	FAYETTE	9.19	10.12	14.66	13.58	11.25
INDIANA	FLOYD			41.47	34.85	30.94
INDIANA	FOUNTAIN	7.06	5.35	4.77	26.61	22.59
INDIANA	FRANKLIN				49.50	36.17
INDIANA	FULTON	1.98	2.37	1.14	.35	2.14
INDIANA	GIBSON		11.25	1.58	.24	55.09
INDIANA	GRANT				.24	.23
INDIANA	GREENE					
INDIANA	HAMILTON					.24
INDIANA	HANCOCK	5.08	7.38	6.32	6.37	.28
INDIANA	HARRISON	.50	.69	.59	.63	1.01
INDIANA	HENDRICKS					14.43
INDIANA	HENRY	6.22	5.47	5.48	11.98	16.74
INDIANA	HOWARD				19.37	
INDIANA	HUNTINGTON					.03
INDIANA	JACKSON	1.48	1.63	.90	7.22	6.65
INDIANA	JASPER	.51	2.26	4.14	8.02	2.69
INDIANA	JAY	13.78	10.19	7.81	4.62	1.33
INDIANA	JEFFERSON	8.93	11.21	10.76	11.91	11.53
INDIANA	JENNINGS	5.87	5.07	4.65	27.66	24.23
INDIANA	JOHNSON					
INDIANA	KNOX	3.50		.01		
INDIANA	KOSCIUSKO	2.63	2.45	3.80	2.92	2.77
INDIANA	LAGRANGE	.18				1.45
INDIANA	LAKE	11.66	7.03	6.08	3.00	2.73
INDIANA	LAPORTE	10.63	14.47	8.01	8.01	5.82
INDIANA	LAWRENCE	.28	.31	.20	6.83	5.59
INDIANA	MADISON				9.88	8.14
INDIANA	MARION					

INDIANA	MARSHALL	2.71	14.33	11.08	11.09	10.18
INDIANA	MARTIN					
INDIANA	MIAMI	3.33	2.79	2.48	1.52	5.36
INDIANA	MONROE		100.00		100.00	100.00
INDIANA	MONTGOMERY	1.28	.87	3.07	6.25	3.66
INDIANA	MORGAN				2.18	
INDIANA	NEWTON	4.77	1.85	5.47	2.43	3.34
INDIANA	NOBLE	2.98	.75	.13	3.34	
INDIANA	OHIO					
INDIANA	ORANGE				8.62	63.76
INDIANA	OWEN			.92	35.60	41.18
INDIANA	PARKE	14.40	5.34	4.15	2.62	12.94
INDIANA	PERRY		.38		8.17	
INDIANA	PIKE					
INDIANA	PORTER		.20	6.22	14.10	8.36
INDIANA	POSEY					
INDIANA	PULASKI	6.16	8.12	7.12	11.70	8.71
INDIANA	PUTNAM	2.71			45.38	49.07
INDIANA	RANDOLPH					.87
INDIANA	RIPLEY		1.14	15.32	3.41	.89
INDIANA	RUSH	.20	14.84	12.99	7.99	7.44
INDIANA	SCOTT	49.49	48.17		.07	.18
INDIANA	SHELBY			.30	.60	.12
INDIANA	SPENCER	90	.12	.36		.14
INDIANA	ST. JOSEPH	2.11	13.88	11.22	12.28	14.48
INDIANA	STARKE	1.54	6.60	4.23	8.38	9.01
INDIANA	STEBEN					2.92
INDIANA	SULLIVAN	2.51	1.45	.73		
INDIANA	SWITZERLAND	22.38	17.80	14.81	13.70	34.26
INDIANA	TIPPECANOE	3.89	2.84	21.70	12.16	23.34
INDIANA	TIPTON					28.35
INDIANA	UNION			.30		3.20
INDIANA	VANDEBURGH					
INDIANA	VERMILLION					
INDIANA	VIGO		.74	.87	1.29	1.11
INDIANA	WABASH				1.01	
INDIANA	WARREN			47.95	43.27	40.09
INDIANA	WARRICK	35.82	35.33	.31	2.25	1.79
INDIANA	WASHINGTON					
INDIANA	WAYNE	20.70			4.54	34.66

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
INDIANA	WELLS				15.39	13.91
INDIANA	WHITE				1.02	.17
INDIANA	WHITLEY	1.62	1.13			5.23
IOWA	ADAIR	2.60	2.78	2.56		
IOWA	ADAMS		.18			
IOWA	ALLAMAKEE					
IOWA	APPANOOSE	.14	.16		.28	7.53
IOWA	AUDUBON			.08		.02
IOWA	BENTON	4.61	3.52	2.51	2.83	3.17
IOWA	BLACK HAWK		12.18	7.91		
IOWA	BOONE		.70	1.09	.96	.57
IOWA	BREMER					.30
IOWA	BUCHANAN	3.06	2.91	3.17	3.14	2.98
IOWA	BUENA VISTA	3.56	1.51	2.59	1.22	1.09
IOWA	BUTLER	1.55	1.66	1.65	1.43	2.47
IOWA	CALHOUN					
IOWA	CARROLL	.07	.06	.09	.17	.36
IOWA	CASS	12.49	11.46	12.53	12.75	10.59
IOWA	CEDAR	1.11	1.32	.87	.69	.41
IOWA	CERRO GORDO	8.96	9.21	4.81	4.39	4.62
IOWA	CHEROKEE					.83
IOWA	CHICKASAW	3.72	3.84	5.34	3.50	4.49
IOWA	CLARKE	.02	.02	.01	.02	.44
IOWA	CLAY					
IOWA	CLAYTON		1.08			
IOWA	CLINTON	.01			.02	.18
IOWA	CRAWFORD					
IOWA	DALLAS		6.07	4.21	2.35	
IOWA	DAVIS	.49	1.96	3.66	2.25	1.29
IOWA	DECATUR	.07	.06	.05	.14	.13
IOWA	DELAWARE			.37	.02	.25
IOWA	DES MOINES	.66				
IOWA	DICKINSON					
IOWA	DUBUQUE	.10	1.04	1.00	3.36	3.62
IOWA	EMMET	.35				

IOWA	FAYETTE	.89	1.19	.88	.94	1.06
IOWA	FLOYD
IOWA	FRANKLIN	1.23	12.54	.27
IOWA	FREMONT
IOWA	GREENE	13.12	10.23	7.75	5.73
IOWA	GRUNDY	1.74
IOWA	GUTHRIE29	.38	.24	1.66
IOWA	HAMILTON	40.07	29.90	32.63	28.80
IOWA	HANCOCK	3.73	2.83	2.47	1.93
IOWA	HARDIN	3.42	1.95	.46
IOWA	HARRISON21	1.59	1.33	1.55
IOWA	HENRY	11.46	2.23	2.22	5.69
IOWA	HOWARD05	.27
IOWA	HUMBOLDT
IOWA	IDA03
IOWA	IOWA25	1.45	1.95	1.36
IOWA	JACKSON	3.69	3.84	3.59	3.05
IOWA	JASPER06
IOWA	JEFFERSON	1.41	1.29	.68	1.73
IOWA	JOHNSON	3.78	2.88	.03	15.34
IOWA	JONES	2.37	1.58	.78	.14
IOWA	KEOKUK18
IOWA	KOSSUTH72	.07	1.10
IOWA	LEE	10.65
IOWA	LINN
IOWA	LOUISA02
IOWA	LUCAS	3.03	2.79	3.11	2.57
IOWA	LYON
IOWA	MADISON	40.71	32.88	29.41	18.51
IOWA	MAHASKA	1.32	1.16	.93	.83
IOWA	MARION12	2.22	.13	.09
IOWA	MARSHALL05	5.01
IOWA	MILLS	6.76	3.66	1.34	1.95
IOWA	MITCHELL	1.82	1.30	9.44	5.67
IOWA	MONONA13	.1085
IOWA	MONROE02	1.31	.37	.39
IOWA	MONTGOMERY	1.92	1.91	1.75	1.71
IOWA	MUSCATINE26	.14
IOWA	O'BRIEN	1.50	4.87
IOWA	OSCEOLA31	.88	1.08	1.21
IOWA			.78			

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
IOWA	PAGE	.65	.49	.61	.75	1.38
IOWA	PALO ALTO	.05			.04	
IOWA	PLYMOUTH	.02	.58	.79	4.59	3.84
IOWA	POCAHONTAS				.03	3.48
IOWA	POLK	17.55	15.65	17.04	5.45	2.57
IOWA	POTTAWATTAMIE	4.57	4.39	5.44	4.77	2.97
IOWA	POWESHIEK				1.23	1.00
IOWA	RINGGOLD				.02	.46
IOWA	SAC	.55	.61	.96	1.06	5.40
IOWA	SCOTT				.19	
IOWA	SHELBY	.55		.11		.21
IOWA	SIoux		.74			.94
IOWA	STORY					
IOWA	TAMA	3.10	3.19	1.51	1.96	.88
IOWA	TAYLOR	22.04	25.04	25.46	22.78	28.09
IOWA	UNION	8.41	6.66	6.18	5.75	5.43
IOWA	VAN BUREN	.36	.33	.37	.75	.74
IOWA	WAPELLO	.28				
IOWA	WARREN					3.44
IOWA	WASHINGTON	.79	.11	.15	4.30	.67
IOWA	WAYNE			.23		2.59
IOWA	WEBSTER					
IOWA	WINNEBAGO	1.22	1.10	4.05	2.45	1.48
IOWA	WINNESHIEK				2.19	1.09
IOWA	WOODBURY					1.65
IOWA	WORTH	.56		.24		
IOWA	WRIGHT					1.00
KANSAS	ALLEN		2.57	7.08	22.93	35.46
KANSAS	ANDERSON	1.11			.07	
KANSAS	ATCHISON	1.37	1.15	1.39	3.36	2.86
KANSAS	BARBER	.05	.92	1.50	1.10	.48
KANSAS	BARTON	.70	.27	.54	.75	.54
KANSAS	BOURBON					
KANSAS	BROWN	.15		.18		1.01
KANSAS	BUTLER				.18	.32

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
KANSAS	KIOWA	2.33	2.13	1.15	1.36
KANSAS	LABETTE72	.87	1.01	.95	.82
KANSAS	LANE39	.84	.90	.75	.85
KANSAS	LEAVENWORTH	23.78	18.46	15.55	12.73	9.82
KANSAS	LINCOLN10	.47	.77	1.18	1.48
KANSAS	LINN18	18.21	15.95
KANSAS	LOGAN	2.91	.69	2.15	2.73	.61
KANSAS	LYON52	.18
KANSAS	MARION	2.23	1.07	1.52	.37
KANSAS	MARSHALL	1.13	1.85	1.21	1.78	2.08
KANSAS	MCPHERSON	2.91	3.19	2.56	4.04	5.57
KANSAS	MEADE32	.86	.72	.79	2.27
KANSAS	MIAMI	9.28	10.80	8.66	6.62	6.56
KANSAS	MITCHELL53
KANSAS	MONTGOMERY46	1.09	6.43	7.64	7.74
KANSAS	MORRIS	5.18	5.19	5.52
KANSAS	MORTON	1.68	1.05	1.76	1.09	.03
KANSAS	NEMAHA05	.06	.06	.06	.15
KANSAS	NEOSHO90	19.53	13.85	1.57
KANSAS	NESS	1.82	.80	.63	.74	.79
KANSAS	NORTON	1.12	.96	.99	1.03	1.12
KANSAS	OSAGE	32.62	31.65
KANSAS	OSBORNE30	.32	2.33	.95	.82
KANSAS	OTAWA
KANSAS	PANTEE32	.85
KANSAS	PHILLIPS63	.18	.70	.56	.57
KANSAS	POTTAWATOMIE28	1.15	.99	1.92	2.11
KANSAS	PRATT91	.39	2.97	1.59	2.90
KANSAS	RAWLINS	3.55	1.61	1.66
KANSAS	RENO60	.35	.33	1.02	5.37
KANSAS	REPUBLIC	2.12	2.34	1.92	2.13	1.56
KANSAS	RICE51	1.57	2.00	2.71	2.41
KANSAS	RILEY74	9.64	12.09	9.53
KANSAS	ROOKS	3.21	3.33	3.76	1.62	3.44
KANSAS	RUSH	2.61	.18	.2732

KANSAS	RUSSELL	2.95	.22	.10	.92	1.14
KANSAS	SALINE	8.89	9.11	7.88	7.50
KANSAS	SCOTT	.68	2.62	2.60	.74	.07
KANSAS	SEDGWICK	.16	.86	.51	.24	1.19
KANSAS	SEWARD	4.57	2.49	10.64	34.22	34.73
KANSAS	SHAWNEE	2.52
KANSAS	SHERIDAN	.47	.65	.79	1.14	1.24
KANSAS	SHERMAN	5.73	4.45	11.27	6.33	6.99
KANSAS	SMITH	.35	.76	.33	.48	.32
KANSAS	STAFFORD	4.70	1.36	1.07	.40	2.77
KANSAS	STANTON	1.37	.63	.82	3.98	.81
KANSAS	STEVENS	1.57	5.29	2.75	8.67	3.74
KANSAS	SUMMER	1.18	1.97	3.65	3.94	5.10
KANSAS	THOMAS	2.82	2.94	3.40	.28	.15
KANSAS	TREGO	5.06	6.49	1.44	1.38	.41
KANSAS	WABAUNSEE75	.77
KANSAS	WALLACE	.1766	5.85	3.33
KANSAS	WASHINGTON	2.42	1.93	2.75	2.60	1.97
KANSAS	WICHITA	5.52	3.74	3.26	3.88	3.62
KANSAS	WILSON	1.97	1.02	.32	5.90	6.18
KANSAS	WOODSON	4.54	2.48
KANSAS	WYANDOTTE
KENTUCKY	ADAIR	.03	.11	.39	.10	.16
KENTUCKY	ALLEN	.63	.55	.10	.16	.02
KENTUCKY	ANDERSON51
KENTUCKY	BALLARD48	.33	4.39	1.99
KENTUCKY	BARREN	7.01	7.16	6.65	6.71	3.91
KENTUCKY	BATH	3.47	3.45	3.25	3.06	.95
KENTUCKY	BELL
KENTUCKY	BOONE
KENTUCKY	BOURBON
KENTUCKY	BOYD
KENTUCKY	BOYLE	.25	.2380	.19
KENTUCKY	BRACKEN16	5.13	3.22
KENTUCKY	BREATHITT	3.30	15.87	4.37	3.38
KENTUCKY	BRECKINRIDGE	.10	.11	.39	.51	.37
KENTUCKY	BULLITT
KENTUCKY	BUTLER21
KENTUCKY	CALDWELL27	3.16
KENTUCKY	CALLOWAY	1.62	.10	2.51	.15

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELQ RATE 12/31/06	DELQ RATE 12/31/05	DELQ RATE 12/31/04	DELQ RATE 12/31/03	DELQ RATE 12/31/02
KENTUCKY	CAMPBELL	.15				1.43
KENTUCKY	CARLSLE	26.22	23.52	24.66	21.13	17.81
KENTUCKY	CARROLL	3.38	.14			1.79
KENTUCKY	CARTER	34.07	29.06	26.41	30.61	17.18
KENTUCKY	CASEY	2.92	2.44	2.19	.87	1.04
KENTUCKY	CHRISTIAN	.11			.47	.35
KENTUCKY	CLARK	10.10	7.56	10.91	8.72	16.83
KENTUCKY	CLAY	.34	2.59	2.41	2.19	7.95
KENTUCKY	CLINTON	.45	3.03	2.18	.18	36.71
KENTUCKY	CRITTENDEN	16.22	19.38	18.40	14.34	11.44
KENTUCKY	CUMBERLAND		29.99	29.32	35.96	35.57
KENTUCKY	DAVIESS	4.71	.87	.01	2.31	3.19
KENTUCKY	EDMONSON		22.40	20.76	14.57	7.74
KENTUCKY	ELLIOTT	.17	.29			3.97
KENTUCKY	ESTILL	1.25				
KENTUCKY	FAYETTE	1.40	1.17	.94	.70	1.00
KENTUCKY	FLEMING				9.26	21.44
KENTUCKY	FLOYD				.03	
KENTUCKY	FRANKLIN				1.14	
KENTUCKY	FULTON	20.52	2.60	2.85	13.72	12.31
KENTUCKY	GALLATIN	.08	17.35	15.70		.92
KENTUCKY	GARRARD	2.22	1.09			
KENTUCKY	GRANT	.61	.26	.24	.28	4.01
KENTUCKY	GRAVES		.84	.54	.61	.32
KENTUCKY	GRAYSON		.78		.04	1.59
KENTUCKY	GREEN	1.80	4.05	1.49	4.37	2.15
KENTUCKY	GREENUP					
KENTUCKY	HANCOCK					
KENTUCKY	HARDIN	100.00	.27		.09	.27
KENTUCKY	HARLAN		100.00	100.00	77.76	
KENTUCKY	HARRISON	1.40	1.21	1.64	1.65	1.51
KENTUCKY	HART	1.00	.97	.96	1.00	.67
KENTUCKY	HENDERSON				2.68	
KENTUCKY	HENRY	5.73	7.97	6.99	5.82	6.46
KENTUCKY	HICKMAN		.59			1.28

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
KENTUCKY	OWEN	27.76	20.59	15.15	11.82	10.09
KENTUCKY	OWSLEY	3.11		35.67	27.86	22.70
KENTUCKY	PENDLETON	5.61	4.87	2.40	.90	
KENTUCKY	PERRY	50.62	15.53	10.13	17.77	13.61
KENTUCKY	PIKE					
KENTUCKY	POWELL		.01	.58	.14	
KENTUCKY	PULASKI	.79	.49	.65	1.05	.40
KENTUCKY	ROBERTSON	6.17	5.29	10.34	8.36	8.22
KENTUCKY	ROCKCASTLE	2.32	1.80	1.33	1.16	1.01
KENTUCKY	ROWAN	.33	3.49			
KENTUCKY	RUSSELL	6.13	4.77	4.31	3.45	3.14
KENTUCKY	SCOTT					6.30
KENTUCKY	SHELBY	.40	.48	.64	2.05	14.96
KENTUCKY	SIMPSON	8.13	11.20	3.43	11.23	9.54
KENTUCKY	SPENCER		3.98	5.31	.83	
KENTUCKY	TAYLOR			.73	.62	1.05
KENTUCKY	TODD	.66	.48	.29	.18	.39
KENTUCKY	TRIGG	15.17	32.97	32.54	30.58	1.05
KENTUCKY	TRIMBLE			.61	.04	
KENTUCKY	UNION					2.53
KENTUCKY	WARREN	6.99	7.14	7.17	5.32	3.59
KENTUCKY	WASHINGTON	3.99	4.96	4.28	4.27	3.68
KENTUCKY	WAYNE	.40	.04	.06	.09	
KENTUCKY	WEBSTER				8.61	1.59
KENTUCKY	WHITLEY					
KENTUCKY	WOLFE	2.76	2.85	2.32	1.14	.72
KENTUCKY	WOODFORD		3.86	2.66	1.67	1.84
LOUISIANA	ACADIA	25.99	36.66	24.63	14.01	15.20
LOUISIANA	ALLEN	25.86	18.36	16.26	11.41	7.05
LOUISIANA	ASCENSION				79.45	78.82
LOUISIANA	ASSUMPTION			.69		
LOUISIANA	AVOUELLES	15.16	19.11	10.01	12.75	11.09
LOUISIANA	BEAUREGARD			7.94	3.81	66.56
LOUISIANA	BREWILLE					
LOUISIANA	BOSSIER	9.13	9.66	27.68	15.89	19.41

LOUISIANA	CADDO60	5.61	20.13	19.70	17.89
LOUISIANA	CALCASIEU	63.06	52.62	59.44	45.12	52.20
LOUISIANA	CALDWELL16	1.78	1.62	1.18	3.26
LOUISIANA	CAMERON
LOUISIANA	CATAHOULA	11.54	12.34	10.28	11.03	11.07
LOUISIANA	CLAIBORNE	9.08
LOUISIANA	CONCORDIA	17.62	17.90	17.72	16.00	17.79
LOUISIANA	DE SOTO	35.54	31.87	29.26	22.72	16.34
LOUISIANA	EAST BATON ROUGE	37.10	29.84	23.11
LOUISIANA	EAST CARROLL	15.81	21.92	20.87	19.07	15.71
LOUISIANA	EAST FELICIANA
LOUISIANA	EVANGELINE49	2.69	.49	44.67	59.04
LOUISIANA	FRANKLIN	21.38	22.94	25.74	26.39	28.61
LOUISIANA	GRANT	8.78	7.41	6.61	6.98	61.45
LOUISIANA	IBERIA	19.46	19.57	19.72	27.57	31.92
LOUISIANA	IBERVILLE	17.74	15.44	19.66	23.98	18.03
LOUISIANA	JACKSON
LOUISIANA	JEFFERSON
LOUISIANA	JEFFERSON DAVIS	5.12	5.16	2.20	2.16	1.27
LOUISIANA	LA SALLE	71.56	53.22	22.51	70.55
LOUISIANA	LAFAYETTE	12.78	16.65	11.12
LOUISIANA	LAFOURCHE	6.40	16.06	25.44
LOUISIANA	LINCOLN65	1.34	3.66
LOUISIANA	LIVINGSTON	21	3.22
LOUISIANA	MADISON	13.32	9.59	6.62	6.76	5.13
LOUISIANA	MOREHOUSE	15.31	14.39	15.09	14.07	12.06
LOUISIANA	NATCHITOCHES	8.62	9.53	8.21	26.06	88.68
LOUISIANA	ORLEANS
LOUISIANA	OUACHITA	47.64	43.12	42.41	17.52	37.71
LOUISIANA	PLAQUEMINES11	.19	1.20	20.90
LOUISIANA	POINTE COUPEE	16.14	17.21	20.79	16.72	26.96
LOUISIANA	RAPIDES	13.27	18.28	21.95	28.31	28.89
LOUISIANA	RED RIVER	25.11
LOUISIANA	RICHLAND	25.48	26.91	27.74	27.03	33.13
LOUISIANA	SABINE	4.59	5.55	5.09	27.05	52.37
LOUISIANA	ST. BERNARD	6.11	2.27	1.41
LOUISIANA	ST. CHARLES	8.29
LOUISIANA	ST. HELENA	22.98	46.15	24.14
LOUISIANA	ST. JAMES	6.18	7.47	19.24	22.41
LOUISIANA	ST. JOHN THE BAPTIST

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
LOUISIANA	ST. LANDRY	8.94	13.93	13.10	21.90	17.72
LOUISIANA	ST. MARTIN	2.29	6.78	10.21	11.82	20.14
LOUISIANA	ST. MARY	25.47	7.71	3.13	.84	7.10
LOUISIANA	ST. TAMMANY					
LOUISIANA	TANGIPAHOA	11.16	13.28	11.80	10.15	7.81
LOUISIANA	TENSAS	38.51	35.93	31.49	31.20	26.90
LOUISIANA	TERREBOUNE					
LOUISIANA	UNION	.16	1.86	1.70	1.72	6.02
LOUISIANA	VERMILION	9.45	11.92	9.61	16.97	17.69
LOUISIANA	VERNON	31.16	6.35	35.00	4.14	29.59
LOUISIANA	WASHINGTON	.17	1.10	2.09	4.39	.85
LOUISIANA	WEBSTER					
LOUISIANA	WEST BATON ROUGE			.54	.53	
LOUISIANA	WEST CARROLL	20.00	18.17	19.49	20.37	18.54
LOUISIANA	WEST FELICIANA					
LOUISIANA	WINN					
MAINE	ANDROSCOGGIN	1.51	1.76	2.00		
MAINE	AROSTOOK, PT.	17.81	18.33	15.98	15.32	20.08
MAINE	CUMBERLAND, PT.					
MAINE	FRANKLIN	2.79		21.15	20.10	14.09
MAINE	HANCOCK, PT.	.84	2.07	4.59	7.82	7.02
MAINE	KENNEBEC, PT.	4.66	4.18	3.69	9.55	12.96
MAINE	KNOX	26.50	15.58	11.13	16.53	12.56
MAINE	LINCOLN			3.69	4.25	29.51
MAINE	OXFORD	11.11	8.52	8.53	6.02	5.09
MAINE	PENOBSCOT, PT.	12.81	14.06	11.72	12.09	10.20
MAINE	PISCATAQUIS				10.13	8.89
MAINE	SAGadahoc			1.12	2.13	
MAINE	SOMERSET	2.11	1.71	2.16	3.14	1.41
MAINE	WALDOO, PT.		15.76			5.82
MAINE	WASHINGTON, PT.	8.21	31.97	18.56	11.35	15.79
MAINE	YORK	11.18	6.49	3.12	1.78	
MARYLAND	ALLEGANY					
MARYLAND	ANNE ARUNDEL					
MARYLAND	BALTIMORE					

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELQ RATE 12/31/06	DELQ RATE 12/31/05	DELQ RATE 12/31/04	DELQ RATE 12/31/03	DELQ RATE 12/31/02
MICHIGAN	ARENAZ					
MICHIGAN	BARAGA					8.89
MICHIGAN	BARRY					21.77
MICHIGAN	BAY	8.97	9.65	13.41	8.94	3.34
MICHIGAN	BENZIE					
MICHIGAN	BERRIEN	4.35	3.79	2.76	20.40	
MICHIGAN	BRANCH	2.81	.77	3.50	1.34	
MICHIGAN	CALHOUN	11.55	6.77	5.13	.80	
MICHIGAN	CASS	5.78	5.23	7.22	3.75	11.15
MICHIGAN	CHARLEVOIX		79.34	77.04	1.78	1.22
MICHIGAN	CHEBOYGAN	1.51	1.70	.93	65.98	52.52
MICHIGAN	CHIPPEWA	.54	.57	1.25	.03	
MICHIGAN	CLARE		1.13		.54	1.06
MICHIGAN	CLINTON					
MICHIGAN	CRAWFORD				.19	
MICHIGAN	DELTA	.76	14.97	15.57	12.46	10.36
MICHIGAN	DICKINSON			5.02		
MICHIGAN	EATON					
MICHIGAN	EMMET			38.71	29.93	26.63
MICHIGAN	GENESEE					
MICHIGAN	GLADWIN	15.11	10.98	10.47	8.33	7.47
MICHIGAN	GOGEBIC					
MICHIGAN	GRAND TRAVERSE	2.01		1.18		1.73
MICHIGAN	GRATIOT	2.47	2.54	3.29	2.85	3.50
MICHIGAN	HILLSDALE	1.86	6.44	5.60	4.38	4.26
MICHIGAN	HOUGHTON					
MICHIGAN	HURON			.55	.13	.31
MICHIGAN	INGHAM	8.56	7.29	2.29	2.00	42.89
MICHIGAN	IONIA	6.29	1.55	2.00		.64
MICHIGAN	IOSCO					
MICHIGAN	IRON	4.85	1.55	36.38	61.81	22.52
MICHIGAN	ISABELLA	.64		.15	1.17	
MICHIGAN	JACKSON	5.38	3.61	3.31	.82	1.02
MICHIGAN	KALAMAZOO	11.95	4.27	2.18	2.22	.15
MICHIGAN	KALKASKA				.82	6.16

MICHIGAN	KENT	25	726	9.33	2.66	70.03
MICHIGAN	KEMENAW					
MICHIGAN	LAKE					
MICHIGAN	LAPEER	4.61	7.78	5.15	4.58	4.25
MICHIGAN	LEELANAU	.30	.42			.56
MICHIGAN	LENAWEE	7.30	6.97	6.38	6.89	4.92
MICHIGAN	LIVINGSTON			4.84	.30	
MICHIGAN	LUCE					
MICHIGAN	MACKINAC	2.40				
MICHIGAN	MACOMB			6.77		
MICHIGAN	MANISTEE					
MICHIGAN	MARQUETTE					
MICHIGAN	MASON	1.36	1.59	1.63	1.55	1.88
MICHIGAN	MECOSTA	6.72	6.64	.37		
MICHIGAN	MENOMINEE	.15	2.58	5.32	3.69	2.34
MICHIGAN	MIDLAND					
MICHIGAN	MISSAUKEE		22.87	21.02	20.24	17.76
MICHIGAN	MONROE				.06	39.39
MICHIGAN	MONTCALM	2.70	2.81	1.43	1.20	1.87
MICHIGAN	MONTMORENCY	1.66	2.24			.39
MICHIGAN	MUSKEGON				3.52	1.11
MICHIGAN	NEWAYGO					
MICHIGAN	OAKLAND	7.95				
MICHIGAN	OCEANA	8.98	16.79	14.20	10.08	15.24
MICHIGAN	OGENAW		.07			
MICHIGAN	ONTONAGON	7.46	5.66	1.00	26.06	24.56
MICHIGAN	OSCEOLA	3.56	2.04	1.27		
MICHIGAN	OSCODA					
MICHIGAN	OTSEGO					
MICHIGAN	OTTAWA		1.69	.66	.58	.53
MICHIGAN	PRESQUE ISLE	7.70	3.69	4.60	5.18	4.84
MICHIGAN	ROSCOMMON					
MICHIGAN	SAGINAW	.16		.04	2.36	2.21
MICHIGAN	SANILAC	4.68	4.47	4.32	4.03	4.19
MICHIGAN	SCHOOLCRAFT	.73				
MICHIGAN	SHAWASSEE	5.65	5.30	5.86	1.21	
MICHIGAN	ST. CLAIR				30.78	28.40
MICHIGAN	ST. JOSEPH	2.49	2.94	2.12	2.43	3.63
MICHIGAN	TUSCOLA	4.02	4.04	3.95	4.29	4.59
MICHIGAN	VAN BUREN			.76	2.03	5.99

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELQ RATE 12/31/06	DELQ RATE 12/31/05	DELQ RATE 12/31/04	DELQ RATE 12/31/03	DELQ RATE 12/31/02
MICHIGAN	WASHTENAW	2.59	2.91	2.89	2.45	1.53
MICHIGAN	WAYNE	.55	.52	.44	.32
MICHIGAN	WEXFORD	25.85	51.85
MINNESOTA	ATKIN	6.78	6.30	10.32	9.88	22.35
MINNESOTA	ANOKA
MINNESOTA	BECKER	.61	.80	.59	11.26	10.95
MINNESOTA	BELTRAMI	4.25	.1638	4.80
MINNESOTA	BENTON	.64	.66	2.54	1.55	1.23
MINNESOTA	BIG STONE	2.0358
MINNESOTA	BLUE EARTH	.15	.2007
MINNESOTA	BROWN	.96	.92	1.84	1.54	1.54
MINNESOTA	CARLTON	3.05	3.08	3.14	2.26
MINNESOTA	CARVER	.5161	.01	.85
MINNESOTA	CASS	8.79	4.55	6.14	8.55	10.30
MINNESOTA	CHIPPEWA78	2.73	2.25
MINNESOTA	CHISAGO71	24.58	32.28
MINNESOTA	CLAY	3.03	5.44	4.51	3.88	8.01
MINNESOTA	CLEARWATER	.68	.28	2.38	3.42	5.62
MINNESOTA	COOK
MINNESOTA	COTTONWOOD	3.16	3.39	5.32	2.77	2.18
MINNESOTA	CROW WING	2.34	4.86	1.51	5.85
MINNESOTA	DAKOTA
MINNESOTA	DODGE	1.10	.01	.07
MINNESOTA	DOUGLAS	3.38	3.08	3.88	1.07	2.53
MINNESOTA	FARIBAUT09
MINNESOTA	FILLMORE	.24	.11	.06	.77	3.50
MINNESOTA	FREEBORN	1.20
MINNESOTA	GOODHUE	3.83	3.25	1.80	.99
MINNESOTA	GRANT	.47	.44	11.19	.09	1.11
MINNESOTA	HENNEPIN
MINNESOTA	HOUSTON25	1.01	16.03
MINNESOTA	HUBBARD	10.51	2.87	2.17
MINNESOTA	ISANTI	2.63	2.70	3.08
MINNESOTA	ITASCA	1.59	13.49
MINNESOTA	JACKSON	2.45	2.36	2.48	1.77	.39

MINNESOTA	KANBEC	.26	.06	1.92	2.17	28.92
MINNESOTA	KANDIYOH39	4.95
MINNESOTA	KITSON	36	.17	.14	1.45	6.70
MINNESOTA	KOOCHICHING	1.56	.72	1.37	1.09	.58
MINNESOTA	LAC QUI PARLE	1.2601	.11	.86
MINNESOTA	LAKE
MINNESOTA	LAKE OF THE WOODS	6.11	8.25	7.90	11.78	11.00
MINNESOTA	LE SUEUR
MINNESOTA	LINCOLN	.87	.64	.10	1.97	2.49
MINNESOTA	LYON	4.42	5.01	6.87	6.88	4.66
MINNESOTA	MAHOMEN, S	.11	.60	3.82	4.20	4.38
MINNESOTA	MARSHALL W	33	.42	1.13	1.13	2.63
MINNESOTA	MARTIN	.28	.03	.20	.32	.59
MINNESOTA	MCLEOD	.55	.36	.65	.20	4.93
MINNESOTA	MEKER	10.10	7.44	6.93	6.52	5.68
MINNESOTA	MILLE LACS99	2.71
MINNESOTA	MORRISON	3.09	1.96	6.00	4.44	6.29
MINNESOTA	MOWER	3.93	5.92
MINNESOTA	MURRAY	1.33	1.20	2.11	1.81	2.44
MINNESOTA	NICOLLET	.43	.41	.49	.53	.42
MINNESOTA	NOBLES	2.73	2.73	3.73	4.31	4.19
MINNESOTA	NORMAN	.2128	.43	2.40
MINNESOTA	OLMSTED
MINNESOTA	PENNINGTON	32	.86	1.20	1.14	1.80
MINNESOTA	PINE	5.82	7.36	3.33	1.29	.39
MINNESOTA	PIPESTONE	1.28	1.34	1.39	2.89	3.70
MINNESOTA	POPE	1.28	.94	.60	13.95	12.36
MINNESOTA	RAMSEY
MINNESOTA	RED LAKE	.72	.54	.18	.11	.88
MINNESOTA	REDWOOD	1.47	2.09	1.87	1.40	1.42
MINNESOTA	RENVILLE	6.42	6.70	9.08	10.10	8.57
MINNESOTA	RICE37
MINNESOTA	ROCK	3.46
MINNESOTA	ROSAU	3.48	4.31	5.99	7.01	8.65
MINNESOTA	SCOTT
MINNESOTA	SHERBURNE
MINNESOTA	SIBLEY	2.18	1.58	3.00	3.83	4.42
MINNESOTA	ST. LOUIS, S	.18	1.06	.82	.57
MINNESOTA	STEARNS	.14	.68	.07	.26	.33
MINNESOTA	STEELE

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELQ RATE 12/31/06	DELQ RATE 12/31/05	DELQ RATE 12/31/04	DELQ RATE 12/31/03	DELQ RATE 12/31/02
MINNESOTA	STEVENS					
MINNESOTA	SWIFT	.63	.62	1.39	1.31	1.83
MINNESOTA	TODD	.74	.53	4.74	3.79	3.03
MINNESOTA	TRAVERSE					
MINNESOTA	WABASHA	1.98	2.86	2.89	1.99	.51
MINNESOTA	WADENA	.84	5.55	6.31	19.55	21.18
MINNESOTA	WASECA					
MINNESOTA	WASHINGTON	22.76	7.86			
MINNESOTA	WATONWAN	.85	.41		.07	
MINNESOTA	WEST OTTER TAIL	.83	.43	1.41	2.50	2.12
MINNESOTA	WEST POLK	.06	.81	.92	.91	1.39
MINNESOTA	WILKIN		.01			.02
MINNESOTA	WINONA	.98	.08	5.15	7.52	7.37
MINNESOTA	WRIGHT	.26				
MINNESOTA	YELLOW MEDICINE	.03	.05	1.31	.49	1.10
MISSISSIPPI	ADAMS			4.15	10.99	10.71
MISSISSIPPI	ALCORN	.23	.38	.16	.13	1.25
MISSISSIPPI	AMITE	18.85	19.52	14.11	7.96	9.83
MISSISSIPPI	ATTALA		.68	7.75	8.64	5.90
MISSISSIPPI	BENTON	24.12	18.35	16.33	25.70	30.75
MISSISSIPPI	BOLIVAR	54.54	61.68	61.76	57.79	56.13
MISSISSIPPI	CALHOUN	.64	6.09	9.04	8.10	8.71
MISSISSIPPI	CARROLL		.27	.44	6.90	34.08
MISSISSIPPI	CHICKASAW	11.33	11.69	12.10	12.22	9.59
MISSISSIPPI	CHOCTAW	21.55	17.82	14.35	10.74	5.58
MISSISSIPPI	CLAIBORNE	9.00	8.88	13.45	11.64	25.27
MISSISSIPPI	CLARKE			1.05	3.23	.65
MISSISSIPPI	CLAY	26.91	25.88	23.45	12.83	8.46
MISSISSIPPI	COAHOMA	42.43	44.60	50.31	44.68	38.84
MISSISSIPPI	COPIAH			23.45	20.20	16.73
MISSISSIPPI	COVINGTON		7.19	5.78	4.35	5.54
MISSISSIPPI	DESO TO	29.20	73.04	67.61	60.75	61.15
MISSISSIPPI	FOREST				49.45	45.67
MISSISSIPPI	FRANKLIN			1.19		6.78
MISSISSIPPI	GEORGE		78.65	82.44	85.35	84.61

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
MISSISSIPPI	RANKIN	67.35	65.85	54.37	51.65	54.04
MISSISSIPPI	SCOTT	6.57	5.90	7.09	4.90	21.02
MISSISSIPPI	SHARKEY	72.34	78.58	78.90	70.64	70.95
MISSISSIPPI	SIMPSON	53.02	48.00	51.34	54.39	50.89
MISSISSIPPI	SMITH	10.31	15.64	10.88	8.96	8.90
MISSISSIPPI	STONE	2.37	62.82	59.21	58.47	58.94
MISSISSIPPI	SUNFLOWER	58.82	61.08	57.47	50.55	56.04
MISSISSIPPI	TALLAHATCHE	26.90	28.06	23.92	21.89	22.51
MISSISSIPPI	TATE	29.10	37.93	51.55	47.39	51.07
MISSISSIPPI	TIPPAH	10.25	8.51	8.60	16.31	12.47
MISSISSIPPI	TISHOMINGO	45.32	50.16	41.78	33.36	29.77
MISSISSIPPI	TUNICA	55.31	57.64	52.72	48.74	49.60
MISSISSIPPI	UNION	8.98	8.63	7.91	7.14	6.01
MISSISSIPPI	WALTHALL	5.38	23.08	23.30	24.17	26.76
MISSISSIPPI	WARREN	22.83	21.01	20.20	27.98	21.97
MISSISSIPPI	WASHINGTON	55.50	56.92	47.24	63.73	60.91
MISSISSIPPI	WAYNE		.51	2.01	1.00	2.62
MISSISSIPPI	WEBSTER	.90	.58	.01	1.67	
MISSISSIPPI	WILKINSON	.49			3.33	14.58
MISSISSIPPI	WINSTON		.08	2.34	1.91	1.12
MISSISSIPPI	YALOBUSHA	5.98	7.15	6.51	4.01	3.66
MISSISSIPPI	YAZOO	15.67	16.37	21.37	30.08	32.13
MISSOURI	ADAIR	.67		.06		.20
MISSOURI	ANDREW			.16	2.08	2.06
MISSOURI	ATCHISON					
MISSOURI	AUDRAIN				.22	1.13
MISSOURI	BARRY	.44	.21			
MISSOURI	BARTON	.24	.06	.01	.60	.80
MISSOURI	BATES	11.69	9.86	8.58	6.23	5.00
MISSOURI	BENTON				.67	1.04
MISSOURI	BOLLINGER					
MISSOURI	BOONE					
MISSOURI	BUCHANAN					
MISSOURI	BUTLER	8.89	7.96	8.01	12.41	9.86
MISSOURI	CALDWELL			.19	.13	

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELQ RATE 12/31/06	DELQ RATE 12/31/05	DELQ RATE 12/31/04	DELQ RATE 12/31/03	DELQ RATE 12/31/02
MISSOURI	LAFAYETTE	.25	.27		.52	
MISSOURI	LAWRENCE		.30	.42	.14	7.99
MISSOURI	LEWIS	.43	4.33	7.09	5.64	3.52
MISSOURI	LINCOLN	1.35				
MISSOURI	LINN	.04	.03	.46	.39	
MISSOURI	LIVINGSTON	3.86	3.04	3.10	3.18	2.58
MISSOURI	MACON	1.20	.95	.41	1.86	.57
MISSOURI	MADISON				.02	5.86
MISSOURI	MARIES	.62	1.10			
MISSOURI	MARION		2.62			
MISSOURI	MCDONALD				12.72	9.54
MISSOURI	MERCER				.01	2.98
MISSOURI	MILLER	1.35	2.15	2.83	1.78	9.40
MISSOURI	MISSISSIPPI	5.39	5.64	7.74	12.63	6.17
MISSOURI	MONTEAU	9.44		2.19	13.69	10.81
MISSOURI	MONROE	1.47	1.33	.48	3.76	
MISSOURI	MONTGOMERY					
MISSOURI	MORGAN		.59	.58		
MISSOURI	NEW MADRID	.33	.20	5.73	6.40	5.61
MISSOURI	NEWTON	2.64		2.45	1.55	.43
MISSOURI	NODAWAY	.04		.03	.40	.27
MISSOURI	OREGON	1.78	.63		.24	5.41
MISSOURI	OSAGE	1.74	1.22	.70	.79	1.28
MISSOURI	OZARK	1.47	1.96	9.54	7.79	7.36
MISSOURI	PEMISCOT	12.97	13.35	11.36	12.77	9.35
MISSOURI	PERRY	2.34				
MISSOURI	PETTIS			.15	.17	.06
MISSOURI	PHELPS	.55			.01	
MISSOURI	Pike		.29		1.16	.17
MISSOURI	PLATTE				3.43	
MISSOURI	POLK	1.08	.17			1.50
MISSOURI	PULASKI					
MISSOURI	PUTNAM		.30	.25	.55	11.98
MISSOURI	RALLS	4.62		.25	.30	
MISSOURI	RANDOLPH	.01				1.52

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
MONTANA	FERGUS	1.58	.35	1.70	2.30	2.88
MONTANA	FLATHEAD		7.14	9.81	23.99	21.19
MONTANA	GALLATIN	.81				
MONTANA	GARFIELD	35.40	19.14	50.87	44.82	35.03
MONTANA	GLACIER					11.63
MONTANA	GOLDEN VALLEY				.86	
MONTANA	GRANITE					1.11
MONTANA	HILL	1.09	1.19		1.58	2.72
MONTANA	JEFFERSON					
MONTANA	JUDITH BASIN		.22			
MONTANA	LAKE					
MONTANA	LEWIS AND CLARK					
MONTANA	LIBERTY	1.30	3.32			5.07
MONTANA	LINCOLN	9.25	8.83	8.25	7.96	6.99
MONTANA	MADISON				.23	1.24
MONTANA	MCCONE	.96	1.39	1.16	1.62	2.52
MONTANA	MEAGHER			.55		1.72
MONTANA	MINERAL					
MONTANA	MISSOULA					.55
MONTANA	MUSSELSHELL			32.28	3.02	1.22
MONTANA	PARK	21.11	18.82	13.87	12.10	10.47
MONTANA	PETROLEUM					
MONTANA	PHILLIPS	10.84	9.07	6.54	6.00	9.33
MONTANA	PONDERA	3.86	2.93	2.67	1.92	1.12
MONTANA	POWDER RIVER		2.68	1.76	3.47	.51
MONTANA	POWELL	.51	5.27	5.22	2.88	2.94
MONTANA	PRAIRIE				6.82	1.93
MONTANA	RAVALLI	12.09	5.59		6.84	2.20
MONTANA	RICHLAND	1.96	5.61	11.20	12.69	7.92
MONTANA	ROOSEVELT	.27				7.22
MONTANA	ROSEBUD	.69		1.18	.20	2.03
MONTANA	SANDERS	9.31	7.13	22.95	12.48	7.97
MONTANA	SHERIDAN		.27	.06		
MONTANA	SILVER BOW					
MONTANA	STILLWATER	6.02	15.91	15.15	14.07	10.75

MONTANA	SWEET GRASS	3.54	1.01	2.93	2.14	28
MONTANA	TETON	15.20	25.81	24.27	4.10	4.06
MONTANA	TOOLE	.23	.30	.35	.43	.22
MONTANA	TREASURE		26.91	24.22	11.38	
MONTANA	VALLEY	17.32	19.80	20.87	19.95	17.15
MONTANA	WHEATLAND				1.76	
MONTANA	WIBAUX	.04		.62	1.24	.14
MONTANA	YELLOWSTONE	21.61	20.18	16.67	13.40	9.39
NEBRASKA	ADAMS	.42	.47	.52	.76	.50
NEBRASKA	ANTELOPE				.29	.25
NEBRASKA	ARTHUR					
NEBRASKA	BANNER					
NEBRASKA	BLAINE	11.81				
NEBRASKA	BOONE	.05			1.01	3.62
NEBRASKA	BOX BUTTE			.09		.23
NEBRASKA	BOYD	1.15	1.20	2.52	1.64	2.57
NEBRASKA	BROWN					.12
NEBRASKA	BUFFALO	1.36	2.77	15.84	14.24	19.72
NEBRASKA	BURT	.39	.39	9.33	12.06	7.38
NEBRASKA	BUTLER	.13	4.60	.09	.03	.63
NEBRASKA	CASS			.25	.79	.39
NEBRASKA	CEDAR	.67	.30	.20	.02	.04
NEBRASKA	CHASE	7.44	3.35	.32	2.35	2.03
NEBRASKA	CHERRY	.55	.84	.49	.38	1.02
NEBRASKA	CHEYENNE	1.59	2.98	1.50	5.19	4.90
NEBRASKA	CLAY	1.00	1.25	.27	14.32	14.32
NEBRASKA	COLFAX	.10	.31	.57	6.96	2.53
NEBRASKA	CUMING	.33	.30	.30	.34	.33
NEBRASKA	CUSTER	5.99	5.20	.34	2.32	2.10
NEBRASKA	DAKOTA					
NEBRASKA	DAMES		1.58	.42		.47
NEBRASKA	DAWSON	.04	.05	1.50	.79	1.03
NEBRASKA	DEUEL					
NEBRASKA	DIXON					.39
NEBRASKA	DODGE	.51	.45	3.16	2.83	2.65
NEBRASKA	DOUGLAS					
NEBRASKA	DUNDY			4.11	17.06	5.79
NEBRASKA	FILLMORE	.79		.07	.66	.77
NEBRASKA	FRANKLIN	1.36		.20	.50	5.90
NEBRASKA	FRONTIER	1.14	.95	4.21	2.02	2.02

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
NEBRASKA	FURNAS	.56	3.49	3.42	3.46	3.63
NEBRASKA	GAGE	.13	.07	.07	.67	.38
NEBRASKA	GARDEN					
NEBRASKA	GARFIELD	1.11		4.02	30.23	31.15
NEBRASKA	GOSPER				1.28	.41
NEBRASKA	GRANT					
NEBRASKA	GREELEY	.87	.77	.75	.69	11.38
NEBRASKA	HALL		.27	1.10	13.11	11.59
NEBRASKA	HAMILTON	.24		.70	.49	.16
NEBRASKA	HARLAN	.70		.57	7.66	2.10
NEBRASKA	HAYES	16.68	15.19	14.26	8.22	7.15
NEBRASKA	HITCHCOCK		9.03	16.46	14.05	12.63
NEBRASKA	HOLT	.12		.45	.09	.06
NEBRASKA	HOOVER					
NEBRASKA	HOWARD	1.88	.29	.46	3.24	1.01
NEBRASKA	JEFFERSON		.36	13.10	14.09	16.90
NEBRASKA	JOHNSON	1.08	.33	1.31	1.14	.51
NEBRASKA	KEARNEY					2.66
NEBRASKA	KEITH				4.64	
NEBRASKA	KEYA PAHA	.49		4.06	6.90	3.02
NEBRASKA	KIMBALL		.79	.49	13.56	.60
NEBRASKA	KNOX	1.89	1.38	1.13	1.10	2.90
NEBRASKA	LANCASTER		.06		.41	.33
NEBRASKA	LINCOLN	1.72	1.40	.70	1.55	3.33
NEBRASKA	LOGAN					2.03
NEBRASKA	LOUP	2.19	.15			
NEBRASKA	MADISON			.15		
NEBRASKA	MCPHERSON					
NEBRASKA	MERRICK	3.09	3.64	4.89	8.04	6.56
NEBRASKA	MORRILL	21.95	18.30	17.96	15.57	14.30
NEBRASKA	NANCE	.68	.10	.24	.25	.23
NEBRASKA	NEMHA	.79	.68	.84	.83	2.84
NEBRASKA	NUCKOLLS	2.59	2.32	6.45	6.12	11.10
NEBRASKA	OTOE	.76	.79	.73	.82	9.64
NEBRASKA	PANNEE	.35	2.27	.89	.88	2.25

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
NEVADA	STOREY					
NEVADA	WASHOE	70.07	68.04	63.04	58.07	54.38
NEVADA	WHITE PINE					
NEW HAMPSHIRE	BELKNAP	2.68	.88	.91	1.59	2.67
NEW HAMPSHIRE	CARROLL	2.61			3.03	
NEW HAMPSHIRE	CHESHIRE		.07		.06	
NEW HAMPSHIRE	COOS	4.40	6.40	6.46	8.17	7.54
NEW HAMPSHIRE	GRAFTON		3.59	4.04	4.72	3.95
NEW HAMPSHIRE	HILLSBOROUGH	.89				
NEW HAMPSHIRE	MERRIMACK	.29				
NEW HAMPSHIRE	ROCKINGHAM	.04			.02	.52
NEW HAMPSHIRE	STRAFFORD	4.61	4.19	4.38	3.73	3.58
NEW HAMPSHIRE	SULLIVAN		.35		4.43	1.56
NEW HAMPSHIRE	ATLANTIC	8.36	25.38	30.29	31.23	28.26
NEW JERSEY	BERGEN					
NEW JERSEY	BURLINGTON	34.19	29.72	25.86	24.93	26.37
NEW JERSEY	CAMDEN		43.62	43.43	29.95	26.95
NEW JERSEY	CAPE MAY		16.01	80.06	79.93	79.95
NEW JERSEY	CUMBERLAND	37.81	35.00	40.14	38.70	42.37
NEW JERSEY	ESSEX					
NEW JERSEY	GLoucester	58.84	67.47	57.78	55.76	53.93
NEW JERSEY	HUDSON					
NEW JERSEY	HUNTERDON	2.46	4.89	11.12	9.30	13.31
NEW JERSEY	MERCER				100.00	
NEW JERSEY	MIDDLESEX	82.88	82.86	82.68	82.66	56.49
NEW JERSEY	MONMOUTH	56.77	75.28	74.72	74.00	59.26
NEW JERSEY	MORRIS		1.98			10.28
NEW JERSEY	OCEAN		90.95			9.43
NEW JERSEY	PASSAIC					
NEW JERSEY	SALEM	48.91	49.26	53.50	46.95	49.33
NEW JERSEY	SOMERSET		.74	40.11	35.87	25.40
NEW JERSEY	SUSSEX	3.77	1.71			
NEW JERSEY	UNION					
NEW JERSEY	WARREN	5.11	4.41	4.24	5.28	4.12
NEW MEXICO	BERNALILLO WEST	41.39	27.29	15.81	1.20	

NEW MEXICO	CATRON	7.28	5.13	6.78	3.70	3.15
NEW MEXICO	CHAVES	31.80	26.59	21.63	18.16	17.87
NEW MEXICO	CIBOLA	47.44	74.12	72.48	68.32	65.66
NEW MEXICO	COLFAX		1.99			
NEW MEXICO	CURRY	4.45	4.19	7.58	11.91	10.09
NEW MEXICO	DEBACA				.96	
NEW MEXICO	DONA ANA	9.27	9.11	7.80	5.96	.65
NEW MEXICO	EDDY	28.85	19.77	13.65	14.74	9.74
NEW MEXICO	GRANT	28.41	23.42	18.45	18.04	10.15
NEW MEXICO	GUADALUPE					
NEW MEXICO	HARDING, PT					
NEW MEXICO	HIDALGO	16.29	17.69	22.09	23.80	8.57
NEW MEXICO	LEA	17.67	15.88	14.62	8.52	8.12
NEW MEXICO	LINCOLN	1.76	2.52	14.11	13.10	11.09
NEW MEXICO	LOS ALAMOS					
NEW MEXICO	LUNA	3.87	6.65	6.84	3.84	2.51
NEW MEXICO	MCKINLEY	8.99	11.57	15.15	26.61	20.31
NEW MEXICO	MORA		26	17	87	1.40
NEW MEXICO	OTERO, PT	27.20	23.35	25.27	13.59	13.43
NEW MEXICO	QUAY		.34	2.08	2.21	1.73
NEW MEXICO	RIO ARriba	9.39	17.54	15.79	12.09	10.74
NEW MEXICO	ROOSEVELT	21.77	22.28	26.80	21.02	18.83
NEW MEXICO	SAN JUAN	45.80	42.09	33.05	9.10	3.37
NEW MEXICO	SAN MIGUEL	.15	44.63	32.06	37.85	45.32
NEW MEXICO	SANDOVAL	6.49	7.84	4.99	.37	.11
NEW MEXICO	SANTA FE, N	9.56	21.99	11.72	7.26	
NEW MEXICO	SIERRA	27.37	19.38	17.14	16.70	14.75
NEW MEXICO	SOCORRO	30.24	31.48	24.60	20.72	19.54
NEW MEXICO	TAOS			2.75	4.02	3.15
NEW MEXICO	TORRANCE	2.33	25.76	22.26	21.53	21.58
NEW MEXICO	UNION	4.21	2.79	1.51		11.38
NEW MEXICO	VALENCIA, WEST	8.20	6.63	9.57	2.27	2.06
NEW YORK	ALBANY	1.62	2.82	8.40		
NEW YORK	ALLEGANY	12.98	11.53	10.78	9.24	4.83
NEW YORK	BRONX					
NEW YORK	BROOME			2.65	1.62	.03
NEW YORK	CATTARAUGUS	.89	5.00	10.69	12.42	21.44
NEW YORK	CAYUGA	17.87	15.49	16.56	18.46	16.03
NEW YORK	CHAUTAUQUA	5.96	9.56	7.83	8.59	8.62
NEW YORK	CHEMUNG		1.69	6.35		

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
NEW YORK	CHEMANGO	6.18	5.41	4.45	12.21	20.02
NEW YORK	CLINTON	4.35		27.49	39.16	31.95
NEW YORK	COLUMBIA	3.49	7.00	5.12	5.88	6.96
NEW YORK	CORTLAND	2.26	1.51	2.26	.93	1.18
NEW YORK	DELAWARE	14.31	14.68	15.85	17.22	26.81
NEW YORK	DUTCHESS		26.31	32.60	45.68	50.85
NEW YORK	ERIE	7.06	7.08	9.73	13.82	16.84
NEW YORK	ESSEX				7.99	
NEW YORK	FRANKLIN	21.37	27.43	25.49	27.46	26.41
NEW YORK	FULTON		.43	.45	1.15	.33
NEW YORK	GENESEE	10.59	27.01	22.99	14.99	13.03
NEW YORK	GREENE	7.40				
NEW YORK	HAMILTON					
NEW YORK	HERKIMER	4.12	4.91	4.99	5.98	4.76
NEW YORK	JEFFERSON	4.68	6.41	7.75	7.55	16.84
NEW YORK	KINGS					
NEW YORK	LEWIS	11.05	9.29	8.62	9.91	26.21
NEW YORK	LIVINGSTON	32.63	34.53	36.79	36.03	36.47
NEW YORK	MADISON	10.01	11.85	12.42	10.81	7.55
NEW YORK	MONROE	4.09	11.20	11.13	14.80	24.48
NEW YORK	MONTGOMERY	2.28	2.93	1.41	5.95	5.01
NEW YORK	NASSAU					
NEW YORK	NEW YORK					
NEW YORK	NIAAGARA	2.08	2.50	1.83	8.02	13.21
NEW YORK	ONEIDA	1.23	5.77	6.12	19.98	17.48
NEW YORK	ONONDAGA	10.50	19.57	10.99	14.55	11.22
NEW YORK	ONTARIO	12.78	14.43	19.41	24.70	26.16
NEW YORK	ORANGE	14.63	10.60	33.45	35.43	44.92
NEW YORK	ORLEANS	29.28	27.80	27.84	19.57	26.08
NEW YORK	OSWEGO	44.08	29.59	24.34	22.63	21.86
NEW YORK	OTSEGO	1.99	2.54	6.26	6.01	10.50
NEW YORK	PUTNAM					
NEW YORK	QUEENS					
NEW YORK	RENSSELAER		5.76	5.22	15.09	10.58
NEW YORK	RICHMOND					

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELQ RATE 12/31/06	DELQ RATE 12/31/05	DELQ RATE 12/31/04	DELQ RATE 12/31/03	DELQ RATE 12/31/02
NORTH CAROLINA	CLAY					.91
NORTH CAROLINA	CLEVELAND	1.18	.15	2.86		2.33
NORTH CAROLINA	COLUMBUS	8.57	9.51	6.02	2.75	19.10
NORTH CAROLINA	Craven	13.86	16.78	11.51	20.12	32.80
NORTH CAROLINA	CUMBERLAND		5.91	23.90	11.36	7.62
NORTH CAROLINA	CURRITUCK					
NORTH CAROLINA	DARE					
NORTH CAROLINA	DAVIDSON					
NORTH CAROLINA	DAVIE		23.14			
NORTH CAROLINA	DUPLIN	2.07	2.01	3.44	2.84	2.49
NORTH CAROLINA	DURHAM					
NORTH CAROLINA	EDGECOMBE	7.20	8.25	10.58	10.74	15.96
NORTH CAROLINA	FORSYTH					
NORTH CAROLINA	FRANKLIN			3.13		12.98
NORTH CAROLINA	GASTON			99.41	100.00	100.00
NORTH CAROLINA	GATES	4.02	7.73	6.89	6.24	7.98
NORTH CAROLINA	GRAHAM				98.17	97.97
NORTH CAROLINA	GRANVILLE		56.27	57.08	41.42	41.78
NORTH CAROLINA	GREENE	10.28	14.61	14.52	11.20	9.73
NORTH CAROLINA	GUILFORD				1.08	
NORTH CAROLINA	HALIFAX	30.11	26.19	24.47	38.17	43.81
NORTH CAROLINA	HARNETT				25.76	28.24
NORTH CAROLINA	HAYWOOD	.61				
NORTH CAROLINA	HENDERSON	62.67	60.55	52.17	44.97	35.67
NORTH CAROLINA	HERTFORD	23.37	20.01	16.94	16.40	18.74
NORTH CAROLINA	Hoke				11.56	11.63
NORTH CAROLINA	HYDE	17.32	11.51	9.02	2.69	3.34
NORTH CAROLINA	IREDELL				.89	.14
NORTH CAROLINA	JACKSON		1.70			
NORTH CAROLINA	JOHNSTON	7.61	11.13	13.08	17.13	21.65
NORTH CAROLINA	JONES	4.55	16.72	9.39		
NORTH CAROLINA	LEE					
NORTH CAROLINA	LENOIR					1.55
NORTH CAROLINA	LINCOLN	5.16	4.53	5.27	2.52	18.22
NORTH CAROLINA	MACON					

NORTH CAROLINA	MADISON	7.78	15.24	13.19	9.55	9.91
NORTH CAROLINA	MARTIN	8.92	8.38	7.77	7.18	12.18
NORTH CAROLINA	MCDOWELL					
NORTH CAROLINA	MECKLENBURG					
NORTH CAROLINA	MITCHELL					
NORTH CAROLINA	MONTGOMERY					
NORTH CAROLINA	MOORE					
NORTH CAROLINA	NASH	2.36	1.04	1.53	7.34	6.45
NORTH CAROLINA	NEW HANOVER					
NORTH CAROLINA	NORTHAMPTON	17.11	14.57	21.63	26.68	31.55
NORTH CAROLINA	ONSLOW	6.50	7.58	9.05	53.65	53.67
NORTH CAROLINA	ORANGE	82.77	69.64	69.25	67.44	56.28
NORTH CAROLINA	PAMLICO	.91	32.13	6.56	11.73	11.04
NORTH CAROLINA	PASQUOTANK	.81	.68	7.21	.86	.69
NORTH CAROLINA	PENDER	72.13	73.16	71.62	74.00	70.98
NORTH CAROLINA	PERQUIMANS	.32	.71	.97		
NORTH CAROLINA	PERSON	31.78	29.28	29.14	25.31	23.54
NORTH CAROLINA	PITT	49.09	45.86	40.08	40.08	39.76
NORTH CAROLINA	POLK	8.52				
NORTH CAROLINA	RANDOLPH			5.15	2.55	2.54
NORTH CAROLINA	RICHMOND				.03	
NORTH CAROLINA	ROBESON	30.76	54.99	49.62	45.28	42.21
NORTH CAROLINA	ROCKINGHAM	6.33	8.13	.75	.37	28.84
NORTH CAROLINA	ROWAN	10.09				
NORTH CAROLINA	RUTHERFORD				3.05	
NORTH CAROLINA	SAMPSON	12.67	9.76	9.26	42.47	47.85
NORTH CAROLINA	SCOTLAND			84.80	69.78	36.99
NORTH CAROLINA	STANLY					4.37
NORTH CAROLINA	STOKES					
NORTH CAROLINA	SURRY	.47				
NORTH CAROLINA	SWAIN					
NORTH CAROLINA	TRANSYLVANIA	72.66	71.39	71.38	70.37	69.91
NORTH CAROLINA	TYRRELL	10.26	3.74	9.79	56.96	55.82
NORTH CAROLINA	UNION	25.12	57.71	20.36	16.83	28.02
NORTH CAROLINA	VANCE			17.09	14.02	15.30
NORTH CAROLINA	WAKE		27.46	32.17	25.91	32.42
NORTH CAROLINA	WARREN	22.33	29.11	23.04	24.36	53.96
NORTH CAROLINA	WASHINGTON	14.61	17.52	6.66	3.41	7.43
NORTH CAROLINA	WATAUGA					
NORTH CAROLINA	WAYNE		5.08	3.55	6.77	8.29

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELQ RATE 12/31/06	DELO RATE 12/31/05	DELQ RATE 12/31/04	DELO RATE 12/31/03	DELQ RATE 12/31/02
NORTH CAROLINA	WILKES	1.78	1.60	2.27	2.22	2.63
NORTH CAROLINA	WILSON	7.63	7.36	.18	.32	1.33
NORTH CAROLINA	YADKIN					
NORTH CAROLINA	YANCEY		.48	1.35		1.12
NORTH DAKOTA	ADAMS	6.20	5.65	4.26	4.30	4.64
NORTH DAKOTA	BARNES			3.97	2.98	2.36
NORTH DAKOTA	BENSON	1.53	3.18	2.75	4.24	4.44
NORTH DAKOTA	BILLINGS	4.37	.63	.14	1.75	1.29
NORTH DAKOTA	BOTTINEAU	2.04	1.63	2.75	2.68	3.25
NORTH DAKOTA	BOWMAN			.85	.20	.58
NORTH DAKOTA	BURKE			.50		.45
NORTH DAKOTA	BURLEIGH	.31	3.06	1.93	1.51	2.14
NORTH DAKOTA	CASS	2.24	.86		.11	.57
NORTH DAKOTA	CAVALIER	.34	.37	.08	.08	.30
NORTH DAKOTA	CORSON SD, PT	.09			.28	3.56
NORTH DAKOTA	DICKEY				1.88	.45
NORTH DAKOTA	DIVIDE	.58	.16	.53	.33	1.50
NORTH DAKOTA	DUNN, PT	51.09	48.57	43.23	39.54	36.15
NORTH DAKOTA	EDDY	.18	5.97	4.09	2.13	3.16
NORTH DAKOTA	EMMONS	.88	1.35	1.06	1.07	3.06
NORTH DAKOTA	FOSTER			10.74	8.71	7.48
NORTH DAKOTA	GOLDEN VALLEY	1.92	.54	1.04	.12	1.14
NORTH DAKOTA	GRAND FORKS	.37		.54	3.45	2.94
NORTH DAKOTA	GRANT	1.86	1.00	1.04	1.74	1.59
NORTH DAKOTA	GRIGGS			2.49	.53	2.76
NORTH DAKOTA	HETTINGER	.35	1.49	.74	1.89	3.45
NORTH DAKOTA	KIDDER	.69	3.00	4.09	1.90	4.81
NORTH DAKOTA	LAMOUR				.53	.20
NORTH DAKOTA	LOGAN	.37	1.34	.45	.56	.64
NORTH DAKOTA	MCHENRY	1.54	1.62	2.29	2.23	1.78
NORTH DAKOTA	MCINTOSH	1.19	.63	.49	1.01	1.72
NORTH DAKOTA	MCKENZIE, PT	23.90	22.20	20.71	19.44	17.73
NORTH DAKOTA	MCLEAN, PT	22.21	19.26	16.05	12.37	13.14
NORTH DAKOTA	MERCER, PT	56.65	52.20	45.12	37.57	32.15
NORTH DAKOTA	MORTON	2.09	1.83	1.76	1.66	2.81

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELQ RATE 12/31/06	DELQ RATE 12/31/05	DELQ RATE 12/31/04	DELQ RATE 12/31/03	DELQ RATE 12/31/02
OHIO	CUYAHOGA	5.21	4.71	10.05	17.04	15.07
OHIO	DARKE	.23	.36			
OHIO	DEFIANCE	42.59	39.65	29.84	44.80	37.91
OHIO	DELAWARE					
OHIO	ERIE					
OHIO	FAIRFIELD	1.49	5.05	5.23	7.54	11.16
OHIO	FAYETTE	9.43	9.13	7.55	8.14	4.14
OHIO	FRANKLIN					
OHIO	FULTON					
OHIO	GALLIA	47.94	72.71	21.20	42.88	1.56
OHIO	GEAUGA					39.03
OHIO	GREENE	7.58	5.53	8.02	15.31	12.55
OHIO	GUERNSEY	.84				.06
OHIO	HAMILTON					
OHIO	HANCOCK					
OHIO	HARDIN					.56
OHIO	HARRISON					
OHIO	HENRY					
OHIO	HIGHLAND			.11	.08	.08
OHIO	HOCKING					
OHIO	HOLMES					3.60
OHIO	HURON		4.54	4.48	13.43	10.01
OHIO	JACKSON			40.48	32.43	32.67
OHIO	JEFFERSON			11.33	5.17	
OHIO	KNOX	6.23	4.63	6.57	4.78	5.46
OHIO	LAKE					
OHIO	LAWRENCE	.30				
OHIO	LICKING			1.21	7.19	4.60
OHIO	LOGAN	1.11	56.54	42.11	38.42	38.54
OHIO	LORAIN	.35	1.79	1.27	12.47	11.49
OHIO	LUCAS					
OHIO	MADISON				.15	.09
OHIO	MAHoning					
OHIO	MARION					
OHIO	MEDINA	19.43	.75	.67	.58	.60

OHIO	MEIGS	19.79	19.80	20.15	8.77	8.13
OHIO	MERCER	26.96	33.16	50.46	42.32	40.86
OHIO	MIAMI		2.72	2.62	1.69	3.99
OHIO	MONROE					
OHIO	MONTGOMERY			19.11	13.76	9.16
OHIO	MORGAN	18.49	11.58	8.28	3.25	2.36
OHIO	MORROW	.29	.74	.92	1.78	.44
OHIO	MUSKINGUM	9.47			.07	.45
OHIO	NOBLE					
OHIO	OTTAWA	.88	.96	.59	.86	.36
OHIO	PAULDING					
OHIO	PERRY			5.19	8.97	1.58
OHIO	PICKAWAY	27.21	25.00	23.90	23.09	35.35
OHIO	PIKE					
OHIO	PORTAGE			3.31	3.07	.33
OHIO	PREBLE	1.28	.96	1.56	11.30	11.93
OHIO	PUTNAM					
OHIO	RICHLAND	.37				
OHIO	ROSS				9.91	9.36
OHIO	SANDUSKY			.95	19.59	18.18
OHIO	SCIOTO					
OHIO	SENECA	.72	.07	.08	.08	.07
OHIO	SHELBY					
OHIO	STARK				7.61	13.89
OHIO	SUMMIT			4.67		17.39
OHIO	TRUMBULL	2.05	.88	1.62	2.21	1.95
OHIO	TUSCARAWAS	.93		12.65	28.39	46.16
OHIO	UNION					58.35
OHIO	VAN WERT					
OHIO	VINTON					
OHIO	WARREN					
OHIO	WASHINGTON		35.66	13.06	8.06	47.60
OHIO	WAYNE	1.38		.63		5.52
OHIO	WILLIAMS					2.93
OHIO	WOOD	5.22	5.93	8.55		
OHIO	WYANDOT					
OKLAHOMA	ADAIR	1.13	6.57	4.90	2.79	2.13
OKLAHOMA	ALFALFA		.43	.23	8.50	6.62
OKLAHOMA	ATOKA	1.99	10.84	11.11	10.21	64.02
OKLAHOMA	BEAVER	1.13	2.00	3.92	8.36	8.10

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
OKLAHOMA	BECKHAM	5.89	7.31	6.57	4.99	5.81
OKLAHOMA	BLAINE	7.43	6.46	6.62	6.12	9.42
OKLAHOMA	BRYAN	4.01	5.96	9.22	10.34	15.21
OKLAHOMA	CADDO	4.97	4.71	6.70	14.94	13.66
OKLAHOMA	CANADIAN	4.81	.50	1.64	1.86	6.11
OKLAHOMA	CARTER	1.13	.13	2.89	1.33	.57
OKLAHOMA	CHEROKEE	1.08	1.24	1.60	2.92	2.01
OKLAHOMA	CHOCTAW	16.45	11.87	11.11	26.33	26.90
OKLAHOMA	CIMARRON	6.54	4.55	3.88	4.46	3.40
OKLAHOMA	CLEVELAND	33.81	25.05	16.25	5.86	4.76
OKLAHOMA	COAL	1.64	.84	2.15	17.12	16.06
OKLAHOMA	COMANCHE	2.42	.75	1.10	7.56	9.06
OKLAHOMA	COTTON	5.65	1.77	3.15	25.87	28.04
OKLAHOMA	CRAIG	.19	15.06	14.74	12.33	12.71
OKLAHOMA	CREEK	1.14	.4891
OKLAHOMA	CUSTER	9.77	4.80	5.12	4.64	2.63
OKLAHOMA	DELAWARE	7.25	5.69	5.23	13.23	12.47
OKLAHOMA	DEWEY	8.78	7.93	7.25	5.85	5.34
OKLAHOMA	ELLIS	8.99	7.63	3.82	4.01	2.89
OKLAHOMA	GARFIELD	1.49	2.98	2.25	.91	2.50
OKLAHOMA	GARVIN	7.44	2.77	5.40	4.86	7.83
OKLAHOMA	GRADY	2.07	2.60	3.09	3.25	2.36
OKLAHOMA	GRANT	2.76	3.31	8.90	10.30	9.06
OKLAHOMA	GREER	5.65	7.94	11.10	5.49	6.13
OKLAHOMA	HARMON	4.74	4.07	4.68	4.89	3.83
OKLAHOMA	HARPER	14.81	10.95	7.11	3.38	1.93
OKLAHOMA	HASKELL	.42	.27	1.40	2.09	2.28
OKLAHOMA	HUGHES	15.62	20.21	23.58	33.96	31.70
OKLAHOMA	JACKSON	5.49	4.27	5.13	4.07	3.96
OKLAHOMA	JEFFERSON	4.59	13.05	16.28	17.55	11.63
OKLAHOMA	JOHNSTON	5.80	5.68	5.97	7.89	10.48
OKLAHOMA	KAY	1.49	1.40	4.28	2.80	3.65
OKLAHOMA	KINGFISHER	4.35	3.97	4.14	7.16	6.71
OKLAHOMA	KIOWA	7.72	5.06	5.14	5.52	11.07
OKLAHOMA	LATIMER	.91	.12	18.81	20.40	14.81

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
OREGON	CLACKAMAS	7.67	9.05	13.39	4.19	3.33
OREGON	CLATSOP	56.61	52.21	36.87	29.98	24.91
OREGON	COLUMBIA	9.91	7.41	7.01	10.21	8.79
OREGON	COOS	2.28	2.01	2.32	5.64	7.90
OREGON	CROOK	11.86	4.57			4.29
OREGON	CURRY	4.41	1.49	1.09		2.60
OREGON	DESCHUTES	6.46		6.79	5.73	.77
OREGON	DOUGLAS	.79	1.15	.85	4.13	3.02
OREGON	GILLIAM	7.47	9.53	3.70	8.74	9.11
OREGON	GRANT	.05	.47	.13		3.69
OREGON	HARNEY	4.07	6.11	7.56	4.59	4.29
OREGON	HOOD RIVER	.44	.43	9.39	23.38	20.31
OREGON	JACKSON	3.03	4.40	3.02	19.39	15.32
OREGON	JEFFERSON			11.12	10.12	8.78
OREGON	JOSEPHINE					
OREGON	KLAMATH	.07	.50	10.22	9.30	6.65
OREGON	LAKE	.45	1.31	3.79	4.00	.41
OREGON	LANE	1.88	2.63	1.96	11.74	10.68
OREGON	LINCOLN					
OREGON	LINN	4.72	5.63	5.52	3.24	3.90
OREGON	MALHEUR	5.69	4.62	4.13	4.48	5.31
OREGON	MARION	5.83	3.12	2.58	2.89	3.95
OREGON	MORROW		2.66			
OREGON	MULTNOMAH					
OREGON	POLK	1.61	.80	.87	3.00	1.51
OREGON	SHERMAN	4.28	1.75	21.84	16.45	14.88
OREGON	TILLAMOOK				.47	.50
OREGON	UMATILLA	1.76	2.25	3.25	3.37	4.49
OREGON	UNION	16.18	13.93	2.71	2.07	2.81
OREGON	WALLOWA	.41	3.03	1.75	1.97	3.77
OREGON	WASCO		.11		.76	.05
OREGON	WASHINGTON	.59	.75	.71	.74	.77
OREGON	WHEELER					
OREGON	YAMHILL	26.59	33.67	22.97	17.20	12.51
PENNSYLVANIA	ADAMS	.55	1.64	3.07	19.39	2.53

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
PENNSYLVANIA	MCKEAN					.03
PENNSYLVANIA	MERCER	6.65	6.40	5.15	8.10	3.01
PENNSYLVANIA	MIFFLIN	1.66	.67	5.64	4.95	4.54
PENNSYLVANIA	MONROE					
PENNSYLVANIA	MONTGOMERY	28.67	30.01	32.24	28.30	33.57
PENNSYLVANIA	MONTGOMERY			2.48	.80	1.58
PENNSYLVANIA	MONTGOMERY			84.03	48.17	42.22
PENNSYLVANIA	NORTHAMPTON	72.55	73.70	1.05	.58	4.80
PENNSYLVANIA	NORTHAMPTON	3.97	3.17	1.19		.58
PENNSYLVANIA	NORTHAMPTON	5.23	4.53			
PENNSYLVANIA	PERRY					
PENNSYLVANIA	PERRY					
PENNSYLVANIA	PHILADELPHIA					
PENNSYLVANIA	PHILADELPHIA					
PENNSYLVANIA	PHE					
PENNSYLVANIA	POTTER	.04			1.23	1.99
PENNSYLVANIA	POTTER			1.27	2.86	.17
PENNSYLVANIA	SCHUYLKILL	2.57	1.56	4.95	4.72	3.47
PENNSYLVANIA	SNYDER	2.63	2.85	.09		.02
PENNSYLVANIA	SOMERSET	1.78	.55			
PENNSYLVANIA	SULLIVAN		2.66			
PENNSYLVANIA	SUSQUEHANNA		.29	.31	9.23	7.06
PENNSYLVANIA	TIOGA	.21	.66	6.07	5.25	7.24
PENNSYLVANIA	UNION		2.00	1.52	1.53	1.99
PENNSYLVANIA	VENANGO	5.49	3.86	2.47	.40	
PENNSYLVANIA	WARREN	.01				2.89
PENNSYLVANIA	WASHINGTON	8.13	5.13	8.51	1.92	.99
PENNSYLVANIA	WAYNE	1.34	34.98	19.69	15.77	19.82
PENNSYLVANIA	WESTMORELAND	17.19	19.44	15.13	11.07	8.10
PENNSYLVANIA	WYOMING					
PENNSYLVANIA	YORK	.06		4.83	4.33	16.28
PUERTO RICO	ADJUNTAS	27.19	25.23	23.03	20.81	18.03
PUERTO RICO	AGUADILLA	82.23	80.72	75.99	66.63	60.99
PUERTO RICO	BARANQUITAS	16.12	13.82	15.33	15.35	14.34
PUERTO RICO	BAYAMON	67.93	62.64	60.00	57.92	59.70
PUERTO RICO	CAGUAS	30.39	26.63	20.94	15.71	14.91
PUERTO RICO	CAMUY	45.93	37.67	31.24	24.49	23.60
PUERTO RICO	CAJES	48.26	45.99	38.05	32.76	24.59
PUERTO RICO	COAMO	28.66	24.99	21.65	17.19	12.28
PUERTO RICO	COROZAL	22.12	17.24	14.77	13.37	17.01

PUERTO RICO	FAJARDO	47.25	50.10	44.53	39.49	36.05
PUERTO RICO	GUAYAMA	48.71	48.91	46.65	44.69	43.21
PUERTO RICO	HUMACAO	28.15	23.76	22.62	22.91	20.16
PUERTO RICO	JAYUYA	7.08	8.25	7.47	7.61	9.90
PUERTO RICO	JUANA DIAZ	20.75	18.93	21.95	27.88	26.87
PUERTO RICO	LARES	25.14	23.69	21.38	20.04	17.21
PUERTO RICO	MAYAGUEZ	13.88	12.57	12.07	12.03	12.05
PUERTO RICO	MOROVIS	43.02	39.79	38.43	31.53	25.85
PUERTO RICO	RIO GRANDE	22.78	20.71	15.63	12.24	9.76
PUERTO RICO	SAN GERMAN	41.89	37.19	34.89	33.26	31.61
PUERTO RICO	SAN LORENZO	19.95	26.07	17.89	11.34	9.17
PUERTO RICO	SAN SEBASTIAN	24.51	22.49	21.44	21.47	24.55
PUERTO RICO	UTUADO	15.45	13.16	11.66	10.28	10.85
PUERTO RICO	YAUCO	35.83	31.87	26.73	22.77	17.73
RHODE ISLAND	BRISTOL	38.13	2.96	11.20
RHODE ISLAND	KENT	34.74	29.11	25.94	22.42	19.75
RHODE ISLAND	NEWPORT	30.40	25.20	22.76	23.11	24.62
RHODE ISLAND	PROVIDENCE	7.70	5.64	4.20	2.26	8.40
RHODE ISLAND	WASHINGTON	1.67	5.20	1.58	1.97	8.34
SOUTH CAROLINA	ABBEVILLE	1.82	1.76	1.41
SOUTH CAROLINA	AKEN	6.75	9.81	4.90
SOUTH CAROLINA	ALLENDALE	1.66	1.75	4.21
SOUTH CAROLINA	ANDERSON	10.74	33.49	20.30	1.41	1.21
SOUTH CAROLINA	BAMBERG	72	46	1.79
SOUTH CAROLINA	BARNWELL	47.59	52.40	48.94	49.41	48.54
SOUTH CAROLINA	BEAUFORT	58.85	98.22	98.17	98.16	98.10
SOUTH CAROLINA	BERKELEY	10.70	5.70	4.56
SOUTH CAROLINA	CALHOUN	24.53	20.48	16.97	13.62	14.31
SOUTH CAROLINA	CHARLESTON	21.55	28.16	15.76	19.03	14.25
SOUTH CAROLINA	CHEROKEE	5.61	4.64
SOUTH CAROLINA	CHESTER	3.47	11.34
SOUTH CAROLINA	CHESTERFIELD3268	.72	1.43
SOUTH CAROLINA	CLARENDON	4.76	19.57	16.33	14.60	12.91
SOUTH CAROLINA	COLLETON	21.81	19.87	17.73	17.72	14.46
SOUTH CAROLINA	DARLINGTON	4.23	4.60	3.60	3.02	3.83
SOUTH CAROLINA	DILLON	1.69	1.16	1.43	1.38	1.15
SOUTH CAROLINA	DORCHESTER94	1.08	16.02	9.73	9.48
SOUTH CAROLINA	EDGEFIELD	72.07	67.44	71.54	73.57
SOUTH CAROLINA	FAIRFIELD
SOUTH CAROLINA	FLORENCE	21.28	20.73	28.95	27.39	25.67

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELQ RATE 12/31/06	DELQ RATE 12/31/05	DELQ RATE 12/31/04	DELQ RATE 12/31/03	DELQ RATE 12/31/02
SOUTH CAROLINA	GEORGETOWN	5.65		3.54	3.07	6.09
SOUTH CAROLINA	GREENVILLE			2.03		
SOUTH CAROLINA	GREENWOOD	14.47	11.76	10.16	9.46	5.07
SOUTH CAROLINA	HAMPTON			14.95	55.76	66.83
SOUTH CAROLINA	HORRY		.13	.18	.09	1.21
SOUTH CAROLINA	JASPER	64.42	80.66	79.83	79.36	74.86
SOUTH CAROLINA	KERSHAW					
SOUTH CAROLINA	LANCASTER					
SOUTH CAROLINA	LAURENS		11.08	19.07	10.73	13.37
SOUTH CAROLINA	LEE	1.13	1.55	9.39	7.89	6.58
SOUTH CAROLINA	LEXINGTON	1.80	1.93	3.36	1.26	4.09
SOUTH CAROLINA	MARION	16.65	16.55	24.16	21.06	14.25
SOUTH CAROLINA	MARLBORO	5.35	5.23	4.60	2.99	9.00
SOUTH CAROLINA	MCCORMICK				12.75	
SOUTH CAROLINA	NEWBERRY	1.10	.60	6.56	3.21	1.97
SOUTH CAROLINA	OCONEE	8.39	12.57	23.55	45.06	43.43
SOUTH CAROLINA	ORANGEBURG	5.13	8.43	7.06	4.91	4.25
SOUTH CAROLINA	PICKENS				.14	
SOUTH CAROLINA	RICHLAND		10.35		1.79	18.54
SOUTH CAROLINA	SALUDA	1.80	1.23	2.51	1.92	3.18
SOUTH CAROLINA	SPARTANBURG	23.15	20.69	5.13	3.22	1.90
SOUTH CAROLINA	SUMTER	7.83	6.16	4.10	4.56	6.65
SOUTH CAROLINA	UNION					
SOUTH CAROLINA	WILLIAMSBURG	15.95	17.11	19.87	17.91	15.60
SOUTH CAROLINA	YORK	.54	.45			
SOUTH DAKOTA	AURORA	3.05	2.37	1.81	1.60	1.24
SOUTH DAKOTA	BEADLE	.56	.80	.87	7.14	13.03
SOUTH DAKOTA	BENNETT	.39	.53	.49	.06	.43
SOUTH DAKOTA	BON HOMME	2.20	1.59	3.03	.86	.18
SOUTH DAKOTA	BROOKINGS	.27	.66	.19	.34	.17
SOUTH DAKOTA	BROWN	.07	.08	.07	.07	.24
SOUTH DAKOTA	BRULE			.56	.01	.68
SOUTH DAKOTA	BUFFALO			.11	.46	.08
SOUTH DAKOTA	BUTTE		.03		.06	1.74
SOUTH DAKOTA	CAMPBELL	.13	.13	.09	.08	8.74

SOUTH DAKOTA	CHARLES MIX	2.46	2.71	2.68	2.48	2.82
SOUTH DAKOTA	CLARK		.02	.01	.63	2.48
SOUTH DAKOTA	CLAY	.12	.14	.12		.74
SOUTH DAKOTA	CODINGTON	1.24	1.63	1.59	.51	4.25
SOUTH DAKOTA	CUSTER	.36				
SOUTH DAKOTA	DAVISON	18.27	15.31	26.96	23.40	19.72
SOUTH DAKOTA	DAY	1.08	.33	6.58	2.52	.90
SOUTH DAKOTA	DEUEL	1.91	.31	.24	.65	.20
SOUTH DAKOTA	DEWEY	5.45	6.77	4.99	4.76	4.12
SOUTH DAKOTA	DOUGLAS	.05	.38	.09	.01	
SOUTH DAKOTA	EDMUNDS	.17		.02	1.37	1.40
SOUTH DAKOTA	FALL RIVER	.24				.39
SOUTH DAKOTA	FAULK	.04	.06		.06	.03
SOUTH DAKOTA	GRANT	.42	.44	.11		.93
SOUTH DAKOTA	GREGORY	.82	.86	.78	.72	3.29
SOUTH DAKOTA	HAKON	.67	.47	.25	1.06	.30
SOUTH DAKOTA	HAMLIN	.93	.94	.79	.64	1.82
SOUTH DAKOTA	HAND	.18	.50	.23	1.05	1.78
SOUTH DAKOTA	HANSON			.10		.47
SOUTH DAKOTA	HARDING	.36				3.49
SOUTH DAKOTA	HUGHES		.03			.01
SOUTH DAKOTA	HUTCHINSON		.02			
SOUTH DAKOTA	HYDE	.26		.24	.39	1.31
SOUTH DAKOTA	JACKSON	1.31	1.21	1.05	.57	.70
SOUTH DAKOTA	JERAULD	.05	.06	.04	.32	.10
SOUTH DAKOTA	JONES	.61	.71	.60	.70	
SOUTH DAKOTA	KINGSBURY	.82	.34	.13	.03	1.87
SOUTH DAKOTA	LAKE		.47	.40	.40	.28
SOUTH DAKOTA	LAWRENCE					
SOUTH DAKOTA	LINCOLN					
SOUTH DAKOTA	LYMAN	.77				4.41
SOUTH DAKOTA	MARSHALL	.11	1.39	1.02	.83	1.25
SOUTH DAKOTA	MCCOOK		15.58	3.88	2.72	1.72
SOUTH DAKOTA	MCPHERSON			.93	1.07	.71
SOUTH DAKOTA	MEADE					
SOUTH DAKOTA	MELLETTE, W					
SOUTH DAKOTA	MINER		1.62	1.70	1.69	
SOUTH DAKOTA	MINNEHAHA		.18	.26	6.22	3.97
SOUTH DAKOTA	MOODY				.54	.37
SOUTH DAKOTA	PENNINGTON	.04			.22	
SOUTH DAKOTA					.09	

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELQ RATE 12/31/06	DELQ RATE 12/31/05	DELQ RATE 12/31/04	DELQ RATE 12/31/03	DELQ RATE 12/31/02
SOUTH DAKOTA	PERKINS	.27	.15	.22	.66	1.17
SOUTH DAKOTA	POTTER	1.01	.90	.68	.51	.16
SOUTH DAKOTA	ROBERTS	.18			.31	1.03
SOUTH DAKOTA	SANBORN			.71		
SOUTH DAKOTA	SHANNON, PT WEST				.10	.10
SOUTH DAKOTA	SINK		.73	.71	4.47	4.03
SOUTH DAKOTA	STANLEY	2.83		.43		
SOUTH DAKOTA	SULLY	.59				39.81
SOUTH DAKOTA	TODD		.94	.82	.77	.68
SOUTH DAKOTA	TRIPP	2.05	2.30	2.73	4.82	3.46
SOUTH DAKOTA	TURNER	.03		.47		.12
SOUTH DAKOTA	UNION	.57	1.24	1.73	.21	
SOUTH DAKOTA	WALWORTH	16.12	13.62	10.14	10.01	13.28
SOUTH DAKOTA	YANKTON	.08	.14	.08	2.42	1.76
SOUTH DAKOTA	ZIEBACH					19.65
TENNESSEE	ANDERSON					
TENNESSEE	BEDFORD	5.06	.73	.68	.67	6.97
TENNESSEE	BENTON			3.55	.87	
TENNESSEE	BLEDSoE	12.10	10.76	9.02	6.96	7.20
TENNESSEE	BLOUNT			8.55	9.96	1.30
TENNESSEE	BRADLEY	13.65	9.96	8.70	14.16	10.29
TENNESSEE	CAMPBELL				5.04	6.10
TENNESSEE	CANNON	5.00	1.80	.85		
TENNESSEE	CARROLL	.07	4.31	6.99	4.39	20.45
TENNESSEE	CARTER	43.56				
TENNESSEE	CHEATHAM	21.19	15.92	34.26	25.99	43.80
TENNESSEE	CHESTER	3.75	2.44	1.55	.80	.66
TENNESSEE	CLAIBORNE	1.99	18.28	22.10	21.90	20.40
TENNESSEE	CLAY			.26	1.64	.95
TENNESSEE	COCKE		7.44	3.37	.10	7.00
TENNESSEE	COFFE	6.24	4.79	3.99	5.43	3.62
TENNESSEE	CROCKETT	6.59	6.12	5.36	4.75	4.94
TENNESSEE	CUMBERLAND	8.91	14.43	100.00	6.02	1.75
TENNESSEE	DAVIDSON					
TENNESSEE	DECATUR	1.86	1.92	4.39	4.62	3.46

TENNESSEE	DEKALB	1.95	11.01	9.42	7.66	6.99
TENNESSEE	DICKSON	5.27	4.66	7.66	12.14	3.62
TENNESSEE	DYER	1.31	5.56	6.76	6.07	4.76
TENNESSEE	FAYETTE	2.21	2.92	3.90	4.10	6.11
TENNESSEE	FENTRESS	20.51	20.06	22.24	14.34	9.48
TENNESSEE	FRANKLIN	8.10	6.41	5.50	3.80	3.53
TENNESSEE	GIBSON59	.86	.01	.01
TENNESSEE	GILES	7.57	5.06	6.41	9.43	3.34
TENNESSEE	GRAINGER	1.35	6.52	4.16	1.37
TENNESSEE	GREENE	10.25	15.03	24.69	24.69	20.52
TENNESSEE	GRUNDY	4.94	4.11	3.37	2.54	9.59
TENNESSEE	HAMBLEN	7.39	34.92
TENNESSEE	HAMILTON	57.11	49.55	21.85	6.52	39.20
TENNESSEE	HANCOCK	13.40	13.37	10.33	10.71
TENNESSEE	HARDAMAN	1.91	.01	.58	2.71	3.23
TENNESSEE	HARDIN42	2.24
TENNESSEE	HAWKINS	9.81	.04	.13	.05	.09
TENNESSEE	HAYWOOD	5.40	5.82	11.03	15.19	11.73
TENNESSEE	HENDERSON	10.27	11.06	5.05	1.80	7.87
TENNESSEE	HENRY	4.90	6.00	10.17	5.47	11.26
TENNESSEE	HICKMAN	2.95	6.71	3.30	.12
TENNESSEE	HOUSTON2455	.49
TENNESSEE	HUMPHREYS	9.19	6.83	.87	2.08	1.71
TENNESSEE	JACKSON	7.82	7.66	.23	.19	5.83
TENNESSEE	JEFFERSON	3.68	3.36	2.57	6.12	7.16
TENNESSEE	JOHNSON	1.8803	.64
TENNESSEE	KNOX	15.79	13.89	.31	.30	.46
TENNESSEE	LAKE	3.34	3.17	2.81
TENNESSEE	LAUDERDALE	8.65	6.41	4.88	7.17	9.67
TENNESSEE	LAWRENCE	5.58	6.65	2.59	2.40	5.08
TENNESSEE	LEWIS12	.08	.04	.04
TENNESSEE	LINCOLN	1.73	8.36	5.78	4.01	2.74
TENNESSEE	LOUDON25	14.68	9.47	5.75
TENNESSEE	MACON60	.80	.53	.59
TENNESSEE	MADISON	7.28	10.27	8.02	5.08	4.70
TENNESSEE	MARION	3.21	1.29	1.57	1.04	4.58
TENNESSEE	MARSHALL	20.32	18.48	14.78	12.91	5.67
TENNESSEE	MAURY	6.95	7.40	9.09	6.41	4.45
TENNESSEE	MCMINN	26.67	22.99	7.09	5.28	20.76
TENNESSEE	MCMURRY53	6.19	4.04	2.88	3.08

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
TENNESSEE	MEIGS
TENNESSEE	MONROE	4.93	1.61	1.00	.59	2.73
TENNESSEE	MONTGOMERY	3.51	4.18	5.76	4.50	11.18
TENNESSEE	MOORE	15.52	12.88
TENNESSEE	MORGAN	1.60	18.03	9.97	1.85
TENNESSEE	OBION	.37	.36	6.59	2.35
TENNESSEE	OVERTON	13.91	12.13	9.58	.32	.23
TENNESSEE	PERRY	8.26	8.29
TENNESSEE	PICKETT	1.31	8.64	1.28
TENNESSEE	POLK	4.01	2.33	.82	.21
TENNESSEE	PUTNAM	2.81	65.22	64.18	61.32
TENNESSEE	RHEA	1.26	1.23	2.96	1.89
TENNESSEE	ROANE	8.55	6.06	5.82	6.27	3.18
TENNESSEE	ROBERTSON	6.41	8.13	8.74	8.28	4.83
TENNESSEE	RUTHERFORD	.41	.21	.65	2.51	9.70
TENNESSEE	SCOTT	1.92	2.24
TENNESSEE	SEQUIATCHIE	17.16	16.69
TENNESSEE	SEVIER	3.36
TENNESSEE	SHELBY	4.12	3.89	4.40	3.85	7.47
TENNESSEE	SMITH	2.05	2.35	2.35	1.71
TENNESSEE	STEWART	2.73	1.94	2.44	2.01	2.59
TENNESSEE	SULLIVAN	32.40	25.75	22.98	18.37	14.99
TENNESSEE	SUMNER	7.75	4.99	2.44	1.44	1.45
TENNESSEE	TIPTON	3.97	2.31	3.84	5.89
TENNESSEE	TROUSDALE
TENNESSEE	UNICOI
TENNESSEE	UNION	2.64	.36
TENNESSEE	VAN BUREN	2.62	2.44	1.12	2.10	1.06
TENNESSEE	WARREN	4.65	3.93	4.51	2.52	7.05
TENNESSEE	WASHINGTON	4.75	4.00	1.82	.68	.55
TENNESSEE	WAYNE	.09	1.02	1.21	.06	2.06
TENNESSEE	WEAVER	2.74	2.13	.87	2.00	3.07
TENNESSEE	WHITE	.90	2.66	3.79	1.49	1.43
TENNESSEE	WILLIAMSON	2.53	3.00	3.89	1.99	1.26
TENNESSEE	WILSON09	3.44	1.95	2.16

TEXAS	ANDERSON	40.46	42.48	38.24	39.01	22.33
TEXAS	ANDREWS			64.50	77.41	65.46
TEXAS	ANGELINA	22.56	4.85	5.59	3.50	76.24
TEXAS	ARANSAS	100.00	100.00	100.00	100.00	100.00
TEXAS	ARCHER	3.26	3.60	6.07	1.76	7.13
TEXAS	ARMSTRONG					
TEXAS	ATASCOSA	.45	.37	38.04	31.00	35.68
TEXAS	AUSTIN					
TEXAS	BAILEY	7.69	13.47	13.84	24.04	26.00
TEXAS	BANDERA			96.81	74.62	70.47
TEXAS	BASTROP					
TEXAS	BAYLOR	10.15				
TEXAS	BEE	22.76	31.12	38.52	41.03	36.51
TEXAS	BELL	37.60	10.68	59.72	55.38	43.71
TEXAS	BEXAR		7.37	9.55	26.53	13.06
TEXAS	BLANCO					
TEXAS	BORDEN	.01	1.13	3.52	2.47	2.00
TEXAS	BOSQUE		1.26			27.83
TEXAS	BOWIE	1.65	2.63	4.12	2.20	2.03
TEXAS	BRAZORIA	42.03	67.46	33.71	55.82	60.22
TEXAS	BRAZOS	73.25	81.70	99.55	97.54	95.36
TEXAS	BREWSTER				39.23	17.21
TEXAS	BRISCOE		1.02	.11		7.39
TEXAS	BROOKS	17.07	16.28	41.66	59.75	50.39
TEXAS	BROWN		22.29	21.34	18.59	27.51
TEXAS	BURLESON		.54		5.49	
TEXAS	BURNET				99.99	100.00
TEXAS	CALDWELL		33.10	25.34	52.02	48.78
TEXAS	CALHOUN	31.39	33.33	31.55	32.77	30.14
TEXAS	CALLAHAN	2.98	2.92	.24	4.36	3.33
TEXAS	CAMERON	38.59	49.93	56.50	65.93	63.10
TEXAS	CAMP			17.40	10.58	12.05
TEXAS	CARSON			27.86	38.54	23.64
TEXAS	CASS	.67	.14	.15		.20
TEXAS	CASTRO	10.91	31.06	44.72	39.96	42.84
TEXAS	CHAMBERS	64.40	58.70	60.40	89.81	81.48
TEXAS	CHEROKEE	3.99	28.21	25.54	32.76	37.21
TEXAS	CHILDRESS	24.31	20.08	16.16	14.79	16.51
TEXAS	CLAY	2.25	1.07	4.10	7.18	8.80
TEXAS	COCHRAN	19.75	37.43	34.17	33.93	29.95

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELQ RATE 12/31/06	DELQ RATE 12/31/05	DELQ RATE 12/31/04	DELQ RATE 12/31/03	DELQ RATE 12/31/02
TEXAS	COKE					
TEXAS	COLEMAN	80.53	74.72	74.34	62.35	60.90
TEXAS	COLLIN	4.76	4.65	.80	.65	3.99
TEXAS	COLLINGSWORTH	22.57	16.82	12.46	10.21	6.33
TEXAS	COLORADO					16.94
TEXAS	COMAL					
TEXAS	COMANCHE	52.33	63.18	62.11	56.87	49.95
TEXAS	CONCHO				25.81	43.42
TEXAS	COOKE					41.59
TEXAS	CORYELL	10.88	59.99	57.20	66.72	59.84
TEXAS	COTILE	35.29	33.76	33.56	33.61	31.43
TEXAS	CRANE					
TEXAS	CROCKETT					
TEXAS	CROSBY	13.41	20.71	21.81	21.16	20.42
TEXAS	CULBERSON					62.15
TEXAS	DALLAM	3.14	2.45	8.04	6.51	3.28
TEXAS	DALLAS		4.35		17.46	15.63
TEXAS	DAWSON	14.72	27.05	36.64	47.28	51.79
TEXAS	DEAF SMITH		3.71	7.91	13.09	28.31
TEXAS	DELTA	6.18	4.06	2.39	5.49	5.33
TEXAS	DENTON			71.01	68.13	49.36
TEXAS	DEWITT			4.00	24.69	30.21
TEXAS	DICKENS	34.01	33.91	35.10	37.23	50.97
TEXAS	DIMMIT	95.24	94.05	65.45	61.16	64.74
TEXAS	DONLEY		3.44	5.20	5.20	13.78
TEXAS	DUVAL	17.71	21.60	24.99	32.58	19.98
TEXAS	EASTLAND	38.53	37.27	31.22	32.52	24.37
TEXAS	ECTOR					
TEXAS	EDWARDS					
TEXAS	EL PASO	36.27	45.16	46.78	46.96	45.39
TEXAS	ELLIS	7.27	26.14	47.05	42.37	39.77
TEXAS	ERATH	40.03	48.82	44.12	39.49	37.00
TEXAS	FALLS	24.72	26.44	36.14	50.05	61.25
TEXAS	FANNIN	7.11	9.77	13.98	31.68	32.18
TEXAS	FAYETTE				65.69	34.85

TEXAS	FSHER	1.12	3.74	4.58	12.90	13.70
TEXAS	FLOYD	9.43	7.04	11.87	11.87	15.79
TEXAS	FOARD	30.72	34.26	43.43	48.08	48.51
TEXAS	FORT BEND		2.30	3.93		
TEXAS	FRANKLIN	2.57	1.17	2.24	1.24	5.75
TEXAS	FREESTONE	10.55	11.60	17.96	33.73	40.06
TEXAS	FRIO	66.56	70.09	63.32	66.32	64.85
TEXAS	GAINES	1.33	2.05	5.16	13.75	15.07
TEXAS	GALVESTON					
TEXAS	GARZA	.51		.14	3.22	.29
TEXAS	GILLESPIE				1.08	10.03
TEXAS	GLASSCOCK	18.32	15.40	13.81	11.48	13.26
TEXAS	GOLIAD			64.24	80.19	47.58
TEXAS	GONZALES	.05	3.86	11.91	18.30	30.41
TEXAS	GRAY		3.10			.73
TEXAS	GRAYSON		44.36	35.21	38.81	27.93
TEXAS	GREGG	28.04	21.67	3.63	2.22	2.39
TEXAS	GRIMES	5.37			.03	2.17
TEXAS	GUADALUPE	.30	.94	3.01	3.37	2.06
TEXAS	HALE	2.15	14.31	16.18	23.58	24.31
TEXAS	HALL	2.46	6.51	4.80	7.22	5.31
TEXAS	HAMILTON		23.36	16.12	21.51	40.02
TEXAS	HANSFORD			21.23	13.93	4.41
TEXAS	HARDEMAN	14.68	20.18	20.63	18.11	14.03
TEXAS	HARDIN					
TEXAS	HARRIS		14.79	14.78	11.52	10.82
TEXAS	HARRISON	28.32	16.28	10.68	2.17	25.18
TEXAS	HARTLEY		12.51	12.60	6.02	4.97
TEXAS	HASKELL	13.34	9.29	24.13	34.22	32.38
TEXAS	HAYS	34.03	39.83	35.54	31.99	28.04
TEXAS	HEMPHILL			.57	4.09	
TEXAS	HENDERSON	39.34	33.15	30.24	29.68	24.58
TEXAS	HIDALGO	34.44	49.30	59.09	57.00	53.27
TEXAS	HILL	1.75	6.26	13.55	18.84	17.31
TEXAS	HOCKLEY	15.47	29.09	37.91	35.76	34.53
TEXAS	HOOD		31.54	34.90	81.74	81.56
TEXAS	HOPKINS	.21	4.28	4.18	12.89	13.61
TEXAS	HOUSTON	65.09	52.43	63.44	64.72	61.69
TEXAS	HOWARD	21.34	28.71	29.59	25.88	29.17
TEXAS	HUDSPETH	16.27	45.67	38.02	37.10	38.82

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
TEXAS	HUNT	.82	1.61	.72	.52
TEXAS	HUTCHINSON	2.06	21.37
TEXAS	IRON	97.01
TEXAS	JACK	34.50
TEXAS	JACKSON	17.78	21.02	23.58	28.14	69.37
TEXAS	JASPER	.40	11.89	78.13	78.14
TEXAS	JEFF DAVIS	78.38
TEXAS	JEFFERSON	27.30	81.72	76.04	69.32	62.29
TEXAS	JIM HOGG	95.59	91.55	90.22	84.79	22.56
TEXAS	JIM WELLS	14.30	24.02	30.25	24.66	23.21
TEXAS	JOHNSON	2.71	25.30	22.05	25.60	21.84
TEXAS	JONES	14.62	14.26	20.66	22.03	27.45
TEXAS	KARNES	7.28	22.04	18.88	19.44	44.00
TEXAS	KAUFMAN	21.96	30.57	30.83	47.37	44.17
TEXAS	KENDALL	44.34
TEXAS	KENEDY	17.36
TEXAS	KENT	13.72	10.23	14.80	37.78	100.00
TEXAS	KERR	23.72	66.30	100.00	1.69
TEXAS	KIMBLE	1.54	2.77	.84
TEXAS	KING	8.43	6.46
TEXAS	KINNEY	4.58	53.05
TEXAS	KLEBERG	47.29	61.82	55.74	56.88	14.53
TEXAS	KNOX	.48	10.41	11.13	8.10	36.12
TEXAS	LA SALLE	34.39	10.36
TEXAS	LAMAR	.92	2.78	3.07	8.36	60.54
TEXAS	LAMB	12.88	41.98	46.54	55.04	29.70
TEXAS	LAMPASAS	44.95	38.58	34.71	92.16
TEXAS	LAVACA	40.22	35.26
TEXAS	LEE	64.37
TEXAS	LEON	33.17	41.82	52.02	47.24
TEXAS	LIBERTY	19.39	13.84	11.20	39.12
TEXAS	LIMESTONE	32.70	36.71	41.62	35.58
TEXAS	LIPSOMB	21.03
TEXAS	LIVE OAK	20.64	16.69	24.17	21.51
TEXAS	LLANO

TEXAS	LOVING		5.98	7.80	14.60	13.72
TEXAS	LUBBOCK	.43		5.47	9.51	8.84
TEXAS	LYNN	.38	1.21			
TEXAS	MADISON	76.09				
TEXAS	MARION	22.95				
TEXAS	MARTIN	6.67	27.47	18.47	18.47	16.61
TEXAS	MASON	44.31	20.48	26.28	29.88	47.24
TEXAS	MATAGORDA	17.97	40.97	32.75	40.35	34.68
TEXAS	MAVERICK		23.69	16.90	17.67	17.64
TEXAS	MCCULLOCH					
TEXAS	MCCLENNAN		8.23	4.73	10.30	17.20
TEXAS	MCMLLEN		4.92	3.30	11.19	11.21
TEXAS	MEDINA					
TEXAS	MENARD			19.75	51.30	41.71
TEXAS	MIDLAND	19.53	16.87	20.61	13.73	30.59
TEXAS	MILAM	6.39	22.33	17.83	28.02	26.38
TEXAS	MILLS	97.12	18.48	31.72	26.87	32.20
TEXAS	MITCHELL	2.86	97.56	67.92	69.82	66.43
TEXAS	MONTAGUE	26.86	3.25	8.08	20.16	16.17
TEXAS	MONTGOMERY	29.73	9.52	4.68	12.02	5.65
TEXAS	MOORE	44.71	28.25	6.68	86.92	37.36
TEXAS	MORRIS	37.70	28.06	24.56	9.49	18.05
TEXAS	MOTLEY		22.23	11.28	7.88	
TEXAS	NACOGDOCHES	29.94				13.39
TEXAS	NAVARRO	55.20	33.24	34.25	33.33	33.30
TEXAS	NEWTON	54.30	43.68	59.73	32.31	51.08
TEXAS	NOLAN	8.71	54.38	48.23	40.69	36.06
TEXAS	NUECES	17.21	5.74	19.48	31.23	27.88
TEXAS	OCHILTREE		19.71	16.38	24.20	21.53
TEXAS	OLDHAM					
TEXAS	ORANGE		22.37	21.58	20.07	23.34
TEXAS	PALO PINTO	31.06	8.09	9.37	21.93	.68
TEXAS	PANOLA	49.64	97.64	97.54	70.26	61.54
TEXAS	PARKER	27.80	35.62	35.60	33.34	31.61
TEXAS	PARMER	1.24	15.93	15.27	5.97	29.53
TEXAS	PECOS		2.23	14.28	15.69	14.80
TEXAS	POLK		2.83	1.46	18.97	18.45
TEXAS	POTTER	43.71	45.33	42.63	39.55	55.69
TEXAS	PRESIDIO					
TEXAS	RAINS	43.37	35.14	28.08	17.18	38.90
TEXAS			1.39	9.25	6.99	31.62

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
TEXAS	RANDALL				18.87	28.88
TEXAS	REAGAN	24.84	24.99	26.01	31.87	30.62
TEXAS	REAL					
TEXAS	RED RIVER	8.68	8.17	9.29	22.46	18.69
TEXAS	REEVES	22.29	31.03	23.89	21.63	40.08
TEXAS	REFUGIO	6.74	14.18	11.17	10.47	9.77
TEXAS	ROBERTS			24.22	14.88	13.65
TEXAS	ROBERTSON	3.97	17.47	21.59	27.45	26.48
TEXAS	ROCKWALL	31.20	37.40	57.82	59.18	53.32
TEXAS	RUNNELS	5.38	14.83	23.18	28.89	28.01
TEXAS	RUSK	3.26	20.15	34.57	30.62	29.82
TEXAS	SABINE					
TEXAS	SAN AUGUSTINE		1.17	.87	14.46	13.01
TEXAS	SAN JACINTO					
TEXAS	SAN PATRICIO	13.01	12.91	24.38	17.91	14.56
TEXAS	SAN SABA	47.77	35.39	28.28	33.45	23.72
TEXAS	SCHLEICHER	.82	18.01	15.36	11.75	12.95
TEXAS	SCURRY		3.58	8.69	5.54	3.46
TEXAS	SHACKELFORD					
TEXAS	SHELBY	19.56	24.00	20.77	22.37	17.91
TEXAS	SHERMAN	2.25		54.85	32.83	35.45
TEXAS	SMITH			27.61	27.99	52.67
TEXAS	SOMERVELL			3.00		
TEXAS	STARR	29.20	53.83	36.97	36.39	35.95
TEXAS	STEPHENS					
TEXAS	STERLING					
TEXAS	STONEWALL	1.84	2.14	.95	12.04	12.18
TEXAS	SUTTON	20.31	20.59	13.82	9.71	10.32
TEXAS	SWISHER	1.83	2.59	3.83	4.21	8.06
TEXAS	TARRANT					
TEXAS	TAYLOR	.23	1.27	.15	.10	.07
TEXAS	TERRELL					14.25
TEXAS	TERRY	6.22	5.92	6.77	12.24	11.69
TEXAS	THROCKMORTON		41.43	35.93	30.39	14.63
TEXAS	TITUS				.70	.43

TEXAS	TOM GREEN	16.22	10.26	14.25	12.17	13.77
TEXAS	TRAVIS			99.57	91.45	88.31
TEXAS	TRINITY	40.71	42.22	46.99	41.74	38.02
TEXAS	TYLER	27.70	24.35	20.29	16.41	14.35
TEXAS	UPSHUR		.47			26.27
TEXAS	UPTON	5.13	2.19	9.09	12.91	25.42
TEXAS	UVALDE	1.06		22.36	24.62	35.92
TEXAS	VAL VERDE		5.68			
TEXAS	VAN ZANDT	2.81	31.40	25.37	41.51	43.15
TEXAS	VICTORIA	40.58	30.21	21.97	38.73	30.34
TEXAS	WALKER			2.78	2.75	.76
TEXAS	WALLER	.95			99.29	24.85
TEXAS	WARD			.44	.53	
TEXAS	WASHINGTON					
TEXAS	WEBB			35.76	34.50	33.55
TEXAS	WHARTON	12.15	16.91	15.20	22.47	23.36
TEXAS	WHEELER		31.49	28.03	20.67	27.88
TEXAS	WICHITA					
TEXAS	WILBARGER	6.58	9.23	14.66	13.72	14.49
TEXAS	WILLACY	53.11	47.35	37.49	32.25	33.08
TEXAS	WILLIAMSON	68.13	69.02	63.64	70.94	54.50
TEXAS	WILSON	27.75	43.71	54.61	55.44	51.59
TEXAS	WINKLER					
TEXAS	WISE			59.90	14.39	75.05
TEXAS	WOOD	3.35	1.49	2.61	4.67	58.36
TEXAS	YOKUM	7.26	9.36	9.94	19.08	17.62
TEXAS	YOUNG					39.62
TEXAS	ZAPATA		38.30	42.45	36.44	30.93
TEXAS	ZAVALA	10.79		29.48	62.95	54.87
UTAH	BEAVER	.23			1.47	.80
UTAH	BOX ELDER	5.58	1.60	9.87	10.85	12.25
UTAH	CACHE	4.61	2.03	2.34	3.36	1.64
UTAH	CARBON		.29			
UTAH	DAGGETT		.28	8.48	5.77	3.64
UTAH	DAVIS					
UTAH	DUCHESNE		2.77	.18	.02	.14
UTAH	EMERY		.35	.69	.33	
UTAH	GARFIELD	.17	.12	.98	1.61	1.62
UTAH	GRAND E		3.75	2.70	3.44	
UTAH	IRON	4.88		1.68	.75	

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
UTAH	JUAB	.84	.81	.57	.64	.56
UTAH	KANE		2.18	1.52	2.60	2.17
UTAH	MILLARD	.90	.73	2.20	5.97	6.01
UTAH	MORGAN					
UTAH	PIUTE	.71	.13	1.78	2.07	3.78
UTAH	RICH			1.94	2.16	1.71
UTAH	SALT LAKE			.59		
UTAH	SAN JUAN	.11	.10	.03		.04
UTAH	SANPETE	.65	1.26	1.25	.69	1.39
UTAH	SEVIER	2.61	2.08	.46	1.25	3.45
UTAH	SUMMIT	.12	.24			1.33
UTAH	TOOELE	2.18	1.25			
UTAH	UINTAH	.49	.03	.50	.18	.15
UTAH	UTAH	2.39	.16	.32	1.41	.91
UTAH	WASATCH					
UTAH	WASHINGTON					
UTAH	WAYNE	.91	.77	4.27	4.02	3.08
UTAH	WEBER					4.36
VERMONT	ADDISON	4.00	6.23	8.61	9.57	8.24
VERMONT	BENNINGTON					22.65
VERMONT	CALEDONIA	13.93	12.49	13.63	11.62	12.33
VERMONT	CHITTENDEN		.98			1.33
VERMONT	ESSEX				1.78	.98
VERMONT	FRANKLIN	1.87	6.05	6.40	5.92	6.79
VERMONT	GRAND ISLE				1.20	1.63
VERMONT	LA MOILLE		2.73		7.43	8.28
VERMONT	ORANGE			3.73	3.22	2.95
VERMONT	ORLEANS	.02	.13			.05
VERMONT	RUTLAND	2.26	2.93	.33	2.22	4.85
VERMONT	WASHINGTON		4.66	2.18		
VERMONT	WINDHAM	.39	4.48	2.45	4.32	3.48
VERMONT	WINDSOR	23.76	20.36	22.63	16.35	18.89
VIRGIN ISLANDS	ST. CROIX	37.62	32.24	26.64	21.58	18.75
VIRGIN ISLANDS	ST. JOHN					
VIRGIN ISLANDS	ST. THOMAS			.53		

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
VIRGINIA	FAIRFAX CITY					
VIRGINIA	FALLS CHURCH					4.89
VIRGINIA	FAUQUIER	2.36	.18	.17	8.25	
VIRGINIA	FLOYD					
VIRGINIA	FLUVANNA			3.41	3.97	15.29
VIRGINIA	FRANKLIN	6.03	9.81	11.81	10.54	24.45
VIRGINIA	FRANKLIN CITY					
VIRGINIA	FREDERICK	2.19	7.53	7.06	6.52	5.00
VIRGINIA	FREDERICKSBURG					
VIRGINIA	GALAX					
VIRGINIA	GILES					
VIRGINIA	GLOUCESTER	10.27	8.81	11.80		
VIRGINIA	GOOCHLAND	.30	.35	.61	.79	
VIRGINIA	GRAYSON	5.80	3.56	1.77	.28	
VIRGINIA	GREENE	3.10			9.05	
VIRGINIA	GREENSVILLE		12.82	1.72		5.89
VIRGINIA	HALIFAX	4.45	3.84	5.76	7.27	18.31
VIRGINIA	HAMPTON					
VIRGINIA	HANOVER	2.98	1.63	2.03	8.15	6.48
VIRGINIA	HARRISONBURG					
VIRGINIA	HENRICO	8.13		9.34		
VIRGINIA	HENRY	24.81	20.54	17.03	13.13	13.56
VIRGINIA	HIGHLAND					
VIRGINIA	HOPWELL					
VIRGINIA	ISLE OF WIGHT	1.85	7.32	10.33	4.57	11.68
VIRGINIA	JAMES CITY	21.38	20.65	19.63	18.81	18.13
VIRGINIA	KING AND QUEEN	8.40	6.37	5.10	20.22	16.10
VIRGINIA	KING GEORGE		1.01	18.53	9.26	11.30
VIRGINIA	KING WILLIAM			4.89		
VIRGINIA	LANCASTER				44.04	68.26
VIRGINIA	LEE	.58		.13		
VIRGINIA	LEXINGTON					
VIRGINIA	LOUDOUN	4.78			14.22	16.94
VIRGINIA	LOUISA	2.80			5.73	
VIRGINIA	LUNENBURG		.67	.71	.55	1.18

VIRGINIA	LYNCHBURG	11.76	7.78	14.81	4.80	8.34
VIRGINIA	MADISON					
VIRGINIA	MANASSA PARK CITY					
VIRGINIA	MANASSAS					
VIRGINIA	MARTINSVILLE					
VIRGINIA	MATHEWS					
VIRGINIA	MECKLENBURG	.69	12.73	12.12	9.78	8.26
VIRGINIA	MIDDLESEX	16.15	7.61	6.73	6.07	.06
VIRGINIA	MONTGOMERY				2.15	
VIRGINIA	NELSON			1.76		
VIRGINIA	NEW KENT					
VIRGINIA	NEWPORT NEWS					
VIRGINIA	NORFOLK CITY					
VIRGINIA	NORTHAMPTON	7.22	15.64	19.20	12.02	1.99
VIRGINIA	NORTHUMBERLAND	90.62	90.22	90.22	89.72	88.58
VIRGINIA	NORTON					
VIRGINIA	NOTTOWAY	.79				8.17
VIRGINIA	ORANGE	1.65				
VIRGINIA	PAGE					
VIRGINIA	PATRICK	4.32	.37		.76	.78
VIRGINIA	PETERSBURG					
VIRGINIA	PITTSYLVANIA	5.84	6.05	5.89	3.79	1.14
VIRGINIA	POQUASON					
VIRGINIA	PORTSMOUTH CITY					
VIRGINIA	POWHATAN					
VIRGINIA	PRINCE EDWARD		8.51	2.91		
VIRGINIA	PRINCE GEORGE	3.03	19.99	5.02	2.94	3.67
VIRGINIA	PRINCE WILLIAM					
VIRGINIA	PULASKI	71.12	72.07	70.96	69.47	48.43
VIRGINIA	RADFORD					
VIRGINIA	RAPPAHANNOCK					
VIRGINIA	RICHMOND	8.44	5.56	1.12	10.91	16.45
VIRGINIA	RICHMOND CITY					
VIRGINIA	ROANOKE					
VIRGINIA	ROANOKE CITY					
VIRGINIA	ROCKBRIDGE	.89	2.29	.45	.96	5.18
VIRGINIA	ROCKINGHAM	1.38	1.29	.57		3.08
VIRGINIA	RUSSELL			1.06	1.25	.40
VIRGINIA	SALEM					
VIRGINIA	SCOTT	31.38	29.03	21.91	21.64	18.60

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
VIRGINIA	SHENANDOAH	1.02	1.28	2.46	4.30	1.22
VIRGINIA	SMYTH		38.87	34.67	31.11	22.97
VIRGINIA	SPOTSYLVANIA	45.60	32.38	25.52	2.66	2.80
VIRGINIA	STAFFORD			2.01	2.66	
VIRGINIA	STAUNTON					
VIRGINIA	SUFFOLK	7.04	2.08	2.31	9.47	8.24
VIRGINIA	SURRY	9.50	4.73	5.72	5.06	.07
VIRGINIA	SUSSEX	11.71	11.49	3.87	6.40	3.36
VIRGINIA	TAZEWELL					
VIRGINIA	VIRGINIA BEACH (CITY)					
VIRGINIA	WARREN					
VIRGINIA	WASHINGTON		3.83	3.25	4.71	2.14
VIRGINIA	WAYNESBORO			19.94	1.26	8.60
VIRGINIA	WESTMORELAND	13.10	7.58			
VIRGINIA	WILLIAMSBURG					
VIRGINIA	WINCHESTER					
VIRGINIA	WISE					
VIRGINIA	WYTHE	36.09	29.32	27.37	21.51	18.52
VIRGINIA	YORK					
WASHINGTON	ADAMS	7.30	11.35	15.57	18.73	10.65
WASHINGTON	ASOTIN			100.00		
WASHINGTON	BENTON	1.68	2.32	4.27	5.39	3.68
WASHINGTON	CHELAN	2.42	3.47	3.07	2.56	6.03
WASHINGTON	CLALLAM					
WASHINGTON	CLARK					
WASHINGTON	COLUMBIA			2.94		
WASHINGTON	COWLITZ					
WASHINGTON	DOUGLAS	1.60	3.41	4.09	4.43	4.20
WASHINGTON	FERRY	35.65	34.59	36.55	32.98	41.27
WASHINGTON	FRANKLIN	4.19	17.04	10.24	10.86	6.74
WASHINGTON	GARFIELD	1.18	4.77			
WASHINGTON	GRANT, N	1.00	2.00	2.21	2.33	2.09
WASHINGTON	GRAYS HARBOR		.15			.93
WASHINGTON	ISLAND					
WASHINGTON	JEFFERSON			25.25		.35

WASHINGTON	KING			8.35			4.04
WASHINGTON	KITSAP					9.99	
WASHINGTON	KITTITAS	.03		.63			9.62
WASHINGTON	KLICHTAT	.21		.29			15.28
WASHINGTON	LEWIS	21.84		34.06		28.02	21.59
WASHINGTON	LINCOLN	1.54		1.78		.66	.22
WASHINGTON	MASON						
WASHINGTON	OKANOGAN	14.55		13.39		12.62	12.77
WASHINGTON	PACIFIC	3.54		2.16		1.31	.98
WASHINGTON	PEND ORELLE						
WASHINGTON	PERCE						
WASHINGTON	SAN JUAN						
WASHINGTON	SKAGIT	14.22		13.15		21.50	19.50
WASHINGTON	SKAMANIA						
WASHINGTON	SNOHOMISH						.69
WASHINGTON	SPOKANE	6.01		1.99		8.09	5.34
WASHINGTON	STEVENS	3.62		.64		9.28	10.21
WASHINGTON	THURSTON						
WASHINGTON	WAHAKUM					13.77	10.96
WASHINGTON	WALLA WALLA	4.32		3.42		4.62	7.06
WASHINGTON	WHATCOM	4.30		2.42		3.43	3.71
WASHINGTON	WHITMAN	1.91		1.54		2.45	2.86
WASHINGTON	YAKIMA	6.28		8.04		6.51	5.05
WEST VIRGINIA	BARBOUR	.20		.12		6.70	8.04
WEST VIRGINIA	BERKELEY	6.35		42.59		4.25	22.99
WEST VIRGINIA	BOONE					37.20	
WEST VIRGINIA	BRAXTON	1.01		1.58		14.37	12.31
WEST VIRGINIA	BROOKE	4.12		13.19			
WEST VIRGINIA	CABELL	4.24		1.21		8.65	6.08
WEST VIRGINIA	CALHOUN	.93		1.02		1.05	2.37
WEST VIRGINIA	CLAY	1.86		.54			
WEST VIRGINIA	DODDRIDGE	.29		10.23			
WEST VIRGINIA	FAYETTE	3.65		12.96		7.24	4.99
WEST VIRGINIA	GILMER	1.84		.77		29.85	11.83
WEST VIRGINIA	GRANT	1.44		1.88		2.93	18.68
WEST VIRGINIA	GREENBRIER	11.65		12.61		.36	.03
WEST VIRGINIA	HAMPSHIRE	9.69		9.54		8.75	6.99
WEST VIRGINIA	HANCOCK	16.16		9.42		7.10	1.96
WEST VIRGINIA	HARDY	1.26		.24			
WEST VIRGINIA	HARRISON	5.81		6.06		1.79	2.96
						7.79	7.55

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELO RATE 12/31/06	DELO RATE 12/31/05	DELO RATE 12/31/04	DELO RATE 12/31/03	DELO RATE 12/31/02
WEST VIRGINIA	JACKSON	1.23	.69	.24	.07
WEST VIRGINIA	JEFFERSON	10.24	8.26	6.36	10.29	3.37
WEST VIRGINIA	KANAWHA
WEST VIRGINIA	LEWIS	.51	18.01	14.41	16.15	22.58
WEST VIRGINIA	LINCOLN	4.11	1.64	6.69	8.65	3.67
WEST VIRGINIA	LOGAN
WEST VIRGINIA	MARION	1.48	8.86	4.81	2.45
WEST VIRGINIA	MARSHALL	10.11	12.10	9.53	8.49	8.20
WEST VIRGINIA	MARSHALL
WEST VIRGINIA	MASON	3.33	6.00	9.15	10.39	8.78
WEST VIRGINIA	MCDOWELL	28.81	24.36	18.97	13.37	7.47
WEST VIRGINIA	MERCER	8.92	10.65	10.32	9.32	6.70
WEST VIRGINIA	MINERAL	1.84
WEST VIRGINIA	MINGO
WEST VIRGINIA	MONONGALIA20	.22	.12
WEST VIRGINIA	MONROE	13.21	14.04	9.98	8.84	7.78
WEST VIRGINIA	MORGAN	6.83	2.91	6.49	2.43
WEST VIRGINIA	NICHOLAS	3.30	1.02	.17	.36	1.45
WEST VIRGINIA	PENDLETON	1.90	.76	1.13	1.25	.02
WEST VIRGINIA	PLEASANTS
WEST VIRGINIA	POCAHONTAS09	.55	1.12	1.26
WEST VIRGINIA	PRESTON	1.22	5.47	1.94	9.33	8.96
WEST VIRGINIA	PUTNAM	.18	3.47	5.09	5.87	4.04
WEST VIRGINIA	RALEIGH	25.55	22.09	20.78	20.47	17.08
WEST VIRGINIA	RANDOLPH	.19	3.49	.15
WEST VIRGINIA	RICHE	1.72	.67	14.10	1.31	9.21
WEST VIRGINIA	ROANE	1.12	1.00	1.06	1.26	6.30
WEST VIRGINIA	SUMMERS	15.57	9.47	7.77	6.25	7.00
WEST VIRGINIA	TAYLOR	1.15	.94	2.91	.87
WEST VIRGINIA	TUCKER
WEST VIRGINIA	TYLER09
WEST VIRGINIA	UPSHUR	5.84	14.17	11.22	10.22	15.91
WEST VIRGINIA	WAYNE	4.70
WEST VIRGINIA	WEBSTER	2.01	1.41	3.49	2.44
WEST VIRGINIA	WETZEL	4.01	2.93

WEST VIRGINIA	WIRT70	2.09	3.05	5.28
WEST VIRGINIA	WOOD	17.00	15.91	35.87	29.28
WEST VIRGINIA	WYOMING	20.44	22.44	10.96	4.80
WISCONSIN	ADAMS
WISCONSIN	ASHLAND20	3.10	3.74	3.47	7.27
WISCONSIN	BARREN	2.1624	2.09	.35
WISCONSIN	BAYFIELD31	.28	1.75	.94	2.94
WISCONSIN	BROWN20	.21	3.22	3.76	1.74
WISCONSIN	BUFFALO42	.51
WISCONSIN	BURNETT38	1.34	.48
WISCONSIN	CALUMET	1.05	4.41	1.16
WISCONSIN	CHIPPewa	1.35	.71	5.69	6.09	3.92
WISCONSIN	CLARK55	.51	.84	1.06	.85
WISCONSIN	COLUMBIA	4.11	1.58	2.54	1.70	2.91
WISCONSIN	CRAWFORD3130	.16
WISCONSIN	DANE82	.71	1.35	9.23
WISCONSIN	DODGE	3.84	3.47	3.49	6.21	3.37
WISCONSIN	DOOR	1.43	.61
WISCONSIN	DOUGLAS3641	5.50	2.31
WISCONSIN	DUNN	1.09	4.13	5.26	9.56	8.23
WISCONSIN	EAU CLAIRE	8.31	2.21	1.12	2.31
WISCONSIN	FLORENCE	11.97	7.08	1.41
WISCONSIN	FOND DU LAC	1.79	2.30	3.56	6.26	4.65
WISCONSIN	FOREST
WISCONSIN	GRANT07	.88	1.07	2.28	1.03
WISCONSIN	GREEN37	1.67	4.27	3.71	4.35
WISCONSIN	GREEN LAKE39	.28	.20	1.37	.98
WISCONSIN	IOWA61	.0150	1.97
WISCONSIN	IRON	1.01
WISCONSIN	JACKSON
WISCONSIN	JEFFERSON19	.0612	1.12
WISCONSIN	JUNEAU	1.56	.18	.18	.97
WISCONSIN	KENOSHA
WISCONSIN	KEWAUNEE	2.85	2.96	2.69	2.44	3.60
WISCONSIN	LA CROSSE41	1.42
WISCONSIN	LAFAYETTE47	.34	.57	.42	.64
WISCONSIN	LANGLADE65	4.62	2.65	3.45	2.62
WISCONSIN	LINCOLN	1.99
WISCONSIN	MANTOWOC04	.34	.28	.12	.15
WISCONSIN	MARATHON14	2.14	1.04	2.74	7.32

DIRECT LOAN PROGRAM DELINQUENCIES (ALL LOAN TYPES)—Continued

STATE NAME	COUNTY NAME	DELQ RATE 12/31/06	DELQ RATE 12/31/05	DELQ RATE 12/31/04	DELQ RATE 12/31/03	DELQ RATE 12/31/02
WISCONSIN	MARINETTE	5.84	5.46	3.94	3.52	4.03
WISCONSIN	MARQUETTE	2.77			11.20	2.25
WISCONSIN	MENOMINEE					
WISCONSIN	MILWAUKEE					
WISCONSIN	MONROE	.03	.91	1.48	.56	.27
WISCONSIN	OCONTO	1.69	2.07	.66	1.38	1.20
WISCONSIN	ONEIDA					
WISCONSIN	OUTAGAMIE	.85	1.37	2.40	.94	.69
WISCONSIN	OZAUKEE			6.58	2.42	
WISCONSIN	PEPIN	.58				6.28
WISCONSIN	PIERCE	2.44	2.28	1.11		.29
WISCONSIN	POLK	1.78	.69	.52	.21	.35
WISCONSIN	PORTAGE	1.46	1.44	.63	.40	1.68
WISCONSIN	PRICE	.24	1.02	1.41	.43	
WISCONSIN	RACINE	3.55				
WISCONSIN	RICHLAND	1.47	.75	1.15	.76	1.00
WISCONSIN	ROCK	.40	4.61	7.76	5.99	8.24
WISCONSIN	RUSK	.54		2.63	1.59	7.86
WISCONSIN	SAUK	1.55	2.74	3.22	2.23	4.12
WISCONSIN	SAWYER			1.27		
WISCONSIN	SHAWANO	2.21	1.95	1.96	2.47	.60
WISCONSIN	SHEBOYGAN		4.56	3.46	1.11	1.02
WISCONSIN	ST. CROIX	.01	.28		.95	.50
WISCONSIN	TAYLOR		.03	.71	.77	.69
WISCONSIN	TREMPEALEAU	2.29	2.29	1.90	1.74	1.88
WISCONSIN	VERNON	.17	.41	.34	.47	1.34
WISCONSIN	VILAS					5.67
WISCONSIN	WALWORTH			1.08	1.61	.27
WISCONSIN	WASHBURN	.22		.33		
WISCONSIN	WASHINGTON	.03			7.00	5.56
WISCONSIN	WAUKESHA					
WISCONSIN	WAUPACA				.96	1.98
WISCONSIN	WAUSHARA					1.00
WISCONSIN	WINNEBAGO			.82		12.93
WISCONSIN	WOOD	1.44	1.06	.84	.33	3.32

WYOMING	ALBANY	2.82	.30	7.08	6.89	7.86
WYOMING	BIG HORN, SOUTHERN	8.53	8.53	18.84	4.87	18.84
WYOMING	CAMPBELL	43.00	25.88	21.15	7.38	5.93
WYOMING	CARBON	1.23		.48		
WYOMING	CONVERSE					
WYOMING	CROOK					
WYOMING	FREMONT	10.62	14.63	13.63	14.11	12.15
WYOMING	GOSHEN	6.54	11.37	9.51	7.25	5.40
WYOMING	HOT SPRINGS	16.64	14.96	12.87	10.20	9.51
WYOMING	JOHNSON					
WYOMING	LARAMIE	13.77	18.56	15.62	14.36	10.50
WYOMING	LINCOLN			1.87		4.13
WYOMING	NATRONA	.33	.19			
WYOMING	NIobrara					
WYOMING	PARK			21	2.00	2.27
WYOMING	PLATTE	5.94	6.06	4.54	8.68	7.66
WYOMING	SHERIDAN					
WYOMING	SUBLETTE	100.00	65.30	70.56		6.48
WYOMING	SWEETWATER	5.59		12.60		
WYOMING	TETON					
WYOMING	UINTA	20.12	13.49	7.44	1.96	1.99
WYOMING	WASHAKE	2.12	1.42	2.35		3.95
WYOMING	WESTON				8.37	

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE

Year	State	County	Date	FEMA No	Incident Type
2002	Alabama	Barbour	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Bibb	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Blount	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Calhoun	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Cherokee	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Cleburne	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Cullman	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Dale	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	DeKalb	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Etowah	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Fayette	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2002	Alabama	Franklin	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Greene	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Hale	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Henry	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Houston	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Jefferson	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Lamar	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Lawrence	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Marion	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Marshall	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Morgan	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Pickens	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Shelby	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	St. Clair	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Talladega	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Tuscaloosa	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Walker	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alabama	Winston	11/14/02	FEMA-1442-DR	Severe Storms and Tornadoes
2002	Alaska	Aniak, Crooked Creek	6/26/02	FEMA-1423-DR	Flooding
2002	Alaska	Chignik Bay area	12/04/02	FEMA-1445-DR	Severe Winter Storms, Flooding, Coastal Erosion and Tidal Surge
2002	Alaska	Delta Greely Regional Educational Attendance Area	11/08/02	FEMA-1440-DR	Earthquake
2002	Alaska	Elwuk and New Stuyahok in the Southwest Region REAA	6/26/02	FEMA-1423-DR	Flooding
2002	Alaska	Fairbanks North Star Borough	6/26/02	FEMA-1423-DR	Flooding
2002	Alaska	Fairbanks North Star Borough	11/08/02	FEMA-1440-DR	Earthquake
2002	Alaska	Kenai Peninsula Borough	12/04/02	FEMA-1445-DR	Severe Winter Storms, Flooding, Coastal Erosion and Tidal Surge
2002	Alaska	Kodiak Island Borough	12/04/02	FEMA-1445-DR	Severe Winter Storms, Flooding, Coastal Erosion and Tidal Surge
2002	Alaska	Kwethluk in the Lower Kuskokwim REAA	6/26/02	FEMA-1423-DR	Flooding
2002	Alaska	McGrath and Lime Village in the Iditarod REAA	6/26/02	FEMA-1423-DR	Flooding

2002	Alaska	Red Devil and Sleetmute in the Kuspuk REAA	6/26/02	FEMA-1423-DR	Flooding
2002	Arizona	Apache	6/25/02	FEMA-1422-DR	Wildfires
2002	Arizona	Coconino	6/25/02	FEMA-1422-DR	Wildfires
2002	Arizona	Fort Apache Indian Reservation	6/25/02	FEMA-1422-DR	Wildfires
2002	Arizona	Gila	6/25/02	FEMA-1422-DR	Wildfires
2002	Arizona	Navajo	6/25/02	FEMA-1422-DR	Wildfires
2002	Colorado	Adams	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Alamosa	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Arapahoe	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Archuleta	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Baca	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Bent	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Boulder	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Broomfield City and County	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Chaffee	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Cheyenne	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Clear Creek	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Conejos	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Costilla	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Crowley	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Custer	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Delta	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Denver City and County	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Dolores	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Douglas	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Eagle	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	El Paso	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Elbert	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Fremont	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Garfield	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Gilpin	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Grand	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Gunnison	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Hinsdale	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Huerfano	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Jackson	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Jefferson	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Kiowa	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Kit Carson	6/19/02	FEMA-1421-DR	Wildfires

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2002	Colorado	La Plata	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Lake	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Larimer	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Las Animas	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Lincoln	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Mesa	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Mineral	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Moffat	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Montezuma	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Montrose	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Otero	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Ouray	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Park	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Pitkin	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Pueblo	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Rio Blanco	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Rio Grande	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Routt	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Saguache	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	San Juan	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	San Miguel	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Southern Ute Reservation	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Summit	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Teller	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Ute Mountain Reservation	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Washington	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Weld	6/19/02	FEMA-1421-DR	Wildfires
2002	Colorado	Yuma	6/19/02	FEMA-1421-DR	Wildfires
2002	Federated States of Micronesia	Chuuk State	7/11/02	FEMA-1427	Tropical Storm Chata'an, including flooding, mudslides and landslides
2002	Guam	Territory of Guam	7/06/02	FEMA-1426-DR	Typhoon Chata'an
2002	Guam	Territory of Guam	12/08/02	FEMA-1446-DR	Super Typhoon Pongsona
2002	Illinois	Adams	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Alexander	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Bond	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Brown	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding

2002	Illinois	Calhoun	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Cass	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Champaign	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Christian	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Clark	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Clay	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Clinton	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Coles	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Crawford	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Cumberland	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	De Witt	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Douglas	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Edgar	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Edwards	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Effingham	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Fayette	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Ford	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Franklin	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Fulton	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Gallatin	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Greene	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Hamilton	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Hancock	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Hardin	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Iroquois	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Jackson	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Jasper	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Jefferson	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Jersey	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Johnson	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Lawrence	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Logan	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Macon	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Macoupin	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Madison	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Marion	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Mason	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Massac	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	McDonough	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Menard	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2002	Illinois	Monroe	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Montgomery	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Morgan	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Moultrie	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Perry	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Piatt	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Pike	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Pope	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Pulaski	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Randolph	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Richland	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Saline	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Sangamon	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Schuyler	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Scott	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Shelby	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	St. Clair	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Union	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Vermilion	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Wabash	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Washington	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Wayne	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	White	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Illinois	Williamson	5/21/02	FEMA-1416-DR	Severe Storms, Tornadoes, and Flooding
2002	Indiana	Martin	6/13/02	FEMA-1418-DR	Severe Storms and Tornadoes
2002	Indiana	Bartholomew	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Blackford	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Brown	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Davess	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Dearborn	6/13/02	FEMA-1418-DR	Severe Storms, Tornadoes and Flooding
2002	Indiana	Dearborn	6/13/02	FEMA-1418-DR	Severe Storms, Tornadoes and Flooding
2002	Indiana	Decatur	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Delaware	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Fayette	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Franklin	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Gibson	6/13/02	FEMA-1418-DR	Severe Storms, Tornadoes and Flooding

2002	Indiana	Gibson	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Grant	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Greene	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Hamilton	6/13/02	FEMA-1418-DR	Severe Storms, Tornadoes and Flooding
2002	Indiana	Hamilton	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Hancock	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Hendricks	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Henry	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Jay	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Johnson	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Knox	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Lawrence	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Madison	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Marion	6/13/02	FEMA-1418-DR	Severe Storms, Tornadoes and Flooding
2002	Indiana	Marion	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Monroe	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Morgan	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Orange	6/13/02	FEMA-1418-DR	Severe Storms, Tornadoes and Flooding
2002	Indiana	Owen	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Pike	6/13/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Pike	9/25/02	FEMA-1418-DR	Severe Storms and Tornadoes
2002	Indiana	Posey	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Posey	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Randolph	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Rush	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Shelby	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Sullivan	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Tipton	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Vanderburg	9/25/02	FEMA-1433-DR	Severe Storms and Tornadoes
2002	Indiana	Vigo	6/13/02	FEMA-1418-DR	Severe Storms, Tornadoes and Flooding
2002	Iowa	Alamakee	6/19/02	FEMA-1420-DR	Severe Storms and Flooding
2002	Iowa	Benton	6/19/02	FEMA-1420-DR	Severe Storms and Flooding
2002	Iowa	Buchanan	6/19/02	FEMA-1420-DR	Severe Storms and Flooding
2002	Iowa	Cedar	6/19/02	FEMA-1420-DR	Severe Storms and Flooding
2002	Iowa	Clayton	6/19/02	FEMA-1420-DR	Severe Storms and Flooding
2002	Iowa	Clinton	6/19/02	FEMA-1420-DR	Severe Storms and Flooding
2002	Iowa	Delaware	6/19/02	FEMA-1420-DR	Severe Storms and Flooding
2002	Iowa	Des Moines	6/19/02	FEMA-1420-DR	Severe Storms and Flooding
2002	Iowa	Dubuque	6/19/02	FEMA-1420-DR	Severe Storms and Flooding
2002	Iowa	Fayette	6/19/02	FEMA-1420-DR	Severe Storms and Flooding

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2002	Iowa	Henry	6/19/02	FEMA-1420-DR	Severe Storms and Flooding
2002	Iowa	Iowa	6/19/02	FEMA-1420-DR	Severe Storms and Flooding
2002	Iowa	Jackson	6/19/02	FEMA-1420-DR	Severe Storms and Flooding
2002	Iowa	Johnson	6/19/02	FEMA-1420-DR	Severe Storms and Flooding
2002	Iowa	Jones	6/19/02	FEMA-1420-DR	Severe Storms and Flooding
2002	Iowa	Lee	6/19/02	FEMA-1420-DR	Severe Storms and Flooding
2002	Iowa	Linn	6/19/02	FEMA-1420-DR	Severe Storms and Flooding
2002	Iowa	Louis	6/19/02	FEMA-1420-DR	Severe Storms and Flooding
2002	Iowa	Muscatine	6/19/02	FEMA-1420-DR	Severe Storms and Flooding
2002	Iowa	Scott	6/19/02	FEMA-1420-DR	Severe Storms and Flooding
2002	Iowa	Winnebago	6/19/02	FEMA-1420-DR	Severe Storms and Flooding
2002	Kansas	Allen	2/06/02	FEMA-1402-DR	Severe Winter Ice Storm
2002	Kansas	Anderson	2/06/02	FEMA-1402-DR	Severe Winter Ice Storm
2002	Kansas	Barber	2/06/02	FEMA-1402-DR	Severe Winter Ice Storm
2002	Kansas	Bourbon	2/06/02	FEMA-1402-DR	Severe Winter Ice Storm
2002	Kansas	Butler	2/06/02	FEMA-1402-DR	Severe Winter Ice Storm
2002	Kansas	Chautauqua	2/06/02	FEMA-1402-DR	Severe Winter Ice Storm
2002	Kansas	Coffey	2/06/02	FEMA-1402-DR	Severe Winter Ice Storm
2002	Kansas	Cowley	2/06/02	FEMA-1402-DR	Severe Winter Ice Storm
2002	Kansas	Crawford	2/06/02	FEMA-1402-DR	Severe Winter Ice Storm
2002	Kansas	Douglas	2/06/02	FEMA-1402-DR	Severe Winter Ice Storm
2002	Kansas	Elk	2/06/02	FEMA-1402-DR	Severe Winter Ice Storm
2002	Kansas	Franklin	2/06/02	FEMA-1402-DR	Severe Winter Ice Storm
2002	Kansas	Greenwood	2/06/02	FEMA-1402-DR	Severe Winter Ice Storm
2002	Kansas	Lafayette	2/06/02	FEMA-1402-DR	Severe Winter Ice Storm
2002	Kansas	Linn	2/06/02	FEMA-1402-DR	Severe Winter Ice Storm
2002	Kansas	Miami	2/06/02	FEMA-1402-DR	Severe Winter Ice Storm
2002	Kansas	Montgomery	2/06/02	FEMA-1402-DR	Severe Winter Ice Storm
2002	Kansas	Neosho	2/06/02	FEMA-1402-DR	Severe Winter Ice Storm
2002	Kansas	Osage	2/06/02	FEMA-1402-DR	Severe Winter Ice Storm
2002	Kansas	Sumner	2/06/02	FEMA-1402-DR	Severe Winter Ice Storm
2002	Kansas	Wilson	2/06/02	FEMA-1402-DR	Severe Winter Ice Storm
2002	Kansas	Woodson	2/06/02	FEMA-1402-DR	Severe Winter Ice Storm
2002	Kentucky	Bath	4/04/02	FEMA-1407-DR	Severe Storms and Flooding
2002	Kentucky	Bell	4/04/02	FEMA-1407-DR	Severe Storms and Flooding
2002	Kentucky	Bourbon	4/04/02	FEMA-1407-DR	Severe Storms and Flooding

2002	Kentucky	Boyd	4/04/02	FEMA-1407-DR	Severe Storms and Flooding
2002	Kentucky	Breckinridge	5/07/02	FEMA-1414-DR	Severe Storms, Tornadoes and Flooding
2002	Kentucky	Cartel	4/04/02	FEMA-1407-DR	Severe Storms and Flooding
2002	Kentucky	Clay	4/04/02	FEMA-1407-DR	Severe Storms and Flooding
2002	Kentucky	Crittenden	5/07/02	FEMA-1414-DR	Severe Storms, Tornadoes and Flooding
2002	Kentucky	Fleming	4/04/02	FEMA-1407-DR	Severe Storms and Flooding
2002	Kentucky	Floyd	5/07/02	FEMA-1414-DR	Severe Storms, Tornadoes and Flooding
2002	Kentucky	Grayson	5/07/02	FEMA-1414-DR	Severe Storms, Tornadoes and Flooding
2002	Kentucky	Greenup	4/04/02	FEMA-1407-DR	Severe Storms and Flooding
2002	Kentucky	Hancock	5/07/02	FEMA-1414-DR	Severe Storms, Tornadoes and Flooding
2002	Kentucky	Hardin	4/04/02	FEMA-1407-DR	Severe Storms and Flooding
2002	Kentucky	Harlan	4/04/02	FEMA-1407-DR	Severe Storms and Flooding
2002	Kentucky	Henderson	5/07/02	FEMA-1414-DR	Severe Storms, Tornadoes and Flooding
2002	Kentucky	Hopkins	5/07/02	FEMA-1414-DR	Severe Storms, Tornadoes and Flooding
2002	Kentucky	Knox	4/04/02	FEMA-1407-DR	Severe Storms and Flooding
2002	Kentucky	Laurel	4/04/02	FEMA-1407-DR	Severe Storms and Flooding
2002	Kentucky	Laurel	5/07/02	FEMA-1414-DR	Severe Storms, Tornadoes and Flooding
2002	Kentucky	Lawrence	4/04/02	FEMA-1407-DR	Severe Storms and Flooding
2002	Kentucky	Leslie	4/04/02	FEMA-1407-DR	Severe Storms and Flooding
2002	Kentucky	Letcher	5/07/02	FEMA-1407-DR	Severe Storms and Flooding
2002	Kentucky	Letcher	4/04/02	FEMA-1414-DR	Severe Storms, Tornadoes and Flooding
2002	Kentucky	Lewis	4/04/02	FEMA-1407-DR	Severe Storms and Flooding
2002	Kentucky	Marion	5/07/02	FEMA-1414-DR	Severe Storms, Tornadoes and Flooding
2002	Kentucky	Martin	5/07/02	FEMA-1414-DR	Severe Storms, Tornadoes and Flooding
2002	Kentucky	McCreary	4/04/02	FEMA-1407-DR	Severe Storms and Flooding
2002	Kentucky	McLean	5/07/02	FEMA-1414-DR	Severe Storms, Tornadoes and Flooding
2002	Kentucky	Meade	5/07/02	FEMA-1414-DR	Severe Storms, Tornadoes and Flooding
2002	Kentucky	Menifee	4/04/02	FEMA-1407-DR	Severe Storms and Flooding
2002	Kentucky	Montgomery	4/04/02	FEMA-1407-DR	Severe Storms and Flooding
2002	Kentucky	Morgan	4/04/02	FEMA-1407-DR	Severe Storms and Flooding
2002	Kentucky	Nicholas	4/04/02	FEMA-1407-DR	Severe Storms and Flooding
2002	Kentucky	Ohio	5/07/02	FEMA-1414-DR	Severe Storms, Tornadoes and Flooding
2002	Kentucky	Perry	4/04/02	FEMA-1407-DR	Severe Storms and Flooding
2002	Kentucky	Pike	5/07/02	FEMA-1414-DR	Severe Storms, Tornadoes and Flooding
2002	Kentucky	Rockcastle	5/07/02	FEMA-1414-DR	Severe Storms, Tornadoes and Flooding
2002	Kentucky	Rowan	4/04/02	FEMA-1407-DR	Severe Storms and Flooding
2002	Kentucky	Union	5/07/02	FEMA-1414-DR	Severe Storms, Tornadoes and Flooding
2002	Kentucky	Webster	5/07/02	FEMA-1414-DR	Severe Storms, Tornadoes and Flooding
2002	Kentucky	Whitley	4/04/02	FEMA-1407-DR	Severe Storms and Flooding
2002	Louisiana	Acadia	10/03/02	FEMA-1437-DR	Hurricane Lili

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2002	Louisiana	Allen	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	Assumption	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	Assumption	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	Avoyelles	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	Beauregard	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	Calcasieu	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	Cameron	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	East Baton Rouge	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	East Feliciana	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	Evangeline	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	Iberia	9/27/02	FEMA-1435-DR	Tropical Storm Isidore
2002	Louisiana	Iberia	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	Iberville	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	Jefferson	9/27/02	FEMA-1435-DR	Tropical Storm Isidore
2002	Louisiana	Jefferson	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	Jefferson Davis	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	Lafayette	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	Lafourche	9/27/02	FEMA-1435-DR	Tropical Storm Isidore
2002	Louisiana	Lafourche	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	Livingston	9/27/02	FEMA-1435-DR	Tropical Storm Isidore
2002	Louisiana	Livingston	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	Orleans	10/03/02	FEMA-1435-DR	Hurricane Lili
2002	Louisiana	Orleans	9/27/02	FEMA-1435-DR	Tropical Storm Isidore
2002	Louisiana	Plaquemines	9/27/02	FEMA-1435-DR	Tropical Storm Isidore
2002	Louisiana	Plaquemines	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	Pointe Coupee	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	Rapides	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	St. Bernard	9/27/02	FEMA-1435-DR	Tropical Storm Isidore
2002	Louisiana	St. Bernard	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	St. Charles	9/27/02	FEMA-1435-DR	Tropical Storm Isidore
2002	Louisiana	St. Charles	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	St. Helena	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	St. James	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	St. John the Baptist	9/27/02	FEMA-1435-DR	Tropical Storm Isidore
2002	Louisiana	St. John the Baptist	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	St. Landry	10/03/02	FEMA-1437-DR	Hurricane Lili

2002	Louisiana	St. Martin	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	St. Mary	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	St. Tammany	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	St. Tammany	9/27/02	FEMA-1435-DR	Tropical Storm Isidore
2002	Louisiana	Tangipahoa	9/27/02	FEMA-1435-DR	Tropical Storm Isidore
2002	Louisiana	Tangipahoa	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	Terrebonne	9/27/02	FEMA-1435-DR	Tropical Storm Isidore
2002	Louisiana	Terrebonne	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	Vermilion	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	Washington	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Louisiana	West Baton Rouge	10/03/02	FEMA-1437-DR	Hurricane Lili
2002	Maryland	Calvert	5/01/02	FEMA-1409-DR	Tornado
2002	Maryland	Charles	5/01/02	FEMA-1409-DR	Tornado
2002	Maryland	Dorchester	5/01/02	FEMA-1409-DR	Tornado
2002	Minnesota	Becker	6/14/02	FEMA-1419-DR	Severe Storms, Flooding and Tornadoes
2002	Minnesota	Beltrami	6/14/02	FEMA-1419-DR	Severe Storms, Flooding and Tornadoes
2002	Minnesota	Clay	6/14/02	FEMA-1419-DR	Severe Storms, Flooding and Tornadoes
2002	Minnesota	Clearwater	6/14/02	FEMA-1419-DR	Severe Storms, Flooding and Tornadoes
2002	Minnesota	Itasca	6/14/02	FEMA-1419-DR	Severe Storms, Flooding and Tornadoes
2002	Minnesota	Kittson	6/14/02	FEMA-1419-DR	Severe Storms, Flooding and Tornadoes
2002	Minnesota	McLeod	6/14/02	FEMA-1419-DR	Severe Storms, Flooding and Tornadoes
2002	Minnesota	Pennington	6/14/02	FEMA-1419-DR	Severe Storms, Flooding and Tornadoes
2002	Minnesota	Polk	6/14/02	FEMA-1419-DR	Severe Storms, Flooding and Tornadoes
2002	Minnesota	Roseau	6/14/02	FEMA-1419-DR	Severe Storms, Flooding and Tornadoes
2002	Minnesota	Wright	6/14/02	FEMA-1419-DR	Severe Storms, Flooding and Tornadoes
2002	Mississippi	Amite	10/01/02	FEMA-1436	Severe Storms, Flooding and Tornadoes
2002	Mississippi	Clay	11/14/02	FEMA-1443-DR	Tropical Storm Isidore
2002	Mississippi	Hancock	10/01/02	FEMA-1436	Tropical Storm Isidore
2002	Mississippi	Harrison	10/01/02	FEMA-1436	Tropical Storm Isidore
2002	Mississippi	Jackson	10/01/02	FEMA-1436	Tropical Storm Isidore
2002	Mississippi	Lowndes	11/14/02	FEMA-1443-DR	Severe Storms and Tornadoes
2002	Mississippi	Monroe	11/14/02	FEMA-1443-DR	Severe Storms and Tornadoes
2002	Mississippi	Noxubee	11/14/02	FEMA-1443-DR	Severe Storms and Tornadoes
2002	Mississippi	Oktibbeha	11/14/02	FEMA-1443-DR	Severe Storms and Tornadoes
2002	Mississippi	Pearl River	10/01/02	FEMA-1436	Tropical Storm Isidore
2002	Mississippi	Pike	10/01/02	FEMA-1436	Tropical Storm Isidore
2002	Mississippi	Stone	10/01/02	FEMA-1436	Tropical Storm Isidore
2002	Missouri	Adair	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Audrain	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Barton	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2002	Missouri	Bates	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Benton	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Bollinger	5/06/02	FEMA-1412-DR	Severe Storms and Tornadoes
2002	Missouri	Boone	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Buchanan	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Butler	5/06/02	FEMA-1412-DR	Severe Storms and Tornadoes
2002	Missouri	Caldwell	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Cape Girardeau	5/06/02	FEMA-1412-DR	Severe Storms and Tornadoes
2002	Missouri	Carroll	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Carter	2/06/02	FEMA-1412-DR	Severe Storms and Tornadoes
2002	Missouri	Cass	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Cedar	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Charlton	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Clair	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Clark	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Clay	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Clinton	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Cooper	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Crawford	2/06/02	FEMA-1412-DR	Severe Storms and Tornadoes
2002	Missouri	Davess	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Dent	5/06/02	FEMA-1412-DR	Severe Storms and Tornadoes
2002	Missouri	Douglas	5/06/02	FEMA-1412-DR	Severe Storms and Tornadoes
2002	Missouri	Dunklin	5/06/02	FEMA-1412-DR	Severe Storms and Tornadoes
2002	Missouri	Grundy	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Henry	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Howard	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Howell	5/06/02	FEMA-1412-DR	Severe Storms and Tornadoes
2002	Missouri	Iron	5/06/02	FEMA-1412-DR	Severe Storms and Tornadoes
2002	Missouri	Jackson	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Jefferson	5/06/02	FEMA-1412-DR	Severe Storms and Tornadoes
2002	Missouri	Johnson	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Knox	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Lafayette	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Lewis	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Linn	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm
2002	Missouri	Livingston	2/06/02	FEMA-1403-DR	Severe Winter Ice Storm

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2002	Oklahoma	Blaine	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Caddo	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Canadian	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Cimarron	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Cleveland	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Comanche	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Creek	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Custer	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Dewey	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Ellis	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Garfield	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Garvin	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Grady	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Grant	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Greer	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Harmon	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Harper	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Jackson	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Key	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Kingfisher	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Kiowa	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Lincoln	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Logan	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Major	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	McClain	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Mills	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Noble	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Nowata	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Oklahoma	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Osage	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Pawnee	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Payne	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Pottawatomie	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Roger	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Rogers	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Stephens	2/01/02	FEMA-1401-DR	Ice Storm

2002	Oklahoma	Texas	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Tillman	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Tulsa	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Washington	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Washita	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Woods	2/01/02	FEMA-1401-DR	Ice Storm
2002	Oklahoma	Woodward	2/01/02	FEMA-1401-DR	Ice Storm
2002	Tennessee	and	4/05/02	FEMA-1408-DR	Severe Storms and Flooding
2002	Tennessee	Anderson	11/13/02	FEMA-1441-DR	Severe Storms, Tornadoes and Flooding
2002	Tennessee	Bedford	11/13/02	FEMA-1441-DR	Severe Storms, Tornadoes and Flooding
2002	Tennessee	Bledsoe	4/05/02	FEMA-1408-DR	Severe Storms and Flooding
2002	Tennessee	Bledsoe	11/13/02	FEMA-1441-DR	Severe Storms, Tornadoes and Flooding
2002	Tennessee	Blount	4/05/02	FEMA-1408-DR	Severe Storms and Flooding
2002	Tennessee	Carroll	11/13/02	FEMA-1441-DR	Severe Storms, Tornadoes and Flooding
2002	Tennessee	Claiborne	4/05/02	FEMA-1408-DR	Severe Storms and Flooding
2002	Tennessee	Cocke	4/05/02	FEMA-1408-DR	Severe Storms and Flooding
2002	Tennessee	Coffee	11/13/02	FEMA-1441-DR	Severe Storms, Tornadoes and Flooding
2002	Tennessee	Crockett	11/13/02	FEMA-1441-DR	Severe Storms, Tornadoes and Flooding
2002	Tennessee	Cumberland	11/13/02	FEMA-1441-DR	Severe Storms, Tornadoes and Flooding
2002	Tennessee	Fentress	11/13/02	FEMA-1441-DR	Severe Storms, Tornadoes and Flooding
2002	Tennessee	Gibson	11/13/02	FEMA-1441-DR	Severe Storms, Tornadoes and Flooding
2002	Tennessee	Hancock	4/05/02	FEMA-1408-DR	Severe Storms and Flooding
2002	Tennessee	Hawkins	4/05/02	FEMA-1408-DR	Severe Storms and Flooding
2002	Tennessee	Henderson	11/13/02	FEMA-1441-DR	Severe Storms, Tornadoes and Flooding
2002	Tennessee	Loudon	4/05/02	FEMA-1408-DR	Severe Storms and Flooding
2002	Tennessee	Madison	11/13/02	FEMA-1441-DR	Severe Storms, Tornadoes and Flooding
2002	Tennessee	Marshall	11/13/02	FEMA-1441-DR	Severe Storms, Tornadoes and Flooding
2002	Tennessee	Montgomery	11/13/02	FEMA-1441-DR	Severe Storms, Tornadoes and Flooding
2002	Tennessee	Morgan	11/13/02	FEMA-1441-DR	Severe Storms, Tornadoes and Flooding
2002	Tennessee	Roane	11/13/02	FEMA-1441-DR	Severe Storms, Tornadoes and Flooding
2002	Tennessee	Rutherford	11/13/02	FEMA-1441-DR	Severe Storms, Tornadoes and Flooding
2002	Tennessee	Scott	11/13/02	FEMA-1441-DR	Severe Storms, Tornadoes and Flooding
2002	Tennessee	Sevier	4/05/02	FEMA-1408-DR	Severe Storms and Flooding
2002	Tennessee	Sumner	11/13/02	FEMA-1441-DR	Severe Storms, Tornadoes and Flooding
2002	Tennessee	Tipton	11/13/02	FEMA-1441-DR	Severe Storms, Tornadoes and Flooding
2002	Tennessee	Van Buren	11/13/02	FEMA-1441-DR	Severe Storms, Tornadoes and Flooding
2002	Texas	Bexar	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Arañas	11/05/02	FEMA-1439-DR	Severe storms, tornadoes, and flooding
2002	Texas	Atascosa	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Bandera	7/04/02	FEMA-1425-DR	Severe Storms and Flooding

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2002	Texas	Bee	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Blanco	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Brazoria	9/26/02	FEMA-1434-DR	Tropical Storm Fay
2002	Texas	Brazoria	11/05/02	FEMA-1439-DR	severe storms, tornadoes, and flooding
2002	Texas	Brown	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Burnet	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Caldwell	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Calhoun	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Callahan	7/04/02	FEMA-1439-DR	severe storms, tornadoes, and flooding
2002	Texas	Cameron	11/05/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Coleman	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Comal	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	DeWitt	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Dimmit	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Duval	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Eastland	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Fort Bend	11/05/02	FEMA-1439-DR	severe storms, tornadoes, and flooding
2002	Texas	Frio	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Frio	9/26/02	FEMA-1434-DR	Tropical Storm Fay
2002	Texas	Galveston	9/26/02	FEMA-1434-DR	Tropical Storm Fay
2002	Texas	Gillespie	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Goliad	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Gonzales	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Guadalupe	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Hardin	11/05/02	FEMA-1439-DR	severe storms, tornadoes, and flooding
2002	Texas	Harris	11/05/02	FEMA-1439-DR	Severe Storms and Flooding
2002	Texas	Hays	7/04/02	FEMA-1425-DR	severe storms, tornadoes, and flooding
2002	Texas	Jasper	11/05/02	FEMA-1439-DR	Severe Storms and Flooding
2002	Texas	Jefferson	11/05/02	FEMA-1439-DR	severe storms, tornadoes, and flooding
2002	Texas	Jim Wells	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Jim Wells	9/26/02	FEMA-1434-DR	Severe Storms and Flooding
2002	Texas	Jim Wells	11/05/02	FEMA-1439-DR	Tropical Storm Fay
2002	Texas	Karnes	7/04/02	FEMA-1425-DR	severe storms, tornadoes, and flooding
2002	Texas	Kendall	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Kerr	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Kleberg	11/05/02	FEMA-1439-DR	severe storms, tornadoes, and flooding

2002	Texas	La Salle	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	La Salle	9/26/02	FEMA-1434-DR	Tropical Storm Fay
2002	Texas	Liberty	11/05/02	FEMA-1439-DR	severe storms, tornadoes, and flooding
2002	Texas	Live Oak	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Live Oak	9/26/02	FEMA-1434-DR	Tropical Storm Fay
2002	Texas	Matagorda	9/26/02	FEMA-1434-DR	Tropical Storm Fay
2002	Texas	McMullen	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Medina	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Montgomery	11/05/02	FEMA-1439-DR	severe storms, tornadoes, and flooding
2002	Texas	Nueces	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Nueces	9/26/02	FEMA-1434-DR	Tropical Storm Fay
2002	Texas	Nueces	11/05/02	FEMA-1439-DR	severe storms, tornadoes, and flooding
2002	Texas	Orange	11/05/02	FEMA-1439-DR	severe storms, tornadoes, and flooding
2002	Texas	Real	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	San Jacinto	11/05/02	FEMA-1439-DR	severe storms, tornadoes, and flooding
2002	Texas	San Patricio	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	San Patricio	9/26/02	FEMA-1434-DR	Tropical Storm Fay
2002	Texas	San Patricio	11/05/02	FEMA-1439-DR	severe storms, tornadoes, and flooding
2002	Texas	Taylor	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Travis	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Uvalde	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Victoria	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Walker	11/05/02	FEMA-1439-DR	severe storms, tornadoes, and flooding
2002	Texas	Webb	9/26/02	FEMA-1434-DR	Tropical Storm Fay
2002	Texas	Wharton	9/26/02	FEMA-1434-DR	Tropical Storm Fay
2002	Texas	Wilson	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Texas	Zavala	7/04/02	FEMA-1425-DR	Severe Storms and Flooding
2002	Vermont	Caledonia	7/12/02	FEMA-1428-DR	Severe storms and flooding
2002	Vermont	Franklin	7/12/02	FEMA-1428-DR	Severe storms and flooding
2002	Vermont	Lamoille	7/12/02	FEMA-1428-DR	Severe storms and flooding
2002	Vermont	Orleans	7/12/02	FEMA-1428-DR	Severe storms and flooding
2002	Virginia	Buchanan	5/05/02	FEMA-1411-DR	Severe Storms and Tornado
2002	Virginia	city of Norton	4/02/02	FEMA-1406-DR	Severe Storms and Flooding
2002	Virginia	Dickenson	4/02/02	FEMA-1406-DR	Severe Storms and Flooding
2002	Virginia	Lee	4/02/02	FEMA-1406-DR	Severe Storms and Flooding
2002	Virginia	Russell	4/02/02	FEMA-1406-DR	Severe Storms and Flooding
2002	Virginia	Scott	4/02/02	FEMA-1406-DR	Severe Storms and Flooding
2002	Virginia	Smyth	4/02/02	FEMA-1406-DR	Severe Storms and Flooding
2002	Virginia	Tazewell	4/02/02	FEMA-1406-DR	Severe Storms and Flooding
2002	Virginia	Tazewell	5/05/02	FEMA-1411-DR	Severe Storms and Tornado

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2002	Virginia	Washington	4/02/02	FEMA-1406-DR	Severe Storms and Flooding
2002	Virginia	Wise	4/02/02	FEMA-1406-DR	Severe Storms and Flooding
2002	West Virginia	McDowell	5/05/02	FEMA-1410-DR	Severe Storms, Flooding, and Landslides
2002	West Virginia	Mercer	5/05/02	FEMA-1410-DR	Severe Storms, Flooding, and Landslides
2002	West Virginia	Mingo	5/05/02	FEMA-1410-DR	Severe Storms, Flooding, and Landslides
2002	West Virginia	Wyoming	5/05/02	FEMA-1410-DR	Severe Storms, Flooding, and Landslides
2002	Wisconsin	Barren	9/10/02	FEMA-1432-DR	Severe storms, tornadoes and flooding
2002	Wisconsin	Burnett	9/10/02	FEMA-1432-DR	Severe storms, tornadoes and flooding
2002	Wisconsin	Chippewa	9/10/02	FEMA-1432-DR	Severe storms, tornadoes and flooding
2002	Wisconsin	Clark	9/10/02	FEMA-1432-DR	Severe storms, tornadoes and flooding
2002	Wisconsin	Dunn	9/10/02	FEMA-1432-DR	Severe storms, tornadoes and flooding
2002	Wisconsin	Langlade	9/10/02	FEMA-1432-DR	Severe storms, tornadoes and flooding
2002	Wisconsin	Lincoln	9/10/02	FEMA-1432-DR	Severe storms, tornadoes and flooding
2002	Wisconsin	Marathon	9/10/02	FEMA-1432-DR	Severe storms, tornadoes and flooding
2002	Wisconsin	Polk	9/10/02	FEMA-1432-DR	Severe storms, tornadoes and flooding
2002	Wisconsin	Portage	9/10/02	FEMA-1432-DR	Severe storms, tornadoes and flooding
2002	Wisconsin	Price	9/10/02	FEMA-1432-DR	Severe storms, tornadoes and flooding
2002	Wisconsin	Rusk	9/10/02	FEMA-1432-DR	Severe storms, tornadoes and flooding
2002	Wisconsin	Sawyer	9/10/02	FEMA-1432-DR	Severe storms, tornadoes and flooding
2002	Wisconsin	Shawano	9/10/02	FEMA-1432-DR	Severe storms, tornadoes and flooding
2002	Wisconsin	St. Croix	9/10/02	FEMA-1432-DR	Severe storms, tornadoes and flooding
2002	Wisconsin	Taylor	9/10/02	FEMA-1432-DR	Severe storms, tornadoes and flooding
2002	Wisconsin	Washburn	9/10/02	FEMA-1432-DR	Severe storms, tornadoes and flooding
2002	Wisconsin	Waupaca	9/10/02	FEMA-1432-DR	Severe storms, tornadoes and flooding
2002	Wisconsin	Wood	9/10/02	FEMA-1432-DR	Severe storms, tornadoes and flooding
2003	Alabama	Baldwin	5/12/03	FEMA-1466-DR	Severe storms, tornadoes, and flooding
2003	Alabama	Bibb	5/12/03	FEMA-1466-DR	Severe storms, tornadoes, and flooding
2003	Alabama	Blount	5/12/03	FEMA-1466-DR	Severe storms, tornadoes, and flooding
2003	Alabama	Calhoun	5/12/03	FEMA-1466-DR	Severe storms, tornadoes, and flooding
2003	Alabama	Clarke	5/12/03	FEMA-1466-DR	Severe storms, tornadoes, and flooding
2003	Alabama	Colbert	5/12/03	FEMA-1466-DR	Severe storms, tornadoes, and flooding
2003	Alabama	Cullman	5/12/03	FEMA-1466-DR	Severe storms, tornadoes, and flooding
2003	Alabama	DeKalb	5/12/03	FEMA-1466-DR	Severe storms, tornadoes, and flooding
2003	Alabama	Escambia	5/12/03	FEMA-1466-DR	Severe storms, tornadoes, and flooding
2003	Alabama	Etowah	5/12/03	FEMA-1466-DR	Severe storms, tornadoes, and flooding
2003	Alabama	Jackson	5/12/03	FEMA-1466-DR	Severe storms, tornadoes, and flooding

2003	Alabama	Jefferson	5/12/03	FEMA-1466-DR	Severe storms, tornadoes, and flooding
2003	Alabama	Madison	5/12/03	FEMA-1466-DR	Severe storms, tornadoes, and flooding
2003	Alabama	Marshall	5/12/03	FEMA-1466-DR	Severe storms, tornadoes, and flooding
2003	Alabama	Mobile	5/12/03	FEMA-1466-DR	Severe storms, tornadoes, and flooding
2003	Alabama	Monroe	5/12/03	FEMA-1466-DR	Severe storms, tornadoes, and flooding
2003	Alabama	Morgan	5/12/03	FEMA-1466-DR	Severe storms, tornadoes, and flooding
2003	Alabama	Shelby	5/12/03	FEMA-1466-DR	Severe storms, tornadoes, and flooding
2003	Alabama	St. Clair	5/12/03	FEMA-1466-DR	Severe storms, tornadoes, and flooding
2003	Alabama	Talladega	5/12/03	FEMA-1466-DR	Severe storms, tornadoes, and flooding
2003	Alabama	Tuscaloosa	5/12/03	FEMA-1466-DR	Severe storms, tornadoes, and flooding
2003	Alabama	Walker	5/12/03	FEMA-1466-DR	Severe storms, tornadoes, and flooding
2003	Alabama	Washington	5/12/03	FEMA-1466-DR	Severe storms, tornadoes, and flooding
2003	Alabama	Kenai Peninsula Borough	4/26/03	FEMA-1461-DR	Severe winter storm, including high winds and freezing temperatures
2003	Alaska	Matanuska-Susitna Borough	4/26/03	FEMA-1461-DR	Severe winter storm, including high winds and freezing temperatures
2003	Alaska	Municipality of Anchorage	4/26/03	FEMA-1461-DR	Severe winter storm, including high winds and freezing temperatures
2003	American Samoa	The Island of Tutuila	6/06/03	FEMA-1473-DR	Heavy Rainfall, Flooding, Landslides, and Mudslides
2003	Arkansas	Benton	6/06/03	FEMA-1472-DR	Severe storms, tornadoes, and flooding
2003	Arkansas	Chicot	6/06/03	FEMA-1472-DR	Severe storms, tornadoes, and flooding
2003	Arkansas	Cleburne	6/06/03	FEMA-1472-DR	Severe storms, tornadoes, and flooding
2003	Arkansas	Columbia	6/06/03	FEMA-1472-DR	Severe storms, tornadoes, and flooding
2003	Arkansas	Conway	6/06/03	FEMA-1472-DR	Severe storms, tornadoes, and flooding
2003	Arkansas	Craighead	6/06/03	FEMA-1472-DR	Severe storms, tornadoes, and flooding
2003	Arkansas	Crittenden	6/06/03	FEMA-1472-DR	Severe storms, tornadoes, and flooding
2003	Arkansas	Cross	6/06/03	FEMA-1472-DR	Severe storms, tornadoes, and flooding
2003	Arkansas	Faulkner	6/06/03	FEMA-1472-DR	Severe storms, tornadoes, and flooding
2003	Arkansas	Fulton	6/06/03	FEMA-1472-DR	Severe storms, tornadoes, and flooding
2003	Arkansas	Jackson	6/06/03	FEMA-1472-DR	Severe storms, tornadoes, and flooding
2003	Arkansas	Lonoke	6/06/03	FEMA-1472-DR	Severe storms, tornadoes, and flooding
2003	Arkansas	Nevada	6/06/03	FEMA-1472-DR	Severe storms, tornadoes, and flooding
2003	Arkansas	Perry	6/06/03	FEMA-1472-DR	Severe storms, tornadoes, and flooding
2003	Arkansas	Phillips	6/06/03	FEMA-1472-DR	Severe storms, tornadoes, and flooding
2003	Arkansas	Poinsett	6/06/03	FEMA-1472-DR	Severe storms, tornadoes, and flooding
2003	Arkansas	St. Francis	6/06/03	FEMA-1472-DR	Severe storms, tornadoes, and flooding
2003	Arkansas	White	6/06/03	FEMA-1472-DR	Severe storms, tornadoes, and flooding
2003	Arkansas	Woodruff	6/06/03	FEMA-1472-DR	Severe storms, tornadoes, and flooding
2003	California	Los Angeles	10/27/03	FEMA-1498-DR	Wildfires

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2003	California	Riverside	10/27/03	FEMA-1498-DR	Wildfires
2003	California	San Bernardino	10/27/03	FEMA-1498-DR	Wildfires
2003	California	San Diego	10/27/03	FEMA-1498-DR	Wildfires
2003	California	Ventura	10/27/03	FEMA-1498-DR	Wildfires
2003	Commonwealth of Puerto Rico	Alfonso	11/21/03	FEMA-1501-DR	Severe Storms, Flooding, Mudslides, and Landslides
2003	Commonwealth of Puerto Rico	Arroyo	11/21/03	FEMA-1501-DR	Severe Storms, Flooding, Mudslides, and Landslides
2003	Commonwealth of Puerto Rico	Cabo Rojo	11/21/03	FEMA-1501-DR	Severe Storms, Flooding, Mudslides, and Landslides
2003	Commonwealth of Puerto Rico	Can?vanas	11/21/03	FEMA-1501-DR	Severe Storms, Flooding, Mudslides, and Landslides
2003	Commonwealth of Puerto Rico	Fajardo	11/21/03	FEMA-1501-DR	Severe Storms, Flooding, Mudslides, and Landslides
2003	Commonwealth of Puerto Rico	Guayama	11/21/03	FEMA-1501-DR	Severe Storms, Flooding, Mudslides, and Landslides
2003	Commonwealth of Puerto Rico	Guayama	11/21/03	FEMA-1501-DR	Severe Storms, Flooding, Mudslides, and Landslides
2003	Commonwealth of Puerto Rico	Juana Diaz	11/21/03	FEMA-1501-DR	Severe Storms, Flooding, Mudslides, and Landslides
2003	Commonwealth of Puerto Rico	Lajas	11/21/03	FEMA-1501-DR	Severe Storms, Flooding, Mudslides, and Landslides
2003	Commonwealth of Puerto Rico	Loiza	11/21/03	FEMA-1501-DR	Severe Storms, Flooding, Mudslides, and Landslides
2003	Commonwealth of Puerto Rico	Luquillo	11/21/03	FEMA-1501-DR	Severe Storms, Flooding, Mudslides, and Landslides
2003	Commonwealth of Puerto Rico	Mamabo	11/21/03	FEMA-1501-DR	Severe Storms, Flooding, Mudslides, and Landslides
2003	Commonwealth of Puerto Rico	Naguabo	11/21/03	FEMA-1501-DR	Severe Storms, Flooding, Mudslides, and Landslides
2003	Commonwealth of Puerto Rico	Naranjito	11/21/03	FEMA-1501-DR	Severe Storms, Flooding, Mudslides, and Landslides
2003	Commonwealth of Puerto Rico	Pailitas	11/21/03	FEMA-1501-DR	Severe Storms, Flooding, Mudslides, and Landslides
2003	Commonwealth of Puerto Rico	Rio Grande	11/21/03	FEMA-1501-DR	Severe Storms, Flooding, Mudslides, and Landslides

2003	Commonwealth of Puerto Rico ..	Salinas	11/21/03	FEMA-1501-DR	Severe Storms, Flooding, Mudslides, and Land-slides
2003	Commonwealth of Puerto Rico ..	Santa Isabel	11/21/03	FEMA-1501-DR	Severe Storms, Flooding, Mudslides, and Land-slides
2003	Commonwealth of Puerto Rico ..	Toa Baja	11/21/03	FEMA-1501-DR	Severe Storms, Flooding, Mudslides, and Land-slides
2003	Commonwealth of Puerto Rico ..	Yabucoa	11/21/03	FEMA-1501-DR	Severe Storms, Flooding, Mudslides, and Land-slides
2003	Commonwealth of Puerto Rico ..	Yauco	11/21/03	FEMA-1501-DR	Severe Storms, Flooding, Mudslides, and Land-slides
2003	Delaware	New Castle	9/23/03	FEMA-1495-DR	Tropical Storm Henri
2003	Delaware	Kent	9/20/03	FEMA-1494-DR	Hurricane Isabel
2003	Delaware	New Castle	9/20/03	FEMA-1494-DR	Hurricane Isabel
2003	Delaware	Sussex	9/20/03	FEMA-1494-DR	Hurricane Isabel
2003	District of Columbia	District of Columbia	9/20/03	FEMA-1493-DR	Hurricane Isabel
2003	Federated States of Micronesia	Island of Eauripik	12/19/03	FEMA-1504-DR	Typhoon Lupit
2003	Federated States of Micronesia	Island of Elato	12/19/03	FEMA-1504-DR	Typhoon Lupit
2003	Federated States of Micronesia	Island of Fais	12/19/03	FEMA-1504-DR	Typhoon Lupit
2003	Federated States of Micronesia	Island of Faraulap	12/19/03	FEMA-1504-DR	Typhoon Lupit
2003	Federated States of Micronesia	Island of Ifalik	12/19/03	FEMA-1504-DR	Typhoon Lupit
2003	Federated States of Micronesia	Lamotrek	12/19/03	FEMA-1504-DR	Typhoon Lupit
2003	Federated States of Micronesia	Nanoniuto Atoll	12/19/03	FEMA-1504-DR	Typhoon Lupit
2003	Federated States of Micronesia	Satawal	12/19/03	FEMA-1504-DR	Typhoon Lupit
2003	Federated States of Micronesia	the Hall Islands	12/19/03	FEMA-1504-DR	Typhoon Lupit
2003	Federated States of Micronesia	Ulithi	12/19/03	FEMA-1504-DR	Typhoon Lupit
2003	Federated States of Micronesia	Western Islands within Chuuk State	12/19/03	FEMA-1504-DR	Typhoon Lupit
2003	Federated States of Micronesia	Woleai within Yap State	12/19/03	FEMA-1504-DR	Typhoon Lupit
2003	Florida	Miami-Dade County	4/25/03	FEMA-1460-DR	Severe storms and tornadoes
2003	Illinois	Adams	5/15/03	FEMA-1469-DR	Severe Storms, Tornadoes, and Flooding
2003	Illinois	Alexander	5/15/03	FEMA-1469-DR	Severe Storms, Tornadoes, and Flooding
2003	Illinois	Brown	5/15/03	FEMA-1469-DR	Severe Storms, Tornadoes, and Flooding
2003	Illinois	Fulton	5/15/03	FEMA-1469-DR	Severe Storms, Tornadoes, and Flooding
2003	Illinois	Hancock	5/15/03	FEMA-1469-DR	Severe Storms, Tornadoes, and Flooding
2003	Illinois	Mason	5/15/03	FEMA-1469-DR	Severe Storms, Tornadoes, and Flooding
2003	Illinois	Massac	5/15/03	FEMA-1469-DR	Severe Storms, Tornadoes, and Flooding
2003	Illinois	Pope	5/15/03	FEMA-1469-DR	Severe Storms, Tornadoes, and Flooding
2003	Illinois	Pulaski	5/15/03	FEMA-1469-DR	Severe Storms, Tornadoes, and Flooding
2003	Illinois	Schuyler	5/15/03	FEMA-1469-DR	Severe Storms, Tornadoes, and Flooding
2003	Illinois	Tazewell	5/15/03	FEMA-1469-DR	Severe Storms, Tornadoes, and Flooding

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2003	Illinois	Union	5/15/03	FEMA-1469-DR	Severe Storms, Tornadoes, and Flooding
2003	Illinois	Woodford	5/15/03	FEMA-1469-DR	Severe Storms, Tornadoes, and Flooding
2003	Indiana	Adams	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Allen	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Benton	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Blackford	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Blackford	9/05/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Boone	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Boone	9/05/03	FEMA-1487-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Carroll	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Cass	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Clay	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Clay	9/05/03	FEMA-1487-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Clinton	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Delaware	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Delaware	9/05/03	FEMA-1487-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Fountain	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Fulton	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Grant	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Grant	9/05/03	FEMA-1487-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Greene	9/05/03	FEMA-1487-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Hamilton	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Hamilton	9/05/03	FEMA-1487-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Hancock	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Hancock	9/05/03	FEMA-1487-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Hendricks	9/05/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Henry	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Henry	9/05/03	FEMA-1487-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Howard	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Huntington	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Jasper	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Jay	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Jay	9/05/03	FEMA-1487-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Johnson	9/05/03	FEMA-1487-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Kosciusko	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Lake	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding

2003	Indiana	Madison	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Madison	9/05/03	FEMA-1487-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Marion	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Marion	9/05/03	FEMA-1487-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Miami	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Monroe	9/05/03	FEMA-1487-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Montgomery	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Montgomery	9/05/03	FEMA-1487-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Morgan	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Morgan	9/05/03	FEMA-1487-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Newton	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Noble	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Owen	9/05/03	FEMA-1487-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Parke	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Porter	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Putnam	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Putnam	9/05/03	FEMA-1487-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Randolph	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Randolph	9/05/03	FEMA-1487-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Shelby	9/05/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Tipton	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Vanderburgh	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Vigo	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Wabash	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Warren	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Wayne	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Wells	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	White	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Indiana	Whitley	7/11/03	FEMA-1476-DR	Severe storms, tornadoes, and flooding
2003	Kansas	Allen	5/06/03	FEMA-1462-DR	Severe storms, tornadoes, and flooding
2003	Kansas	Cherokee	5/06/03	FEMA-1462-DR	Severe storms, tornadoes, and flooding
2003	Kansas	Crawford	5/06/03	FEMA-1462-DR	Severe storms, tornadoes, and flooding
2003	Kansas	Haskell	5/06/03	FEMA-1462-DR	Severe storms, tornadoes, and flooding
2003	Kansas	Labette	5/06/03	FEMA-1462-DR	Severe storms, tornadoes, and flooding
2003	Kansas	Leavenworth	5/06/03	FEMA-1462-DR	Severe storms, tornadoes, and flooding
2003	Kansas	Meade	5/06/03	FEMA-1462-DR	Severe storms, tornadoes, and flooding
2003	Kansas	Miami	5/06/03	FEMA-1462-DR	Severe storms, tornadoes, and flooding
2003	Kansas	Neosho	5/06/03	FEMA-1462-DR	Severe storms, tornadoes, and flooding
2003	Kansas	Seward	5/06/03	FEMA-1462-DR	Severe storms, tornadoes, and flooding

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2003	Kansas	Wandotte	5/06/03	FEMA-1462-DR	Severe storms, tornadoes, and flooding
2003	Kentucky	Anderson	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Boyd	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Boyd	7/02/03	FEMA-1475-DR	Severe Storms, Flooding, Mud and Rock Slides, and Tornadoes
2003	Kentucky	Boyle	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Breathitt	3/14/03	FEMA-1454-DR	Severe winter ice and snow storms, heavy rain, flooding, tornadoes, and mud and rock slides
2003	Kentucky	Breathitt	7/02/03	FEMA-1475-DR	Severe Storms, Flooding, Mud and Rock Slides, and Tornadoes
2003	Kentucky	Breckenridge	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Bullitt	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Caldwell	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Carter	3/14/03	FEMA-1454-DR	Severe winter ice and snow storms, heavy rain, flooding, tornadoes, and mud and rock slides
2003	Kentucky	Carter	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Carter	7/02/03	FEMA-1475-DR	Severe Storms, Flooding, Mud and Rock Slides, and Tornadoes
2003	Kentucky	Clarke	3/14/03	FEMA-1454-DR	Severe winter ice and snow storms, heavy rain, flooding, tornadoes, and mud and rock slides
2003	Kentucky	Clay	7/02/03	FEMA-1475-DR	Severe Storms, Flooding, Mud and Rock Slides, and Tornadoes
2003	Kentucky	Crittenden	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Elliott	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes

2003	Kentucky	Elliott	7/02/03	FEWA-1475-DR	Severe Storms, Flooding, Mud and Rock Slides, and Tornadoes
2003	Kentucky	Estill	6/03/03	FEWA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Fayette	3/14/03	FEWA-1454-DR	Severe winter ice and snow storms, heavy rain, flooding, tornadoes, and mud and rock slides
2003	Kentucky	Fleming	6/03/03	FEWA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Floyd	3/14/03	FEWA-1454-DR	Severe winter ice and snow storms, heavy rain, flooding, tornadoes, and mud and rock slides
2003	Kentucky	Floyd	7/02/03	FEWA-1475-DR	Severe Storms, Flooding, Mud and Rock Slides, and Tornadoes
2003	Kentucky	Garrard	6/03/03	FEWA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Graves	6/03/03	FEWA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Grayson	6/03/03	FEWA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Greenup	3/14/03	FEWA-1454-DR	Severe winter ice and snow storms, heavy rain, flooding, tornadoes, and mud and rock slides
2003	Kentucky	Greenup	6/03/03	FEWA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Greenup	7/02/03	FEWA-1475-DR	Severe Storms, Flooding, Mud and Rock Slides, and Tornadoes
2003	Kentucky	Hardin	6/03/03	FEWA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Harlan	7/02/03	FEWA-1475-DR	Severe Storms, Flooding, Mud and Rock Slides, and Tornadoes
2003	Kentucky	Hart	6/03/03	FEWA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Henderson	6/03/03	FEWA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Hopkins	6/03/03	FEWA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Jefferson	6/03/03	FEWA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2003	Kentucky	Jessamine	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Johnson	3/14/03	FEMA-1454-DR	Severe winter ice and snow storms, heavy rain, flooding, tornadoes, and mud and rock slides
2003	Kentucky	Johnson	7/02/03	FEMA-1475-DR	Severe Storms, Flooding, Mud and Rock Slides, and Tornadoes
2003	Kentucky	Knott	3/14/03	FEMA-1454-DR	Severe winter ice and snow storms, heavy rain, flooding, tornadoes, and mud and rock slides
2003	Kentucky	Knott	7/02/03	FEMA-1475-DR	Severe Storms, Flooding, Mud and Rock Slides, and Tornadoes
2003	Kentucky	Knox	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Knox	7/02/03	FEMA-1475-DR	Severe Storms, Flooding, Mud and Rock Slides, and Tornadoes
2003	Kentucky	Larue	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Lawrence	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Lawrence	7/02/03	FEMA-1475-DR	Severe Storms, Flooding, Mud and Rock Slides, and Tornadoes
2003	Kentucky	Leslie	3/14/03	FEMA-1454-DR	Severe winter ice and snow storms, heavy rain, flooding, tornadoes, and mud and rock slides
2003	Kentucky	Leslie	7/02/03	FEMA-1475-DR	Severe Storms, Flooding, Mud and Rock Slides, and Tornadoes
2003	Kentucky	Letcher	3/14/03	FEMA-1454-DR	Severe winter ice and snow storms, heavy rain, flooding, tornadoes, and mud and rock slides
2003	Kentucky	Letcher	7/02/03	FEMA-1475-DR	Severe Storms, Flooding, Mud and Rock Slides, and Tornadoes
2003	Kentucky	Lewis	3/14/03	FEMA-1454-DR	Severe winter ice and snow storms, heavy rain, flooding, tornadoes, and mud and rock slides

2003	Kentucky	Lewis	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Lewis	7/02/03	FEMA-1475-DR	Severe Storms, Flooding, Mud and Rock Slides, and Tornadoes
2003	Kentucky	Madison	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Magoffin	7/02/03	FEMA-1475-DR	Severe Storms, Flooding, Mud and Rock Slides, and Tornadoes
2003	Kentucky	Martin	3/14/03	FEMA-1454-DR	Severe winter ice and snow storms, heavy rain, flooding, tornadoes, and mud and rock slides
2003	Kentucky	Martin	7/02/03	FEMA-1475-DR	Severe Storms, Flooding, Mud and Rock Slides, and Tornadoes
2003	Kentucky	Mason	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	McLean	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Meade	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Mercer	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Nelson	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Owsley	3/14/03	FEMA-1454-DR	Severe winter ice and snow storms, heavy rain, flooding, tornadoes, and mud and rock slides
2003	Kentucky	Owsley	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Owsley	7/02/03	FEMA-1475-DR	Severe Storms, Flooding, Mud and Rock Slides, and Tornadoes
2003	Kentucky	Perry	3/14/03	FEMA-1454-DR	Severe winter ice and snow storms, heavy rain, flooding, tornadoes, and mud and rock slides
2003	Kentucky	Perry	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Perry	7/02/03	FEMA-1475-DR	Severe Storms, Flooding, Mud and Rock Slides, and Tornadoes
2003	Kentucky	Pike	3/14/03	FEMA-1454-DR	Severe winter ice and snow storms, heavy rain, flooding, tornadoes, and mud and rock slides

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2003	Kentucky	Pike	7/02/03	FEMA-1475-DR	Severe Storms, Flooding, Mud and Rock Slides, and Tornadoes
2003	Kentucky	Rowan	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Rowan	7/02/03	FEMA-1475-DR	Severe Storms, Flooding, Mud and Rock Slides, and Tornadoes
2003	Kentucky	Union	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Washington	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Webster	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Kentucky	Woodford	6/03/03	FEMA-1471-DR	Severe storms, flooding, mud and rock slides, and tornadoes
2003	Maryland	Allegany	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	Anne	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	Anne's	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	Arundel	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	Baltimore	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	Calvert	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	Caroline	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	Carroll	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	Cecil	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	Charles	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	City of Baltimore	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	Dorchester	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	Frederick	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	Garrett	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	George's	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	Harford	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	Howard	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	Kent	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	Mary's	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	Montgomery	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	Prince	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	Queen	9/18/03	FEMA-1492-DR	Hurricane Isabel

2003	Maryland	Somerset	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	St	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	Talbot	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	Washington	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	Wicomico	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Maryland	Worcester	9/18/03	FEMA-1492-DR	Hurricane Isabel
2003	Mississippi	Amite	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Attala	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Calhoun	5/23/03	FEMA-1470-DR	Severe Storms, Tornadoes and High Winds
2003	Mississippi	Chickasaw	5/23/03	FEMA-1470-DR	Severe Storms, Tornadoes and High Winds
2003	Mississippi	Claiborne	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Clarke	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Clay	5/23/03	FEMA-1470-DR	Severe Storms, Tornadoes and High Winds
2003	Mississippi	Copiah	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Davis	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Franklin	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Hinds	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Holmes	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Issaquena	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Itawamba	5/23/03	FEMA-1470-DR	Severe Storms, Tornadoes and High Winds
2003	Mississippi	Jasper	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Jefferson	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Jefferson	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Kemper	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Lauderdale	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Lawrence	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Leake	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Lee	5/23/03	FEMA-1470-DR	Severe Storms, Tornadoes and High Winds
2003	Mississippi	Lincoln	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Lowndes	5/23/03	FEMA-1470-DR	Severe Storms, Tornadoes and High Winds
2003	Mississippi	Madison	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Marion	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Monroe	5/23/03	FEMA-1470-DR	Severe Storms, Tornadoes and High Winds
2003	Mississippi	Neshoba	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Newton	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Pearl	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Pike	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Pontotoc	4/23/03	FEMA-1470-DR	Severe Storms, Tornadoes and High Winds
2003	Mississippi	Rankin	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	River	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2003	Mississippi	Scott	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Simpson	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Smith	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Walhall	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Warren	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Wayne	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Mississippi	Webster	5/23/03	FEMA-1470-DR	Severe Storms, Tornadoes and High Winds
2003	Mississippi	Yazoo	4/23/03	FEMA-1459-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Barry	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Barton	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Bates	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Benton	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Bollinger	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Buchanan	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Camden	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Cape	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Cass	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Cedar	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Christian	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Clair	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Clay	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Clinton	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Cooper	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Crawford	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Dade	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Dallas	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Dent	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Douglas	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Frankois	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Franklin	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Gasconade	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Genevieve	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Girardeau	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Greene	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Henry	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding
2003	Missouri	Hickory	5/06/03	FEMA-1463-DR	Severe Storms, tornadoes, and flooding

2003	Missouri	Iron	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Jackson	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Jasper	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Jefferson	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Johnson	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Knox	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Laclede	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Lafayette	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Lawrence	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Louis	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Marion	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	McDonald	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Miller	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Monroe	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Morgan	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Newton	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Osage	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Perry	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Pettis	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Phelps	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Platte	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Polk	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Pulaski	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Ray	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Saint	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Saint	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Sainte	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Saline	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Scott	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	St	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Stoddard	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Stone	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Taney	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Vernon	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Washington	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	Missouri	Webster	5/06/03	FEMA-1463-DR	Severe storms, tornadoes, and flooding
2003	New York	Allegany	8/29/03	FEMA-1486-DR	Severe Storms, Flooding, and Tornadoes
2003	New York	Cattaraugus	8/29/03	FEMA-1486-DR	Severe Storms, Flooding, and Tornadoes
2003	New York	Cayuga	5/12/03	FEMA-1467-DR	Ice Storm
2003	New York	Chemung	8/29/03	FEMA-1486-DR	Severe Storms, Flooding, and Tornadoes

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2003	New York	Columbia	8/29/03	FEMA-1486-DR	Severe Storms, Flooding, and Tornadoes
2003	New York	Delaware	8/29/03	FEMA-1486-DR	Severe Storms, Flooding, and Tornadoes
2003	New York	Fulton	8/29/03	FEMA-1486-DR	Severe Storms, Flooding, and Tornadoes
2003	New York	Greene	8/29/03	FEMA-1486-DR	Severe Storms, Flooding, and Tornadoes
2003	New York	Livingston	8/29/03	FEMA-1486-DR	Severe Storms, Flooding, and Tornadoes
2003	New York	Monroe	5/12/03	FEMA-1467-DR	Ice Storm
2003	New York	Montgomery	8/29/03	FEMA-1486-DR	Severe Storms, Flooding, and Tornadoes
2003	New York	Oneida	5/12/03	FEMA-1467-DR	Ice Storm
2003	New York	Onondaga	5/12/03	FEMA-1467-DR	Ice Storm
2003	New York	Ontario	5/12/03	FEMA-1467-DR	Ice Storm
2003	New York	Ontario	8/29/03	FEMA-1486-DR	Severe Storms, Flooding, and Tornadoes
2003	New York	Oswego	5/12/03	FEMA-1467-DR	Ice Storm
2003	New York	Rensselaer	8/29/03	FEMA-1486-DR	Severe Storms, Flooding, and Tornadoes
2003	New York	Schuyler	8/29/03	FEMA-1467-DR	Ice Storm
2003	New York	Seneca	5/12/03	FEMA-1467-DR	Ice Storm
2003	New York	Steuben	8/29/03	FEMA-1486-DR	Severe Storms, Flooding, and Tornadoes
2003	New York	Wayne	5/12/03	FEMA-1467-DR	Ice Storm
2003	New York	Yates	8/29/03	FEMA-1486-DR	Severe Storms, Flooding, and Tornadoes
2003	North Carolina	Beaufort	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Bertie	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Bladen	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Brunswick	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Camden	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Carteret	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Chowan	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Columbus	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Craven	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Cumberland	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Currituck	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Dare	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Davidson	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Duplin	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Durham	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Edgecombe	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Franklin	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Gates	9/18/03	FEMA-1490-DR	Hurricane Isabel

2003	North Carolina	Granville	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Greene	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Halifax	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Hanover	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Harnett	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Hertford	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Hyde	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Johnston	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Jones	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Lenoir	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Martin	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Nash	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	New	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Northampton	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Onslow	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Pamlico	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Pasquotank	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Pender	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Perquimans	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Person	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Pitt	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Robeson	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Sampson	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Tyrrell	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Vance	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Wake	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Warren	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Washington	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Wayne	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Wilson	9/18/03	FEMA-1490-DR	Hurricane Isabel
2003	North Carolina	Adams	3/14/03	FEMA-1453-DR	Severe Winter Storm
2003	Ohio	Auglaize	7/15/03	FEMA-1478-DR	Severe Storms and Flooding
2003	Ohio	Carroll	8/01/03	FEMA-1484-DR	Tornadoes, Flooding, Severe Storms, and High Winds
2003	Ohio	Columbiana	7/15/03	FEMA-1478-DR	Severe Storms and Flooding
2003	Ohio	Columbiana	8/01/03	FEMA-1484-DR	Tornadoes, Flooding, Severe Storms, and High Winds
2003	Ohio	Crawford	7/15/03	FEMA-1478-DR	Severe Storms and Flooding
2003	Ohio	Cuyahoga	8/01/03	FEMA-1484-DR	Tornadoes, Flooding, Severe Storms, and High Winds

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2003	Ohio	Darke	7/15/03	FEMA-1478-DR	Severe Storms and Flooding
2003	Ohio	Franklin	8/01/03	FEMA-1484-DR	Tornadoes, Flooding, Severe Storms, and High Winds
2003	Ohio	Jackson	3/14/03	FEMA-1453-DR	Severe Winter Storm
2003	Ohio	Jefferson	8/01/03	FEMA-1484-DR	Tornadoes, Flooding, Severe Storms, and High Winds
2003	Ohio	Lawrence	3/14/03	FEMA-1453-DR	Severe Winter Storm
2003	Ohio	Logan	7/15/03	FEMA-1478-DR	Severe Storms and Flooding
2003	Ohio	Marioning	7/15/03	FEMA-1478-DR	Severe Storms and Flooding
2003	Ohio	Mahoning	8/01/03	FEMA-1484-DR	Tornadoes, Flooding, Severe Storms, and High Winds
2003	Ohio	Medina	8/01/03	FEMA-1484-DR	Tornadoes, Flooding, Severe Storms, and High Winds
2003	Ohio	Mercer	7/15/03	FEMA-1478-DR	Severe Storms and Flooding
2003	Ohio	Pike	3/14/03	FEMA-1453-DR	Severe Winter Storm
2003	Ohio	Pike	7/15/03	FEMA-1478-DR	Severe Storms and Flooding
2003	Ohio	Portage	8/01/03	FEMA-1484-DR	Tornadoes, Flooding, Severe Storms, and High Winds
2003	Ohio	Richland	8/01/03	FEMA-1484-DR	Tornadoes, Flooding, Severe Storms, and High Winds
2003	Ohio	Scioto	3/14/03	FEMA-1453-DR	Severe Winter Storm
2003	Ohio	Shelby	7/15/03	FEMA-1478-DR	Severe Storms and Flooding
2003	Ohio	Stark	8/01/03	FEMA-1484-DR	Tornadoes, Flooding, Severe Storms, and High Winds
2003	Ohio	Summit	8/01/03	FEMA-1484-DR	Tornadoes, Flooding, Severe Storms, and High Winds
2003	Ohio	Trumbull	8/01/03	FEMA-1484-DR	Tornadoes, Flooding, Severe Storms, and High Winds
2003	Ohio	Van Wert	7/15/03	FEMA-1478-DR	Severe Storms and Flooding
2003	Oklahoma	Canadian	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Oklahoma	Carter	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Oklahoma	Cherokee	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Oklahoma	Cleveland	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Oklahoma	Creek	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Oklahoma	Delaware	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Oklahoma	Garvin	5/10/03	FEMA-1465-DR	Severe storms and tornadoes

2003	Oklahoma	Grady	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Oklahoma	Key	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Oklahoma	Kingfisher	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Oklahoma	Lincoln	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Oklahoma	Logan	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Oklahoma	McClain	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Oklahoma	Mills	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Oklahoma	Muskogee	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Oklahoma	Nowata	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Oklahoma	Okfuskee	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Oklahoma	Oklahoma	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Oklahoma	Oklmulgee	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Oklahoma	Osage	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Oklahoma	Pontotoc	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Oklahoma	Pottawatomie	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Oklahoma	Roger	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Oklahoma	Seminole	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Oklahoma	Texas	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Oklahoma	Washington	5/10/03	FEMA-1465-DR	Severe storms and tornadoes
2003	Pennsylvania	Blair	8/23/03	FEMA-1485-DR	Severe storms, Tornadoes, and Flooding
2003	Pennsylvania	Chester	9/26/03	FEMA-1497-DR	Tropical Storms Henri and Isabel, and related severe storms and flooding
2003	Pennsylvania	Crawford	8/23/03	FEMA-1485-DR	Severe Storms, Tornadoes, and Flooding
2003	Pennsylvania	Lackawanna	8/23/03	FEMA-1485-DR	Severe Storms, Tornadoes, and Flooding
2003	Pennsylvania	Lawrence	8/23/03	FEMA-1485-DR	Severe Storms, Tornadoes, and Flooding
2003	Pennsylvania	McKean	8/23/03	FEMA-1485-DR	Severe Storms, Tornadoes, and Flooding
2003	Pennsylvania	Mercer	8/23/03	FEMA-1485-DR	Severe Storms, Tornadoes, and Flooding
2003	Pennsylvania	Potter	8/23/03	FEMA-1485-DR	Severe Storms, Tornadoes, and Flooding
2003	Pennsylvania	Toga	8/23/03	FEMA-1485-DR	Severe Storms, Tornadoes, and Flooding
2003	Pennsylvania	Venango	8/23/03	FEMA-1485-DR	Severe Storms, Tornadoes, and Flooding
2003	Pennsylvania	Wayne	8/23/03	FEMA-1485-DR	Severe Storms, Tornadoes, and Flooding
2003	Pennsylvania	Warren	8/23/03	FEMA-1485-DR	Severe Storms, Tornadoes, and Flooding
2003	Tennessee	Anderson	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Bedford	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Benton	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Bledsoe	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Blount	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Bradley	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Cannon	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Carroll	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2003	Tennessee	Cheatham	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Chester	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Cocke	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Coffee	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Crockett	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Cumberland	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Davidson	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Decatur	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Dekalb	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Dickson	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Dyer	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Fayette	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Fayette	7/29/03	FEMA-1482-DR	Severe storms, high winds, and heavy rain
2003	Tennessee	Gibson	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Giles	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Hamilton	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Hardeman	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Hardin	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Haywood	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Henderson	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Henry	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Hickman	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Houston	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Humphreys	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Jefferson	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Knox	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Lake	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Lauderdale	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Lawrence	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Lewis	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Lincoln	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Loudon	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Macon	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Madison	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Marion	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Marshall	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding

2003	Tennessee	Maury	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	McMinn	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Meigs	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Monroe	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Montgomery	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Obion	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Perry	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Polk	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Rhea	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Roane	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Robertson	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Rutherford	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Squatchie	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Sevier	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Shelby	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Shelby	7/29/03	FEMA-1482-DR	Severe storms, high winds, and heavy rain
2003	Tennessee	Smith	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Stewart	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Tipton	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Trousdale	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Warren	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Wayne	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Weakley	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Williamson	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Tennessee	Wilson	5/08/03	FEMA-1464-DR	Severe storms, tornadoes, and flooding
2003	Texas	Aransas	7/17/03	FEMA-1479-DR	Hurricane Claudette
2003	Texas	Atascosa	7/17/03	FEMA-1479-DR	Hurricane Claudette
2003	Texas	Bee	7/17/03	FEMA-1479-DR	Hurricane Claudette
2003	Texas	Brazoria	7/17/03	FEMA-1479-DR	Hurricane Claudette
2003	Texas	Calhoun	7/17/03	FEMA-1479-DR	Hurricane Claudette
2003	Texas	DeWitt	7/17/03	FEMA-1479-DR	Hurricane Claudette
2003	Texas	Frio	7/17/03	FEMA-1479-DR	Hurricane Claudette
2003	Texas	Galveston	7/17/03	FEMA-1479-DR	Hurricane Claudette
2003	Texas	Goliad	7/17/03	FEMA-1479-DR	Hurricane Claudette
2003	Texas	Jackson	7/17/03	FEMA-1479-DR	Hurricane Claudette
2003	Texas	Karnes	7/17/03	FEMA-1479-DR	Hurricane Claudette
2003	Texas	Live Oak	7/17/03	FEMA-1479-DR	Hurricane Claudette
2003	Texas	Matagorda	7/17/03	FEMA-1479-DR	Hurricane Claudette
2003	Texas	McMullen	7/17/03	FEMA-1479-DR	Hurricane Claudette
2003	Texas	Refugio	7/17/03	FEMA-1479-DR	Hurricane Claudette

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2003	Texas	San Patricio	7/17/03	FEMA-1479-DR	Hurricane Claudette
2003	Texas	Victoria	7/17/03	FEMA-1479-DR	Hurricane Claudette
2003	Texas	Zavala	7/17/03	FEMA-1479-DR	Hurricane Claudette
2003	Virginia	Acomack	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Albemarle	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Amelia	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Amherst	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Appomattox	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Arlington	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Augusta	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Bedford	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Bland	12/09/03	FEMA-1502-DR	Severe Storms and Flooding
2003	Virginia	Brunswick	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Buchanan	3/27/03	FEMA-1458-DR	Severe winter storm, record/near-record, snow-fall, heavy rain, flooding, and mudslides
2003	Virginia	Buchanan	12/09/03	FEMA-1502-DR	Severe Storms and Flooding
2003	Virginia	Buckingham	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Campbell	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Caroline	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Charles City	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Charlotte	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Chesterfield	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Alexandria	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Bedford	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Buena	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Charlottesville	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Chesapeake	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Colonial Heights	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Danville	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Emporia	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Fairfax	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Falls Church	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Franklin	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Fredericksburg	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Galax	12/09/03	FEMA-1502-DR	Severe Storms and Flooding
2003	Virginia	City of Hampton	9/18/03	FEMA-1491-DR	Hurricane Isabel

2003	Virginia	City of Harrisonburg	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Hopewell	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Lynchburg	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Manassas	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Manassas Park	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Newport	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of News	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Norfolk	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Norton	3/27/03	FEMA-1458-DR	Severe winter storm, record/near-record snow-fall, heavy rain, flooding, and mudslides
2003	Virginia	City of Petersburg	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Poquoson	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Portsmouth	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Richmond	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Roanoke	3/27/03	FEMA-1458-DR	Severe winter storm, record/near-record snow-fall, heavy rain, flooding, and mudslides
2003	Virginia	City of Salem	3/27/03	FEMA-1458-DR	Severe winter storm, record/near-record snow-fall, heavy rain, flooding, and mudslides
2003	Virginia	City of Staunton	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Suffolk	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Virginia Beach	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Vista	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Waynesboro	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Williamsburg	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	City of Winchester	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Clarke	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Culpeper	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Cumberland	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Dickenson	3/27/03	FEMA-1458-DR	Severe winter storm, record/near-record snow-fall, heavy rain, flooding, and mudslides
2003	Virginia	Dinwiddie	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Essex	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Fairfax	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Fauquier	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Fluvanna	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Frederick	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Giles	12/09/03	FEMA-1502-DR	Severe Storms and Flooding
2003	Virginia	Gloucester	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Gochoiland	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Greene	9/18/03	FEMA-1491-DR	Hurricane Isabel

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2003	Virginia	Greensville	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Halifax	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Hanover	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Henrico	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Isle of Wight	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	James City	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	King and Queen	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	King George	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	King William	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Lancaster	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Loudoun	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Louisa	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Lunenburg	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Madison	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Mathews	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Mecklenburg	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Middlesex	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Montgomery	3/27/03	FEMA-1458-DR	Severe winter storm, record/near-record snow-fall, heavy rain, flooding, and mudslides
2003	Virginia	Nelson	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	New Kent	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Northampton	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Northumberland	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Nottoway	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Orange	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Page	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Pittsylvania	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Powhatan	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Prince Edward	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Prince George	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Prince William	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Rappahannock	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Richmond	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Rockbridge	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Rockingham	9/18/03	FEMA-1491-DR	Hurricane Isabel

2003	Virginia	Russell	3/27/03	FEMA-1458-DR	Severe winter storm, record/near-record snow-fall, heavy rain, flooding, and mudslides
2003	Virginia	Shenandoah	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Smyth	12/09/03	FEMA-1502-DR	Severe Storms and Flooding
2003	Virginia	Southampton	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Spotsylvania	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Stafford	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Surry	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Sussex	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Tazewell	3/27/03	FEMA-1458-DR	Severe winter storm, record/near-record snow-fall, heavy rain, flooding, and mudslides
2003	Virginia	Tazewell	12/09/03	FEMA-1502-DR	Severe Storms and Flooding
2003	Virginia	Warren	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Westmoreland	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Virginia	Wise	3/27/03	FEMA-1458-DR	Severe winter storm, record/near-record snow-fall, heavy rain, flooding, and mudslides
2003	Virginia	York	9/18/03	FEMA-1491-DR	Hurricane Isabel
2003	Washington	Chelan	11/07/03	FEMA-1499-DR	Severe Storms and Flooding
2003	Washington	Ciallam	11/07/03	FEMA-1499-DR	Severe Storms and Flooding
2003	Washington	Grays	11/07/03	FEMA-1499-DR	Severe Storms and Flooding
2003	Washington	Harbor	11/07/03	FEMA-1499-DR	Severe Storms and Flooding
2003	Washington	Island	11/07/03	FEMA-1499-DR	Severe Storms and Flooding
2003	Washington	Jefferson	11/07/03	FEMA-1499-DR	Severe Storms and Flooding
2003	Washington	Juan	11/07/03	FEMA-1499-DR	Severe Storms and Flooding
2003	Washington	King	11/07/03	FEMA-1499-DR	Severe Storms and Flooding
2003	Washington	Kitsap	11/07/03	FEMA-1499-DR	Severe Storms and Flooding
2003	Washington	Mason	11/07/03	FEMA-1499-DR	Severe Storms and Flooding
2003	Washington	Okanogan	11/07/03	FEMA-1499-DR	Severe Storms and Flooding
2003	Washington	Pierce	11/07/03	FEMA-1499-DR	Severe Storms and Flooding
2003	Washington	San	11/07/03	FEMA-1499-DR	Severe Storms and Flooding
2003	Washington	Skagit	11/07/03	FEMA-1499-DR	Severe Storms and Flooding
2003	Washington	Snohomish	11/07/03	FEMA-1499-DR	Severe Storms and Flooding
2003	Washington	Thurston	11/07/03	FEMA-1499-DR	Severe Storms and Flooding
2003	Washington	Whatcom	11/07/03	FEMA-1499-DR	Severe Storms and Flooding
2003	West Virginia	Berkeley	6/21/03	FEMA-1474-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Boone	6/21/03	FEMA-1474-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Boone	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Braxton	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Cabel	6/21/03	FEMA-1474-DR	Severe Storms, Flooding, and Landslides

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2003	West Virginia	Cabell	3/14/03	FEMA-1455-DR	Severe Winter Storm, Record/Near Record Snow, Heavy Rains, Flooding and Landslides
2003	West Virginia	Cabell	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Calhoun	3/14/03	FEMA-1455-DR	Severe Winter Storm, Record/Near Record Snow, Heavy Rains, Flooding and Landslides
2003	West Virginia	Calhoun	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Clay	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Doddridge	6/21/03	FEMA-1474-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Fayette	3/14/03	FEMA-1455-DR	Severe Winter Storm, Record/Near Record Snow, Heavy Rains, Flooding and Landslides
2003	West Virginia	Fayette	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Glimer	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Greenbrier	3/14/03	FEMA-1455-DR	Severe Winter Storm, Record/Near Record Snow, Heavy Rains, Flooding and Landslides
2003	West Virginia	Greenbrier	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Harrison	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Jackson	3/14/03	FEMA-1455-DR	Severe Winter Storm, Record/Near Record Snow, Heavy Rains, Flooding and Landslides
2003	West Virginia	Kanawha	3/14/03	FEMA-1455-DR	Severe Winter Storm, Record/Near Record Snow, Heavy Rains, Flooding and Landslides
2003	West Virginia	Kanawha	6/21/03	FEMA-1474-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Kanawha	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Lewis	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Lincoln	3/14/03	FEMA-1455-DR	Severe Winter Storm, Record/Near Record Snow, Heavy Rains, Flooding and Landslides
2003	West Virginia	Lincoln	6/21/03	FEMA-1474-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Lincoln	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Logan	6/21/03	FEMA-1474-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Logan	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Marion	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Mason	3/14/03	FEMA-1455-DR	Severe Winter Storm, Record/Near Record Snow, Heavy Rains, Flooding and Landslides
2003	West Virginia	Mason	6/21/03	FEMA-1474-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	McDowell	3/14/03	FEMA-1455-DR	Severe Winter Storm, Record/Near Record Snow, Heavy Rains, Flooding and Landslides
2003	West Virginia	McDowell	6/21/03	FEMA-1474-DR	Severe Storms, Flooding, and Landslides

2003	West Virginia	McDowell	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Mercer	3/14/03	FEMA-1455-DR	Severe Winter Storm, Record/Near Record Snow, Heavy Rains, Flooding and Landslides
2003	West Virginia	Mercer	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Mingo	3/14/03	FEMA-1455-DR	Severe Winter Storm, Record/Near Record Snow, Heavy Rains, Flooding and Landslides
2003	West Virginia	Mingo	6/21/03	FEMA-1474-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Monongalia	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Monroe	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Nicholas	3/14/03	FEMA-1455-DR	Severe Winter Storm, Record/Near Record Snow, Heavy Rains, Flooding and Landslides
2003	West Virginia	Nicholas	6/21/03	FEMA-1474-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Nicholas	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Preston	6/21/03	FEMA-1474-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Putnam	6/21/03	FEMA-1474-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Putnam	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Raleigh	3/14/03	FEMA-1455-DR	Severe Winter Storm, Record/Near Record Snow, Heavy Rains, Flooding and Landslides
2003	West Virginia	Raleigh	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Roane	3/14/03	FEMA-1455-DR	Severe Winter Storm, Record/Near Record Snow, Heavy Rains, Flooding and Landslides
2003	West Virginia	Summers	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Taylor	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Upshur	3/14/03	FEMA-1455-DR	Severe Winter Storm, Record/Near Record Snow, Heavy Rains, Flooding and Landslides
2003	West Virginia	Wayne	3/14/03	FEMA-1455-DR	Severe Winter Storm, Record/Near Record Snow, Heavy Rains, Flooding and Landslides
2003	West Virginia	Wayne	6/21/03	FEMA-1474-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Wayne	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Webster	3/14/03	FEMA-1455-DR	Severe Winter Storm, Record/Near Record Snow, Heavy Rains, Flooding and Landslides
2003	West Virginia	Webster	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Wetzel	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Wyoming	3/14/03	FEMA-1455-DR	Severe Winter Storm, Record/Near Record Snow, Heavy Rains, Flooding and Landslides
2003	West Virginia	Wyoming	6/21/03	FEMA-1474-DR	Severe Storms, Flooding, and Landslides
2003	West Virginia	Wyoming	11/21/03	FEMA-1500-DR	Severe Storms, Flooding, and Landslides
2004	Alabama	Autauga	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Baldwin	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Barbour	9/15/04	FEMA-1549-DR	Hurricane Ivan

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2004	Alabama	Bibb	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Blount	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Bullock	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Butler	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Calhoun	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Chambers	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Chilton	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Choctaw	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Clarke	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Clay	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Coffee	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Colbert	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Coosa	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Conecuh	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Covington	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Crenshaw	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Cullman	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Dale	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Dallas	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Dekalb	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Elmore	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Escambia	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Etowah	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Fayette	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Franklin	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Geneva	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Greene	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Hale	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Henry	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Houston	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Jackson	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Jefferson	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Lamar	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Lauderdale	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Lawrence	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Lee	9/15/04	FEMA-1549-DR	Hurricane Ivan

2004	Alabama	Limestone	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Lowndes	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Macon	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Madison	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Marengo	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Marshall	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Marion	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Mobile	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Monroe	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Montgomery	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Morgan	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Perry	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Pickens	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Pike	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Randolph	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Russell	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Shelby	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	St. Clair	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Sumter	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Talladega	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Tallapoosa	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Tuscaloosa	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Walker	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Washington	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Wilcox	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	Alabama	Winston	9/15/04	FEMA-1549-DR	Hurricane Ivan
2004	American Samoa	Island of Tutuila	1/13/04	FEMA-1506-DR	High Winds, High Surf and Heavy Rainfall Associated With Tropical Cyclone Heta
2004	American Samoa	The Manu'a Islands	1/13/04	FEMA-1506-DR	High Winds, High Surf and Heavy Rainfall Associated With Tropical Cyclone Heta
2004	California	San Luis Obispo	1/13/04	FEMA-1505-DR	Earthquake
2004	Florida	Alachua	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Baker	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Bradford	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Brevard	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Charlotte	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Citrus	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Clay	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Columbia	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	DeSoto	9/26/04	FEMA-1561-DR	Hurricane Jeanne

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2004	Florida	Dixie	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Duval	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Flagler	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Gilchrist	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Glades	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Hamilton	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Hardee	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Hendry	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Hernando	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Highlands	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Hillsborough	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Indian River	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Jefferson	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Lafayette	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Lake	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Levy	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Madison	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Manatee	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Marion	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Martin	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Nassau	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Okeechobee	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Orange	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Osceola	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Palm Beach	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Pasco	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Pinellas	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Polk	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Putnam	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	St. Johns	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	St. Lucie	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Sarasota	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Seminole	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Sumter	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Suwannee	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Taylor	9/26/04	FEMA-1561-DR	Hurricane Jeanne

2004	Florida	Union	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Volusia	9/26/04	FEMA-1561-DR	Hurricane Jeanne
2004	Florida	Bay	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Brevard	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Calhoun	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Clay	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Citrus	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Duval	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Escambia	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Flagler	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Franklin	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Gadsden	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Gulf	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Highlands	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Holmes	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Indian River	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Jackson	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Lake	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Lee	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Leon	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Liberty	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Manatee	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Marion	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Martin	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Okaloosa	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Okeechobee	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Osceola	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Orange	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Palm Beach	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Pasco	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Polk	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Santa Rosa	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Seminole	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	St. Johns	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	St. Lucie	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Taylor	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Volusia	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Wakulla	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Walton	9/16/04	FEMA-1551-DR	Hurricane Ivan
2004	Florida	Washington	9/16/04	FEMA-1551-DR	Hurricane Ivan

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2004	Florida	Alachua	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Baker	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Bradford	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Brevard	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Broward	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Charlotte	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Citrus	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Clay	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Columbia	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	DeSoto	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Dixie	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Duval	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Flagler	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Glachrist	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Glades	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Hardee	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Henry	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Herrando	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Hillborough	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Hillsborough	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Indian River	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Lake	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Lee	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Levy	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Manatee	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Marion	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Martin	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Miami-Dade	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Nassau	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Okeechobee	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Orange	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Oscola	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Palm Beach	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Pasco	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Pinellas	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Polk	9/04/04	FEMA-1545-DR	Hurricane Frances

2004	Florida	Putnam	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Sarasota	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Seminole	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	St. Johns	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	St. Lucie	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Sumter	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Suwannee	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Union	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Volusia	9/04/04	FEMA-1545-DR	Hurricane Frances
2004	Florida	Brevard	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	Charlotte	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	Collier	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	DeSoto	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	Dixie	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	Duval	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	Flagler	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	Glades	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	Hardee	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	Hendry	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	Highlands	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	Indian River	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	Lake	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	Lee	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	Lewy	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	Manatee	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	Monroe	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	Okeechobee	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	Orange	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	Osceola	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	Pasco	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	Polk	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	St. Johns	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	Sarasota	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	Seminole	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Florida	Volusia	8/13/04	FEMA-1539-DR	Tropical Storm Bonnie and Hurricane Charley
2004	Georgia	Carroll	9/18/04	FEMA-1554-DR	Hurricane Ivan
2004	Georgia	Cherokee	9/18/04	FEMA-1554-DR	Hurricane Ivan
2004	Georgia	Clayton	9/18/04	FEMA-1554-DR	Hurricane Ivan
2004	Georgia	Cobb	9/18/04	FEMA-1554-DR	Hurricane Ivan
2004	Georgia	Dade	9/18/04	FEMA-1554-DR	Hurricane Ivan

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2004	Georgia	Dawson	9/18/04	FEMA-1554-DR	Hurricane Ivan
2004	Georgia	Dekalb	9/18/04	FEMA-1554-DR	Hurricane Ivan
2004	Georgia	Early	9/18/04	FEMA-1554-DR	Hurricane Ivan
2004	Georgia	Forsyth	9/18/04	FEMA-1554-DR	Hurricane Ivan
2004	Georgia	Franklin	9/18/04	FEMA-1554-DR	Hurricane Ivan
2004	Georgia	Fulton	9/18/04	FEMA-1554-DR	Hurricane Ivan
2004	Georgia	Gilmer	9/18/04	FEMA-1554-DR	Hurricane Ivan
2004	Georgia	Heard	9/18/04	FEMA-1554-DR	Hurricane Ivan
2004	Georgia	Madison	9/18/04	FEMA-1554-DR	Hurricane Ivan
2004	Georgia	Miller	9/18/04	FEMA-1554-DR	Hurricane Ivan
2004	Georgia	Pickens	9/18/04	FEMA-1554-DR	Hurricane Ivan
2004	Georgia	Rabun	9/18/04	FEMA-1554-DR	Hurricane Ivan
2004	Georgia	Towns	9/18/04	FEMA-1554-DR	Hurricane Ivan
2004	Georgia	Union	9/18/04	FEMA-1554-DR	Hurricane Ivan
2004	Georgia	White	9/18/04	FEMA-1554-DR	Hurricane Ivan
2004	Georgia	Wilkes	9/18/04	FEMA-1554-DR	Hurricane Ivan
2004	Illinois	Kankakee	4/23/04	FEMA-1513-DR	Severe Storms and Tornadoes
2004	Illinois	LaSalle	4/23/04	FEMA-1513-DR	Severe Storms and Tornadoes
2004	Illinois	Putnam	4/23/04	FEMA-1513-DR	Severe Storms and Tornadoes
2004	Illinois	Will	4/23/04	FEMA-1513-DR	Severe Storms and Tornadoes
2004	Indiana	Adams	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Allen	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Benton	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Boone	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Brown	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Carroll	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Cass	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Clark	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Clay	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Clinton	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Crawford	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Dearborn	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Decatur	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Dekalb	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Delaware	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Dubois	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding

2004	Indiana	Floyd	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Fountain	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Franklin	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Fulton	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Gibson	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Grant	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Greene	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Hamilton	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Hancock	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Harrison	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Hendricks	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Henry	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Howard	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Huntington	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Jackson	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Jasper	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Jefferson	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Jennings	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Johnson	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Kosciusko	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Lake	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Lawrence	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Madison	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Marion	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Martin	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Miami	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Monroe	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Montgomery	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Morgan	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Newton	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Noble	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Ohio	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Orange	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Owen	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Perry	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Pike	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Putnam	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Ripley	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Scott	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Shelby	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2004	Indiana	Spencer	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Switzerland	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Tippecanoe	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Tipton	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Vanderburgh	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Wabash	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Warren	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Warrick	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Washington	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Wells	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	White	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Indiana	Whitley	6/03/04	FEMA-1520-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Adair	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Adams	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Alamakee	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Appanoose	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Audubon	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Benton	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Black Hawk	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Boone	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Bremer	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Buchanan	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Buena Vista	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Butler	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Calhoun	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Cass	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Cedar	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Cerro Gordo	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Chickasaw	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Clay	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Clayton	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Clinton	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Dallas	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Davis	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Delaware	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Des Moines	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding

2004	Iowa	Dubuque	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Fayette	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Floyd	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Franklin	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Greene	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Gundy	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Guthrie	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Hamilton	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Hancock	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Henry	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Hardin	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Howard	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Humboldt	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Iowa	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Jackson	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Jasper	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Jones	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Johnson	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Kossuth	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Leim	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Louisa	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Lucas	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Madison	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Marshall	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Mitchell	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Monroe	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Montgomery	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Muscataine	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Palo Alto	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Pocahontas	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Polk	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Pottawattamie	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Poweshiek	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Sac	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Scott	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Shelby	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Story	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Tama	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Wapello	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Warren	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2004	Iowa	Washington	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Wayne	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Webster	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Winnebago	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Winnebago	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Winneshiek	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Worth	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Iowa	Wright	5/25/04	FEMA-1518-DR	Severe Storms, Tornadoes, and Flooding
2004	Kentucky	Bell	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, Flooding, and Mudslides
2004	Kentucky	Bourbon	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, Flooding, and Mudslides
2004	Kentucky	Boyd	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, Flooding, and Mudslides
2004	Kentucky	Boyle	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, Flooding, and Mudslides
2004	Kentucky	Breathitt	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, Flooding, and Mudslides
2004	Kentucky	Breckinridge	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, Flooding, and Mudslides
2004	Kentucky	Bullitt	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, Flooding, and Mudslides
2004	Kentucky	Butler	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, Flooding, and Mudslides
2004	Kentucky	Caldwell	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, Flooding, and Mudslides
2004	Kentucky	Carroll	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, Flooding, and Mudslides
2004	Kentucky	Carter	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, Flooding, and Mudslides
2004	Kentucky	Casey	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, Flooding, and Mudslides
2004	Kentucky	Christian	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, Flooding, and Mudslides
2004	Kentucky	Clark	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, Flooding, and Mudslides

2004	Kentucky	Clay	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Tornadoes, Flooding, and
2004	Kentucky	Crittenden	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Edmonson	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Elliott	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Estill	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Fayette	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Floyd	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Franklin	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Garrard	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Grayson	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Greenup	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Hardin	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Harlan	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Hart	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Henderson	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Henry	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Hopkins	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Jackson	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Jefferson	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Jessamine	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2004	Kentucky	Johnson	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, and Mudslides
2004	Kentucky	Knott	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, and Mudslides
2004	Kentucky	Knox	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, and Mudslides
2004	Kentucky	Laurel	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, and Mudslides
2004	Kentucky	Lawrence	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, and Mudslides
2004	Kentucky	Lee	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, and Mudslides
2004	Kentucky	Leslie	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, and Mudslides
2004	Kentucky	Letcher	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, and Mudslides
2004	Kentucky	Lincoln	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, and Mudslides
2004	Kentucky	Madison	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, and Mudslides
2004	Kentucky	Magoffin	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, and Mudslides
2004	Kentucky	Martin	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, and Mudslides
2004	Kentucky	McLean	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, and Mudslides
2004	Kentucky	Menifee	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, and Mudslides
2004	Kentucky	Montgomery	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, and Mudslides
2004	Kentucky	Morgan	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, and Mudslides
2004	Kentucky	Muhlenberg	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, and Mudslides
2004	Kentucky	Ohio	6/10/04	FEMA-1523-DR	Severe Storms, Tornadoes, and Mudslides

2004	Kentucky	Oldham	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Tornadoes, Flooding, and
2004	Kentucky	Owen	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Owsley	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Perry	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Pike	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Powell	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Pulaski	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Rockcastle	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Rowan	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Scott	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Shelby	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Spencer	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Trimble	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Union	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Webster	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Whitely	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Wolfe	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Kentucky	Woodford	6/10/04	FEMA-1523-DR	Severe Storms, Mudslides	Flooding, and
2004	Louisiana	Jefferson	9/15/04	FEMA-1548-DR	Hurricane Ivan	
2004	Louisiana	Lafourche	9/15/04	FEMA-1548-DR	Hurricane Ivan	
2004	Louisiana	Orleans	9/15/04	FEMA-1548-DR	Hurricane Ivan	
2004	Louisiana	Plaquemines	9/15/04	FEMA-1548-DR	Hurricane Ivan	

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2004	Louisiana	St. Bernard	9/15/04	FEMA-1548-DR	Hurricane Ivan
2004	Louisiana	St. Charles	9/15/04	FEMA-1548-DR	Hurricane Ivan
2004	Louisiana	St. Tammany	9/15/04	FEMA-1548-DR	Hurricane Ivan
2004	Louisiana	Terrebonne	9/15/04	FEMA-1548-DR	Hurricane Ivan
2004	Louisiana	Acadia	6/08/04	FEMA-1521-DR	Severe Storms and Flooding
2004	Louisiana	Iberville	6/08/04	FEMA-1521-DR	Severe Storms and Flooding
2004	Louisiana	Jefferson Davis	6/08/04	FEMA-1521-DR	Severe Storms and Flooding
2004	Louisiana	Lafayette	6/08/04	FEMA-1521-DR	Severe Storms and Flooding
2004	Louisiana	Livingston	6/08/04	FEMA-1521-DR	Severe Storms and Flooding
2004	Louisiana	Pointe Coupee	6/08/04	FEMA-1521-DR	Severe Storms and Flooding
2004	Louisiana	St. Landry	6/08/04	FEMA-1521-DR	Severe Storms and Flooding
2004	Louisiana	St. Martin	6/08/04	FEMA-1521-DR	Severe Storms and Flooding
2004	Louisiana	West Baton Rouge	6/08/04	FEMA-1521-DR	Severe Storms and Flooding
2004	Massachusetts	Essex	4/21/04	FEMA-1512-DR	Severe Winter Storms
2004	Massachusetts	Middlesex	4/21/04	FEMA-1512-DR	Severe Winter Storms
2004	Massachusetts	Norfolk	4/21/04	FEMA-1512-DR	Severe Winter Storms
2004	Massachusetts	Suffolk	4/21/04	FEMA-1512-DR	Severe Winter Storms
2004	Massachusetts	Worcester	4/21/04	FEMA-1512-DR	Severe Winter Storms
2004	Michigan	Barry	6/30/04	FEMA-1527-DR	Severe Storms, Tornadoes, and Flooding
2004	Michigan	Berrien	6/30/04	FEMA-1527-DR	Severe Storms, Tornadoes, and Flooding
2004	Michigan	Cass	6/30/04	FEMA-1527-DR	Severe Storms, Tornadoes, and Flooding
2004	Michigan	Eaton	6/30/04	FEMA-1527-DR	Severe Storms, Tornadoes, and Flooding
2004	Michigan	Genesee	6/30/04	FEMA-1527-DR	Severe Storms, Tornadoes, and Flooding
2004	Michigan	Gladwin	6/30/04	FEMA-1527-DR	Severe Storms, Tornadoes, and Flooding
2004	Michigan	Ingham	6/30/04	FEMA-1527-DR	Severe Storms, Tornadoes, and Flooding
2004	Michigan	Ionia	6/30/04	FEMA-1527-DR	Severe Storms, Tornadoes, and Flooding
2004	Michigan	Jackson	6/30/04	FEMA-1527-DR	Severe Storms, Tornadoes, and Flooding
2004	Michigan	Kent	6/30/04	FEMA-1527-DR	Severe Storms, Tornadoes, and Flooding
2004	Michigan	Livingston	6/30/04	FEMA-1527-DR	Severe Storms, Tornadoes, and Flooding
2004	Michigan	Macomb	6/30/04	FEMA-1527-DR	Severe Storms, Tornadoes, and Flooding
2004	Michigan	Mecosta	6/30/04	FEMA-1527-DR	Severe Storms, Tornadoes, and Flooding
2004	Michigan	Muskegon	6/30/04	FEMA-1527-DR	Severe Storms, Tornadoes, and Flooding
2004	Michigan	Oakland	6/30/04	FEMA-1527-DR	Severe Storms, Tornadoes, and Flooding
2004	Michigan	Ottawa	6/30/04	FEMA-1527-DR	Severe Storms, Tornadoes, and Flooding
2004	Michigan	Saginaw	6/30/04	FEMA-1527-DR	Severe Storms, Tornadoes, and Flooding
2004	Michigan	Sanilac	6/30/04	FEMA-1527-DR	Severe Storms, Tornadoes, and Flooding

2004	Michigan	Shiawassee	6/30/04	FEMA-1527-DR	Severe Storms, Tornadoes, and Flooding
2004	Michigan	St. Clair	6/30/04	FEMA-1527-DR	Severe Storms, Tornadoes, and Flooding
2004	Michigan	St. Joseph	6/30/04	FEMA-1527-DR	Severe Storms, Tornadoes, and Flooding
2004	Michigan	Washtenaw	6/30/04	FEMA-1527-DR	Severe Storms, Tornadoes, and Flooding
2004	Michigan	Wayne	6/30/04	FEMA-1527-DR	Severe Storms, Tornadoes, and Flooding
2004	Minnesota	Dodge	10/07/04	FEMA-1569-DR	Severe Storms and Flooding
2004	Minnesota	Fairbault	10/07/04	FEMA-1569-DR	Severe Storms and Flooding
2004	Minnesota	Freeborn	10/07/04	FEMA-1569-DR	Severe Storms and Flooding
2004	Minnesota	Martin	10/07/04	FEMA-1569-DR	Severe Storms and Flooding
2004	Minnesota	Mower	10/07/04	FEMA-1569-DR	Severe Storms and Flooding
2004	Minnesota	Olmsted	10/07/04	FEMA-1569-DR	Severe Storms and Flooding
2004	Minnesota	Steele	10/07/04	FEMA-1569-DR	Severe Storms and Flooding
2004	Mississippi	Clarke	9/15/04	FEMA-1550-DR	Hurricane Ivan
2004	Mississippi	George	9/15/04	FEMA-1550-DR	Hurricane Ivan
2004	Mississippi	Hancock	9/15/04	FEMA-1550-DR	Hurricane Ivan
2004	Mississippi	Harrison	9/15/04	FEMA-1550-DR	Hurricane Ivan
2004	Mississippi	Jackson	9/15/04	FEMA-1550-DR	Hurricane Ivan
2004	Mississippi	Lauderdale	9/15/04	FEMA-1550-DR	Hurricane Ivan
2004	Mississippi	Perry	9/15/04	FEMA-1550-DR	Hurricane Ivan
2004	Mississippi	Stone	9/15/04	FEMA-1550-DR	Hurricane Ivan
2004	Mississippi	Wayne	9/15/04	FEMA-1550-DR	Hurricane Ivan
2004	Missouri	Adair	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Andrew	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Bates	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Benton	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Buchanan	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Caldwell	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Carroll	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Cass	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Cedar	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Chariton	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Clay	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Clinton	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Davess	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Dekalb	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Gentry	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Grundy	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Harrison	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Henry	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Hickory	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2004	Missouri	Jackson	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Johnson	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Knock	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Linn	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Livingston	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Macon	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Mercer	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Monroe	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Nodaway	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Platte	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Polk	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Randolph	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Ray	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Shelby	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	St-Clair	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Sullivan	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Vernon	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Missouri	Worth	6/10/04	FEMA-1524-DR	Severe storms, tornadoes, and flooding
2004	Nebraska	Adams	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	Buffalo	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	Butler	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	Cass	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	Clay	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	Dodge	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	Douglas	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	Fillmore	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	Franklin	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	Gage	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	Hall	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	Hamilton	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	Jefferson	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	Johnson	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	Kearney	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	Lancaster	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	Nuckolls	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	Otoe	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding

2004	Nebraska	Pawnee	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	Saline	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	Sarpy	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	Saunders	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	Seward	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	Thayer	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	Washington	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	Webster	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	Nebraska	York	5/23/04	FEMA-1517-DR	Severe Storms, Tornadoes, and Flooding
2004	New Jersey	Hunterdon	10/01/04	FEMA-1563-DR	Tropical Depression Ivan
2004	New Jersey	Mercer	10/01/04	FEMA-1563-DR	Tropical Depression Ivan
2004	New Jersey	Sussex	10/01/04	FEMA-1563-DR	Tropical Depression Ivan
2004	New Jersey	Warren	10/01/04	FEMA-1563-DR	Tropical Depression Ivan
2004	New Jersey	Burlington	7/16/04	FEMA-1530-DR	Severe Storms and Flooding
2004	New Jersey	Camden	7/16/04	FEMA-1530-DR	Severe Storms and Flooding
2004	New York	Broome	10/01/04	FEMA-1565-DR	Tropical Depression Ivan
2004	New York	Chenango	10/01/04	FEMA-1565-DR	Tropical Depression Ivan
2004	New York	Delaware	10/01/04	FEMA-1565-DR	Tropical Depression Ivan
2004	New York	Orange	10/01/04	FEMA-1565-DR	Tropical Depression Ivan
2004	New York	Sullivan	10/01/04	FEMA-1565-DR	Tropical Depression Ivan
2004	New York	Ulster	10/01/04	FEMA-1565-DR	Tropical Depression Ivan
2004	New York	Allegany	10/01/04	FEMA-1564-DR	Severe Storms and Flooding
2004	New York	Broome	10/01/04	FEMA-1564-DR	Severe Storms and Flooding
2004	New York	Cattaraugus	10/01/04	FEMA-1564-DR	Severe Storms and Flooding
2004	New York	Madison	10/01/04	FEMA-1564-DR	Severe Storms and Flooding
2004	New York	Monroe	10/01/04	FEMA-1564-DR	Severe Storms and Flooding
2004	New York	Niagara	10/01/04	FEMA-1564-DR	Severe Storms and Flooding
2004	New York	Oneida	10/01/04	FEMA-1564-DR	Severe Storms and Flooding
2004	New York	Onondaga	10/01/04	FEMA-1564-DR	Severe Storms and Flooding
2004	New York	Orange	10/01/04	FEMA-1564-DR	Severe Storms and Flooding
2004	New York	Orleans	10/01/04	FEMA-1564-DR	Severe Storms and Flooding
2004	New York	Steuben	10/01/04	FEMA-1564-DR	Severe Storms and Flooding
2004	New York	Sullivan	10/01/04	FEMA-1564-DR	Severe Storms and Flooding
2004	New York	Ulster	10/01/04	FEMA-1564-DR	Severe Storms and Flooding
2004	New York	Wayne	10/01/04	FEMA-1564-DR	Severe Storms and Flooding
2004	North Carolina	Alamance	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Alleghany	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Ashe	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Avery	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Buncombe	9/18/04	FEMA-1553-DR	Hurricane Ivan

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2004	North Carolina	Burke	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Caldwell	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Caswell	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Davidson	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Forsyth	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Graham	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Guilford	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Haywood	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Henderson	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Jackson	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Macon	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Madison	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	McDowell	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Mitchell	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Polk	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Randolph	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Rockingham	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Rutherford	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Stokes	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Swain	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Transylvania	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Watauga	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Wilkes	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Yancey	9/18/04	FEMA-1553-DR	Hurricane Ivan
2004	North Carolina	Alleghany	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Alexander	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Ashe	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Avery	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Bladen	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Buncombe	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Burke	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Cabarrus	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Caldwell	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Catawba	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Cleveland	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Columbus	9/10/04	FEMA-1546-DR	Tropical Storm Frances

2004	North Carolina	Cumberland	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Gaston	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Haywood	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Henderson	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Jackson	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Hoke	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Iredell	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Lincoln	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Madison	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	McDowell	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Mecklenburg	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Mitchell	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Polk	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Robeson	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Rutherford	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Scotland	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Transylvania	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Union	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Watauga	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Wilkes	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Yancey	9/10/04	FEMA-1546-DR	Tropical Storm Frances
2004	North Carolina	Rota	8/26/04	FEMA-1541-DR	Tropical Storm Frances
2004	Northern Mariana Islands	Saipan	8/26/04	FEMA-1541-DR	Flooding, High Surf, Storm Surge, and High Winds as a result of Super Typhoon Chaba
2004	Northern Mariana Islands	Tinian	8/26/04	FEMA-1541-DR	Flooding, High Surf, Storm Surge, and High Winds as a result of Super Typhoon Chaba
2004	Northern Mariana Islands	Rota	7/29/04	FEMA-1532-DR	Flooding, High Surf, Storm Surge, and High Winds as a result of Super Typhoon Chaba
2004	Northern Mariana Islands	Saipan	7/29/04	FEMA-1532-DR	Flooding, High Surf, High Winds, and Wind-Driven Rain associated with Typhoon Tinting
2004	Northern Mariana Islands	Tinian	7/29/04	FEMA-1532-DR	Flooding, High Surf, High Winds, and Wind-Driven Rain associated with Typhoon Tinting
2004	Ohio	Athens	9/19/04	FEMA-1556-DR	Severe Storms and Flooding
2004	Ohio	Belmont	9/19/04	FEMA-1556-DR	Severe Storms and Flooding
2004	Ohio	Carroll	9/19/04	FEMA-1556-DR	Severe Storms and Flooding
2004	Ohio	Columbiana	9/19/04	FEMA-1556-DR	Severe Storms and Flooding

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2004	Ohio	Gallia	9/19/04	FEMA-1556-DR	Severe Storms and Flooding
2004	Ohio	Guernsey	9/19/04	FEMA-1556-DR	Severe Storms and Flooding
2004	Ohio	Harrison	9/19/04	FEMA-1556-DR	Severe Storms and Flooding
2004	Ohio	Jefferson	9/19/04	FEMA-1556-DR	Severe Storms and Flooding
2004	Ohio	Lawrence	9/19/04	FEMA-1556-DR	Severe Storms and Flooding
2004	Ohio	Maioning	9/19/04	FEMA-1556-DR	Severe Storms and Flooding
2004	Ohio	Meigs	9/19/04	FEMA-1556-DR	Severe Storms and Flooding
2004	Ohio	Monroe	9/19/04	FEMA-1556-DR	Severe Storms and Flooding
2004	Ohio	Morgan	9/19/04	FEMA-1556-DR	Severe Storms and Flooding
2004	Ohio	Muskingum	9/19/04	FEMA-1556-DR	Severe Storms and Flooding
2004	Ohio	Noble	9/19/04	FEMA-1556-DR	Severe Storms and Flooding
2004	Ohio	Perry	9/19/04	FEMA-1556-DR	Severe Storms and Flooding
2004	Ohio	Stark	9/19/04	FEMA-1556-DR	Severe Storms and Flooding
2004	Ohio	Trumbull	9/19/04	FEMA-1556-DR	Severe Storms and Flooding
2004	Ohio	Tuscarawas	9/19/04	FEMA-1556-DR	Severe Storms and Flooding
2004	Ohio	Vinton	9/19/04	FEMA-1556-DR	Severe Storms and Flooding
2004	Ohio	Washington	9/19/04	FEMA-1556-DR	Severe Storms and Flooding
2004	Ohio	Athens	6/03/04	FEMA-1519-DR	Severe Storms and Flooding
2004	Ohio	Carroll	6/03/04	FEMA-1519-DR	Severe Storms and Flooding
2004	Ohio	Columbiana	6/03/04	FEMA-1519-DR	Severe Storms and Flooding
2004	Ohio	Crawford	6/03/04	FEMA-1519-DR	Severe Storms and Flooding
2004	Ohio	Cuyahoga	6/03/04	FEMA-1519-DR	Severe Storms and Flooding
2004	Ohio	Delaware	6/03/04	FEMA-1519-DR	Severe Storms and Flooding
2004	Ohio	Gauga	6/03/04	FEMA-1519-DR	Severe Storms and Flooding
2004	Ohio	Guernsey	6/03/04	FEMA-1519-DR	Severe Storms and Flooding
2004	Ohio	Harrison	6/03/04	FEMA-1519-DR	Severe Storms and Flooding
2004	Ohio	Hocking	6/03/04	FEMA-1519-DR	Severe Storms and Flooding
2004	Ohio	Holmes	6/03/04	FEMA-1519-DR	Severe Storms and Flooding
2004	Ohio	Licking	6/03/04	FEMA-1519-DR	Severe Storms and Flooding
2004	Ohio	Logan	6/03/04	FEMA-1519-DR	Severe Storms and Flooding
2004	Ohio	Lorain	6/03/04	FEMA-1519-DR	Severe Storms and Flooding
2004	Ohio	Mahoning	6/03/04	FEMA-1519-DR	Severe Storms and Flooding
2004	Ohio	Medina	6/03/04	FEMA-1519-DR	Severe Storms and Flooding
2004	Ohio	Noble	6/03/04	FEMA-1519-DR	Severe Storms and Flooding
2004	Ohio	Perry	6/03/04	FEMA-1519-DR	Severe Storms and Flooding
2004	Ohio	Portage	6/03/04	FEMA-1519-DR	Severe Storms and Flooding

2004	Ohio	Richland	6/03/04	FEMA-1519-DR	Severe Storms and Flooding
2004	Ohio	Stark	6/03/04	FEMA-1519-DR	Severe Storms and Flooding
2004	Ohio	Summit	6/03/04	FEMA-1519-DR	Severe Storms and Flooding
2004	Ohio	Tuscarawas	6/03/04	FEMA-1519-DR	Severe Storms and Flooding
2004	Ohio	Belmont	1/26/04	FEMA-1507-DR	Severe Storms, Flooding, Mudslides, and Land-slides
2004	Ohio	Franklin	1/26/04	FEMA-1507-DR	Severe Storms, Flooding, Mudslides, and Land-slides
2004	Ohio	Jefferson	1/26/04	FEMA-1507-DR	Severe Storms, Flooding, Mudslides, and Land-slides
2004	Ohio	Licking	1/26/04	FEMA-1507-DR	Severe Storms, Flooding, Mudslides, and Land-slides
2004	Ohio	Morgan	1/26/04	FEMA-1507-DR	Severe Storms, Flooding, Mudslides, and Land-slides
2004	Ohio	Ross	1/26/04	FEMA-1507-DR	Severe Storms, Flooding, Mudslides, and Land-slides
2004	Ohio	Tuscarawas	1/26/04	FEMA-1507-DR	Severe Storms, Flooding, Mudslides, and Land-slides
2004	Ohio	Washington	1/26/04	FEMA-1507-DR	Severe Storms, Flooding, Mudslides, and Land-slides
2004	Pennsylvania	Allegheny	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Armstrong	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Beaver	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Bedford	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Blair	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Bradford	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Bucks	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Butler	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Cameron	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Carbon	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Centre	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Chester	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Clarion	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Clearfield	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Clinton	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Columbia	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Crawford	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Cumberland	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Dauphin	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Delaware	9/19/04	FEMA-1557-DR	Tropical Depression Ivan

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2004	Pennsylvania	Elk	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Franklin	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Fulton	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Green	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Huntingdon	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Indiana	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Jefferson	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Juniata	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Lackawanna	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Lawrence	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Lebanon	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Léhigh	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Luzerne	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Lycoming	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Mifflin	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Monroe	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Montgomery	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Montour	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Northampton	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Northumberland	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Perry	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Philadelphia	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Pike	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Potter	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Schuylkill	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Snyder	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Somerset	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Sullivan	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Susquehanna	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Tioga	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Union	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Washington	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Wayne	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Westmoreland	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	Worming	9/19/04	FEMA-1557-DR	Tropical Depression Ivan
2004	Pennsylvania	York	9/19/04	FEMA-1557-DR	Tropical Depression Ivan

2004	Pennsylvania	Beaver	9/19/04	FEMA-1555-DR	Severe Storms and Flooding associated with Tropical Depression Frances
2004	Pennsylvania	Bedford	9/19/04	FEMA-1555-DR	Severe Storms and Flooding associated with Tropical Depression Frances
2004	Pennsylvania	Blair	9/19/04	FEMA-1555-DR	Severe Storms and Flooding associated with Tropical Depression Frances
2004	Pennsylvania	Butler	9/19/04	FEMA-1555-DR	Severe Storms and Flooding associated with Tropical Depression Frances
2004	Pennsylvania	Crawford	9/19/04	FEMA-1555-DR	Severe Storms and Flooding associated with Tropical Depression Frances
2004	Pennsylvania	Erie	9/19/04	FEMA-1555-DR	Severe Storms and Flooding associated with Tropical Depression Frances
2004	Pennsylvania	Huntingdon	9/19/04	FEMA-1555-DR	Severe Storms and Flooding associated with Tropical Depression Frances
2004	Pennsylvania	Lawrence	9/19/04	FEMA-1555-DR	Severe Storms and Flooding associated with Tropical Depression Frances
2004	Pennsylvania	Warren	9/19/04	FEMA-1555-DR	Severe Storms and Flooding associated with Tropical Depression Frances
2004	Pennsylvania	Washington	9/19/04	FEMA-1555-DR	Severe Storms and Flooding associated with Tropical Depression Frances
2004	Pennsylvania	Delaware	8/06/04	FEMA-1538-DR	Severe Storms and Flooding
2004	Pennsylvania	Montgomery	8/06/04	FEMA-1538-DR	Severe Storms and Flooding
2004	Pennsylvania	Philadelphia	8/06/04	FEMA-1538-DR	Severe Storms and Flooding
2004	Puerto Rico	Aguada	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Aguadilla	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Agua	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Buenas	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Albonito	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Asasco	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Arecibo	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Arroyo	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2004	Puerto Rico	Barceloneta	9/17/04	FEWA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Barranquitas	9/17/04	FEWA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Bayamon	9/17/04	FEWA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Caguas	9/17/04	FEWA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Camuy	9/17/04	FEWA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Canovanas	9/17/04	FEWA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Carolina	9/17/04	FEWA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Cataao	9/17/04	FEWA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Cayey	9/17/04	FEWA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Celba	9/17/04	FEWA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Ciales	9/17/04	FEWA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Cidra	9/17/04	FEWA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Coamo	9/17/04	FEWA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Comerio	9/17/04	FEWA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Corozal	9/17/04	FEWA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Dorado	9/17/04	FEWA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Fajardo	9/17/04	FEWA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Florida	9/17/04	FEWA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides

2004	Puerto Rico	Guayama	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Guarabo	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Hatillo	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Humacao	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Isabela	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Juana Doaz	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Juncos	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Lares	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Las Piedras	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Looza	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Marato	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Maunabo	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Moca	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Morovis	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Naguabo	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Naranjito	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Orocovis	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Patillas	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Quebradillas	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Rincon	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2004	Puerto Rico	Roo Grande	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Salinas	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	San Lorenzo	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	San Sebastian	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Santa Isabel	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Toa Alta	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Toa Baja	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Utua	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Vega Alta	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Vega Baja	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Villalba	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Vieques	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	Puerto Rico	Yabucoa	9/17/04	FEMA-1552-DR	Tropical Storm Jeanne and resulting landslides and mudslides
2004	South Carolina	Berkeley	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Calhoun	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Charleston	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Cherokee	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Chester	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Chesterfield	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Clarendon	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Darlington	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Dillon	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Fairfield	10/07/04	FEMA-1566-DR	Tropical Storm Frances

2004	South Carolina	Florence	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Georgetown	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Greenville	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Horry	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Kershaw	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Lancaster	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Lee	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Lexington	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Marion	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Marlboro	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Newberry	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Oconee	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Pickens	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Richland	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Spartanburg	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Sumter	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	Williamsburg	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	South Carolina	York	10/07/04	FEMA-1566-DR	Tropical Storm Frances
2004	Virginia	Alleghany	10/18/04	FEMA-1570-DR	Severe Storms and Flooding from the remnants of Hurricane Jeanne
2004	Virginia	Botetourt	10/18/04	FEMA-1570-DR	Severe Storms and Flooding from the remnants of Hurricane Jeanne
2004	Virginia	Craig	10/18/04	FEMA-1570-DR	Severe Storms and Flooding from the remnants of Hurricane Jeanne
2004	Virginia	Floyd	10/18/04	FEMA-1570-DR	Severe Storms and Flooding from the remnants of Hurricane Jeanne
2004	Virginia	Giles	10/18/04	FEMA-1570-DR	Severe Storms and Flooding from the remnants of Hurricane Jeanne
2004	Virginia	Montgomery	10/18/04	FEMA-1570-DR	Severe Storms and Flooding from the remnants of Hurricane Jeanne
2004	Virginia	Patrick	10/18/04	FEMA-1570-DR	Severe Storms and Flooding from the remnants of Hurricane Jeanne
2004	Virginia	Roanoke	10/18/04	FEMA-1570-DR	Severe Storms and Flooding from the remnants of Hurricane Jeanne
2004	Virginia	Chesterfield	9/03/04	FEMA-1544-DR	Severe Storms, Flooding and Tornadoes associated with Tropical Depression Gaston
2004	Virginia	Dinwiddie	9/03/04	FEMA-1544-DR	Severe Storms, Flooding and Tornadoes associated with Tropical Depression Gaston
2004	Virginia	Hanover	9/03/04	FEMA-1544-DR	Severe Storms, Flooding and Tornadoes associated with Tropical Depression Gaston

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2004	Virginia	Henrico	9/03/04	FEMA-1544-DR	Severe Storms, Flooding and Tornadoes associated with Tropical Depression Gaston
2004	Virginia	Prince George	9/03/04	FEMA-1544-DR	Severe Storms, Flooding and Tornadoes associated with Tropical Depression Gaston
2004	Virginia	Buchanan	6/15/04	FEMA-1525-DR	Severe Storms, Tornadoes, and Flooding
2004	Virginia	Lee	6/15/04	FEMA-1525-DR	Severe Storms, Tornadoes, and Flooding
2004	Virginia	Russell	6/15/04	FEMA-1525-DR	Severe Storms, Tornadoes, and Flooding
2004	Virginia	Tazewell	6/15/04	FEMA-1525-DR	Severe Storms, Tornadoes, and Flooding
2004	West Virginia	Berkeley	9/20/04	FEMA-1558-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Brooke	9/20/04	FEMA-1558-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Cabell	9/20/04	FEMA-1558-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Hancock	9/20/04	FEMA-1558-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Jackson	9/20/04	FEMA-1558-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Kanawha	9/20/04	FEMA-1558-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Lincoln	9/20/04	FEMA-1558-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Logan	9/20/04	FEMA-1558-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Marshall	9/20/04	FEMA-1558-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Mason	9/20/04	FEMA-1558-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Mingo	9/20/04	FEMA-1558-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Morgan	9/20/04	FEMA-1558-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Ohio	9/20/04	FEMA-1558-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Pleasants	9/20/04	FEMA-1558-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Tyler	9/20/04	FEMA-1558-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Wayne	9/20/04	FEMA-1558-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Wetzel	9/20/04	FEMA-1558-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Wirt	9/20/04	FEMA-1558-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Wood	9/20/04	FEMA-1558-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Fayette	8/06/04	FEMA-1536-DR	Severe Storms, Flooding, and Tornadoes
2004	West Virginia	Lincoln	8/06/04	FEMA-1536-DR	Severe Storms, Flooding, and Tornadoes
2004	West Virginia	Logan	8/06/04	FEMA-1536-DR	Severe Storms, Flooding, and Tornadoes
2004	West Virginia	Mingo	8/06/04	FEMA-1536-DR	Severe Storms, Flooding, and Tornadoes
2004	West Virginia	Boone	6/07/04	FEMA-1522-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Braxton	6/07/04	FEMA-1522-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Cabell	6/07/04	FEMA-1522-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Calhoun	6/07/04	FEMA-1522-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Clay	6/07/04	FEMA-1522-DR	Severe Storms, Flooding and Landslides

2004	West Virginia	Fayette	6/07/04	FEMA-1522-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Gilmer	6/07/04	FEMA-1522-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Jackson	6/07/04	FEMA-1522-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Kanawha	6/07/04	FEMA-1522-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Lewis	6/07/04	FEMA-1522-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Lincoln	6/07/04	FEMA-1522-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Logan	6/07/04	FEMA-1522-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Mason	6/07/04	FEMA-1522-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	McDowell	6/07/04	FEMA-1522-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Mercer	6/07/04	FEMA-1522-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Mingo	6/07/04	FEMA-1522-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Nicholas	6/07/04	FEMA-1522-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Putnam	6/07/04	FEMA-1522-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Raleigh	6/07/04	FEMA-1522-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Roane	6/07/04	FEMA-1522-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Wayne	6/07/04	FEMA-1522-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Webster	6/07/04	FEMA-1522-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Wirt	6/07/04	FEMA-1522-DR	Severe Storms, Flooding and Landslides
2004	West Virginia	Wyoming	6/07/04	FEMA-1522-DR	Severe Storms, Flooding and Landslides
2004	Wisconsin	Clark	6/19/04	FEMA-1526-DR	Severe Storms and Flooding
2004	Wisconsin	Columbia	6/19/04	FEMA-1526-DR	Severe Storms and Flooding
2004	Wisconsin	Crawford	6/19/04	FEMA-1526-DR	Severe Storms and Flooding
2004	Wisconsin	Dodge	6/19/04	FEMA-1526-DR	Severe Storms and Flooding
2004	Wisconsin	Fond du Lac	6/19/04	FEMA-1526-DR	Severe Storms and Flooding
2004	Wisconsin	Grant	6/19/04	FEMA-1526-DR	Severe Storms and Flooding
2004	Wisconsin	Green Lake	6/19/04	FEMA-1526-DR	Severe Storms and Flooding
2004	Wisconsin	Jefferson	6/19/04	FEMA-1526-DR	Severe Storms and Flooding
2004	Wisconsin	Kenosha	6/19/04	FEMA-1526-DR	Severe Storms and Flooding
2004	Wisconsin	Ozaukee	6/19/04	FEMA-1526-DR	Severe Storms and Flooding
2004	Wisconsin	Vernon	6/19/04	FEMA-1526-DR	Severe Storms and Flooding
2004	Wisconsin	Winnebago	6/19/04	FEMA-1526-DR	Severe Storms and Flooding
2005	Alabama	Baldwin	7/10/05	FEMA-1593-DR	Hurricane Dennis
2005	Alabama	Baldwin	8/29/05	FEMA-1605-DR	Hurricane Katrina
2005	Alabama	Greene	8/29/05	FEMA-1605-DR	Hurricane Katrina
2005	Alabama	Hale	8/29/05	FEMA-1605-DR	Hurricane Katrina
2005	Alabama	Marengo	8/29/05	FEMA-1605-DR	Hurricane Katrina
2005	Alabama	Mobile	7/10/05	FEMA-1593-DR	Hurricane Dennis
2005	Alabama	Mobile	8/29/05	FEMA-1605-DR	Hurricane Katrina
2005	Alabama	Pickens	8/29/05	FEMA-1605-DR	Hurricane Katrina

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2005	Alabama	Tuscaloosa	8/29/05	FEMA-1605-DR	Hurricane Katrina
2005	Alabama	Washington	8/29/05	FEMA-1605-DR	Hurricane Katrina
2005	California	Kern	2/04/05	FEMA-1577	Severe Storms, Flooding, Debris Flows, and Mudslides
2005	California	Los Angeles	2/04/05	FEMA-1577	Severe Storms, Flooding, Debris Flows, and Mudslides
2005	California	Orange	2/04/05	FEMA-1577	Severe Storms, Flooding, Debris Flows, and Mudslides
2005	California	Riverside	2/04/05	FEMA-1577	Severe Storms, Flooding, Debris Flows, and Mudslides
2005	California	San Bernardino	2/04/05	FEMA-1577	Severe Storms, Flooding, Debris Flows, and Mudslides
2005	California	San Diego	2/04/05	FEMA-1577	Severe Storms, Flooding, Debris Flows, and Mudslides
2005	California	Santa Barbara	2/04/05	FEMA-1577	Severe Storms, Flooding, Debris Flows, and Mudslides
2005	California	Ventura	2/04/05	FEMA-1577	Severe Storms, Flooding, Debris Flows, and Mudslides
2005	Florida	Bay	7/10/05	FEMA-1595-DR	Hurricane Dennis
2005	Florida	Brevard	10/24/05	FEMA-1609-DR	Hurricane Wilma
2005	Florida	Broward	10/24/05	FEMA-1609-DR	Hurricane Wilma
2005	Florida	Collier	10/24/05	FEMA-1609-DR	Hurricane Wilma
2005	Florida	Dixie	7/10/05	FEMA-1595-DR	Hurricane Dennis
2005	Florida	Escambia	7/10/05	FEMA-1595-DR	Hurricane Dennis
2005	Florida	Franklin	7/10/05	FEMA-1595-DR	Hurricane Dennis
2005	Florida	Glades	10/24/05	FEMA-1609-DR	Hurricane Wilma
2005	Florida	Gulf	7/10/05	FEMA-1595-DR	Hurricane Dennis
2005	Florida	Hendry	10/24/05	FEMA-1609-DR	Hurricane Wilma
2005	Florida	Indian River	10/24/05	FEMA-1609-DR	Hurricane Wilma
2005	Florida	Lee	10/24/05	FEMA-1609-DR	Hurricane Wilma
2005	Florida	Martin	10/24/05	FEMA-1609-DR	Hurricane Wilma
2005	Florida	Miami-Dade	10/24/05	FEMA-1609-DR	Hurricane Wilma
2005	Florida	Monroe	10/24/05	FEMA-1609-DR	Hurricane Wilma
2005	Florida	Okaloosa	7/10/05	FEMA-1595-DR	Hurricane Dennis
2005	Florida	Okeechobee	10/24/05	FEMA-1609-DR	Hurricane Wilma
2005	Florida	Palm Beach	10/24/05	FEMA-1609-DR	Hurricane Wilma

2005	Florida	Santa Rosa	7/10/05	FEMA-1595-DR	Hurricane Dennis
2005	Florida	St. Lucie	10/24/05	FEMA-1609-DR	Hurricane Wilma
2005	Florida	Taylor	7/10/05	FEMA-1595-DR	Hurricane Dennis
2005	Florida	Wakulla	7/10/05	FEMA-1595-DR	Hurricane Dennis
2005	Florida	Walton	7/10/05	FEMA-1595-DR	Hurricane Dennis
2005	Indiana	Adams	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Allen	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Bartholomew	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Benton	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Blackford	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Boone	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Brown	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Carroll	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Cass	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Clark	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Clay	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Clinton	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Crawford	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Davess	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Dearborn	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Decatur	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	DeKalb	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Delaware	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Dubois	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Elkhart	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Fayette	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Floyd	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Fountain	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Franklin	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Fulton	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Gibson	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Grant	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Greene	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Hamilton	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Hancock	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Harrison	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Hendricks	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Henry	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Howard	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Huntington	1/21/05	FEMA-1573	Severe Winter Storms and Flooding

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2005	Indiana	Jackson	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Jasper	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Jay	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Jennings	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Johnson	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Knox	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Kosciusko	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Lake	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Laporte	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Lawrence	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Madison	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Marion	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Marshall	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Martin	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Miami	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Monroe	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Montgomery	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Morgan	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Newton	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Noble	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Orange	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Owen	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Parke	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Pike	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Porter	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Posey	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Pulaski	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Putnam	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Randolph	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Ripley	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Rush	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Scott	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Shelby	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	St. Joseph	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Starke	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Sullivan	1/21/05	FEMA-1573	Severe Winter Storms and Flooding

2005	Indiana	Tippecanoe	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Tipton	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Union	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Vanderburgh	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Vanderburgh	11/08/05	FEMA-1612-DR	Tornado and Severe Storms
2005	Indiana	Vermillion	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Vigo	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Wabash	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Warren	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Warrick	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Warrick	11/08/05	FEMA-1612-DR	Tornado and Severe Storms
2005	Indiana	Washington	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Wayne	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Wells	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	White	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Whitley	1/21/05	FEMA-1573	Severe Winter Storms and Flooding
2005	Indiana	Whitley	12/01/05	FEMA-1617-DR	Severe Storms and Tornadoes
2005	Kentucky	Hopkins	12/01/05	FEMA-1617-DR	Hurricane Katrina
2005	Kentucky	Marshall	8/29/05	FEMA-1603-DR	Hurricane Rita
2005	Louisiana	Acadia	9/24/05	FEMA-1607-DR	Hurricane Rita
2005	Louisiana	Acadia	9/24/05	FEMA-1607-DR	Hurricane Rita
2005	Louisiana	Allen	9/24/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	Ascension	8/29/05	FEMA-1603-DR	Hurricane Rita
2005	Louisiana	Ascension	9/24/05	FEMA-1607-DR	Hurricane Katrina
2005	Louisiana	Assumption	8/29/05	FEMA-1603-DR	Hurricane Rita
2005	Louisiana	Assumption	9/24/05	FEMA-1607-DR	Hurricane Katrina
2005	Louisiana	Beauregard	8/29/05	FEMA-1603-DR	Hurricane Rita
2005	Louisiana	Calcasieu	9/24/05	FEMA-1607-DR	Hurricane Katrina
2005	Louisiana	Calcasieu	9/24/05	FEMA-1607-DR	Hurricane Rita
2005	Louisiana	Cameron	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	Cameron	9/24/05	FEMA-1607-DR	Hurricane Rita
2005	Louisiana	Cameron	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	East Baton Rouge	8/29/05	FEMA-1603-DR	Hurricane Rita
2005	Louisiana	East Feliciana	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	East Feliciana	9/24/05	FEMA-1607-DR	Hurricane Rita
2005	Louisiana	Evangeline	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	Evangeline	9/24/05	FEMA-1607-DR	Hurricane Rita
2005	Louisiana	Iberia	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	Iberia	9/24/05	FEMA-1607-DR	Hurricane Rita
2005	Louisiana	Iberia	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	Iberville	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	Iberville	9/24/05	FEMA-1607-DR	Hurricane Rita
2005	Louisiana	Jefferson	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	Jefferson	9/24/05	FEMA-1607-DR	Hurricane Rita
2005	Louisiana	Jefferson	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	Jefferson Davis	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	Jefferson Davis	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	Lafayette	8/29/05	FEMA-1603-DR	Hurricane Katrina

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2005	Louisiana	Lafayette	9/24/05	FEMA-1607-DR	Hurricane Rita
2005	Louisiana	Lafourche	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	Lafourche	9/24/05	FEMA-1607-DR	Hurricane Rita
2005	Louisiana	Livingston	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	Livingston	9/24/05	FEMA-1607-DR	Hurricane Rita
2005	Louisiana	Orleans	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	Orleans	9/24/05	FEMA-1607-DR	Hurricane Rita
2005	Louisiana	Plaquemines	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	Plaquemines	9/24/05	FEMA-1607-DR	Hurricane Rita
2005	Louisiana	Pointe Coupee	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	Sabine	9/24/05	FEMA-1607-DR	Hurricane Rita
2005	Louisiana	St. Bernard	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	St. Charles	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	St. Helena	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	St. James	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	St. John	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	St. Landry	9/24/05	FEMA-1607-DR	Hurricane Rita
2005	Louisiana	St. Martin	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	St. Martin	9/24/05	FEMA-1607-DR	Hurricane Rita
2005	Louisiana	St. Mary	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	St. Mary	9/24/05	FEMA-1607-DR	Hurricane Rita
2005	Louisiana	St. Tammany	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	Tangipahoa, Terrebonne, Vermilion, Washington, West Baton Rouge, and West Feliciana	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	Terrebonne	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	Terrebonne	9/24/05	FEMA-1607-DR	Hurricane Rita
2005	Louisiana	Vermilion	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	Vermilion	9/24/05	FEMA-1607-DR	Hurricane Rita
2005	Louisiana	Vernon	9/24/05	FEMA-1607-DR	Hurricane Rita
2005	Louisiana	Washington	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	West Baton Rouge	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Louisiana	West Baton Rouge	9/24/05	FEMA-1607-DR	Hurricane Rita
2005	Louisiana	West Feliciana	8/29/05	FEMA-1603-DR	Hurricane Katrina
2005	Massachusetts	Berkshire	11/10/05	FEMA-1614-DR	Severe Storms, Flooding, Landslides, and Mudslides

2005	Massachusetts	Bristol	11/10/05	FEMA-1614-DR	Severe Storms, Mudslides	Flooding, Landslides, and
2005	Massachusetts	Franklin	11/10/05	FEMA-1614-DR	Severe Storms, Mudslides	Flooding, Landslides, and
2005	Massachusetts	Hampden	11/10/05	FEMA-1614-DR	Severe Storms, Mudslides	Flooding, Landslides, and
2005	Massachusetts	Hampshire	11/10/05	FEMA-1614-DR	Severe Storms, Mudslides	Flooding, Landslides, and
2005	Massachusetts	Middlesex	11/10/05	FEMA-1614-DR	Severe Storms, Mudslides	Flooding, Landslides, and
2005	Massachusetts	Norfolk	11/10/05	FEMA-1614-DR	Severe Storms, Mudslides	Flooding, Landslides, and
2005	Massachusetts	Plymouth	11/10/05	FEMA-1614-DR	Severe Storms, Mudslides	Flooding, Landslides, and
2005	Massachusetts	Worcester	11/10/05	FEMA-1614-DR	Severe Storms, Mudslides	Flooding, Landslides, and
2005	Mississippi	Adams	8/29/05	FEMA-1604-DR	Hurricane Katrina	
2005	Mississippi	Amite	8/29/05	FEMA-1604-DR	Hurricane Katrina	
2005	Mississippi	Attala	8/29/05	FEMA-1604-DR	Hurricane Katrina	
2005	Mississippi	Choctaw	8/29/05	FEMA-1604-DR	Hurricane Katrina	
2005	Mississippi	Claiborne	8/29/05	FEMA-1604-DR	Hurricane Katrina	
2005	Mississippi	Clarke	8/29/05	FEMA-1604-DR	Hurricane Katrina	
2005	Mississippi	Copiah	8/29/05	FEMA-1604-DR	Hurricane Katrina	
2005	Mississippi	Covington	8/29/05	FEMA-1604-DR	Hurricane Katrina	
2005	Mississippi	Forrest	8/29/05	FEMA-1604-DR	Hurricane Katrina	
2005	Mississippi	Franklin	8/29/05	FEMA-1604-DR	Hurricane Katrina	
2005	Mississippi	George	8/29/05	FEMA-1604-DR	Hurricane Katrina	
2005	Mississippi	Greene	8/29/05	FEMA-1604-DR	Hurricane Katrina	
2005	Mississippi	Hancock	8/29/05	FEMA-1604-DR	Hurricane Katrina	
2005	Mississippi	Harrison	8/29/05	FEMA-1604-DR	Hurricane Katrina	
2005	Mississippi	Hinds	8/29/05	FEMA-1604-DR	Hurricane Katrina	
2005	Mississippi	Holmes	8/29/05	FEMA-1604-DR	Hurricane Katrina	
2005	Mississippi	Humphreys	8/29/05	FEMA-1604-DR	Hurricane Katrina	
2005	Mississippi	Jackson	8/29/05	FEMA-1604-DR	Hurricane Katrina	
2005	Mississippi	Jasper	8/29/05	FEMA-1604-DR	Hurricane Katrina	
2005	Mississippi	Jefferson	8/29/05	FEMA-1604-DR	Hurricane Katrina	
2005	Mississippi	Jefferson Davis	8/29/05	FEMA-1604-DR	Hurricane Katrina	
2005	Mississippi	Jones	8/29/05	FEMA-1604-DR	Hurricane Katrina	
2005	Mississippi	Kemper	8/29/05	FEMA-1604-DR	Hurricane Katrina	
2005	Mississippi	Lamar	8/29/05	FEMA-1604-DR	Hurricane Katrina	

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2005	Mississippi	Lauderdale	8/29/05	FEMA-1604-DR	Hurricane Katrina
2005	Mississippi	Lawrence	8/29/05	FEMA-1604-DR	Hurricane Katrina
2005	Mississippi	Leake	8/29/05	FEMA-1604-DR	Hurricane Katrina
2005	Mississippi	Lincoln	8/29/05	FEMA-1604-DR	Hurricane Katrina
2005	Mississippi	Lowndes	8/29/05	FEMA-1604-DR	Hurricane Katrina
2005	Mississippi	Madison	8/29/05	FEMA-1604-DR	Hurricane Katrina
2005	Mississippi	Marion	8/29/05	FEMA-1604-DR	Hurricane Katrina
2005	Mississippi	Neshoba	8/29/05	FEMA-1604-DR	Hurricane Katrina
2005	Mississippi	Newton	8/29/05	FEMA-1604-DR	Hurricane Katrina
2005	Mississippi	Noxubee	8/29/05	FEMA-1604-DR	Hurricane Katrina
2005	Mississippi	Oktibbeha	8/29/05	FEMA-1604-DR	Hurricane Katrina
2005	Mississippi	Pearl River	8/29/05	FEMA-1604-DR	Hurricane Katrina
2005	Mississippi	Perry	8/29/05	FEMA-1604-DR	Hurricane Katrina
2005	Mississippi	Pike	8/29/05	FEMA-1604-DR	Hurricane Katrina
2005	Mississippi	Rankin	8/29/05	FEMA-1604-DR	Hurricane Katrina
2005	Mississippi	Scott	8/29/05	FEMA-1604-DR	Hurricane Katrina
2005	Mississippi	Simpson	8/29/05	FEMA-1604-DR	Hurricane Katrina
2005	Mississippi	Stone	8/29/05	FEMA-1604-DR	Hurricane Katrina
2005	Mississippi	Walhall	8/29/05	FEMA-1604-DR	Hurricane Katrina
2005	Mississippi	Warren	8/29/05	FEMA-1604-DR	Hurricane Katrina
2005	Mississippi	Wayne	8/29/05	FEMA-1604-DR	Hurricane Katrina
2005	Mississippi	Wilkinson	8/29/05	FEMA-1604-DR	Hurricane Katrina
2005	Mississippi	Winston	8/29/05	FEMA-1604-DR	Hurricane Katrina
2005	Mississippi	Yazoo	8/29/05	FEMA-1604-DR	Hurricane Katrina
2005	New Hampshire	Cheshire	10/26/05	FEMA-1610-DR	Severe Storms and Flooding
2005	New Hampshire	Grafton	10/26/05	FEMA-1610-DR	Severe Storms and Flooding
2005	New Hampshire	Hillsborough	10/26/05	FEMA-1610-DR	Severe Storms and Flooding
2005	New Hampshire	Merrimack	10/26/05	FEMA-1610-DR	Severe Storms and Flooding
2005	New Hampshire	Sullivan	10/26/05	FEMA-1610-DR	Severe Storms and Flooding
2005	New Jersey	Bergen	4/19/05	FEMA-1588-DR	Severe Storms and Flooding
2005	New Jersey	Essex	4/19/05	FEMA-1588-DR	Severe Storms and Flooding
2005	New Jersey	Gloucester	4/19/05	FEMA-1588-DR	Severe Storms and Flooding
2005	New Jersey	Hunterdon	4/19/05	FEMA-1588-DR	Severe Storms and Flooding
2005	New Jersey	Mercer	4/19/05	FEMA-1588-DR	Severe Storms and Flooding
2005	New Jersey	Morris	4/19/05	FEMA-1588-DR	Severe Storms and Flooding

2005	New Jersey	Passaic	4/19/05	FEMA-1588-DR	Severe Storms and Flooding
2005	New Jersey	Sussex	4/19/05	FEMA-1588-DR	Severe Storms and Flooding
2005	New Jersey	Warren	4/19/05	FEMA-1588-DR	Severe Storms and Flooding
2005	New York	Broome	4/19/05	FEMA-1589-DR	Severe Storms and Flooding
2005	New York	Chenango	4/19/05	FEMA-1589-DR	Severe Storms and Flooding
2005	New York	Cortland	4/19/05	FEMA-1589-DR	Severe Storms and Flooding
2005	New York	Delaware	4/19/05	FEMA-1589-DR	Severe Storms and Flooding
2005	New York	Orange	4/19/05	FEMA-1589-DR	Severe Storms and Flooding
2005	New York	Rensselaer	4/19/05	FEMA-1589-DR	Severe Storms and Flooding
2005	New York	Schenectady	4/19/05	FEMA-1589-DR	Severe Storms and Flooding
2005	New York	Schoharie	4/19/05	FEMA-1589-DR	Severe Storms and Flooding
2005	New York	Sullivan	4/19/05	FEMA-1589-DR	Severe Storms and Flooding
2005	New York	Tioga	4/19/05	FEMA-1589-DR	Severe Storms and Flooding
2005	New York	Ulster	4/19/05	FEMA-1589-DR	Severe Storms and Flooding
2005	Ohio	Ashland	2/15/05	FEMA-1580	Severe Storms and Flooding
2005	Ohio	Athens	2/15/05	FEMA-1580	Severe Winter Storms, Heavy Rains, and Flooding
2005	Ohio	Auglaize	2/15/05	FEMA-1580	Severe Winter Storms, Heavy Rains, and Flooding
2005	Ohio	Belmont	2/15/05	FEMA-1580	Severe Winter Storms, Heavy Rains, and Flooding
2005	Ohio	Clark	2/15/05	FEMA-1580	Severe Winter Storms, Heavy Rains, and Flooding
2005	Ohio	Coshocton	2/15/05	FEMA-1580	Severe Winter Storms, Heavy Rains, and Flooding
2005	Ohio	Crawford	2/15/05	FEMA-1580	Severe Winter Storms, Heavy Rains, and Flooding
2005	Ohio	Delaware	2/15/05	FEMA-1580	Severe Winter Storms, Heavy Rains, and Flooding
2005	Ohio	Franklin	2/15/05	FEMA-1580	Severe Winter Storms, Heavy Rains, and Flooding
2005	Ohio	Henry	2/15/05	FEMA-1580	Severe Winter Storms, Heavy Rains, and Flooding
2005	Ohio	Huron	2/15/05	FEMA-1580	Severe Winter Storms, Heavy Rains, and Flooding
2005	Ohio	Jefferson	2/15/05	FEMA-1580	Severe Winter Storms, Heavy Rains, and Flooding
2005	Ohio	Logan	2/15/05	FEMA-1580	Severe Winter Storms, Heavy Rains, and Flooding

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2005	Ohio	Miami	2/15/05	FEMA-1580	Severe Winter Storms, Heavy Rains, and Flooding
2005	Ohio	Morgan	2/15/05	FEMA-1580	Severe Winter Storms, Heavy Rains, and Flooding
2005	Ohio	Muskingum	2/15/05	FEMA-1580	Severe Winter Storms, Heavy Rains, and Flooding
2005	Ohio	Pickaway	2/15/05	FEMA-1580	Severe Winter Storms, Heavy Rains, and Flooding
2005	Ohio	Pike	2/15/05	FEMA-1580	Severe Winter Storms, Heavy Rains, and Flooding
2005	Ohio	Ross	2/15/05	FEMA-1580	Severe Winter Storms, Heavy Rains, and Flooding
2005	Ohio	Scioto	2/15/05	FEMA-1580	Severe Winter Storms, Heavy Rains, and Flooding
2005	Ohio	Warren	2/15/05	FEMA-1580	Severe Winter Storms, Heavy Rains, and Flooding
2005	Ohio	Washington	2/15/05	FEMA-1580	Severe Winter Storms, Heavy Rains, and Flooding
2005	Ohio	Wyandot	2/15/05	FEMA-1580	Severe Winter Storms, Heavy Rains, and Flooding
2005	Pennsylvania	Bradford	4/14/05	FEMA-1587-DR	Severe Storms and Flooding
2005	Pennsylvania	Bucks	4/14/05	FEMA-1587-DR	Severe Storms and Flooding
2005	Pennsylvania	Columbia	4/14/05	FEMA-1587-DR	Severe Storms and Flooding
2005	Pennsylvania	Luzerne	4/14/05	FEMA-1587-DR	Severe Storms and Flooding
2005	Pennsylvania	Monroe	4/14/05	FEMA-1587-DR	Severe Storms and Flooding
2005	Pennsylvania	Northampton	4/14/05	FEMA-1587-DR	Severe Storms and Flooding
2005	Pennsylvania	Pike	4/14/05	FEMA-1587-DR	Severe Storms and Flooding
2005	Pennsylvania	Wayne	4/14/05	FEMA-1587-DR	Severe Storms and Flooding
2005	Pennsylvania	Wyoming	4/14/05	FEMA-1587-DR	Severe Storms and Flooding
2005	Texas	Angelina	9/24/05	FEMA-1606-DR	Hurricane Rita
2005	Texas	Brazoria	9/24/05	FEMA-1606-DR	Hurricane Rita
2005	Texas	Chambers	9/24/05	FEMA-1606-DR	Hurricane Rita
2005	Texas	Fort Bend	9/24/05	FEMA-1606-DR	Hurricane Rita
2005	Texas	Galveston	9/24/05	FEMA-1606-DR	Hurricane Rita
2005	Texas	Hardin	9/24/05	FEMA-1606-DR	Hurricane Rita
2005	Texas	Harris	9/24/05	FEMA-1606-DR	Hurricane Rita

2005	Texas	Jasper	9/24/05	FEMA-1606-DR	Hurricane Rita
2005	Texas	Jefferson	9/24/05	FEMA-1606-DR	Hurricane Rita
2005	Texas	Liberty	9/24/05	FEMA-1606-DR	Hurricane Rita
2005	Texas	Montgomery	9/24/05	FEMA-1606-DR	Hurricane Rita
2005	Texas	Nacogdoches	9/24/05	FEMA-1606-DR	Hurricane Rita
2005	Texas	Newton	9/24/05	FEMA-1606-DR	Hurricane Rita
2005	Texas	Orange	9/24/05	FEMA-1606-DR	Hurricane Rita
2005	Texas	Polk	9/24/05	FEMA-1606-DR	Hurricane Rita
2005	Texas	Sabine	9/24/05	FEMA-1606-DR	Hurricane Rita
2005	Texas	San Augustine	9/24/05	FEMA-1606-DR	Hurricane Rita
2005	Texas	San Jacinto	9/24/05	FEMA-1606-DR	Hurricane Rita
2005	Texas	Shelby	9/24/05	FEMA-1606-DR	Hurricane Rita
2005	Texas	Trinity	9/24/05	FEMA-1606-DR	Hurricane Rita
2005	Texas	Tyler	9/24/05	FEMA-1606-DR	Hurricane Rita
2005	Texas	Walker	9/24/05	FEMA-1606-DR	Hurricane Rita
2005	Wyoming	Campbell	8/12/05	FEMA-1599-DR	Tornado
2006	Arkansas	Conway	4/13/06	FEMA-1636-DR	Severe Storms and Tornadoes
2006	Arkansas	Cross	4/13/06	FEMA-1636-DR	Severe Storms and Tornadoes
2006	Arkansas	Fulton	4/13/06	FEMA-1636-DR	Severe Storms and Tornadoes
2006	Arkansas	Greene	4/13/06	FEMA-1636-DR	Severe Storms and Tornadoes
2006	Arkansas	Lawrence	4/13/06	FEMA-1636-DR	Severe Storms and Tornadoes
2006	Arkansas	Randolph	4/13/06	FEMA-1636-DR	Severe Storms and Tornadoes
2006	Arkansas	White	4/13/06	FEMA-1636-DR	Severe Storms and Tornadoes
2006	California	Contra Costa	2/03/06	FEMA-1628-DR	Severe Storms, Flooding, Mudslides, and Landslides
2006	California	Del Norte	2/03/06	FEMA-1628-DR	Severe Storms, Flooding, Mudslides, and Landslides
2006	California	Lake	2/03/06	FEMA-1628-DR	Severe Storms, Flooding, Mudslides, and Landslides
2006	California	Marin	2/03/06	FEMA-1628-DR	Severe Storms, Flooding, Mudslides, and Landslides
2006	California	Mendocino	2/03/06	FEMA-1628-DR	Severe Storms, Flooding, Mudslides, and Landslides
2006	California	Napa	2/03/06	FEMA-1628-DR	Severe Storms, Flooding, Mudslides, and Landslides
2006	California	Sacramento	2/03/06	FEMA-1628-DR	Severe Storms, Flooding, Mudslides, and Landslides
2006	California	Siskiyou	2/03/06	FEMA-1628-DR	Severe Storms, Flooding, Mudslides, and Landslides

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2006	California	Solano	2/03/06	FEMA-1628-DR	Severe Storms, Flooding, Mudslides, and Landslides
2006	California	Sonoma	2/03/06	FEMA-1628-DR	Severe Storms, Flooding, Mudslides, and Landslides
2006	Hawaii	Hawaii	10/17/06	FEMA-1664-DR	Earthquake
2006	Hawaii	Honolulu	5/02/06	FEMA-1640-DR	Severe Storms, Flooding, Landslides, and Mudslides
2006	Hawaii	Kauai	5/02/06	FEMA-1640-DR	Severe Storms, Flooding, Landslides, and Mudslides
2006	Illinois	Sangamon	3/28/06	FEMA-1633-DR	Tornadoes and Severe Storms
2006	Indiana	Lake	10/06/06	FEMA-1662-DR	Severe Storms and Flooding
2006	Indiana	Vanderburgh	10/06/06	FEMA-1662-DR	Severe Storms and Flooding
2006	Indiana	Warrick	10/06/06	FEMA-1662-DR	Severe Storms and Flooding
2006	Louisiana	Allen	11/02/06	FEMA-1668-DR	Severe Storms and Flooding
2006	Louisiana	Beauregard	11/02/06	FEMA-1668-DR	Severe Storms and Flooding
2006	Louisiana	Calcasieu	11/02/06	FEMA-1668-DR	Severe Storms and Flooding
2006	Louisiana	Caldwell	11/02/06	FEMA-1668-DR	Severe Storms and Flooding
2006	Louisiana	Franklin	11/02/06	FEMA-1668-DR	Severe Storms and Flooding
2006	Louisiana	Grant	11/02/06	FEMA-1668-DR	Severe Storms and Flooding
2006	Louisiana	Jefferson Davis	11/02/06	FEMA-1668-DR	Severe Storms and Flooding
2006	Louisiana	LaSalle	11/02/06	FEMA-1668-DR	Severe Storms and Flooding
2006	Louisiana	Madison	11/02/06	FEMA-1668-DR	Severe Storms and Flooding
2006	Louisiana	Morehouse	11/02/06	FEMA-1668-DR	Severe Storms and Flooding
2006	Louisiana	Natchitoches	11/02/06	FEMA-1668-DR	Severe Storms and Flooding
2006	Louisiana	Richland	11/02/06	FEMA-1668-DR	Severe Storms and Flooding
2006	Louisiana	Sabine	11/02/06	FEMA-1668-DR	Severe Storms and Flooding
2006	Louisiana	St. Helena	11/02/06	FEMA-1668-DR	Severe Storms and Flooding
2006	Louisiana	St. Landry	11/02/06	FEMA-1668-DR	Severe Storms and Flooding
2006	Louisiana	Vernon	11/02/06	FEMA-1668-DR	Severe Storms and Flooding
2006	Louisiana	Winn	11/02/06	FEMA-1668-DR	Severe Storms and Flooding
2006	Maine	York	5/25/06	FEMA-1644-DR	Severe Storms and Flooding
2006	Massachusetts	Essex	5/25/06	FEMA-1642-DR	Severe Storms and Flooding
2006	Massachusetts	Middlesex	5/25/06	FEMA-1642-DR	Severe Storms and Flooding
2006	Massachusetts	Suffolk	5/25/06	FEMA-1642-DR	Severe Storms and Flooding
2006	Missouri	Andrew	4/05/06	FEMA-1635-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Benton	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding

2006	Missouri	Boone	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Butler	4/05/06	FEMA-1635-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Carroll	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Cass	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Cedar	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Christian	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Cooper	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Dunklin	4/05/06	FEMA-1635-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Greene	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Henry	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Hickory	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Iron	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Johnson	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Lawrence	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Lincoln	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Mississippi	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Monroe	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Morgan	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	New Madrid	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Newton	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Penisoot	4/05/06	FEMA-1635-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Perry	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Pettis	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Pettis	4/05/06	FEMA-1635-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Phelps	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Putnam	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Randolph	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Saline	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Scott	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	St. Clair	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	St. Francois	4/05/06	FEMA-1635-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Ste. Genevieve	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Stoddard	4/05/06	FEMA-1635-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Taney	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Vernon	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Webster	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	Missouri	Wright	3/16/06	FEMA-1631-DR	Severe Storms, Tornadoes, and Flooding
2006	New Hampshire	Beknap	5/25/06	FEMA-1643-DR	Severe Storms and Flooding
2006	New Hampshire	Carroll	5/25/06	FEMA-1643-DR	Severe Storms and Flooding
2006	New Hampshire	Hillsborough	5/25/06	FEMA-1643-DR	Severe Storms and Flooding

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2006	New Hampshire	Merrimack	5/25/06	FEMA-1643-DR	Severe Storms and Flooding
2006	New Hampshire	Rockingham	5/25/06	FEMA-1643-DR	Severe Storms and Flooding
2006	New Hampshire	Stratford	5/25/06	FEMA-1643-DR	Severe Storms and Flooding
2006	New Jersey	Hunterdon	7/07/06	FEMA-1653-DR	Severe Storms and Flooding
2006	New Jersey	Mercer	7/07/06	FEMA-1653-DR	Severe Storms and Flooding
2006	New Jersey	Warren	7/07/06	FEMA-1653-DR	Severe Storms and Flooding
2006	New Mexico	Dona Ana	8/30/06	FEMA-1659-DR	Severe Storms and Flooding
2006	New Mexico	Otero	8/30/06	FEMA-1659-DR	Severe Storms and Flooding
2006	New York	Broome	7/01/06	FEMA-1650-DR	Severe Storms and Flooding
2006	New York	Chenango	7/01/06	FEMA-1650-DR	Severe Storms and Flooding
2006	New York	Delaware	7/01/06	FEMA-1650-DR	Severe Storms and Flooding
2006	New York	Erie	10/24/06	FEMA-1665-DR	Severe Storms and Flooding
2006	New York	Genesee	10/24/06	FEMA-1665-DR	Severe Storms and Flooding
2006	New York	Herkimer	7/01/06	FEMA-1650-DR	Severe Storms and Flooding
2006	New York	Montgomery	7/01/06	FEMA-1650-DR	Severe Storms and Flooding
2006	New York	Niagara	10/24/06	FEMA-1665-DR	Severe Storms and Flooding
2006	New York	Oneida	7/01/06	FEMA-1650-DR	Severe Storms and Flooding
2006	New York	Orange	7/01/06	FEMA-1650-DR	Severe Storms and Flooding
2006	New York	Orleans	10/24/06	FEMA-1665-DR	Severe Storms and Flooding
2006	New York	Otsego	7/01/06	FEMA-1650-DR	Severe Storms and Flooding
2006	New York	Schoharie	7/01/06	FEMA-1650-DR	Severe Storms and Flooding
2006	New York	Sullivan	7/01/06	FEMA-1650-DR	Severe Storms and Flooding
2006	New York	Tioga	7/01/06	FEMA-1650-DR	Severe Storms and Flooding
2006	New York	Ulster	7/01/06	FEMA-1650-DR	Severe Storms and Flooding
2006	Ohio	Ashtabula	8/01/06	FEMA-1656-DR	Severe Storms, Straight Line Winds, and Flooding
2006	Ohio	Cuyahoga	7/02/06	FEMA-1651-DR	Severe Storms, Tornadoes, Straight Line Winds, and Flooding
2006	Ohio	Erie	7/02/06	FEMA-1651-DR	Severe Storms, Tornadoes, Straight Line Winds, and Flooding
2006	Ohio	Geauga	8/01/06	FEMA-1656-DR	Severe Storms, Straight Line Winds, and Flooding
2006	Ohio	Huron	7/02/06	FEMA-1651-DR	Severe Storms, Tornadoes, Straight Line Winds, and Flooding
2006	Ohio	Lake	8/01/06	FEMA-1656-DR	Severe Storms, Straight Line Winds, and Flooding

2006	Ohio	Lucas	7/02/06	FEMA-1651-DR	Severe Storms, Tornadoes, Straight Line Winds, and Flooding
2006	Ohio	Sandusky	7/02/06	FEMA-1651-DR	Severe Storms, Tornadoes, Straight Line Winds, and Flooding
2006	Ohio	Stark	7/02/06	FEMA-1651-DR	Severe Storms, Tornadoes, Straight Line Winds, and Flooding
2006	Oklahoma	Canadian	1/10/06	FEMA-1623-DR	Severe Wildfire Threat
2006	Oklahoma	Cotton	1/10/06	FEMA-1623-DR	Severe Wildfire Threat
2006	Oklahoma	Delaware	4/13/06	FEMA-1637-DR	Severe Storms and Tornadoes
2006	Oklahoma	Garvin	1/10/06	FEMA-1623-DR	Severe Wildfire Threat
2006	Oklahoma	Hughes	1/10/06	FEMA-1623-DR	Severe Wildfire Threat
2006	Oklahoma	Lincoln	1/10/06	FEMA-1623-DR	Severe Wildfire Threat
2006	Oklahoma	Logan	1/10/06	FEMA-1623-DR	Severe Wildfire Threat
2006	Oklahoma	Mayes	1/10/06	FEMA-1623-DR	Severe Wildfire Threat
2006	Oklahoma	Okfuskee	1/10/06	FEMA-1623-DR	Severe Wildfire Threat
2006	Oklahoma	Oklahoma	1/10/06	FEMA-1623-DR	Severe Wildfire Threat
2006	Oklahoma	Pottawatomie	1/10/06	FEMA-1623-DR	Severe Wildfire Threat
2006	Oklahoma	Seminole	1/10/06	FEMA-1623-DR	Severe Wildfire Threat
2006	Oklahoma	Stephens	1/10/06	FEMA-1623-DR	Severe Wildfire Threat
2006	Pennsylvania	Berks	6/30/06	FEMA-1649-DR	Severe Storms, Flooding, and Mudslides
2006	Pennsylvania	Bradford	6/30/06	FEMA-1649-DR	Severe Storms, Flooding, and Mudslides
2006	Pennsylvania	Carbon	6/30/06	FEMA-1649-DR	Severe Storms, Flooding, and Mudslides
2006	Pennsylvania	Chester	6/30/06	FEMA-1649-DR	Severe Storms, Flooding, and Mudslides
2006	Pennsylvania	Dauphin	6/30/06	FEMA-1649-DR	Severe Storms, Flooding, and Mudslides
2006	Pennsylvania	Franklin	6/30/06	FEMA-1649-DR	Severe Storms, Flooding, and Mudslides
2006	Pennsylvania	Lackawanna	6/30/06	FEMA-1649-DR	Severe Storms, Flooding, and Mudslides
2006	Pennsylvania	Lancaster	6/30/06	FEMA-1649-DR	Severe Storms, Flooding, and Mudslides
2006	Pennsylvania	Lebanon	6/30/06	FEMA-1649-DR	Severe Storms, Flooding, and Mudslides
2006	Pennsylvania	Luzerne	6/30/06	FEMA-1649-DR	Severe Storms, Flooding, and Mudslides
2006	Pennsylvania	Monroe	6/30/06	FEMA-1649-DR	Severe Storms, Flooding, and Mudslides
2006	Pennsylvania	Montgomery	6/30/06	FEMA-1649-DR	Severe Storms, Flooding, and Mudslides
2006	Pennsylvania	Montour	6/30/06	FEMA-1649-DR	Severe Storms, Flooding, and Mudslides
2006	Pennsylvania	Pike	6/30/06	FEMA-1649-DR	Severe Storms, Flooding, and Mudslides
2006	Pennsylvania	Schuylkill	6/30/06	FEMA-1649-DR	Severe Storms, Flooding, and Mudslides
2006	Pennsylvania	Susquehanna	6/30/06	FEMA-1649-DR	Severe Storms, Flooding, and Mudslides
2006	Pennsylvania	Wayne	6/30/06	FEMA-1649-DR	Severe Storms, Flooding, and Mudslides
2006	Pennsylvania	Wyoming	6/30/06	FEMA-1649-DR	Severe Storms, Flooding, and Mudslides
2006	Tennessee	Benton	4/05/06	FEMA-1634-DR	Tornadoes and Severe Storms
2006	Tennessee	Cannon	4/05/06	FEMA-1634-DR	Tornadoes and Severe Storms
2006	Tennessee	Carroll	4/05/06	FEMA-1634-DR	Tornadoes and Severe Storms

PRESIDENTIAL DISASTER DECLARATIONS WITH INDIVIDUAL ASSISTANCE—Continued

Year	State	County	Date	FEMA No	Incident Type
2006	Tennessee	Cheatham	4/05/06	FEMA-1634-DR	Tornadoes and Severe Storms
2006	Tennessee	Cumberland	4/05/06	FEMA-1634-DR	Tornadoes and Severe Storms
2006	Tennessee	Davidson	4/05/06	FEMA-1634-DR	Tornadoes and Severe Storms
2006	Tennessee	Dickson	4/05/06	FEMA-1634-DR	Tornadoes and Severe Storms
2006	Tennessee	Dyer	4/05/06	FEMA-1634-DR	Tornadoes and Severe Storms
2006	Tennessee	Fayette	4/05/06	FEMA-1634-DR	Tornadoes and Severe Storms
2006	Tennessee	Gibson	4/05/06	FEMA-1634-DR	Tornadoes and Severe Storms
2006	Tennessee	Haywood	4/05/06	FEMA-1634-DR	Tornadoes and Severe Storms
2006	Tennessee	Maury	4/05/06	FEMA-1634-DR	Tornadoes and Severe Storms
2006	Tennessee	Sumner	4/05/06	FEMA-1634-DR	Tornadoes and Severe Storms
2006	Tennessee	Warren	4/05/06	FEMA-1634-DR	Tornadoes and Severe Storms
2006	Tennessee	Weakley	4/05/06	FEMA-1634-DR	Tornadoes and Severe Storms
2006	Texas	Callahan	1/11/06	FEMA-1624-DR	Extreme Wildfire Threat
2006	Texas	Cooke	1/11/06	FEMA-1624-DR	Extreme Wildfire Threat
2006	Texas	Eastland	1/11/06	FEMA-1624-DR	Extreme Wildfire Threat
2006	Texas	Erath	1/11/06	FEMA-1624-DR	Extreme Wildfire Threat
2006	Texas	Hood	1/11/06	FEMA-1624-DR	Extreme Wildfire Threat
2006	Texas	Kerr	1/11/06	FEMA-1624-DR	Extreme Wildfire Threat
2006	Texas	Montague	1/11/06	FEMA-1624-DR	Extreme Wildfire Threat
2006	Texas	Palo Pinto	1/11/06	FEMA-1624-DR	Extreme Wildfire Threat
2006	Texas	Potter	1/11/06	FEMA-1624-DR	Extreme Wildfire Threat
2006	Texas	Tarrant	1/11/06	FEMA-1624-DR	Extreme Wildfire Threat
2006	Texas	Wise	1/11/06	FEMA-1624-DR	Extreme Wildfire Threat
2006	Texas	El Paso	8/15/06	FEMA-1658-DR	Flooding
2006	Washington	Clark	12/12/06	FEMA-1671-DR	Severe Storms, Flooding, Landslides, and Mudslides
2006	Washington	Cowlitz	12/12/06	FEMA-1671-DR	Severe Storms, Flooding, Landslides, and Mudslides
2006	Washington	Grays Harbor	12/12/06	FEMA-1671-DR	Severe Storms, Flooding, Landslides, and Mudslides
2006	Washington	King	12/12/06	FEMA-1671-DR	Severe Storms, Flooding, Landslides, and Mudslides
2006	Washington	Lewis	12/12/06	FEMA-1671-DR	Severe Storms, Flooding, Landslides, and Mudslides
2006	Washington	Pierce	12/12/06	FEMA-1671-DR	Severe Storms, Flooding, Landslides, and Mudslides

2006	Washington	Skagit	12/12/06	FEMA-1671-DR	Severe Storms, Flooding, Landslides, and Mudslides
2006	Washington	Skamania	12/12/06	FEMA-1671-DR	Severe Storms, Flooding, Landslides, and Mudslides
2006	Washington	Snohomish	12/12/06	FEMA-1671-DR	Severe Storms, Flooding, Landslides, and Mudslides
2006	Washington	Thurston	12/12/06	FEMA-1671-DR	Severe Storms, Flooding, Landslides, and Mudslides
2006	Washington	Wahkiakum	12/12/06	FEMA-1671-DR	Severe Storms, Flooding, Landslides, and Mudslides

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPB) DISASTER DESIGNATION REQUESTS: SECRETARIAL

[Fiscal Year 2002—Secretarial Designations for Production Losses]

State	Countries requested	Beginning date of disaster	Ending date of disaster	Approved by secretary	Termination date	Designation number	Description of disaster	Primary	Contiguous
NY	Albany, Columbia, Dutchess, Niagara, Orange, Ulster.	4-15-2001	6-20-2001	10-16-2001	6-17-2002	S1564	Albany: Hail, excessive rain; Columbia: Hail, high winds; Dutchess: Hail; Niagara: Flooding, hail; Orange: Drought; Ulster: Hail; Ulster: Hail, high winds.	6	12
CT	6-03-2001	6-03-2001	10-16-2001	6-17-2002	S1564	Hail	2
MA	5-28-2001	6-20-2001	10-16-2001	6-17-2002	S1564	Hail, high winds	1
OR	Jackson	9-01-2000	4-16-2002	10-16-2001	12-18-2001	S1565	Drought	1
OR	Josephine	9-01-2000	4-16-2002	10-16-2001	2-14-2002	S1565	Drought	1
OR	Union	9-01-2000	4-16-2002	10-16-2001	6-17-2002	S1565	Drought	1	4
TN	Anderson, Campbell, Carroll, Carter, Crockett, Dyer, Giles, Greene, Hancock, Johnson, Maury, Obion, Weakley.	1-01-2001	4-16-2002	10-16-2001	6-17-2002	S1566	Drought, excessive heat, insect infestation, hail, excessive rain, freezing conditions.	13	28
AL	4-01-2001	4-16-2002	10-16-2001	6-17-2002	S1566	Drought, insect infestation	2
AR	4-01-2001	4-16-2002	10-16-2001	6-17-2002	S1566	Drought, insect infestation	1
KY	3-15-2001	4-16-2002	10-16-2001	6-17-2002	S1566	Drought, insect infestation, excessive heat	5
MO	4-01-2001	4-16-2002	10-16-2001	6-17-2002	S1566	Drought, insect infestation	1
NC	3-15-2001	6-15-2001	10-16-2001	6-17-2002	S1566	Drought, excessive heat	4
VA	1-01-2001	4-16-2002	10-16-2001	6-17-2002	S1566	Drought, excessive heat, hail, excessive rain.	5

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPBP) DISASTER DESIGNATION REQUESTS: SECRETARIAL—Continued
[Fiscal Year 2002—Secretarial Designations for Production Losses]

State	Counties requested	Beginning date of disaster	Ending date of disaster	Approved by secretary	Termination date	Designation number	Description of disaster	Primary	Contiguous
WA	Chelan	6-26-2001	6-27-2001	10-16-2001	6-17-2002	S1567	Severe storms with damaging wind, rain, hail	1	3
WA	Douglas, Klickitat, Walla Walla	6-26-2001	6-27-2001	10-16-2001	4-23-2002	S1567	Severe storms with damaging wind, rain, hail	3
OR		6-26-2001	6-27-2001	10-16-2001	6-17-2002	S1567	Severe storms with damaging wind, rain, hail	4
CA	Madera	4-04-2001	4-20-2001	10-25-2001	6-25-2002	S1568	Freezing temperatures, hailstorms	1	5
CA	Mendocino	1-01-2001	7-30-2001	10-25-2001	6-25-2002	S1569	(1) Freezing temperatures; (2) severe heat; (3) Unseasonable rainfall; (4) Drought	1	4
CO	Eagle, Garfield, Pitkin	7-09-2001	4-25-2002	10-25-2001	6-25-2002	S1570	Drought	3	8
UT		7-09-2001	4-25-2002	10-25-2001	6-25-2002	S1570	Drought	2
KS	Atchison, Greeley, Hamilton, Jefferson, Jewell, Kearny, Kingman, Lane, Leavenworth, Logan, Morton, Scott, Wichita	1-01-2001	4-25-2002	10-25-2001	6-25-2002	S1571	Drought, excessive rains, flash flooding, tornadoes, hail, repeated excessive winds	13	28
CO		1-01-2001	4-25-2002	10-25-2001	6-25-2002	S1571	Drought, excessive rains, flash flooding, tornadoes, hail, repeated excessive winds	4
MO		1-01-2001	4-25-2002	10-25-2001	6-25-2002	S1571	Drought, excessive rains, flash flooding, tornadoes, hail, repeated excessive winds	2
NE		1-01-2001	4-25-2002	10-25-2001	6-25-2002	S1571	Drought, excessive rains, flash flooding, tornadoes, hail, repeated excessive winds	2
NE	Holt	7-03-2001	4-25-2002	10-25-2001	6-25-2002	S1572	Storms, hail	1	8
OK	All counties except Choctaw, McCurtain	6-01-2001	4-25-2002	10-25-2001	6-25-2002	S1573	Drought	75	2
AR		6-01-2001	4-25-2002	10-25-2001	6-25-2002	S1573	Drought	6
CO		6-01-2001	4-25-2002	10-25-2001	6-25-2002	S1573	Drought	1
KS		6-01-2001	4-25-2002	10-25-2001	6-25-2002	S1573	Drought	14
MO		6-01-2001	4-25-2002	10-25-2001	6-25-2002	S1573	Drought	2
NM		6-01-2001	4-25-2002	10-25-2001	6-25-2002	S1573	Drought	1

TX	6-01-2001	4-25-2002	10-25-2001	6-25-2002	S1573	Drought	18
OR	Baker	9-01-2000	4-25-2002	10-25-2001	6-25-2002	S1574	Drought	1
OR	Gilliam	9-01-2000	4-25-2002	10-25-2001	6-25-2002	S1574	Drought	1
ID	9-01-2000	4-25-2002	10-25-2001	6-25-2002	S1574	Drought	1
TX	Cottle	7-23-2001	7-23-2001	10-25-2001	6-25-2002	S1575	Fire, excessive temperatures	1
UT	Beaver	1-01-2001	4-25-2002	10-25-2001	6-25-2002	S1576	(1) Drought, Grasshopper and Mor- mon Cricket infestation; (2) Freezing temperatures, high winds	23
AZ	Davis, Emery, Iron, Juab, Kane, Millard, Morgan, Plute, Rich, San Juan, Sanpete, Sevier, Summit, Tooele, Utah, Wasatch, Washington, Wayne, Weber.	1-01-2001	4-25-2002	10-25-2001	6-25-2002	S1576	(1) Drought, Grasshopper and Mor- mon Cricket infestation; (2) Freezing temperatures, high winds	4
CO	1-01-2001	4-25-2002	10-25-2001	6-25-2002	S1576	(1) Drought, Grasshopper and Mor- mon Cricket infestation; Freezing temperatures, high winds	5
ID	1-01-2001	4-25-2002	10-25-2001	6-25-2002	S1576	(1) Drought, Grasshopper and Mor- mon Cricket infestation; Freezing temperatures, high winds	1
NM	1-01-2001	4-25-2002	10-25-2001	6-25-2002	S1576	(1) Drought, Grasshopper and Mor- mon Cricket infestation; Freezing temperatures, high winds	1
NV	1-01-2001	4-25-2002	10-25-2001	6-25-2002	S1576	(1) Drought, Grasshopper and Mor- mon Cricket infestation; Freezing temperatures, high winds	3
WY	1-01-2001	4-25-2002	10-25-2001	6-25-2002	S1576	(1) Drought, Grasshopper and Mor- mon Cricket infestation; Freezing temperatures, high winds	3
OR	Morrow	9-01-2000	4-29-2002	10-29-2001	6-25-2002	S1577	Drought	1
WA	Saratoga	9-01-2000	4-29-2002	10-29-2001	6-29-2002	S1577	Drought	1
NY	Lincoln, Sweetwater	4-01-2001	5-28-2001	10-29-2001	6-29-2002	S1578	Low rainfall (Drought), hail, lightning	8
WY	Big Horn, Campbell, Park, Sheri- dan.	1-01-2001	5-01-2002	11-01-2001	6-25-2002	S1579	Drought, wildfire conditions	2
WY	Fremont, Hot Springs, Johnson, Natrona, Sublette, Washakie, Wind River Indian Reservation.	1-01-2001	5-01-2002	11-01-2001	1-29-2002	S1579	Drought, wildfire conditions	2
WY	1-01-2001	5-01-2002	11-01-2001	7-01-2002	S1579	Drought, wildfire conditions	4
CO	1-01-2001	5-01-2002	11-01-2001	7-01-2002	S1579	Drought, wildfire conditions	1
CO	1-01-2001	5-01-2002	11-01-2001	6-25-2002	S1579	Drought, wildfire conditions	1

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPBP) DISASTER DESIGNATION REQUESTS: SECRETARIAL—Continued
[Fiscal Year 2002—Secretarial Designations for Production Losses]

State	Counties requested	Beginning date of disaster	Ending date of disaster	Approved by secretary	Termination date	Designation number	Description of disaster	Primary	Contiguous
ID	1-01-2001	5-01-2002	11-01-2001	7-01-2002	S1579	Drought, wildfire conditions	2
MT	1-01-2001	5-01-2002	11-01-2001	1-29-2002	S1579	Drought, wildfire conditions	4
UT	1-01-2001	5-01-2002	11-01-2001	6-25-2002	S1579	Drought, wildfire conditions	3
OH	Brown, Clermont, Defiance, Fulton, Gallia, Hancock, Jackson, Ottawa, Paulding, Putnam, Vinton, Wyandot.	5-01-2001	5-02-2002	11-02-2001	7-02-2002	S1580	Extreme weather conditions with excessive rain, flooding, armyworms.	12	24
IN	5-01-2001	5-02-2002	11-02-2001	7-02-2002	S1580	Extreme weather conditions with excessive rain, flooding, armyworms.	2
KY	5-01-2001	5-02-2002	11-02-2001	7-02-2002	S1580	Extreme weather conditions with excessive rain, flooding, armyworms.	4
WV	5-01-2001	5-02-2002	11-02-2001	7-02-2002	S1580	Extreme weather conditions with excessive rain, flooding, armyworms.	2
LA	Acadia, Avoyelles, Beauregard, Bossier, Caddo, Caldwell, Cameron, Catahoula, Concordia, De Soto, East Carroll, Evangeline, Franklin, Grant, Iberville, Jefferson Davis, La Salle, Madison, Morehouse, Natchitoches, Ouachita, Pointe Coupee, Rapides, Red River, Richland, St. Landry, St. Martin, Tensas, Vermilion, Vernon, West Baton Rouge, West Carroll.	8-27-2001	5-02-2002	11-02-2001	7-02-2001	S1581	Excessive rainfall, high humidity	32	17
AR	8-27-2001	5-02-2002	11-02-2001	7-02-2001	S1581	Excessive rainfall, high humidity	5
MS	8-27-2001	5-02-2002	11-02-2001	7-02-2001	S1581	Excessive rainfall, high humidity	6
TX	8-27-2001	5-02-2002	11-02-2001	7-02-2001	S1581	Excessive rainfall, high humidity	8
TX	Bee, San Patricio	5-01-2001	5-02-2002	11-02-2001	7-02-2001	S1582	Drought	2	7
WA	Chelan	6-08-2001	5-02-2002	11-02-2001	7-02-2001	S1583	Hailstorm	1	6
WA	Lincoln	5-21-2001	5-24-2001	11-02-2001	7-02-2001	S1583	Freeze	1	7
WA	Asotin, Benton, Douglas, Klickitat, Lincoln, Stevens.	1-01-2001	5-02-2002	11-02-2001	7-02-2001	S1583	Drought	6	14
ID	1-01-2001	5-02-2002	11-02-2001	7-02-2001	S1583	Drought	1

State	County	Year	Event	Severity	Notes	Count
OR	Jackson, Lake, Mason, Oceana	1-01-2001	Excessive rain, flash flooding, hail	SI583	Drought	7
MI	Allegan, Berrien, Cass, Kalamazoo, Van Buren	5-15-2001	Frost, freezing temperatures, cooler than normal temperatures.	SI584	Excessive rain, flash flooding, hail	4
MI		5-12-2001	Frost, freezing temperatures, cooler than normal temperatures.	SI584	Frost, freezing temperatures, cooler than normal temperatures.	5
IN		5-12-2001	Frost, freezing temperatures, cooler than normal temperatures.	SI584	Frost, freezing temperatures, cooler than normal temperatures.	3
TX	Borden, Brown, Concho, Dimmitt, Duval, Gaines, Mitchell, Runnels, Tom Green, Wilbarger.	1-01-2001	Drought	SI585	Drought	10
NM		1-01-2001	Drought	SI585	Drought	2
OK	Chippewa, Clare, Clinton, Delta, Dickinson, Emmet, Genesee, Gladwin, Grand Traverse, Gratiot, Hillsdale, Huron, Ingham, Ionia, Iscoco, Iron, Isabella, Jackson, Kalamazoo, Kalkaska, Kent, Lake, Lapeer, Leelanau, Lenawee, Livingston, Luce, Mackinac, Macomb, Manistee, Marquette, Mason, Mecosta, Menominee, Midland, Missaukee, Monroe, Montcalm, Montmorency, Muskegon, Newaygo, Oakland, Oceana, Ogemaw, Osceola, Oscoda, Otsego, Ottawa, Presque Isle, Roscommon, Saginaw, Sanilac, Schoolcraft, Shiawassee, St. Clair, St. Joseph, Tuscola, Van Buren, Washtenaw, Wayne, Wexford.	1-01-2001	Drought	SI585	Drought	1
CA		1-01-2001	Drought	SI586	Drought, excessive temperatures	1
MI	Alcona, Alger, Alpena, Antrim, Arenac, Bay, Benzie, Berrien, Cass, Charlevoix, Cheboygan, Chippewa, Clare, Clinton, Delta, Dickinson, Emmet, Genesee, Gladwin, Grand Traverse, Gratiot, Hillsdale, Huron, Ingham, Ionia, Iscoco, Iron, Isabella, Jackson, Kalamazoo, Kalkaska, Kent, Lake, Lapeer, Leelanau, Lenawee, Livingston, Luce, Mackinac, Macomb, Manistee, Marquette, Mason, Mecosta, Menominee, Midland, Missaukee, Monroe, Montcalm, Montmorency, Muskegon, Newaygo, Oakland, Oceana, Ogemaw, Osceola, Oscoda, Otsego, Ottawa, Presque Isle, Roscommon, Saginaw, Sanilac, Schoolcraft, Shiawassee, St. Clair, St. Joseph, Tuscola, Van Buren, Washtenaw, Wayne, Wexford.	6-12-2001	Drought	SI587	Drought	72
IN		6-12-2001	Drought	SI587	Drought	5
OH		6-12-2001	Drought	SI587	Drought	4
WI		6-12-2001	Drought	SI587	Drought	4

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPBP) DISASTER DESIGNATION REQUESTS: SECRETARIAL—Continued
[Fiscal Year 2002—Secretarial Designations for Production Losses]

State	Countries requested	Beginning date of disaster	Ending date of disaster	Approved by secretary	Termination date	Designation number	Description of disaster	Primary	Contiguous
TX	Glasscock, Howard, Jim Hogg, Kleberg, Zapata.	1-01-2001	6-05-2002	12-05-2001	8-05-2002	S1588	Drought, excessive temperatures (heat), high winds, low humidity.	5	16
TX	Collingsworth	6-01-2001	6-05-2002	12-05-2001	8-05-2002	S1589	Drought; Lightning, wildfires	1	5
OK		6-01-2001	6-05-2002	12-05-2001	8-05-2002	S1589	Drought; Lightning, wildfires	2
TX	Hardenan, Maverick	1-01-2001	6-05-2002	12-05-2001	7-26-2002	S1590	2	10
TX	Childress, Cottle, Hidalgo, Kent, Starr.	1-01-2001	6-05-2002	12-05-2001	8-05-2002	S1590	Drought, excessive heat	5	15
OK		1-01-2001	6-05-2002	12-05-2001	8-05-2002	S1590	Drought, excessive heat	2
PA	Adams, Allegheny, Armstrong, Beaver, Bedford, Berks, Blair, Butler, Cambria, Centre, Clinton, Chester, Clarion, Clearfield, Columbia, Cumberland, Dauphin, Elk, Erie, Forest, Franklin, Fulton, Huntingdon, Indiana, Jefferson, Juniata, Lancaster, Lawrence, Lebanon, Lycoming, Mercer, Mifflin, Montour, Northumberland, Perry, Schuylkill, Snyder, Somerset, Union, Venango, Warren, Washington, Westmoreland, York.	1-01-2001	6-05-2002	12-05-2001	8-05-2002	S1591	Drought	44	14
DE		1-01-2001	6-05-2002	12-05-2001	8-05-2002	S1591	Drought	1
MD		1-01-2001	6-05-2002	12-05-2001	8-05-2002	S1591	Drought	8
NY		1-01-2001	6-05-2002	12-05-2001	8-05-2002	S1591	Drought	2
OH		1-01-2001	6-05-2002	12-05-2001	8-05-2002	S1591	Drought	4
WV		1-01-2001	6-05-2002	12-05-2001	8-05-2002	S1591	Drought	4
TX	Austin, Burleson, Chambers, Colorado, Fort Bend, Goliad, Jefferson, Matagorda, Wharton.	8-20-2001	9-19-2001	12-13-2001	8-13-2002	S1592	Excessive rain, flooding, flash flooding.	9	21
LA		8-20-2001	9-19-2001	12-13-2001	8-13-2002	S1592	Excessive rain, flooding, flash flooding.	1

TX	Cottle	9-20-2001	9-20-2001	12-13-2001	8-13-2002	S1593	Excessive rain, flash flooding, hail, high winds.	1	7
TX	Floyd	6-01-2001	6-05-2001	12-13-2001	8-13-2002	S1594	Excessive rain, flash flooding, flooding, high winds, hail, lightning, tornado.	1	7
TX	Uvalde	5-24-2001	5-24-2001	12-13-2001	8-13-2002	S1595	High wind, hail	1	8
TX	Wilson	9-20-2001	9-20-2001	12-13-2001	8-13-2002	S1596	Extreme amount of hail, high winds	1	5
ID	Franklin, Oneida	1-01-2001	6-18-2002	12-18-2001	6-25-2002	S1597	Drought, heat	2
ID	Camas, Power	1-01-2001	6-18-2002	12-18-2001	8-19-2002	S1597	Drought, heat	2	6
ME	Androscoggin, Cumberland, Kennebec, Lincoln, Oxford, Penobscot, Piscataquis, Sagadahoc, Somerset, Waldo, Washington, York	6-01-2001	9-10-2001	12-20-2001	8-20-2002	S1598	Armyworm infestation	12	4
NH	6-01-2001	9-10-2001	12-20-2001	8-20-2002	S1598	Armyworm infestation	4
PA	Erle	7-04-2001	7-03-2002	1-03-2002	9-03-2002	S1599	Storms with high winds, excessive hail.	1	2
NY	7-04-2001	7-03-2002	1-03-2002	9-03-2002	S1599	Storms with high winds, excessive hail.	1
OH	7-04-2001	7-03-2002	1-03-2002	9-03-2002	S1599	Storms with high winds, excessive hail.	1
NM	Chaves, Eddy, Otero	1-01-2001	7-09-2002	1-08-2002	9-09-2002	S1600	Drought	3	5
TX	1-01-2001	7-09-2002	1-08-2002	9-09-2002	S1600	Drought	5
AR	Ashley, Chicot, Columbia, Desha, Drew, Lafayette.	8-31-2001	9-07-2001	1-08-2002	9-09-2002	S1601	Excessive rain	6	10
LA	8-31-2001	9-07-2001	1-08-2002	9-09-2002	S1601	Excessive rain	8
MS	8-31-2001	9-07-2001	1-08-2002	9-09-2002	S1601	Excessive rain	4
TN	Cocke	6-26-2001	6-26-2001	1-08-2002	9-09-2002	S1602	Hail, wind, flash flooding	1	4
TN	Rutherford	4-01-2001	7-09-2002	1-08-2002	9-09-2002	S1602	Drought, insect infestation	1	5
TN	Morgan, Scott	3-15-2001	6-15-2001	1-08-2002	6-17-2002	S1602	Drought, excessive heat	2
TN	3-15-2001	6-15-2001	1-08-2002	9-09-2002	S1602	Drought, excessive heat	3
KY	3-15-2001	6-15-2001	1-08-2002	9-09-2002	S1602	Drought, excessive heat	1
NC	6-26-2001	6-26-2001	1-08-2002	9-09-2002	S1602	Hail, wind, flash flooding	2
MN	Cass, Crow Wing	11-15-2000	6-28-2001	1-08-2002	9-09-2002	S1603	Heavier than normal precip, followed by severe cold.	2	8
NE	Buffalo, Butler, Cass, Dundy, Nance, Platte, Polk, Saunders, Seward, Sherman.	5-01-2001	7-09-2002	1-08-2002	9-09-2002	S1604	Drought, severe heat	10	26
CO	5-01-2001	7-09-2002	1-08-2002	9-09-2002	S1604	Drought, severe heat	1
IA	5-01-2001	7-09-2002	1-08-2002	9-09-2002	S1604	Drought, severe heat	2

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPBP) DISASTER DESIGNATION REQUESTS: SECRETARIAL—Continued
[Fiscal Year 2002—Secretarial Designations for Production Losses]

State	Countries requested	Beginning date of disaster	Ending date of disaster	Approved by secretary	Termination date	Designation number	Description of disaster	Primary	Contiguous
KS NY Broome, Columbia, Dutchess, Greene, Jefferson, Lewis, Livingston, Onondaga, Sullivan, Ulster, Wyoming.	5-01-2001 4-01-2001	7-09-2002 7-09-2002	1-08-2002 1-08-2002	9-09-2002 9-09-2002	S1604 S1605	Drought, severe heat Columbia; Drought; Dutchess: Hail, High Winds; Greene: Drought + Hail, High Winds; Rain; Jefferson: Drought; Lewis: Flash Flooding, Excessive rain & Drought; Livingston: Drought; Onondaga: Hail; Sullivan: Army Cut Worms; Ulster: Hail High Winds; Wyoming: Drought. 11	2 22
CT	7-01-2001 4-01-2001	7-01-2001 7-09-2002	1-08-2002 1-08-2002	9-09-2002 9-09-2002	S1605 S1605	Hail, high winds Hail, high winds: 07/01/01; Drought: 04/01/01—continuing.	2 1
MA	4-01-2001	7-09-2002	1-08-2002	9-09-2002	S1605	Drought: 04/01/01—05/31/01; Army- worm infestation: 07/01/01—con- tinuing.	3
PA	4-01-2001	7-09-2002	1-08-2002	9-09-2002	S1605	Drought, extreme fires Drought, extreme fires Drought, extreme fires Drought, army cut worms, hail	1 12	6 5 2 13
NV	Washoe	5-01-2001 5-01-2001	9-30-2001 9-30-2001	1-08-2002 1-08-2002	9-09-2002 9-09-2002	S1606 S1606	Drought, extreme fires Drought, extreme fires Drought, extreme fires Drought, army cut worms, hail
CA	5-01-2001 5-01-2001	9-30-2001 9-30-2001	1-08-2002 1-08-2002	9-09-2002 9-09-2002	S1606 S1606	Drought, extreme fires Drought, extreme fires Drought, extreme fires Drought, army cut worms, hail
OR	5-01-2001 5-01-2001	9-30-2001 9-30-2001	1-08-2002 1-08-2002	9-09-2002 9-09-2002	S1606 S1606	Drought, extreme fires Drought, extreme fires Drought, extreme fires Drought, army cut worms, hail
NY	Alegany, Cattaraugus, Chau- tauqua, Clinton, Essex, Niag- ara, Orleans, Putnam, Schuyler, Seneca, Wayne, Westchester.	4-01-2001 5-01-2001	7-22-2002 7-22-2002	1-22-2002 1-22-2002	9-23-2002 9-23-2002	S1607 S1607	Drought, army cut worms, hail Drought Drought, Army Cut worms, hail Drought Severe storms, high winds, tornadoes, hail, excessive rain.	4 2 4 2 3 5 16
IN	Lagrange, Perry	6-15-2001 10-24-2001	9-09-2001 10-25-2001	2-07-2002 2-07-2002	10-07-2002 10-07-2002	S1608 S1608	Severe storms, high winds, tornadoes, hail, excessive rain.	2
IL	Benton, Clay, Elkhart, St. Joseph ..	10-24-2001 10-24-2001	10-25-2001 10-25-2001	2-07-2002 2-07-2002	10-07-2002 10-07-2002	S1608 S1608	Severe storms, high winds, tornadoes, hail, excessive rain.	2
KY	6-15-2001 10-24-2001	9-09-2001 10-25-2001	2-07-2002 2-07-2002	10-07-2002 10-07-2002	S1608 S1608	Severe storms, high winds, tornadoes, hail, excessive rain.	3
MI	6-15-2001 10-24-2001	9-09-2001 10-25-2001	2-07-2002 2-07-2002	10-07-2002 10-07-2002	S1608 S1608	Severe storms, high winds, tornadoes, hail, excessive rain.	3

OH	5-01-2002	8-07-2002	2-07-2002	10-07-2002	S1609	Severe drought, high temperatures	22	26
	Ashtland, Ashtabula, Brown, Carroll, Columbiana, Cuyahoga, Fulton, Geauga, Hancock, Holmes, Knox, Lake, Lucas, Mahoning, Medina, Sandusky, Seneca, Stark, Tuscarawas, Wayne, Wood, Wyandot.							
KY	5-01-2002	8-07-2002	2-07-2002	10-07-2002	S1609	Severe drought, high temperatures	2
MI	5-01-2002	8-07-2002	2-07-2002	10-07-2002	S1609	Severe drought, high temperatures	3
PA	5-01-2002	8-07-2002	2-07-2002	10-07-2002	S1609	Severe drought, high temperatures	5
WV	5-01-2002	8-07-2002	2-07-2002	10-07-2002	S1609	Severe drought, high temperatures	1
GA	1-01-2001	8-07-2002	2-07-2002	10-07-2002	S1610	Drought	19	50
	Banks, Butts, Candler, Clayton, Elbert, Emanuel, Fayette, Glascock, Henry, Jackson, Jefferson, Johnson, Laurens, Madison, Oglethorpe, Tattnall, Taylor, Washington, Wilkinson.							
SC	1-01-2001	8-07-2002	2-07-2002	10-07-2002	S1610	Drought	3
KS	1-01-2001	8-19-2002	2-19-2002	10-21-2002	S1611	Drought, excessive rains, flash flooding, tornadoes, hail, repeatedly excessive winds.	5	14
	Chautauqua, Elk, Montgomery, Sumner, Reno.							
OK	1-01-2001	8-19-2002	2-19-2002	10-21-2002	S1611	Drought, excessive rains, flash flooding, tornadoes, hail, repeatedly excessive winds.	5
ND	3-01-2001	8-21-2002	2-21-2002	10-21-2002	S1612	Flooding, ground saturation, subsidence, storms, wind tornadoes, drought, high humidity, severe temperatures during the growing season.	32	18
	Barnes, Benson, Bottineau, Bowman, Burke, Cass, Cavalier, Divide, Eddy, Emmons, Foster, Grand Forks, Kidder, Logan, Mountrail, Nelson, Pembina, Pierce, Ramsey, Ransom, Renville, Richland, Rolette, Sargent, Slope, Stutsman, Towner, Traill, Walsh, Ward, Wells, Williams.							
MN	3-01-2001	8-21-2002	2-21-2002	10-21-2002	S1612	Flooding, ground saturation, subsidence, storms, wind tornadoes, drought, high humidity, severe temperatures during the growing season.	7

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPBP) DISASTER DESIGNATION REQUESTS: SECRETARIAL—Continued
[Fiscal Year 2002—Secretarial Designations for Production Losses]

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MT	3-01-2001	8-21-2002	2-21-2002	10-21-2002	S1612	Flooding, ground saturation, subsidence, storms, wind tornadoes, drought, high humidity, severe temperatures during the growing season.	4
SD	3-01-2001	8-21-2002	2-21-2002	10-21-2002	S1612	Flooding, ground saturation, subsidence, storms, wind tornadoes, drought, high humidity, severe temperatures during the growing season.	6
ID	Butte, Custer, Lemhi	1-01-2001	9-01-2002	3-01-2002	11-01-2002	S1613	Drought, heat, low snow pack conditions.	3	5
MT	1-01-2001	9-01-2002	3-01-2002	11-01-2002	S1613	Drought, heat, low snow pack conditions.	2
CA	Tehama	4-08-2001	4-08-2001	3-01-2002	11-01-2002	S1614	Freezing temperatures	1	3
NY	Chemung, Tioga	4-01-2001	9-01-2002	3-01-2002	11-01-2002	S1615	Drought	2	4
PA	4-01-2001	9-01-2002	3-01-2002	11-01-2002	S1615	Drought	3
NY	Seneca	10-21-2001	10-21-2001	3-01-2002	11-01-2002	S1615	Hail, high winds	1	6
SC	Entire State	4-01-2001	9-01-2002	3-01-2002	11-01-2002	S1616	Drought	46
GA	4-01-2001	9-01-2002	3-01-2002	11-01-2002	S1616	Drought	13
NC	4-01-2001	9-01-2002	3-01-2002	11-01-2002	S1616	Drought	16
TN	Clabornie, Union	7-01-2001	9-30-2001	3-01-2002	11-01-2002	S1617	Excessive rain	2	5
KY	7-01-2001	9-30-2001	3-01-2002	11-01-2002	S1617	Excessive rain	2
TN	Hamblen	8-05-2001	8-05-2001	3-01-2002	11-01-2002	S1617	Flooding	1	5
TN	Jefferson	4-01-2001	9-01-2002	3-01-2002	11-01-2002	S1617	Drought	1	5
VA	Goochland	10-01-2000	9-01-2002	3-01-2002	11-01-2002	S1618	Drought, excessive heat	1	7
WY	Albany	1-01-2001	9-01-2002	3-01-2002	11-01-2002	S1619	Drought, late frosts, untimely rain, hail	1	2
CO	1-01-2001	9-01-2002	3-01-2002	11-01-2002	S1619	Drought, late frosts, untimely rain, hail	2
VT	Addison, Bennington, Caledonia, Chittenden, Orange, Orleans, Rutland, Washington.	4-01-2001	9-01-2002	3-01-2002	11-01-2002	S1620	Drought	8	6
MA	4-01-2001	9-01-2002	3-01-2002	11-01-2002	S1620	Drought	2
NH	4-01-2001	9-01-2002	3-01-2002	11-01-2002	S1620	Drought	1
NY	4-01-2001	9-01-2002	3-01-2002	11-01-2002	S1620	Drought	4

WA	Yakima	1-01-2001	9-01-2002	3-01-2002	11-01-2002	S1621	Drought	1	3
ME	Androscoggin, Arnooscooq, Cumberland, Hancock, Kennebec, Knox, Lincoln, Oxford, Penobscot, Piscataquis, Sagadahoc, Somerset, Waldo, Washington, York.	6-01-2002 6-01-2002	9-11-2002 9-11-2002	3-11-2002 3-11-2002	11-11-2002 11-11-2002	S1622 S1622	Drought	15	1
NH		6-01-2002	9-11-2002	3-11-2002	11-11-2002	S1622	Drought	4	4
MA	Franklin, Hampden, Hampshire, Worcester.	5-01-2000	9-22-2002	3-22-2002	11-22-2002	S1623	Excessive rainfall, limited sunshine, below-average temperatures.	4	3
CT		5-01-2000	9-22-2002	3-22-2002	11-22-2002	S1623	Excessive rainfall, limited sunshine, below-average temperatures.	4	4
NH		5-01-2000	9-22-2002	3-22-2002	11-22-2002	S1623	Excessive rainfall, limited sunshine, below-average temperatures.	2	2
RI		5-01-2000	9-22-2002	3-22-2002	11-22-2002	S1623	Excessive rainfall, limited sunshine, below-average temperatures.	1	1
VT		5-01-2000	9-22-2002	3-22-2002	11-22-2002	S1623	Excessive rainfall, limited sunshine, below-average temperatures.	2	2
MT	Entire State	1-01-2002	9-27-2002	3-27-2002	11-27-2002	S1624	Drought	56	8
ID		1-01-2002	9-27-2002	3-27-2002	11-27-2002	S1624	Drought	6	6
ND		1-01-2002	9-27-2002	3-27-2002	11-27-2002	S1624	Drought	2	2
SD		1-01-2002	9-27-2002	3-27-2002	11-27-2002	S1624	Drought	6	6
WY		1-01-2002	9-27-2002	3-27-2002	11-27-2002	S1624	Drought	1	1
KS	Cowley	6-01-2001	10-04-2002	4-04-2002	6-25-2002	S1625	Drought, excessive rains, flash flooding, tornadoes, hail, repeatedly excessive winds.	2	4
KS	Edwards, Ford	6-01-2001	10-04-2002	4-04-2002	12-04-2002	S1625	Drought, excessive rains, flash flooding, tornadoes, hail, repeatedly excessive winds.	1	7
VA	Prince Edward	8-01-2001	12-10-2001	4-04-2002	12-04-2002	S1626	Erratic weather pattern: Record high temp. early spring-low rain; high	3	4
MA	Barnstable, Bristol, Plymouth	3-01-2001	10-04-2002	4-04-2002	12-04-2002	S1627	temp.—June w/above ave. rain; Below normal temp.—Jul, Aug, w/normal rain; Normal temp.—Sep. w/below norm. rain.	3	4

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPBP) DISASTER DESIGNATION REQUESTS: SECRETARIAL—Continued
[Fiscal Year 2002—Secretarial Designations for Production Losses]

State	Counties requested	Beginning date of disaster	Ending date of disaster	Approved by secretary	Termination date	Designation number	Description of disaster	Primary	Contiguous
RI		3-01-2001	10-04-2002	4-04-2002	12-04-2002	S1627	Erratic weather pattern: Record high temp. early spring-low rain; high temp.—June w/above ave. rain; Below normal temp.-Jul. Aug. w/normal rain; Normal temp.—Sep. w/below norm. rain.	3
GA	Dooly	1-01-2001	10-05-2002	4-05-2002	12-05-2002	S1628	Drought	1	5
SD	Haakon, Meade, Pennington	6-01-2001	10-05-2002	4-05-2002	12-05-2002	S1629	Drought, extreme heat	3	10
CA	Calaveras	8-19-2001	9-05-2001	4-05-2002	12-05-2002	S1630	High winds, drought, two separate fires.	1	5
ID	Cassia	10-01-2001	12-31-2001	4-19-2002	6-25-2002	S1631	Drought	1
ID	Bolivar, Calhoun, Carroll, Chickasaw, Hinds, Holmes, Itawamba, Jefferson Davis, Lee, Leflore, Marshall, Monroe, Noxubee, Panola, Pontotoc, Sunflower, Tallahatchie, Union, Washington.	10-01-2001	12-31-2001	4-19-2002	12-19-2002	S1631	Drought	3
MS		8-15-2001	9-30-2001	4-19-2002	12-19-2002	S1632	Excessive moisture, high humidity	19	31
MS	Claiborne, Warren	8-15-2001	9-30-2001	4-19-2002	7-02-2002	S1632	Excessive moisture, high humidity	2
AL		8-15-2001	9-30-2001	4-19-2002	12-19-2002	S1632	Excessive moisture, high humidity	5
AR		8-15-2001	9-30-2001	4-19-2002	12-19-2002	S1632	Excessive moisture, high humidity	2
TN		8-15-2001	9-30-2001	4-19-2002	12-19-2002	S1632	Excessive moisture, high humidity	2
IA	Lucas	10-22-2001	11-01-2001	4-23-2002	12-23-2002	S1633	High winds, heavy rains, flooding	1	7
IA	Guthrie	6-01-2001	10-23-2002	4-23-2002	12-23-2002	S1634	Drought	1	6
CO	Kit Carson, Phillips	9-01-2000	11-02-2002	5-02-2002	1-02-2003	S1635	Drought	2	5
KS		9-01-2000	11-02-2002	5-02-2002	1-02-2003	S1635	Drought	1
NE		9-01-2000	11-02-2002	5-02-2002	1-02-2003	S1635	Drought	2
TX	Schleicher, Sutton, Zavala	1-01-2001	11-02-2002	5-02-2002	1-02-2003	S1636	Drought, excessive heat	3	5
TX		1-01-2001	11-02-2002	5-02-2002	1-02-2003	S1636	Excessive heat	6
TX	Garza, Lubbock, Menard, Nolan, Terry.	1-01-2001	11-02-2002	5-02-2002	1-02-2003	S1637	Drought	5	9
TX	Brooks, Callahan, Eastland, Jim Wells, Presidio, Stephens, Webb.	1-01-2001	11-02-2002	5-02-2002	1-02-2003	S1638	Drought, high winds, high temperatures.	7	20

TX	Loving, Pecos, Reeves	1-01-2001	11-02-2002	5-02-2002	1-02-2003	S1639	Drought, high winds	3	8
NM	1-01-2001	11-02-2002	5-02-2002	1-02-2003	S1639	Drought, high winds	2
ID	Elmore	10-01-2000	11-10-2002	5-10-2002	1-10-2003	S1640	Drought, insect losses (Mormon Crickets).	1	8
ID	Twin Falls	11-01-2000	9-30-2001	5-10-2002	1-10-2003	S1640	Drought, excessive heat	1	2
NV	11-01-2000	9-30-2001	5-10-2002	1-10-2003	S1640	Drought, excessive heat	1
AZ	All counties, except Yuma	1-01-2001	11-17-2002	5-17-2002	1-17-2003	S1641	Drought	14	1
CA	1-01-2001	11-17-2002	5-17-2002	1-17-2003	S1641	Drought	3
NV	1-01-2001	11-17-2002	5-17-2002	1-17-2003	S1641	Drought	2
NM	1-01-2001	11-17-2002	5-17-2002	1-17-2003	S1641	Drought	5
TX	Comanche	5-01-2001	11-24-2002	5-24-2002	1-24-2003	S1642	Drought, heat, insects	1	5
CO	Adams, Alamosa, Archuleta, Baca, Bent, Boulder, Chaffee, Conejos, Costilla, Crowley, Custer, Dolores, Douglas, Eagle, El Paso, Elbert, Fremont, Garfield, Grand, Hinsdale, Huerfano, Jackson, Jefferson, Kiowa, La Plata, Lake, Larimer, Las Animas, Logan, Mesa, Mineral, Montezuma, Morgan, Otero, Pitkin, Prowers, Pueblo, Rio Grande, Routt, Saguache, San Miguel, Sedgwick, Summit, Washington.	5-15-2001	11-30-2002	5-30-2002	1-30-2003	S1643	Drought	44	16
KS	5-15-2001	11-30-2002	5-30-2002	1-30-2003	S1643	Drought	4
NE	5-15-2001	11-30-2002	5-30-2002	1-30-2003	S1643	Drought	5
NM	5-15-2001	11-30-2002	5-30-2002	1-30-2003	S1643	Drought	4
OK	5-15-2001	11-30-2002	5-30-2002	1-30-2003	S1643	Drought	1
NE	Banner, Chase, Cheyenne, Custer, Dawson, Deuel, Dundy, Frontier, Hayes, Hitchcock, Keith, Kimball, Perkins, Red Willow, Scotts Bluff, Sioux	10-01-2001	11-30-2002	5-30-2002	1-30-2003	S1644	Drought, unseasonably cold spring temperatures, high winds, frost.	16	17
CO	10-01-2001	11-30-2002	5-30-2002	1-30-2003	S1644	Drought, unseasonably cold spring temperatures, high winds, frost.	5
KS	10-01-2001	11-30-2002	5-30-2002	1-30-2003	S1644	Drought, unseasonably cold spring temperatures, high winds, frost.	3
SD	10-01-2001	11-30-2002	5-30-2002	1-30-2003	S1644	Drought, unseasonably cold spring temperatures, high winds, frost.	1

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: SECRETARIAL—Continued
[Fiscal Year 2002—Secretarial Designations for Production Losses]

State	Countries requested	Beginning date of disaster	Ending date of disaster	Approved by secretary	Termination date	Designation number	Description of disaster	Primary	Contiguous
WY	10-01-2001	11-30-2002	5-30-2002	1-30-2003	S1644	Drought, unseasonably cold spring temperatures, high winds, frost.	3
WY	Albany, Big Horn, Campbell, Carbon, Crook, Fremont, Hot Springs, Johnson, Laramie, Natrona, Park, Sheridan, Washakie.	1-01-2002	12-01-2002	5-31-2002	1-31-2003	S1645	Drought	13	7
CO	1-01-2002	12-01-2002	5-31-2002	1-31-2003	S1645	Drought	5
MT	1-01-2002	12-01-2002	5-31-2002	1-31-2003	S1645	Drought	6
NE	1-01-2002	12-01-2002	5-31-2002	1-31-2003	S1645	Drought	2
SD	1-01-2002	12-01-2002	5-31-2002	1-31-2003	S1645	Drought	2
TX	Haskell	1-01-2002	12-04-2002	6-04-2002	2-04-2003	S1646	Drought, high winds, excessive heat (temperatures).	1	7
GA	Evans, Montgomery, Tattnall, Toombs.	2-28-2002	2-28-2002	6-17-2002	2-18-2003	S1647	Freezing weather	4	11
NM	Bernalillo, Catron, Cibola, Colfax, Curry, De Baca, Dona Ana, Grant, Guadalupe, Harding, Hidalgo, Lea, Lincoln, Luna, McKinley, Mora, Quay, Rio Arriba, Roosevelt, San Juan, San Miguel, Sandoval, Santa Fe, Sierra, Socorro, Taos, Torrance, Union, Valencia.	1-01-2002	12-18-2002	6-17-2002	2-18-2003	S1648	Drought	29	4
WY	Campbell	1-01-2001	12-18-2002	6-17-2002	2-18-2003	S1649	Drought	1	5
MT	1-01-2001	12-18-2002	6-17-2002	2-18-2003	S1649	Drought	1
NE	Arthur, Box Butte, Franklin, Garden, Harlan, Kearney, Lincoln, Logan, McPherson, Morrill.	10-01-2001	12-20-2003	6-20-2002	2-20-2003	S1650	Drought, unseasonably cold spring temperatures, high winds, frost.	10	22
KS	10-01-2001	12-20-2003	6-20-2002	2-20-2003	S1650	Drought, unseasonably cold spring temperatures, high winds, frost.	3
UT	Entire State	1-01-2002	1-02-2003	7-01-2002	3-03-2003	S1651	Drought, Mormon crickets, grasshoppers, frost, hail, high winds.	29

AZ	1-01-2002	1-02-2003	7-01-2002	3-03-2003	S1651	Drought, Mormon crickets, grasshoppers, frost, hail, high winds.	4
CO	1-01-2002	1-02-2003	7-01-2002	3-03-2003	S1651	Drought, Mormon crickets, grasshoppers, frost, hail, high winds.	8
ID	1-01-2002	1-02-2003	7-01-2002	3-03-2003	S1651	Drought, Mormon crickets, grasshoppers, frost, hail, high winds.	4
NM	1-01-2002	1-02-2003	7-01-2002	3-03-2003	S1651	Drought, Mormon crickets, grasshoppers, frost, hail, high winds.	1
NV	1-01-2002	1-02-2003	7-01-2002	3-03-2003	S1651	Drought, Mormon crickets, grasshoppers, frost, hail, high winds.	3
WY	1-01-2002	1-02-2003	7-01-2002	3-03-2003	S1651	Drought, Mormon crickets, grasshoppers, frost, hail, high winds.	3
AZ	1-01-2001	1-12-2003	7-12-2002	3-12-2003	S1652	Drought, Mormon crickets, grasshoppers, frost, hail, high winds.	3
VA	4-15-2001	1-13-2003	7-12-2002	3-12-2003	S1653	Drought	15
NC	4-15-2001	1-13-2003	7-12-2002	3-12-2003	S1653	Drought	2
CA	1-30-2002	3-04-2002	7-12-2002	3-12-2003	S1654	Fire, wind, drought, freezing conditions.	3
TX	1-01-2002	1-12-2003	7-12-2002	3-12-2003	S1655	Drought, high winds, heat	3
MI	4-21-2002	5-31-2002	7-15-2002	3-17-2003	S1656	(1) Frost, freezing temperatures, wind (2) Cold temperatures, hail, wet weather. (3) Frost, freezing temperatures	26
IN	4-21-2002	5-31-2002	7-15-2002	3-17-2003	S1656	(1) Frost, freezing temperatures, wind (2) Cold temperatures, hail, wet weather. (3) Frost, freezing temperatures	3
CA	3-08-2002	3-24-2002	7-01-2002	3-03-2003	S1657	Freeze followed by hail	5
AZ	1-01-2002	1-02-2003	7-02-2002	3-03-2003	S1658	Drought	3
NM	1-01-2002	1-02-2003	7-02-2002	3-03-2003	S1658	Drought	6

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPBP) DISASTER DESIGNATION REQUESTS: SECRETARIAL—Continued
[Fiscal Year 2002—Secretarial Designations for Production Losses]

State	Countries requested	Beginning date of disaster	Ending date of disaster	Approved by secretary	Termination date	Designation number	Description of disaster	Primary	Contiguous
UT	Navajo Nation (located in several NE AZ, NW NM, and SE UT counties.	1-01-2002	1-02-2003	7-02-2002	3-03-2003	S1658	Drought	1
CA	Colusa	3-08-2002	3-08-2002	7-01-2002	3-03-2003	S1659	Freeze, frost	1	5
NC	Alleghany, Ashe, Avery, Mitchell, Watauga, Yancey.	5-19-2002	5-23-2002	7-23-2002	3-24-2003	S1660	Abnormally low temperatures; freezes	6	7
TN	5-19-2002	5-23-2002	7-23-2002	3-24-2003	S1660	Abnormally low temperatures; freezes	3
VA	Alamance, Alexander, Alleghany, Anson, Ashe, Burke, Cabarrus, Caldwell, Caswell, Catawba, Chatham, Cleveland, Cumberland, Davidson, Davie, Durham, Forsyth, Franklin, Gaston, Granville, Guilford, Halifax, Harnett, Hoke, Iredell, Johnston, Lee, Lincoln, McDowell, Mecklenburg, Montgomery, Moore, Nash, Northampton, Orange, Person, Randolph, Richmond, Robeson, Rockingham, Rowan, Rutherford, Scotland, Stanly, Stokes, Surry, Union, Vance, Wake, Warren, Wayne, Wilkes, Wilson, Yadkin.	5-19-2002	5-23-2002	7-23-2002	3-24-2003	S1660	Abnormally low temperatures; freezes	1
NC	1-01-2002	1-23-2003	7-23-2002	3-24-2003	S1661	Drought	54	18
SC	1-01-2002	1-23-2003	7-23-2002	3-24-2003	S1661	Drought	8
TN	1-01-2002	1-23-2003	7-23-2002	3-24-2003	S1661	Drought	1
VA	1-01-2002	1-23-2003	7-23-2002	3-24-2003	S1661	Drought	11
GA	Mitchell	4-03-2002	4-03-2002	8-02-2002	4-02-2003	S1662	Hailstorm	1	7
PA	5-20-2002	5-22-2002	8-07-2002	4-07-2003	S1663	Severe frost, freezing conditions	1	2
NY	Erie	5-20-2002	5-22-2002	8-07-2002	4-07-2003	S1663	Severe frost, freezing conditions	1
OH	5-20-2002	5-22-2002	8-07-2002	4-07-2003	S1663	Severe frost, freezing conditions	1

MN	Beltrami, Kittson, Koochiching, Lake of the Woods, Mahnommen, Marshall, Norman, Pennington, Polk, Red Lake, Roseau.	6-28-2002	2-07-2003	8-07-2002	4-07-2003	S1664	Excessive rainfall, flash flooding, hail	13	11
ND	Bedford, Orange, Rockbridge	6-28-2002	2-07-2003	8-07-2002	4-07-2003	S1664	Excessive rainfall, flash flooding, hail	5	5
VA	Aurora, Brule, Buffalo, Butte,	1-01-2001	2-08-2003	8-08-2002	4-08-2003	S1665	Drought, excessive heat	3	20
SD	Campbell, Dewey, Edmunds, Faulk, Hand, Hughes, Hyde, Lyman, Pennington, Perkins, Potter, Stanley, Sully, Ziebach, Beadle, Bennett, Brown, Charles Mix, Davison, Day, Deuel, Fall River, Gregory, Hamlin, Hanson, Hutchinson, Jerauld, Jones, Marshall, Mellette, Shannon, Spink, Todd, Tripp, Yankton, Bon Homme, Clark, Corson, Douglas, Lake, McPherson, Miner, Sanborn, Walworth, Harding, Kingsbury, McCook, Meade.	7-01-2001	2-14-2003	8-14-2002	4-14-2003	S1666	Extreme heat, wind, late frosts, drought, fire.	52	12
MN		7-01-2001	2-14-2003	8-14-2002	4-14-2003	S1666	Extreme heat, wind, late frosts, drought, fire.	3	3
MT		7-01-2001	2-14-2003	8-14-2002	4-14-2003	S1666	Extreme heat, wind, late frosts, drought, fire.	2	2
NE		7-01-2001	2-14-2003	8-14-2002	4-14-2003	S1666	Extreme heat, wind, late frosts, drought, fire.	8	8
ND		7-01-2001	2-14-2003	8-14-2002	4-14-2003	S1666	Extreme heat, wind, late frosts, drought, fire.	8	8
WY		7-01-2001	2-14-2003	8-14-2002	4-14-2003	S1666	Extreme heat, wind, late frosts, drought, fire.	3	3

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: SECRETARIAL—Continued
[Fiscal Year 2002—Secretarial Designations for Production Losses]

State	Countries requested	Beginning date of disaster	Ending date of disaster	Approved by secretary	Termination date	Designation number	Description of disaster	Primary	Contiguous
KS	Barber, Cheyenne, Comanche, Decatur, Edwards, Ellsworth, Finney, Ford, Gove, Graham, Grant, Gray, Greeley, Hamilton, Hodgeman, Jewell, Kearny, Lane, Lincoln, Logan, Meade, Morton, Norton, Osborne, Pawnee, Phillips, Rawlins, Rooks, Russell, Scott, Seward, Sheridan, Sherman, Smith, Stanton, Stevens, Thomas, Trego, Wallace, Wichita.	1-01-2002	2-14-2003	8-14-2002	4-14-2003	S1667	Drought, frost, excessive winds	40	18
NE		1-01-2002	2-14-2003	8-14-2002	4-14-2003	S1667	Drought, frost, excessive winds	3
OK		1-01-2002	2-14-2003	8-14-2002	4-14-2003	S1667	Drought, frost, excessive winds	5
NE	Blaine, Buffalo, Cherry, Dawes, Furnas, Gosper, Grant, Hooker, Phelps, Sheridan, Thomas.	10-01-2001	2-14-2003	8-14-2002	4-14-2003	S1668	Unseasonably cold spring temperatures, drought, high winds, frost, extreme heat, hail, grasshopper infestation.	11	21
KS		10-01-2001	2-14-2003	8-14-2002	4-14-2003	S1668	Unseasonably cold spring temperatures, drought, high winds, frost, extreme heat, hail, grasshopper infestation.	3
SD		10-01-2001	2-14-2003	8-14-2002	4-14-2003	S1668	Unseasonably cold spring temperatures, drought, high winds, frost, extreme heat, hail, grasshopper infestation.	5
CA	Riverside	2-01-2002	2-28-2002	8-16-2002	4-16-2003	S1669	Freezing conditions, followed by Santa Ana winds.	1	4
AZ	La Paz	2-01-2002	2-28-2002	8-16-2002	4-16-2003	S1669	Freezing conditions, followed by Santa Ana winds.	1
CA	Solano	3-06-2002	3-10-2002	8-16-2002	4-16-2003	S1670	Hail, extreme freezing conditions	1	6

CO	Arapahoe, Cheyenne, Delta, Gunnison, Lincoln, Moffat, Montrose, Ouray, Park, Rio Blanco, Teller, Weld, Yuma.	5-15-2001	2-16-2003	8-16-2002	4-16-2003	SI643, Amend-ment 1.	Drought	13
KS	Wallace	5-15-2001	2-16-2003	8-16-2002	4-16-2003	SI643	Drought	1
NE	Dundy	5-15-2001	2-16-2003	8-16-2002	4-16-2003	SI643, Amend-ment 1.	Drought	1
NY	Chautauqua, Columbia, Dutchess, Essex, Greene, Orange, Rensselaer, Saratoga, Schenectady, Schoharie, Steuben, Ulster, Wayne, Yates.	4-06-2002	5-27-2002	8-16-2002	4-16-2003	SI671	Various disasters for each county including: Excessive rain, freeze, frost, hail, high winds, snow, wet weather.	14	24
CT	Fairfield	4-06-2002	5-27-2002	8-16-2002	4-16-2003	SI671	Excessive rain, freeze, frost, hail, high winds, snow, wet weather.	2
MA	Litchfield	4-06-2002	5-27-2002	8-16-2002	4-16-2003	SI671	Excessive rain, freeze, frost, hail, high winds, snow, wet weather.	1
PA	Erie, Potter, Pike, Tioga, Warren	4-06-2002	5-27-2002	8-16-2002	4-16-2003	SI671	Excessive rain, freeze, frost, hail, high winds, snow, wet weather.	5
VT	Addison, Bennington, Chittenden	4-06-2002	5-27-2002	8-16-2002	4-16-2003	SI671	Excessive rain, freeze, frost, hail, high winds, snow, wet weather.	3
TX	Duval, Live Oak	12-01-2001	2-16-2003	8-16-2002	4-16-2003	SI672	Drought, high winds	2	10
TX	Jim Wells, Kleberg	12-11-2001	2-16-2003	8-16-2002	4-16-2003	SI673	Drought, high winds, excessive heat (temperatures).	2	6
VA	Grayson, Smyth, Washington	5-19-2002	5-23-2002	8-16-2002	4-16-2003	SI674	Freeze	3	8
NC	Alleghany, Ashe, Surry	5-19-2002	5-23-2002	8-16-2002	4-16-2003	SI674	Freeze	3
TN	Johnson, Sullivan	5-19-2002	5-23-2002	8-16-2002	4-16-2003	SI674	Freeze	2
TX	Gillespie, Karnes	1-01-2002	2-21-2003	8-20-2002	4-21-2003	SI675	Drought	2	13
IA	Clayton, Clinton, Delaware, Jackson, Jones, Scott.	6-03-2002	6-07-2002	8-22-2002	4-22-2003	SI676	Severe storms, heavy rains, flooding, flash flooding.	6	8
IL	6-03-2002	6-07-2002	8-22-2002	4-22-2003	SI676	Severe storms, heavy rains, flooding, flash flooding.	4
WI	6-03-2002	6-07-2002	8-22-2002	4-22-2003	SI676	Severe storms, heavy rains, flooding, flash flooding.	2

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: SECRETARIAL—Continued
[Fiscal Year 2002—Secretarial Designations for Production Losses]

State	Countries requested	Beginning date of disaster	Ending date of disaster	Approved by secretary	Termination date	Designation number	Description of disaster	Primary	Contiguous
ND	Adams, Barnes, Benson, Billings, Bottineau, Bowman, Burke, Burleigh, Cass, Cavalier, Dickey, Divide, Dunn, Eddy, Emmons, Foster, Golden Valley, Grand Forks, Grant, Griggs, Hettinger, Kidder, La Moure, Logan, McHenry, McIntosh, McKenzie, McLean, Mercer, Morton, Nelson, Oliver, Pembina, Pierce, Ramsey, Ransom, Renville, Sheridan, Rolette, Sargent, Sheridan, Sioux, Slope, Stark, Steele, Stutsman, Towner, Traill, Walsh, Ward, Wells.	4-01-2002	2-22-2003	8-22-2002	4-22-2003	S1677	Drought, fire, insects, above and below normal temperatures, frost, severe storms, hail, flooding, wind, crop disease.	51	2
MN	4-01-2002	2-22-2003	8-22-2002	4-22-2003	S1677	Drought, fire, insects, above and below normal temperatures, frost, severe storms, hail, flooding, wind, crop disease.	7
MT	4-01-2002	2-22-2003	8-22-2002	4-22-2003	S1677	Drought, fire, insects, above and below normal temperatures, frost, severe storms, hail, flooding, wind, crop disease.	5
SD	4-01-2002	2-22-2003	8-22-2002	4-22-2003	S1677	Drought, fire, insects, above and below normal temperatures, frost, severe storms, hail, flooding, wind, crop disease.	8

NE	Adams, Antelope, Boone, Boyd, Brown, Burt, Butler, Cass, Cedar, Clay, Colfax, Cuming, Dakota, Dixon, Dodge, Douglas, Fillmore, Gage, Garfield, Greeley, Hall, Hamilton, Holt, Howard, Jefferson, Johnson, Keya Paha, Knox, Lancaster, Loup, Madison, Merrick, Nance, Nemaha, Nuckolls, Otoe, Pawnee, Pierce, Platte, Polk, Richardson, Rock, Saline, Sarpy, Saunders, Seward, Sherman, Stanton, Thayer, Thurston, Valley, Washington, Wayne, Webster, Wheeler, York,	10-01-2001	2-22-2003	8-22-2002	4-22-2003	S1678	Unseasonably cold spring temperatures, high winds, frost, extreme heat, hail, grasshopper infestation, drought.	56	6
IA	10-01-2001	2-22-2003	8-22-2002	4-22-2003	S1678	Unseasonably cold spring temperatures, drought, high winds, frost, extreme heat, hail, grasshopper infestation.	6
KS	10-01-2001	2-22-2003	8-22-2002	4-22-2003	S1678	Unseasonably cold spring temperatures, drought, high winds, frost, extreme heat, hail, grasshopper infestation.	8
MO	10-01-2001	2-22-2003	8-22-2002	4-22-2003	S1678	Unseasonably cold spring temperatures, drought, high winds, frost, extreme heat, hail, grasshopper infestation.	2
SD	10-01-2001	2-22-2003	8-22-2002	4-22-2003	S1678	Unseasonably cold spring temperatures, drought, high winds, frost, extreme heat, hail, grasshopper infestation.	8

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: SECRETARIAL—Continued
[Fiscal Year 2002—Secretarial Designations for Production Losses]

State	Counties requested	Beginning date of disaster	Ending date of disaster	Approved by secretary	Termination date	Designation number	Description of disaster	Primary	Contiguous
OK	Alfalfa, Beaver, Beckham, Blaine, Caddo, Canadian, Cimarron, Comanche, Cotton, Custer, Dewey, Ellis, Garfield, Grady, Grant, Greer, Harmon, Harger, Jackson, Jefferson, Kiowa, Kingfisher, Major, Roger Mills, Stephens, Texas, Tillman, Washita, Woods, Woodward.	8-01-2001	2-23-2003	8-22-2002	4-22-2003	S1679	Drought	30	9
KS		8-01-2001	2-23-2003	8-22-2002	4-22-2003	S1679	Drought	1
TX		8-01-2001	2-23-2003	8-22-2002	4-22-2003	S1679	Drought	13
KS	Crawford, Ford, Jewell, Kiowa, Neosho, Pratt.	5-07-2002	5-26-2002	8-22-2002	4-22-2003	S1680	Severe storms including, hail, high winds, tornadoes, excessive rain, flash flooding, flooding, lightning.	6	22
MO		5-07-2002	5-26-2002	8-22-2002	4-22-2003	S1680	Severe storms including, hail, high winds, tornadoes, excessive rain, flash flooding, flooding, lightning.	3
NE		5-07-2002	5-26-2002	8-22-2002	4-22-2003	S1680	Severe storms including, hail, high winds, tornadoes, excessive rain, flash flooding, flooding, lightning.	2
WY	Lincoln, Uinta	1-01-2002	3-11-2003	9-11-2002	5-12-2003	S1681	Drought	2	2
ID	Adair, BOLLINGER, Cape Girardeau, Charlton, Howard, Knox.	1-01-2002	3-11-2003	9-11-2002	5-12-2003	S1681	Drought	2
MO	Laclede, Lafayette, Lincoln, Macon, Madison, Moniteau, Scott, Wayne.	3-01-2002	3-20-2003	9-20-2002	5-20-2003	S1682	Hail, tornadoes, high winds, flooding, unseasonably cool temperatures.	14	41
IL		3-01-2002	3-20-2003	9-20-2002	5-20-2003	S1682	Excessive rain, flooding	3
OH	Auglaize, Fairfield, Morgan, Muskingum, Perry, Portage, Ross, Summit, Wood.	3-01-2002	5-31-2002	9-20-2002	5-20-2003	S1683	Frost, freeze, hail, tornado	9	35
VA		5-19-2002	5-23-2002	9-20-2002	5-20-2003	S1684	Freeze, frost conditions	1	6
NC	Carroll	5-19-2002	5-23-2002	9-20-2002	5-20-2003	S1684	Freeze, frost conditions	1
WA	Chelan, Douglas, Okanogan	4-23-2002	5-07-2002	9-20-2002	5-20-2003	S1685	Freezing temperatures	3	8

KS	Clark, Clay, Geary, Mitchell, Pottawatomie, Riley, Rush, Sa- line.	1-01-2002	3-18-2003	9-18-2002	5-19-2003	SI686	Drought	8	9
OR	Wasco	9-01-2001	3-18-2003	9-18-2002	5-19-2003	SI687	Drought	1	7
WA	9-01-2001	3-18-2003	9-18-2002	5-19-2003	SI687	Drought	1	1
NY	Albany, Clinton, Erie	4-15-2002	5-22-2002	9-18-2002	5-19-2003	SI688	Albany: Freeze, frost, excessive rain; Clinton: freeze, Erie: Freeze, frost	3	9
VT	Albany, Clinton, Erie	4-15-2002	5-22-2002	9-18-2002	5-19-2003	SI688	Albany: Freeze, frost, excessive rain; Clinton: freeze, Erie: Freeze, frost	3	2
TN	Carter, Johnson, Lauderdale, Mor- gan, Scott, Shelby.	4-01-2002	3-18-2003	9-18-2002	5-19-2003	SI689	Flooding, frost, freeze, cold wind, low temperatures, drought, high tem- peratures.	6	14
AR	4-01-2002	3-18-2003	9-18-2002	5-19-2003	SI689	Flooding, frost, freeze, cold wind, low temperatures, drought, high tem- peratures.	2
KY	4-01-2002	3-18-2003	9-18-2002	5-19-2003	SI689	Flooding, frost, freeze, cold wind, low temperatures, drought, high tem- peratures.	2
MS	4-01-2002	3-18-2003	9-18-2002	5-19-2003	SI689	Flooding, frost, freeze, cold wind, low temperatures, drought, high tem- peratures.	2
TX	Matagorda	2-01-2002	6-20-2002	9-26-2002	5-26-2003	SI690	Drought	1	4
TX	Jim Hogg	1-01-2002	3-26-2003	9-26-2002	5-26-2003	SI691	Drought, high temperatures, high winds.	1	5
TX	Edwards	1-01-2002	3-26-2003	9-26-2002	5-26-2003	SI692	Drought, excessive temperatures	1	7
TOTAL ACTIVE	1363	1995

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPB) DISASTER DESIGNATION REQUESTS: FINAL TOTAL—SECRETARIAL
[Fiscal Year 2003—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contig- uous
VT	Essex, Franklin, Grand Isle, Lamoille, Windham, Windsor.	4-01-2001 ..	5-21-2003 ..	11-21-2002	7-21-2003 ..	SI620, Amend- ment 1.	Drought	6	6

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTAL—SECRETARIAL—Continued
[Fiscal Year 2003—Secretarial Designations for Production Losses]

State	Countries requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
TN	Dyer	5-10-2002	5-25-2002	10-21-2002	6-23-2003	S1689, Amendment 1.	Flooding	1	3
MO		5-10-2002	5-25-2002	10-21-2002	6-23-2003	S1689, Amendment 1.			1
OH	ENTIRE STATE	3-01-2002	4-09-2003	10-09-2002	6-09-2003	S1693	Drought	88	
IN		3-01-2002	4-09-2003	10-09-2002	6-09-2003	S1693	Drought		10
KY		3-01-2002	4-09-2003	10-09-2002	6-09-2003	S1693	Drought		9
MI		3-01-2002	4-09-2003	10-09-2002	6-09-2003	S1693	Drought		3
PA		3-01-2002	4-09-2003	10-09-2002	6-09-2003	S1693	Drought		5
WV		3-01-2002	4-09-2003	10-09-2002	6-09-2003	S1693	Drought		12
PA	Adams, Allegheny, Armstrong, Beaver, Bedford, Berks, Blair, Bradford, Bucks, Butler, Cambria, Cameron, Carbon, Centre, Chester, Clearfield, Clinton, Columbia, Cumberland, Dauphin, Elk, Forest, Franklin, Fulton, Huntingdon, Indiana, Juniata, Lackawanna, Lancaster, Lawrence, Lebanon, Lehigh, Luzerne, Lycoming, McKean, Mifflin, Monroe, Montgomery, Montour, Northampton, Northumberland, Perry, Pike, Potter, Schuylkill, Snyder, Somerset, Sullivan, Susquehanna, Union, Venango, Wayne, Wyoming, York.	1-01-2002	4-11-2003	10-11-2002	6-11-2003	S1694	Drought	54	11
DE		1-01-2002	4-11-2003	10-11-2002	6-11-2003	S1694	Drought		1
MD		1-01-2002	4-11-2003	10-11-2002	6-11-2003	S1694	Drought		8
NJ		1-01-2002	4-11-2003	10-11-2002	6-11-2003	S1694	Drought		5
NY		1-01-2002	4-11-2003	10-11-2002	6-11-2003	S1694	Drought		9
OH		1-01-2002	4-11-2003	10-11-2002	6-11-2003	S1694	Drought		2
WV		1-01-2002	4-11-2003	10-11-2002	6-11-2003	S1694	Drought		1

GA	Entire State except for Bibb, Camden, Crawford, Early, Evans, Glynn, Liberty, Long, McIntosh, Peach, Tattnall, Wayne counties.	1-01-2002 ..	4-11-2003 ..	10-11-2002	6-11-2003 ..	SI695	Drought	147	10
AL	1-01-2002 ..	4-11-2003 ..	10-11-2002	6-11-2003 ..	SI695	Drought	11
FL	1-01-2002 ..	4-11-2003 ..	10-11-2002	6-11-2003 ..	SI695	Drought	9
NC	1-01-2002 ..	4-11-2003 ..	10-11-2002	6-11-2003 ..	SI695	Drought	4
SC	1-01-2002 ..	4-11-2003 ..	10-11-2002	6-11-2003 ..	SI695	Drought	10
TN	1-01-2002 ..	4-11-2003 ..	10-11-2002	6-11-2003 ..	SI695	Drought	4
GA	Bibb, Crawford, Early, Peach	1-01-2002 ..	4-11-2003 ..	10-11-2002	6-11-2003 ..	SI695	Drought
			4/31/03	10-21-2002	6-23-2003 ..	SI695, Amendment 1.	Drought	4
GA	Evans	1-01-2002 ..	5-21-2003 ..	11-21-2002	7-21-2003 ..	SI695, Amendment 2.	Drought	1
OR	Gilliam, Morrow	9-01-2000 ..	4-16-2003 ..	10-16-2002	6-16-2003 ..	SI696	Drought	2	2
WA	9-01-2000 ..	4-16-2003 ..	10-16-2002	6-16-2003 ..	SI696	Drought	1
AR	Arkansas, Clay, Craighead, Crittenden, Cross, Greene, Independence, Jefferson, Lawrence, Lee, Mississippi, Monroe, Poinsett, Randolph, St. Francis, Sebastian, Woodruff.	3-18-2002 ..	4-16-2003 ..	10-16-2002	6-16-2003 ..	SI697	Excessive rain, flooding, hail	17	18
MO	3-18-2002 ..	4-16-2003 ..	10-16-2002	6-16-2003 ..	SI697	Excessive rain, flooding, hail	4
MS	3-18-2002 ..	4-16-2003 ..	10-16-2002	6-16-2003 ..	SI697	Excessive rain, flooding, hail	2
OK	3-18-2002 ..	4-16-2003 ..	10-16-2002	6-16-2003 ..	SI697	Excessive rain, flooding, hail	2
TN	3-18-2002 ..	4-16-2003 ..	10-16-2002	6-16-2003 ..	SI697	Excessive rain, flooding, hail	4
NU	Atlantic, Bergen, Burlington, Camden, Cape May, Cumberland, Essex, Gloucester, Hunterdon, Mercer, Middlesex, Monmouth, Morris, Ocean, Passaic, Salem, Somerset, Sussex, Warren.	3-04-2002 ..	4-17-2003 ..	10-17-2002	6-17-2003 ..	SI698	Drought, excessive temperatures	19	2
DE	3-04-2002 ..	4-17-2003 ..	10-17-2002	6-17-2003 ..	SI698	Drought, excessive temperatures	3
NY	3-04-2002 ..	4-17-2003 ..	10-17-2002	6-17-2003 ..	SI698	Drought, excessive temperatures	6
DE	Entire State	1-01-2002 ..	4-17-2003 ..	10-17-2002	6-17-2003 ..	SI699	Drought, high temperatures	3
NU	1-01-2002 ..	4-17-2003 ..	10-17-2002	6-17-2003 ..	SI699	Drought, high temperatures	4
PA	1-01-2002 ..	4-17-2003 ..	10-17-2002	6-17-2003 ..	SI699	Drought, high temperatures	2

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTAL—SECRETARIAL—Continued
[Fiscal Year 2003—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
IL	Alexander, Bond, Boone, Calhoun, Clark, Clay, Clinton, Coles, Cook, Crawford, Cumberland, Dekalb, Dupage, Edgar, Edwards, Effingham, Fayette, Franklin, Gallatin, Greene, Grundy, Hamilton, Hardin, Jackson, Jasper, Jefferson, Jersey, Johnson, Kane, Kendall, Lake, LaSalle, Lawrence, Lee, Madison, Marion, Massac, McHenry, Monroe, Montgomery, Ogle, Perry, Piatt, Pope, Pulkaski, Randolph, Richland, Saline, Scott, Shelby, St. Clair, Union, Wabash, Washington, Wayne, White, Will, Williamson.	1-01-2002 ..	4-17-2003 ..	10-17-2002	6-17-2003 ..	S1700	Drought	58	22
IN	1-01-2002 ..	4-17-2003 ..	10-17-2002	6-17-2003 ..	S1700	Drought	7
KY	1-01-2002 ..	4-17-2003 ..	10-17-2002	6-17-2003 ..	S1700	Drought	5
MO	1-01-2002 ..	4-17-2003 ..	10-17-2002	6-17-2003 ..	S1700	Drought	11
WI	1-01-2002 ..	4-17-2003 ..	10-17-2002	6-17-2003 ..	S1700	Drought	3
MD	Anne Arundel, Baltimore, Calvert, Caroline, Carroll, Cecil, Charles, Dorchester, Frederick, Harford, Howard, Kent, Montgomery, Prince George's, Queen Anne's, St. Mary's, Somerset, Talbot, Washington, Wicomico, Worcester.	1-01-2002 ..	4-17-2003 ..	10-17-2002	6-17-2003 ..	S1701	Drought, excessive heat	21	2
DE	1-01-2002 ..	4-17-2003 ..	10-17-2002	6-17-2003 ..	S1701	Drought, excessive heat	3
PA	1-01-2002 ..	4-17-2003 ..	10-17-2002	6-17-2003 ..	S1701	Drought, excessive heat	5
VA	1-01-2002 ..	4-17-2003 ..	10-17-2002	6-17-2003 ..	S1701	Drought, excessive heat	10
WV	1-01-2002 ..	4-17-2003 ..	10-17-2002	6-17-2003 ..	S1701	Drought, excessive heat	3

IN	Adams, Allen, Bartholomew, Blackford, Brown, Clark, Clay, Crawford, Davies, Dearborn, Decatur, Dekalb, Delaware, Dubois, Elkhart, Fayette, Floyd, Franklin, Fulton, Gibson, Grant, Greene, Hamilton, Hancock, Harrison, Henry, Huntington, Jackson, Jay, Jefferson, Jennings, Johnson, Knox, Kosciusko, Lagrange, Lake, LaPorte, Lawrence, Madison, Marion, Marshall, Martin, Monroe, Morgan, Noble, Ohio, Orange, Owen, Perry, Pike, Porter, Posey, Randolph, Ripley, Rush, Scott, Shelby, Spencer, St. Joseph, Starke, Steuben, Sullivan , Switzerland, Tipton, Union, Vanderburg, Vermillion, Vigo, Wabash, Warrick, Washington, Wayne, Wells, Whitley.	6-01-2002 ..	8-25-2002 ..	10-18-2002	6-18-2003 ..	S1702	Drought	74	13
IL	6-01-2002 ..	8-25-2002 ..	10-18-2002	6-18-2003 ..	S1702	Drought	11
KY	6-01-2002 ..	8-25-2002 ..	10-18-2002	6-18-2003 ..	S1702	Drought	12
MI	6-01-2002 ..	8-25-2002 ..	10-18-2002	6-18-2003 ..	S1702	Drought	5
AL	All counties except, Baldwin, Clarke, Escambia, Lamar, Marion, Mobile, Washington, Winston.	1-01-2002 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1703	Drought	59	7
FL	1-01-2002 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1703	Drought	3
MS	1-01-2002 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1703	Drought	8
TN	1-01-2002 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1703	Drought	6
AL	Baldwin, Clarke, Escambia, Lamar, Marion, Mobile, Washington, Winston.	1-01-2002 ..	5-21-2003 ..	11-21-2002	7-21-2003 ..	S1703, Amendment 1.	Drought	8

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTAL—SECRETARIAL—Continued
[Fiscal Year 2003—Secretarial Designations for Production Losses]

State	Countries requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
LA	Ascension, Avoyelles, Beauregard, Bienville, Bossier, Caddo, Caldwell, Catahoula, Claiborne, Concordia, DeSoto, East Baton Rouge, East Feliciana, Franklin, Grant, Iberville, Jackson, Lafourche, LaSalle, Lincoln, Livingston, Matchitoches, Ouachita, Pointe Coupee, Rapides, Red River, Richland, Sabine, St. Helena, St. James, St. Landry, St. Tammany, Tangipahoa, Tensas, Terrebonne, Union, Vernon, Washington, Webster, West Baton Rouge, West Carroll, West Feliciana, Winn.	4-02-2002 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1704	Drought	43	18
AR	4-02-2002 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1704	Drought	6
MS	4-02-2002 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1704	Drought	11
TX	4-02-2002 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1704	Drought	7
IA	Adams, Audubon, Cass, Clay, Decatur, Dickinson, Fremont, Harrison, Lyon, Mills, Monona, Montgomery, O'Brien, Page, Palo Alto, Pottawattamie, Shelby, Taylor.	9-01-2001 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1705	Drought, high winds, cold spring temperatures, grasshopper infestation, extreme heat, hail.	18	19
MN	9-01-2001 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1705	3
MO	9-01-2001 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1705	4
SD	9-01-2001 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1705	2

TX	Andrews, Aransas, Archer, Armstrong, Atascosa, Bailey, Bandera, Baylor, Bee, Bexar, Blanco, Bosque, Brewster, Briscoe, Burnet, Cameron, Carson, Castro, Clay, Cochran, Coke, Coleman, Comal, Conell, Cottle, Crane, Crockett, Crosby, Culberson, Dallam, Dawson, Deaf Smith, DeWitt, Dickens, Dimmit, Donley, Ector, El Paso, Erath, Fisher, Floyd, Frio, Gaines, Goliad, Gonzales, Gray, Guadalupe, Hale, Hall, Hamilton, Hansford, Hartley, Hays, Hemphill, Hockley, Hood, Hudspeth, Hutchinson, Irion, Jack, Jeff Davis, Johnson, Jones, Kendall, Kenedy, Kent, Kerr, Kimble, King, Kinney, Knox, La Salle, Lamb, Lampasas, Lipscomb, Llano, Lynn, Mason, McCulloch, McMullen, Medina, Midland, Mills, Montague, Moore, Motley, Nueces, Ochiltree, Oldham, Palo Pinto, Parker, Parmer, Potter, Randall, Reagan, Real, Refugio, Roberts, San Patricio, San Saba, Scurry, Shackelford, Sherman, Somervell, Sterling, Stonewall, Swisher, Tarrant, Taylor, Terrell, Throckmorton, Travis, Upton, Uvalde, Val Verde, Ward, Wichita, Wilson, Winkler, Wise, Yoakum, Young.	1-01-2002 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1706	Drought, excessive temperatures	122	58
NM	1-01-2002 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1706	Drought, excessive temperatures	8
OK	1-01-2002 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1706	Drought, excessive temperatures	9

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTAL—SECRETARIAL—Continued
[Fiscal Year 2003—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
VA	Appomattox, Augusta, Bedford, Bland, Botetourt, Buckingham, Campbell, Caroline, Craig, Cumberland, Floyd, Franklin, Goochland, Greene, Hanover, Henry, King And Queen, King George, King William, Lunenburg, Madison, Mecklenburg, Middlesex, Montgomery, Nelson, New Kent, Nottoway, Page, Pittsylvania, Powhatan, Prince William, Richmond, Rockingham, Spotsylvania, Stafford, Suffolk city, Surry, Westmoreland, Wythe.	1-01-2002 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1707	Drought, excessive heat	39	41
MD	1-01-2002 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1707	2
NC	1-01-2002 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1707	8
WV	1-01-2002 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1707	4
KS	Clark, Finney, Norton, Phillips, Reno, Rice, Rooks.	6-09-2002 ..	7-05-2002 ..	10-21-2002	6-23-2003 ..	S1708	Hail, high winds, tornadoes, excessive rain, flash flooding, flooding, lightning.	7	21
NE	6-09-2002 ..	7-05-2002 ..	10-21-2002	6-23-2003 ..	S1708	Hail, high winds, tornadoes, excessive rain, flash flooding, flooding, lightning.	3
OK	6-09-2002 ..	7-05-2002 ..	10-21-2002	6-23-2003 ..	S1708	Hail, high winds, tornadoes, excessive rain, flash flooding, flooding, lightning.	2
NH	Entire State	6-01-2001 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1709	Drought	10
MA	6-01-2001 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1709	Drought	4
ME	6-01-2001 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1709	Drought	2
VT	6-01-2001 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1709	Drought	5
RI	Entire State	10-01-2001 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1710	Drought	5
CT	10-01-2001 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1710	Drought	2
MA	10-01-2001 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1710	Drought	3
KY	Entire State	1-01-2002 ..	4-24-2003 ..	10-24-2002	6-24-2003 ..	S1711	Drought	6
IL	1-01-2002 ..	4-24-2003 ..	10-24-2002	6-24-2003 ..	S1711	Drought	13
IN	1-01-2002 ..	4-24-2003 ..	10-24-2002	6-24-2003 ..	S1711	Drought

MO	1-01-2002 ..	4-24-2003 ..	10-24-2002	6-24-2003 ..	S1711	Drought	1
TN	1-01-2002 ..	4-24-2003 ..	10-24-2002	6-24-2003 ..	S1711	Drought	14
VA	1-01-2002 ..	4-24-2003 ..	10-24-2002	6-24-2003 ..	S1711	Drought	4
WV	1-01-2002 ..	4-24-2003 ..	10-24-2002	6-24-2003 ..	S1711	Drought	2
SD	7-01-2001 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1712	Drought, extreme heat, winds, late frosts, fire.	3
NV	1-01-2002 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1713	Drought, Mormon crickets, grasshoppers.	17
CA	1-01-2002 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1713	Drought, Mormon crickets, grasshoppers.	10
ID	1-01-2002 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1713	Drought, Mormon crickets, grasshoppers.	2
OR	1-01-2002 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1713	Drought, Mormon crickets, grasshoppers.	3
NV	1-01-2001 ..	4-21-2003 ..	11-21-2002	6-23-2003 ..	S1713, Amendment 1.	Severe insect infestations	17
ID	1-01-2002 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1714	Drought	13	12
MT	1-01-2002 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1714	Drought	3
NV	1-01-2002 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1714	Drought	1
OR	1-01-2002 ..	4-21-2003 ..	10-21-2002	6-23-2003 ..	S1714	Drought	3
ID	1-01-2002 ..	6-04-2003 ..	12-04-2002	8-04-2003 ..	S1714, Amendment 1.	Drought	3
KS	1-01-2002 ..	4-25-2003 ..	10-25-2002	6-25-2002 ..	S1715	Drought	54	3
MO	1-01-2002 ..	4-25-2003 ..	10-25-2002	6-25-2002 ..	S1715	Drought	12

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTAL—SECRETARIAL—Continued
[Fiscal Year 2003—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
OK	1-01-2002 ..	4-25-2003 ..	10-25-2002 ..	6-25-2002 ..	S1715	Drought	3
WY	Converse, Goshen, Niobrara, Platte, Sublette, Sweetwater, Weston.	1-01-2002 ..	4-28-2003 ..	10-28-2002 ..	6-30-2003 ..	S1716	Drought	7	5
CO	1-01-2002 ..	4-28-2003 ..	10-28-2002 ..	6-30-2003 ..	S1716	Drought	1
NE	1-01-2002 ..	4-28-2003 ..	10-28-2002 ..	6-30-2003 ..	S1716	Drought	2
SD	1-01-2002 ..	4-28-2003 ..	10-28-2002 ..	6-30-2003 ..	S1716	Drought	4
UT	1-01-2002 ..	4-28-2003 ..	10-28-2002 ..	6-30-2003 ..	S1716	Drought	2
WI	Door	5-15-2002 ..	5-20-2002 ..	11-08-2002 ..	7-08-2003 ..	S1717	Frost, freezing temperatures	1	1
MN	Benton, Crow Wing, Jackson, Mille Lacs, Nobles, Rock.	4-01-2002 ..	7-10-2002 ..	11-15-2002 ..	7-15-2003 ..	S1718	Crow Wing, Jackson, Nobles, Rock; Drought Benton, Mille Lacs; Heavy rain, hail, flooding, severe thunderstorms.	6	12
IA	4-01-2002 ..	7-10-2002 ..	11-15-2002 ..	7-15-2003 ..	S1718	Crow Wing, Jackson, Nobles, Rock; Drought Benton, Mille Lacs; Heavy rain, hail, flooding, severe thunderstorms.	4
SD	4-01-2002 ..	7-10-2002 ..	11-15-2002 ..	7-15-2003 ..	S1718	Crow Wing, Jackson, Nobles, Rock; Drought Benton, Mille Lacs; Heavy rain, hail, flooding, severe thunderstorms.	2
NY	Albany, Allegany, Broome, Cattaraugus, Cayuga, Chautauqua, Chenango, Clinton, Cortland, Delaware, Erie, Essex, Franklin, Fulton, Genesee, Herkimer, Jefferson, Lewis, Livingston, Madison, Monroe, Montgomery, Niagara, Oneida, Onondaga, Ontario, Orleans, Oswego, Otsego, Rensselaer, Rockland, St. Lawrence, Saratoga, Steuben, Suffolk, Sullivan, Warren, Washington, Wayne, Wyoming, Yates.	6-01-2002 ..	5-15-2003 ..	11-15-2002 ..	7-15-2003 ..	S1719	Drought	41	15
CT	6-01-2002 ..	5-15-2003 ..	11-15-2002 ..	7-15-2003 ..	S1719	Drought	4
MA	6-01-2002 ..	5-15-2003 ..	11-15-2002 ..	7-15-2003 ..	S1719	Drought	1
NU	6-01-2002 ..	5-15-2003 ..	11-15-2002 ..	7-15-2003 ..	S1719	Drought	2

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTAL—SECRETARIAL—Continued
[Fiscal Year 2003—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
MA	Barnstable, Berkshire, Bristol, Dukes, Essex, Franklin, Hampden, Hampshire, Middlesex, Norfolk, Plymouth, Worcester.	10-01-2001	5-21-2003 ..	11-21-2002	7-21-2003 ..	S1725	Drought	12	2
CT	10-01-2001	5-21-2003 ..	11-21-2002	7-21-2003 ..	S1725	Drought	3
NY	10-01-2001	5-21-2003 ..	11-21-2002	7-21-2003 ..	S1725	Drought	3
VT	10-01-2001	5-21-2003 ..	11-21-2002	7-21-2003 ..	S1725	Drought	1
OR	Baker, Jefferson, Umatilla	10-01-2000	5-21-2003 ..	11-21-2002	7-21-2003 ..	S1726	Drought, colder than normal weather, frosts.	3	11
WA	10-01-2000	5-21-2003 ..	11-21-2002	7-21-2003 ..	S1726	Drought, colder than normal weather, frosts.	5
TN	Anderson, Bedford, Benton, Bledsoe, Blount, Bradley, Campbell, Cannon, Carroll, Carter, Chester, Claiborne, Clay, Coffee, Crockett, Cumberland, De Kalb, Dyer, Fentress, Franklin, Giles, Greene, Grundy, Hamilton, Hancock, Hardeman, Hardin, Hawkins, Haywood, Houston, Jackson, Jefferson, Johnson, Knox, Lake, Lauderdale, Lawrence, Lincoln, Loudon, McMinn, McNairy, Macon, Madison, Marshall, Maury, Meigs, Monroe, Moore, Obion, Overton, Pickett, Polk, Putnam, Rhea, Roane, Rutherford, Sevier, Shelby, Smith, Stewart, Sullivan, Sumner, Tipton, Trousdale, Unicoi, Union, Warren, Washington, Wayne, Weakley, Williamson, Wilson.	1-01-2002 ..	5-21-2003 ..	11-21-2002	7-21-2003 ..	S1727	Drought, high temperatures, high wind, hail.	72	23
AL	1-01-2002 ..	5-21-2003 ..	11-21-2002	7-21-2003 ..	S1727	Drought, high temperatures, high wind, hail.	4
AR	1-01-2002 ..	5-21-2003 ..	11-21-2002	7-21-2003 ..	S1727	Drought, high temperatures, high wind, hail.	2

GA	1-01-2002 ..	5-21-2003 ..	11-21-2002	7-21-2003 ..	S1727	Drought, high temperatures, high wind, hail.	6
KY	1-01-2002 ..	5-21-2003 ..	11-21-2002	7-21-2003 ..	S1727	Drought, high temperatures, high wind, hail.	15
TN	Cooke	1-01-2002 ..	10-18-2002	12-13-2002	8-13-2002	S1727, Amend-ment 1.	Drought, high temperatures, high wind, hail, spring flooding, late freezes.	1
WA	Franklin	9-01-2001 ..	5-27-2003 ..	11-27-2002	7-28-2003 ..	S1728	(1) Drought, High winds, excessive rainfall, hailstorms. (2) Freezing weather, high winds ...	1	6
SD	Kingsbury	7-28-2002 ..	7-28-2002 ..	12-13-2002	8-13-2002 ..	S1729	Hailstorm	1	7
CT	Entire State (8 counties)	10-01-2001	6-30-2003 ..	12-30-2002	9-01-2003 ..	S1730	Drought	8
ID	Bear Lake, Butte, Custer, Franklin, Lemhi, Oneida, Payette, Power.	1-01-2002 ..	6-30-2003 ..	12-30-2002	9-01-2003 ..	S1731	Drought	8	2
UT	1-01-2002 ..	6-30-2003 ..	12-30-2002	9-01-2003 ..	S1731	Drought	3
KS	Meade, Rice	8-12-2002 ..	8-13-2002 ..	12-30-2002	9-01-2003 ..	S1732	Hail, high winds, excessive rain, flash flooding, flooding.	2	10
OK	8-12-2002 ..	8-13-2002 ..	12-30-2002	9-01-2003 ..	S1732	Hail, high winds, excessive rain, flash flooding, flooding.	1
NY	Alegany, Broome, Cattaraugus, Cayuga, Clinton, Dutchess, Franklin, Jefferson, Madison, Niagara, Ontario, Otsego, Putnam, Rensselaer, Schuyler, Seneca, Steuben, Toga, Tompkins, Ulster, Wayne, Westchester, Wyoming, Yates.	4-01-2002 ..	6-30-2002 ..	12-30-2002	9-01-2003 ..	S1733	Various disasters: Excessive Rain, Flash Flooding, Flooding, Freeze, Frost , Hail, High Winds, Lightning, Tornado.	25	29
CT	4-24-2002 ..	5-31-2002 ..	12-30-2002	9-01-2003 ..	S1733	Various disasters: Excessive Rain, Freeze, Frost , Hail, High Winds.	2
MA	6-05-2002 ..	6-05-2002 ..	12-30-2002	9-01-2003 ..	S1733	Various disasters: Excessive Rain, High Winds, Lightning.	1
NU	4-24-2002 ..	5-20-2002 ..	12-30-2002	9-01-2003 ..	S1733	Various disasters: Excessive RainFreeze, Frost.	3
PA	4-01-2002 ..	6-30-2002 ..	12-30-2002	9-01-2003 ..	S1733	Various disasters: Excessive Rain, Flash Flooding, Frost, Tornado.	8
VT	5-23-2002 ..	6-28-2002 ..	12-30-2002	9-01-2003 ..	S1733	Various disasters: Excessive Rain, Flash Flooding, High Winds, Lightning.	3

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTAL—SECRETARIAL—Continued
[Fiscal Year 2003—Secretarial Designations for Production Losses]

State	Countries requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
OK	Choctaw, Creek, Haskell, Hughes, Latimer, LeFlore, McCurtain, McIntosh, Okfuskee, Okmulgee, Ottawa, Pittsburg, Pottawatomie, Pushmataha, Rogers, Tulsa.	5-01-2002 ..	6-30-2003 ..	12-30-2002	9-01-2003 ..	S1734	Drought	16	14
AR	5-01-2002 ..	6-30-2003 ..	12-30-2002	9-01-2003 ..	S1734	Drought	5
MO	5-01-2002 ..	6-30-2003 ..	12-30-2002	9-01-2003 ..	S1734	Drought	1
TX	5-01-2002 ..	6-30-2003 ..	12-30-2002	9-01-2003 ..	S1734	Drought	3
TX	Runnels	1-01-2002 ..	6-30-2003 ..	12-30-2002	9-01-2003 ..	S1735	Drought	1
WA	Spokane	4-23-2002 ..	6-08-2002 ..	12-30-2002	9-01-2003 ..	S1736	Freezing weather	1	4
ID	ID	4-23-2002 ..	6-08-2002 ..	12-30-2002	9-01-2003 ..	S1736	Freezing weather	3
WA	Whitman	4-24-2002 ..	6-08-2002 ..	12-30-2002	9-01-2003 ..	S1737	Frost damage	1	7
ID	4-24-2002 ..	6-08-2002 ..	12-30-2002	9-01-2003 ..	S1737	Frost damage	3
LA	Beauregard, Calcasieu, Cameron, Catahoula, Concordia, DeSoto, East Carroll, Franklin, Grant, LaSalle, Madison, Morehouse, Natchitoches, Pointe Coupee, Red River, Richland, Tensas, Vernon, West Carroll, Winn.	9-16-2002 ..	7-15-2003 ..	1-15-2003 ..	9-15-2003 ..	S1738	Excessive rainfall	20	19
AR	9-16-2002 ..	7-15-2003 ..	1-15-2003 ..	9-15-2003 ..	S1738	Excessive rainfall	3
MS	9-16-2002 ..	7-15-2003 ..	1-15-2003 ..	9-15-2003 ..	S1738	Excessive rainfall	6
TX	9-16-2002 ..	7-15-2003 ..	1-15-2003 ..	9-15-2003 ..	S1738	Excessive rainfall	5
IA	Clay, O'Brien, Sioux	9-30-2002 ..	7-15-2003 ..	1-15-2003 ..	9-15-2003 ..	S1739	Severe storms, including, hail and high winds.	3	9
SD	Clay, O'Brien, Sioux	9-30-2002 ..	7-15-2003 ..	1-15-2003 ..	9-15-2003 ..	S1739	Severe storms, including, hail and high winds.	2
MT	BLACKFEET NATION—(Glacier, Pondera Counties).	6-07-2002 ..	6-12-2002 ..	1-15-2003 ..	9-15-2003 ..	S1740	Heavy snow, wind, rain, blizzard conditions, flooding, unseasonably cold weather.	2
SC	Entire State	4-01-2002 ..	11-30-2002	1-15-2003 ..	9-15-2003 ..	S1741	Drought	46
NC	Entire State	4-01-2002 ..	11-30-2002	1-15-2003 ..	9-15-2003 ..	S1741	Drought	9

VA	Albenarle, Amelia, Amherst, Campbell, Charlotte, Chesterfield, Culpeper, Dinwiddie, Essex, Fauquier, Halifax, Henrico, Isle of Wight, Louisa, Prince George, Pulaski, Scott, Warren.	1-01-2002 ..	7-31-2003 ..	1-31-2003 ..	10-01-2003	S1742	Drought, excessive heat	18	12
VA	Accomack, Alleghany, Bath, Buchanan, Carroll, Charles City, Clarke, Dickenson, Giles, Gloucester, Grayson, Greensville, James City, Lancaster, Lee, Mathews, Northampton, Northumberland, Orange, Patrick, Rappahannock, Roanoke, Russell, Shenandoah, Smyth, Southampton, Tazewell, Wise.	1-01-2002 ..	7-31-2003 ..	1-31-2003 ..	10-01-2003	S1743	Drought, excessive heat	28	9
NC	1-01-2002 ..	7-31-2003 ..	1-31-2003 ..	10-01-2003	S1743	Drought, excessive heat	3
WV	1-01-2002 ..	7-31-2003 ..	1-31-2003 ..	10-01-2003	S1743	Drought, excessive heat	4
TN	Creatham, Decatur, Gibson, Grainger, Hamblen, Henderson, Montgomery, Van Buren, White.	8-01-2002 ..	8-07-2003 ..	2-07-2003 ..	10-07-2003	S1744	Armyworms, drought, excessive heat, excessive rain, moisture, flooding.	9	42
TN	Bradley, Chester, Haywood, Lauderdale, Madison, Marshall, Maury, McNairy, Obion, Polk, Shelby, Tipton, Weakley.	5-01-2002 ..	8-07-2003 ..	2-07-2003 ..	10-07-2003	S1744	Armyworms, excessive rain, moisture, flooding.	13
AR	8-01-2002 ..	8-07-2003 ..	2-07-2003 ..	10-07-2003	S1744	Armyworms, excessive rain, moisture, flooding.	2
GA	8-01-2002 ..	8-07-2003 ..	2-07-2003 ..	10-07-2003	S1744	Armyworms, excessive rain, moisture, flooding.	4
KY	8-01-2002 ..	8-07-2003 ..	2-07-2003 ..	10-07-2003	S1744	Armyworms, excessive rain, moisture, flooding.	4
KY	5-01-2002 ..	8-07-2003 ..	2-07-2003 ..	10-07-2003	S1744	Armyworms, drought, excessive heat, excessive rain, moisture, flooding.	1
MS	8-01-2002 ..	8-07-2003 ..	2-07-2003 ..	10-07-2003	S1744	Armyworms, excessive rain, moisture, flooding.	3
NC	8-01-2002 ..	8-07-2003 ..	2-07-2003 ..	10-07-2003	S1744	Armyworms, excessive rain, moisture, flooding.	1

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTAL—SECRETARIAL—Continued
[Fiscal Year 2003—Secretarial Designations for Production Losses]

State	Countries requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
MO	Andrew, Atchison, Bates, Buchanan, Caldwell, Carroll, Cass, Cedar, Clinton, Daviess, Dekalb, Gentry, Grundy, Harrison, Henry, Holt, Jackson, Johnson, Linn, Livingston, Mercer, Nodaway, Platte, Putnam, Ray, Schuyler, Sullivan, Vernon, Worth.	6-01-2002 ..	8-07-2003 ..	2-07-2003 ..	10-07-2003	S1745	Drought	29	13
IA	6-01-2002 ..	8-07-2003 ..	2-07-2003 ..	10-07-2003	S1745	Drought	2
KS	6-01-2002 ..	8-07-2003 ..	2-07-2003 ..	10-07-2003	S1745	Drought	9
NE	6-01-2002 ..	8-07-2003 ..	2-07-2003 ..	10-07-2003	S1745	Drought	3
PA	Delaware, Fayette, Greene, Tioga, Washington.	6-01-2002 ..	8-11-2003 ..	2-11-2003 ..	10-14-2003	S1746	Drought	5
NU	6-01-2002 ..	8-11-2003 ..	2-11-2003 ..	10-14-2003	S1746	Drought	1
WV	6-01-2002 ..	8-11-2003 ..	2-11-2003 ..	10-14-2003	S1746	Drought	6
WV	Berkeley, Boone, Braxton, Brooke, Cabell, Calhoun, Clay, Doddridge, Glimer, Grant, Greenbrier, Hampshire, Hancock, Harrison, Jackson, Kanawha, Lewis, Lincoln, Logan, Marshall, Mason, Mercer, Mineral, Mingo, Monroe, Morgan, Nicholas, Ohio, Pendleton, Pleasants, Pocahontas, Ritchie, Roane, Taylor, Tyler, Upshur, Wayne, Webster, Wetzel, Wirt, Wood.	1-01-2002 ..	11-19-2002	2-13-2003 ..	10-14-2003	S1747	Drought	41	12
KY	1-01-2002 ..	11-19-2002	2-13-2003 ..	10-14-2003	S1747	Drought	4
OH	1-01-2002 ..	11-19-2002	2-13-2003 ..	10-14-2003	S1747	Drought	8
PA	1-01-2002 ..	11-19-2002	2-13-2003 ..	10-14-2003	S1747	Drought	1
VA	1-01-2002 ..	11-19-2002	2-13-2003 ..	10-14-2003	S1747	Drought	5

MS	Adams, Alcorn, Amite, Benton, Bolivar, Calhoun, Carroll, Chickasaw, Choctaw, Claiborne, Clay, Coahoma, Covington, De Soto, Forrest, Franklin, George, Greene, Grenada, Hancock, Harrison, Hinds, Holmes, Humphreys, Issaquena, Itawamba, Jackson, Jefferson, Jefferson Davis, Jones, Lafayette, Lawrence, Lee, Leflore, Lincoln, Lowndes, Madison, Marion, Marshall, Monroe, Newton, Noxubee, Oktibbeha, Panda, Pearl River, Perry, Pike, Pontotoc, Prentiss, Quitman, Rankin, Scott, Sharkey, Simpson, Stone, Sunflower, Tallahatchie, Tate, Tippah, Tishomingo, Tunica, Union, Walthall, Warren, Washington, Wayne, Webster, Wilkinson, Winston, Yalobusha, Yazoo.	9-26-2003 ..	8-13-2003 ..	2-13-2003 ..	10-14-2003	S1748	Tropical Storm Isidore; Hurricane Lili.	71	11
AL	9-26-2003 ..	8-13-2003 ..	2-13-2003 ..	10-14-2003	S1748	Tropical Storm Isidore; Hurricane Lili.	10
AR	9-26-2003 ..	8-13-2003 ..	2-13-2003 ..	10-14-2003	S1748	Tropical Storm Isidore; Hurricane Lili.	6
LA	9-26-2003 ..	8-13-2003 ..	2-13-2003 ..	10-14-2003	S1748	Tropical Storm Isidore; Hurricane Lili.	10
TN	9-26-2003 ..	8-13-2003 ..	2-13-2003 ..	10-14-2003	S1748	Tropical Storm Isidore; Hurricane Lili.	5
MS	Attala, Clarke, Copiah, Jasper, Kemper, Lamar, Lauderdale, Leake, Montgomery, Neshoba.	9-26-2003 ..	8-13-2003 ..	3-12-2003 ..	11-12-2003	S1748, Amendment 1.	Tropical Storm Isidore; Hurricane Lili.	11
CA	Inyo, Mono	12-01-2001	11-25-2002	2-13-2003 ..	10-14-2003	S1749	Drought, fires	2
MI	(1) Alger, Baraga, Chippewa, Delta, Dickinson, Gogebic, Houghton, Iron, Keweenaw, Luce, Mackinaw, Marquette, Ontonagon, Houghton, Schoolcraft;	4-01-2002 ..	8-13-2003 ..	2-13-2003 ..	10-14-2003	S1750	Excessive rainfall	14	3
MI	(2) Barry, Berrien, Branch, Calhoun, Cass, Eaton, Genesee, Hillsdale, Ingham, Jackson, Kalamazoo, Lenawee, Livingston, Monroe, Shiawassee, St. Joseph, Van Buren, Washtenaw, Wayne.	6-15-2002 ..	8-13-2003 ..	2-13-2003 ..	10-14-2003	S1750	Drought	19	10

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTAL—SECRETARIAL—Continued
[Fiscal Year 2003—Secretarial Designations for Production Losses]

State	Countries requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
WI	6-15-2002 ..	8-13-2003 ..	2-13-2003 ..	10-14-2003	S1750	Excessive rainfall	5
CA	Humboldt	1-01-2002 ..	8-14-2003 ..	2-14-2003 ..	10-14-2003	S1751	Drought	1	4
OR	Coos, Crook, Curry, Grant, Union, Wheeler	9-01-2000 ..	8-14-2003 ..	2-14-2003 ..	10-14-2003	S1752	Drought	6	1
CA	9-01-2000 ..	8-14-2003 ..	2-14-2003 ..	10-14-2003	S1752	Drought	1
CA	Lassen	1-01-2002 ..	8-24-2003 ..	2-24-2003 ..	10-24-2003	S1753	Drought	1
OR	Harney	10-01-2001	9-07-2003 ..	3-07-2003 ..	11-07-2003	S1754	Drought	1
WA	Benton	1-01-2002 ..	7-08-2002 ..	3-12-2003 ..	11-12-2003	S1755	(1) Drought, freezing temperatures, high winds. (2) High winds, excessive rainfall, hailstorms.	1	2
OR	1-01-2002 ..	7-08-2002 ..	3-12-2003 ..	11-12-2003	S1755	(1) Drought, freezing temperatures, high winds. (2) High winds, excessive rainfall, hailstorms.	2
TX	Uvalde	2-26-2002 ..	3-04-2002 ..	3-12-2003 ..	11-12-2003	S1756	Freeze, high winds	1	8
TX	Lubbock	6-04-2002 ..	6-04-2002 ..	3-12-2003 ..	11-12-2003	S1757	Excessive rain, flash flooding, flooding, hail, high winds	1	8
ME	Entire State	1-01-2002 ..	9-12-2003 ..	3-12-2003 ..	11-12-2003	S1758	Drought	16

GA	Bacon, Banks, Barrow, Bartow, Ben Hill, Bibb, Bleckley, Brantley, Bryan, Bulloch, Burke, Butts, Calhoun, Candler, Carroll, Catosa, Chattooga, Clarke, Clay, Clayton, Colquitt, Cook, Coweta, Crawford, Crisp, Dade, Dawson, De Kalb, Decatur, Dodge, Dooly, Dougherty, Douglas, Early, Echols, Effingham, Elbert, Emanuel, Evans, Fayette, Floyd, Forsyth, Franklin, Fulton, Glascock, Gordon, Gwinnett, Habersham, Hall, Haralson, Hart, Henry, Houston, Jackson, Jeff Davis, Jefferson, Jenkins, Johnson, Lamar, Laurens, Liberty, Long, Lowndes, Lumpkin, Macon, Madison, Marion, McDuffie, Miller, Mitchell, Monroe, Montgomery, Morgan, Murray, Oconee, Oglethorpe, Paulding, Peach, Pierce, Pike, Polk, Pulaski, Quitman, Rabun, Randolph, Rockdale, Schley, Screven, Seminole, Spalding, Stephens, Stewart, Sumter, Tattnall, Taylor, Telfair, Terrell, Thomas, Tift, Towns, Treutlen, Troup, Turner, Twiggs, Upson, Walker, Walton, Ware, Warren, Washington, Wayne, Webster, Wheeler, White, Whitfield, Wilcox, Wilkinson, Worth.	9-01-2002 ..	1-14-2003 ..	3-12-2003 ..	11-12-2003	S1759	Wet, unseasonably cool fall weather.	118	40
AL	9-01-2002 ..	1-14-2003 ..	3-12-2003 ..	11-12-2003	S1759	Wet, unseasonably cool fall weather.	10
FL	9-01-2002 ..	1-14-2003 ..	3-12-2003 ..	11-12-2003	S1759	Wet, unseasonably cool fall weather.	8
NC	9-01-2002 ..	1-14-2003 ..	3-12-2003 ..	11-12-2003	S1759	Wet, unseasonably cool fall weather.	3
SC	9-01-2002 ..	1-14-2003 ..	3-12-2003 ..	11-12-2003	S1759	Wet, unseasonably cool fall weather.	9
TN	9-01-2002 ..	1-14-2003 ..	3-12-2003 ..	11-12-2003	S1759	Wet, unseasonably cool fall weather.	4
TN	Giles, Hardeman, Lawrence, Marion, Sequatchie, Wayne.	7-01-2002 ..	2-05-2003 ..	3-12-2003 ..	11-12-2003	S1760	(1) Drought (2) Excessive rain	6	18

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTAL—SECRETARIAL—Continued
[Fiscal Year 2003—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Continuous
NE	Adams, Arthur, Banner, Blaine, Box Butte, Boyd, Brown, Buffalo, Chase, Cherry, Cheyenne, Custer, Dawes, Dawson, Deuel, Dundy, Franklin, Frontier, Furnas, Garden, Garfield, Gosper, Grant, Greeley, Hall, Harlan, Hayes, Hitchcock, Holt, Hooker, Howard, Kearney, Keith, Keya Paha, Kimball, Lincoln, Logan, Loup, McPherson, Morrill, Nuckolls, Perkins, Phelps, Red Willow, Rock, Scotts Bluff, Sheridan, Sherman, Sioux, Thomas, Valley, Webster, Wheeler.	7-01-2002 ..	11-14-2003	5-14-2003 ..	1-14-2004 ..	S1780	Drought, extreme heat, grasshopper infestation, high winds.	53	9
CO	7-01-2002 ..	11-14-2003	5-14-2003 ..	1-14-2004 ..	S1780	Drought, extreme heat, grasshopper infestation, high winds.	5
KS	7-01-2002 ..	11-14-2003	5-14-2003 ..	1-14-2004 ..	S1780	Drought, extreme heat, grasshopper infestation, high winds.	8
SD	7-01-2002 ..	11-14-2003	5-14-2003 ..	1-14-2004 ..	S1780	Drought, extreme heat, grasshopper infestation, high winds.	7
WY	7-01-2002 ..	11-14-2003	5-14-2003 ..	1-14-2004 ..	S1780	Drought, extreme heat, grasshopper infestation, high winds.	3
TX	Robertson, Van Zandt	1-01-2001 ..	2-12-2003 ..	5-22-2003 ..	1-22-2004 ..	S1781	Flooding, excessive temperatures ..	2	3
WA	Asotin, Chelan, Columbia, Douglas, Garfield, Grant, Kittitas, Lewis, Lincoln, Pend Oreille, Spokane, Stevens, Walla Walla, Whitman.	1-01-2002 ..	11-22-2003	5-22-2003 ..	1-22-2004 ..	S1782	Drought	14	17
ID	1-01-2002 ..	11-22-2003	5-22-2003 ..	1-22-2004 ..	S1782	Drought	6
OR	1-01-2002 ..	11-22-2003	5-22-2003 ..	1-22-2004 ..	S1782	Drought	7
WA	(1) Benton, Columbia, Franklin, Spokane, Walla Walla, Whatcom, Yakima.	1-01-2002 ..	11-22-2003	5-22-2003 ..	1-22-2004 ..	S1783	(1) Severe cold temperatures;	8	17
	(2) Ferry, Yakima						(2) Drought		
ID	10-12-2002	11-06-2002	5-22-2003 ..	1-22-2004 ..	S1783	Severe cold	3
OR	10-12-2002	11-06-2002	5-22-2003 ..	1-22-2004 ..	S1783	Severe cold	3

WI	Door, Kewaunee	4-01-2002 ..	11-22-2003	5-22-2003 ..	1-22-2004 ..	S1784	Exceptionally cold, wet conditions in spring, followed by warmer and dryer conditions through the growing season.	2	2
CA	Trinity	1-01-2002 ..	11-30-2002	6-03-2003 ..	2-03-2004 ..	S1785	Drought	1	2
NC	Beaufort, Camden, Cartaret, Currituck, Hyde, New Hanover, Onslow, Pamlico, Pasquotank.	4-01-2002 ..	12-03-2003	6-03-2003 ..	2-03-2004 ..	S1786	(1) Excessive rainfall	9	15
VA	Kenosha, Racine, Rock, Walworth	4-01-2002 ..	12-03-2003	6-03-2003 ..	2-03-2004 ..	S1786	(2) Drought (New Hanover, Onslow Only).	3
WI	Kenosha, Racine, Rock, Walworth	6-01-2002 ..	12-03-2003	6-03-2003 ..	2-03-2004 ..	S1787	Excessive rainfall	4	5
IL	6-01-2002 ..	12-03-2003	6-03-2003 ..	2-03-2004 ..	S1787	Drought	4
HI	Hawaii	1-01-2001 ..	12-31-2002	6-03-2003 ..	2-03-2004 ..	S1788	Drought	1
WA	Clark, Cowlitz, Skamania, Wahkiakum	6-01-2002 ..	11-30-2002	6-23-2003 ..	2-23-2004 ..	S1789	Cool, wet weather, followed by hot, dry weather.	4	4
OR	6-01-2002 ..	11-30-2002	6-23-2003 ..	2-23-2004 ..	S1789	Cool, wet weather, followed by hot, dry weather.	4
AR	Stone	3-25-2003 ..	3-25-2003 ..	6-27-2003 ..	2-27-2004 ..	S1790	Hail	1	6
UT	Entire State	1-01-2003 ..	12-27-2003	6-27-2003 ..	2-27-2004 ..	S1791	Drought: Very low snow pack combined with low soil moisture.	29
AZ	1-01-2003 ..	12-27-2003	6-27-2003 ..	2-27-2004 ..	S1791	Drought: Very low snow pack combined with low soil moisture.	4
CO	1-01-2003 ..	12-27-2003	6-27-2003 ..	2-27-2004 ..	S1791	Drought: Very low snow pack combined with low soil moisture.	8
ID	1-01-2003 ..	12-27-2003	6-27-2003 ..	2-27-2004 ..	S1791	Drought: Very low snow pack combined with low soil moisture.	4
NM	1-01-2003 ..	12-27-2003	6-27-2003 ..	2-27-2004 ..	S1791	Drought: Very low snow pack combined with low soil moisture.	1
NV	1-01-2003 ..	12-27-2003	6-27-2003 ..	2-27-2004 ..	S1791	Drought: Very low snow pack combined with low soil moisture.	3
WY	1-01-2003 ..	12-27-2003	6-27-2003 ..	2-27-2004 ..	S1791	Drought: Very low snow pack combined with low soil moisture.	3
TX	Waller	10-01-2002	11-30-2002	6-27-2003 ..	2-27-2004 ..	S1792	Excessive rain	1	6
TX	San Saba	3-29-2003 ..	3-29-2003 ..	6-27-2003 ..	2-27-2004 ..	S1793	Freeze	1	7
TX	Calhoun, Collingsworth, Concho, Glascock, Hardeman, Howard, Jackson, Mitchell, Tom Green, Victoria, Wilbarger.	1-01-2002 ..	12-27-2003	6-27-2003 ..	2-27-2004 ..	S1794	Drought, low humidity	11	35
OK	1-01-2002 ..	12-27-2003	6-27-2003 ..	2-27-2004 ..	S1794	Drought, low humidity	4
TX	Martin	1-01-2002 ..	12-27-2003	6-27-2003 ..	2-27-2004 ..	S1795	Drought, high winds	1	7
CA	San Diego	11-25-2002	1-08-2003 ..	7-01-2003 ..	3-01-2004 ..	S1796	Damaging Santa Ana Winds	1	3

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTAL—SECRETARIAL—Continued
[Fiscal Year 2003—Secretarial Designations for Production Losses]

State	Countries requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
CO	Baca, Bent, Elbert, Kiowa, Lincoln, Prowers.	9-01-2000 ..	1-15-2004 ..	7-15-2003 ..	3-15-2004 ..	S1797	Drought	6	10
KS	9-01-2000 ..	1-15-2004 ..	7-15-2003 ..	3-15-2004 ..	S1797	Drought	4
NM	9-01-2000 ..	1-15-2004 ..	7-15-2003 ..	3-15-2004 ..	S1797	Drought	1
OK	9-01-2000 ..	1-15-2004 ..	7-15-2003 ..	3-15-2004 ..	S1797	Drought	1
TX	Williamson	7-01-2002 ..	12-31-2002 ..	7-15-2003 ..	3-15-2004 ..	S1798	Excessive rain, flooding	1	6
CA	Glenn	12-13-2002 ..	12-27-2002 ..	8-01-2003 ..	4-01-2004 ..	S1799	Rain, saturated soil, high winds	1	3
CA	Contra Costa	3-16-2003 ..	5-15-2003 ..	8-06-2003 ..	4-06-2004 ..	S1800	(1) Hailstorm	1
VA	Anelia	5-09-2003 ..	5-09-2003 ..	8-29-2003 ..	4-29-2004 ..	S1801	(2) Rain	1	6
OH	Adams, Allen, Ashland, Ashtabula, Athens, Auglaize, Brown, Butler, Carroll, Clark, Clermont, Clinton, Columbiana, Coshocton, Crawford, Cuyahoga, Darke, Delaware, Erie, Fairfield, Fayette, Franklin, Gallia, Geauga, Greene, Hamilton, Hancock, Hardin, Highland, Hocking, Holmes, Huron, Jackson, Knox, Lake Lawrence, Licking, Logan, Lorain, Mahoning, Marion, Medina, Meigs, Mercer, Miami, Montgomery, Morgan, Morrow, Muskingum, Paulding, Perry, Pickaway, Pike, Portage, Preble, Putnam, Richland, Ross, Sandusky, Scioto, Shelby, Summit, Trumbull, Tuscarawas, Union, Van Wert, Vinton, Warren, Washington, Wyandot.	5-01-2003 ..	2-29-2004 ..	8-29-2003 ..	4-29-2004 ..	S1802	Tornado, excessive rain, large hail	70	14
IN	5-01-2003 ..	2-29-2004 ..	8-29-2003 ..	4-29-2004 ..	S1802	Excessive rain, flooding, hail, high wind, tornado damage.	8
KY	5-01-2003 ..	2-29-2004 ..	8-29-2003 ..	4-29-2004 ..	S1802	Excessive rain, flooding, hail, high wind, tornado damage.	9

PA	5-01-2003 ..	2-29-2004 ..	8-29-2003 ..	4-29-2004 ..	SI802	Excessive rain, flooding, hail, high wind, tornado damage.	5
WV	5-01-2003 ..	2-29-2004 ..	8-29-2003 ..	4-29-2004 ..	SI802	Excessive rain, flooding, hail, high wind, tornado damage.	8
AZ	Entire State	1-01-2003 ..	2-29-2004 ..	8-29-2003 ..	4-29-2004 ..	SI803	Drought	15
CA	1-01-2003 ..	2-29-2004 ..	8-29-2003 ..	4-29-2004 ..	SI803	Drought	3
CO	1-01-2003 ..	2-29-2004 ..	8-29-2003 ..	4-29-2004 ..	SI803	Drought	1
NM	1-01-2003 ..	2-29-2004 ..	8-29-2003 ..	4-29-2004 ..	SI803	Drought	6
NV	1-01-2003 ..	2-29-2004 ..	8-29-2003 ..	4-29-2004 ..	SI803	Drought	2
UT	1-01-2003 ..	2-29-2004 ..	8-29-2003 ..	4-29-2004 ..	SI803	Drought	3
CA	Merced	4-21-2003 ..	4-21-2003 ..	9-11-2003 ..	5-11-2004 ..	SI804	Hail	7
VA	Campbell, Charlotte, Culpeper, Halifax, Page, Rappahannock, Russell, Shenandoah.	1-01-2003 ..	3-22-2004 ..	9-22-2003 ..	5-24-2004 ..	SI805	Excessive rainfall	24
NC	Campbell, Charlotte, Culpeper, Halifax, Page, Rappahannock, Russell, Shenandoah.	1-01-2003 ..	3-22-2004 ..	9-22-2003 ..	5-24-2004 ..	SI805	Excessive rainfall	3
WV	Campbell, Charlotte, Culpeper, Halifax, Page, Rappahannock, Russell, Shenandoah.	1-01-2003 ..	3-22-2004 ..	9-22-2003 ..	5-24-2004 ..	SI805	Excessive rainfall	1
WI	Barron, Brown, Buffalo, Burnett, Chippewa, Clark, Dunn, Eau Claire, Forest, Florence, Jackson, Langlade, Lincoln, Marathon, Marinette, Marquette, Menominee, Oconto, Oneida, Outagamie, Pepin, Pierce, Polk, Portage, Price, Rusk, St. Croix, Sawyer, Shawano, Taylor, Vilas, Washburn, Waupaca, Wood.	7-01-2002 ..	3-22-2004 ..	9-22-2003 ..	5-24-2004 ..	SI806	Exceptionally cold temperatures, lack of snow, very deep frost, drought.	34	16
MI	7-01-2002 ..	3-22-2004 ..	9-22-2003 ..	5-24-2004 ..	SI806	Exceptionally cold temperatures, lack of snow, very deep frost, drought.	4
MN	7-01-2002 ..	3-22-2004 ..	9-22-2003 ..	5-24-2004 ..	SI806	Exceptionally cold temperatures, lack of snow, very deep frost, drought.	7
VA	Appomattox, Augusta, Buckingham, Nottoway, Patrick, Pittsylvania, Prince Edward.	2-01-2003 ..	3-29-2004 ..	9-29-2003 ..	6-01-2004 ..	SI807	Excessive rainfall	7	21
NC	2-01-2003 ..	3-29-2004 ..	9-29-2003 ..	6-01-2004 ..	SI807	Excessive rainfall	4
WV	2-01-2003 ..	3-29-2004 ..	9-29-2003 ..	6-01-2004 ..	SI807	Excessive rainfall	1
VA	Virginia Beach (I), Washington	7-01-2002 ..	3-01-2003 ..	9-30-2003 ..	6-01-2004 ..	SI808	Drought	7

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTAL—SECRETARIAL—Continued
[Fiscal Year 2003—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
NC	Virginia Beach (I), Washington	7-01-2002 ..	3-01-2003 ..	9-30-2003 ..	6-01-2004 ..	S1808	Drought	1
TN	Virginia Beach (I), Washington	7-01-2002 ..	3-01-2003 ..	9-30-2003 ..	6-01-2004 ..	S1808	Drought	2
OK	Alfalfa, Atoka, Beaver, Beckham, Blaine, Bryan, Caddo, Canadian, Carter, Cimarron, Cleveland, Coal., Comanche, Cotton, Creek, Custer, Dewey, Ellis, Garfield, Garvin, Grady, Grant, Greer, Harmon, Harper, Hughes, Jackson, Johnston, Kay, Kingfisher, Kiowa, L.	7-01-2003 ..	3-30-2004 ..	9-30-2003 ..	6-01-2004 ..	S1809	Drought	59	10
CO	7-01-2003 ..	3-30-2004 ..	9-30-2003 ..	6-01-2004 ..	S1809	Drought	1
KS	7-01-2003 ..	3-30-2004 ..	9-30-2003 ..	6-01-2004 ..	S1809	Drought	11
NM	7-01-2003 ..	3-30-2004 ..	9-30-2003 ..	6-01-2004 ..	S1809	Drought	1
TX	7-01-2003 ..	3-30-2004 ..	9-30-2003 ..	6-01-2004 ..	S1809	Drought	18
TOTAL ACTIVE	2309	2029

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL
[Fiscal Year 2004—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
AR	Arkansas, Ashley, Clay, Cleburne, Conway, Craighead, Crittenden, Cross, Faulkner, Greene, Hempstead, Independence, Jackson, Jefferson, Lafayette, Lawrence, Lee, Little River, Lonoke, Mississippi, Monroe, Nevada, Perry, Phillips, Poinsett, Polk, Pope, Prairie, Pulaski, Randolph, Sevier, Sharp, St. Francis, Stone, White, Woodruff.	5-01-2003	5-01-2003	10-10-2003	6-10-2004	S1810	Excessive rain, flash flooding, hail, tornadoes.	36	27
LA		5-01-2003	5-31-2003	10-10-2003	6-10-2004	S1810	Excessive rain, flash flooding, hail, tornadoes.	5
MS		5-01-2003	5-31-2003	10-10-2003	6-10-2004	S1810	Excessive rain, flash flooding, hail, tornadoes.	4
MO		5-01-2003	5-31-2003	10-10-2003	6-10-2004	S1810	Excessive rain, flash flooding, hail, tornadoes.	5
OK		5-01-2003	5-31-2003	10-10-2003	6-10-2004	S1810	Excessive rain, flash flooding, hail, tornadoes.	2
TN		5-01-2003	5-31-2003	10-10-2003	6-10-2004	S1810	Excessive rain, flash flooding, hail, tornadoes.	4
TX		5-01-2003	5-31-2003	10-10-2003	6-10-2004	S1810	Excessive rain, flash flooding, hail, tornadoes.	1
KS	(1) Dickinson, Jewell, Republic (2) Morton	1-01-2003	4-20-2004	10-20-2003	6-21-2004	S1811	(1) Tornado, hail, high winds, lightning, excessive rain, flash flooding, flooding. (2) Excessive heat, drought, high winds.	3	14

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal Year 2004—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
CO	1-01-2003	4-20-2004	10-20-2003	6-21-2004	S1811	(1) Tornado, hail, high winds, lightning, excessive rain, flash flooding. (2) Excessive heat, drought, high winds.	1
NE	1-01-2003	4-20-2004	10-20-2003	6-21-2004	S1811	(1) Tornado, hail, high winds, lightning, excessive rain, flash flooding. (2) Excessive heat, drought, high winds.	4
OK	1-01-2003	4-20-2004	10-20-2003	6-21-2004	S1811	(1) Tornado, hail, high winds, lightning, excessive rain, flash flooding. (2) Excessive heat, drought, high winds.	2
CA	Alameda, Contra Costa, Fresno, Glenn, Kern, Madera, Sacramento, San Joaquin, Tulare, Yuba. Entire State (17 counties)	1-01-2003	5-31-2003	10-23-2003	6-23-2004	S1812	Excessive rain, wheat stripe rust	10	30
NV	1-01-2003	4-23-2004	10-23-2003	6-23-2004	S1813	Drought, insect infestation	17
AZ	1-01-2003	4-23-2004	10-23-2003	6-23-2004	S1813	Drought, insect infestation	1
CA	1-01-2003	4-23-2004	10-23-2003	6-23-2004	S1813	Drought, insect infestation	10
ID	1-01-2003	4-23-2004	10-23-2003	6-23-2004	S1813	Drought, insect infestation	3
OR	1-01-2003	4-23-2004	10-23-2003	6-23-2004	S1813	Drought, insect infestation	3
UT	1-01-2003	4-23-2004	10-23-2003	6-23-2004	S1813	Drought, insect infestation	7

IA	Adair, Adams, Allamakee, Audubon, Benton, Black Hawk, Bremer, Buchanan, Buena Vista, Calhoun, Carroll, Cass, Cherokee, Chickasaw, Clarke, Clay, Clayton, Clinton, Crawford, Dallas, Davis, Decatur, Dickinson, Dubuque, Floyd, Franklin, Fremont, Grundy, Guthrie, Harrison, Henry, Howard, Humboldt, Ida, Jefferson, Johnson, Jones, Keokuk, Lee, Linn, Louisa, Lucas, Lyon, Madison, Marion, Mitchell, Monona, Monroe, Montgomery, O'Brien, Page, Pottawattamie, Polk, Pottawattamie, Ringgold, Sac, Shelby, Story, Taylor, Union, Van Buren, Wapello, Warren, Washington, Wayne, Winnebago, Winneshek, Worth.	7-01-2003	4-23-2004	10-23-2003	6-23-2004	S1814	68	31
IL	7-01-2003	4-23-2004	10-23-2003	6-23-2004	S1814	Drought, related impacts	7
MN	7-01-2003	4-23-2004	10-23-2003	6-23-2004	S1814	Drought, related impacts	8
MO	7-01-2003	4-23-2004	10-23-2003	6-23-2004	S1814	Drought, related impacts	9
NE	7-01-2003	4-23-2004	10-23-2003	6-23-2004	S1814	Drought, related impacts	7
SD	7-01-2003	4-23-2004	10-23-2003	6-23-2004	S1814	Drought, related impacts	2
WI	7-01-2003	4-23-2004	10-23-2003	6-23-2004	S1814	Drought, related impacts	3

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal Year 2004—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
MN	Atkin, Anoka, Becker, Beltrami, Benton, Big Stone, Carlton, Cass, Chippewa, Chisago, Clearwater, Cook, Crow Wing, Dakota, Dodge, Douglas, Faribault, Fillmore, Freeborn, Goodhue, Hennepin, Houston, Hubbard, Isanti, Itasca, Kanabec, Kandiyohi, Kittson, Lac Qui Parle, Lake, Lincoln, Mahnommen, Meeker, Mille Lacs, Morrison, Mower, Nicollet, Olmsted, Otter Tail, Pine, Pipestone, Pope, Ramsey, Red Lake, Renville, Rice, St. Louis, Scott, Sherburne, Sibley, Stearns, Steele, Swift, Todd, Traverse, Wabasha, Wadena, Waseca, Washington, Winona, Wright, Yellow Medicine.	7-01-2003	4-23-2004	10-23-2003	6-23-2004	S1815	Drought	62	21
IA		7-01-2003	4-23-2004	10-23-2003	6-23-2004	S1815	Drought		7
ND		7-01-2003	4-23-2004	10-23-2003	6-23-2004	S1815	Drought		3
SD		7-01-2003	4-23-2004	10-23-2003	6-23-2004	S1815	Drought		6
WI		7-01-2003	4-23-2004	10-23-2003	6-23-2004	S1815	Drought		10
WY	Lincoln, Sublette, Sweetwater	1-01-2003	4-23-2004	10-23-2003	6-23-2004	S1816	Drought	3	4
CO		1-01-2003	4-23-2004	10-23-2003	6-23-2004	S1816	Drought		4
ID		1-01-2003	4-23-2004	10-23-2003	6-23-2004	S1816	Drought		3
UT		1-01-2003	4-23-2004	10-23-2003	6-23-2004	S1816	Drought		3
CA	El Dorado	4-01-2003	5-15-2003	10-30-2003	6-30-2004	S1817	Excessive rain, hail, freezing temperatures.	1	3
CA	Nevada	3-01-2003	5-15-2003	10-30-2003	6-30-2004	S1817	Rain, hail, freezing temperatures	1	3
CA	Sutter	4-04-2003	5-09-2003	10-30-2003	6-30-2004	S1817	Hail	1	2

CA	Yolo	4-01-2003	5-15-2003	10-30-2003	6-30-2004	S1817	Freezing temperatures	1	3
NV	3-01-2003	5-15-2003	10-30-2003	6-30-2004	S1817	Rain, hail, freezing temperatures	1
NV	4-01-2003	5-15-2003	10-30-2003	6-30-2004	S1817	Excessive rain, hail, freezing temperatures	1
CA	Butte	3-01-2003	5-14-2003	10-30-2003	6-30-2004	S1818	Spring rains, wheat stripe rust	1	6
CA	Merced	4-01-2003	5-14-2003	10-30-2003	6-30-2004	S1818	Spring rains, cool temperatures, wheat stripe rust	1	7
CA	Solano	4-01-2003	5-31-2003	10-30-2003	6-30-2004	S1818	Spring rains, wheat stripe rust	1	5
CA	Stanislaus	4-01-2003	5-14-2003	10-30-2003	6-30-2004	S1818	Rains, wheat stripe rust	1	3
IN	Union	6-11-2003	6-16-2003	11-04-2003	7-06-2004	S1819	Excessive rain, flooding	1	3
OH	6-11-2003	6-16-2003	11-04-2003	7-06-2004	S1819	Excessive rain, flooding	2
VA	Bedford, Mecklenburg, Rockingham, Scott	1-01-2003	5-04-2004	11-04-2003	7-06-2004	S1820	Excessive rainfall	4	20
NC	Bedford, Mecklenburg, Rockingham, Scott	1-01-2003	5-04-2004	11-04-2003	7-06-2004	S1820	Excessive rainfall	3
TN	Bedford, Mecklenburg, Rockingham, Scott	1-01-2003	5-04-2004	11-04-2003	7-06-2004	S1820	Excessive rainfall	3
WV	Bedford, Mecklenburg, Rockingham, Scott	1-01-2003	5-04-2004	11-04-2003	7-06-2004	S1820	Excessive rainfall	2
TX	Lamb	6-05-2003	6-20-2003	11-04-2003	7-06-2004	S1821	(1) Excessive rain, hail, high winds, sand, static electricity;	1	7
TX	Calhoun, Coke, Foard, Gillespie, Karnes, Matagorda, Rumsels, Sterling, Wharton, Bailey	1-01-2003	5-06-2004	11-04-2003	7-06-2004	S1822	(2) Excessive rain, hail, high wind, tornado;	9	36
TX	6-03-2003	6-20-2003	11-04-2003	7-06-2004	S1823	Drought	4
NM	6-03-2003	6-20-2003	11-04-2003	7-06-2004	S1823	Excessive rain, flash flooding, hail, high winds, lightning	1	4
TX	Hale	5-20-2003	6-25-2003	11-04-2003	7-06-2004	S1824	Excessive rain, flash flooding, hail, high winds, lightning	2
TX	Hall	6-22-2003	6-22-2003	11-04-2003	7-06-2004	S1825	Flooding, hail, high winds	1	7
NM	Entire State (except Los Alamos County)	1-01-2003	5-21-2004	11-21-2003	7-21-2004	S1826	Excessive rain, hail, high winds, lightning	1	6
AZ	1-01-2003	5-21-2004	11-21-2003	7-21-2004	S1826	Drought, excessive heat	32	1
CO	1-01-2003	5-21-2004	11-21-2003	7-21-2004	S1826	Drought, excessive heat	3
OK	1-01-2003	5-21-2004	11-21-2003	7-21-2004	S1826	Drought, excessive heat	7
TX	1-01-2003	5-21-2004	11-21-2003	7-21-2004	S1826	Drought, excessive heat	1
UT	1-01-2003	5-21-2004	11-21-2003	7-21-2004	S1826	Drought, excessive heat	16
UT	1-01-2003	5-21-2004	11-21-2003	7-21-2004	S1826	Drought, excessive heat	1

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal Year 2004—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
LA	Acadia, Beauregard, Calcasieu, Cameron, Evangeline, Lafayette, Rapides, St. Landry, St. Martin.	6-01-2003	7-31-2003	11-04-2003	7-06-2004	S1827	Excessive rain	9	13
TX	Baker, Giliam	6-01-2003	7-31-2003	11-04-2003	7-06-2004	S1827	Excessive rain	2	2
OR		10-01-2001	5-06-2004	11-04-2003	7-06-2004	S1828	Drought	2	8
ID		10-01-2001	5-06-2004	11-04-2003	7-06-2004	S1828	Drought	2	2
WA		10-01-2001	5-06-2004	11-04-2003	7-06-2004	S1828	Drought	2	1
TX	Hockley, Lubbock	6-01-2003	6-30-2003	11-05-2003	7-06-2004	S1829	Excessive rain, hail, high wind	2	10
TX	Bexar	3-01-2003	5-27-2003	11-05-2003	7-06-2004	S1830	Drought, high temperatures	1	7
TX	Crosby	6-04-2003	6-20-2003	11-05-2003	7-06-2004	S1831	Excessive rain, flash flooding, hail, high winds, lightning	1	8
TX	Briscoe	6-01-2003	5-06-2004	11-06-2003	7-06-2004	S1832	Drought, high winds, static electricity, heat	1	6
TX	Parmer	5-01-2003	6-30-2003	11-06-2003	7-06-2004	S1833	Excessive rain, hail, high winds, cool weather	1	4
NM		5-01-2003	6-30-2003	11-06-2003	7-06-2004	S1833	Excessive rain, hail, high winds, cool weather	1	1
TX	Deaf Smith	6-01-2003	6-30-2003	11-06-2003	7-06-2004	S1834	Hail, tornado	1	5
NM		6-01-2003	6-30-2003	11-06-2003	7-06-2004	S1834	Hail, tornado	2	2
NY	Seneca	4-03-2003	4-04-2003	11-10-2003	7-12-2004	S1835	Excessive rain, ice, high winds	1	6
NY	Wayne	4-04-2003	4-04-2003	11-10-2003	7-12-2004	S1835	Ice Storm	1	1
IN	Bartholomew, Brown, Clark, Daviess, Dearborn, Decatur, Dubois, Franklin, Gibson, Jackson, Jefferson, Jennings, Knox, Martin, Monroe, Morgan, Ohio, Orange, Owen, Perry, Pike, Posey, Ripley, Scott, Spencer, Switzerland, Vanderburgh, Warrick, Washington.	4-01-2003	7-15-2003	11-13-2003	7-13-2004	S1836	Excessive rainfall, cool temperatures	29	15
IL		4-01-2003	7-15-2003	11-13-2003	7-13-2004	S1836	Excessive rainfall, cool temperatures	5	5
KY		4-01-2003	7-15-2003	11-13-2003	7-13-2004	S1836	Excessive rainfall, cool temperatures	12	12

OH	4-01-2003	7-15-2003	11-13-2003	7-13-2004	SI836	Excessive rainfall, cool temperatures	2
MO	1-01-2003	5-13-2004	11-13-2003	7-13-2004	SI837	Drought	39	13
		Andrew, Atchison, Barton, Bates, Benton, Buchanan, Caldwell, Carroll, Cass, Cedar, Chariton, Clay, Clin- ton, Cooper, Daviess , DeKalb, Gentry, Grundy, Har- rison, Henry, Hickory, Holt, Jackson, Johnson, Lafayette, Linn, Livingston, Mercer, Morgan, Nodaway, Pettis, Platte, Putnam, Ray, Saline, St. Clair, Sullivan, Vernon, Worth.	1-01-2003	5-13-2004	11-13-2003	7-13-2004	SI837	Drought	7
IA	1-01-2003	5-13-2004	11-13-2003	7-13-2004	SI837	Drought	9
KS	1-01-2003	5-13-2004	11-13-2003	7-13-2004	SI837	Drought	3
NE	1-01-2003	5-13-2004	11-13-2003	7-13-2004	SI837	Drought	5
TX	6-03-2003	6-23-2003	11-13-2003	7-13-2004	SI838	Excessive rain, hail, high winds, lightning, tornado.	1	
NM	6-03-2003	6-23-2003	11-13-2003	7-13-2004	SI838	Excessive rain, hail, high winds, lightning, tornado.	2
TX	6-22-2003	6-22-2003	11-13-2003	7-13-2004	SI839	Excessive rain, hail, high winds, stat- ic electricity.	1	7
AR	9-01-2003	9-08-2003	11-21-2003	7-21-2004	SI840	Excessive rain, flash flooding	1	5
CA	Lawrence	4-01-2003	5-14-2003	11-21-2003	7-21-2004	SI841	Excessive rain, wheat stripe rust	1	5
CA	Tehama	4-01-2003	5-09-2003	11-21-2003	7-21-2004	SI842	(1) Storms	1	6
								(2) Storms with hail, extended wet periods, below average tempera- tures-causing wheat stripe rust.	
CO	Alamosa, Archuleta, Chaffee, Conejos, Costilla, Crowley, Custer, Dolores, Fremont, Garfield, Hinsdale, Huerfano, Lake, La Plata, Las Animas Mesa, Mineral, Moffat, Mon- tezuma, Otero, Pueblo, Rio Blanco, Rio Grande, Routt, Saguache, San Miguel.	1-31-2003	5-21-2004	11-21-2003	7-21-2004	SI843	Drought, insect infestation	26	17
AZ	1-31-2003	5-21-2004	11-21-2003	7-21-2004	SI843	Drought, insect infestation	1
NM	1-31-2003	5-21-2004	11-21-2003	7-21-2004	SI843	Drought, insect infestation	5

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal Year 2004—Secretarial Designations for Production Losses]

State	Countries requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
UT	1-31-2003	5-21-2004	11-21-2003	7-21-2004	S1843	Drought, insect infestation	4
WY	1-31-2003	5-21-2004	11-21-2003	7-21-2004	S1843	Drought, insect infestation	2
SD	Beadle, Bennett, Bon Homme, Brule, Buffalo, Butte, Campbell, Charles Mix, Corson, Deuel, Dewey, Grant, Gregory, Haakon, Hamlin, Hand, Harding, Hughes, Hyde, Jackson, Jones, Meade, Mellette, Perkins, Potter, Shannon, Spink, Stanley, Sully, Todd, Tripp, Walworth, Ziebach.	1-01-2003	6-02-2004	12-02-2003	8-02-2004	S1844	Extreme heat, high winds, severe storms, significantly below normal precipitation (drought) resulting in numerous prairie and forest fires.	33	22
MN	1-01-2003	6-02-2004	12-02-2003	8-02-2004	S1844	Extreme heat, high winds, severe storms, significantly below normal precipitation (drought) resulting in numerous prairie and forest fires.	4
MT	1-01-2003	6-02-2004	12-02-2003	8-02-2004	S1844	Extreme heat, high winds, severe storms, significantly below normal precipitation (drought) resulting in numerous prairie and forest fires.	2
ND	1-01-2003	6-02-2004	12-02-2003	8-02-2004	S1844	Extreme heat, high winds, severe storms, significantly below normal precipitation (drought) resulting in numerous prairie and forest fires.	5
NE	1-01-2003	6-02-2004	12-02-2003	8-02-2004	S1844	Extreme heat, high winds, severe storms, significantly below normal precipitation (drought) resulting in numerous prairie and forest fires.	6
WY	1-01-2003	6-02-2004	12-02-2003	8-02-2004	S1844	Extreme heat, high winds, severe storms, significantly below normal precipitation (drought) resulting in numerous prairie and forest fires.	1

SD	Brookings, Codington, Custer, Fall River, Faulk, Jerauld, Lyman, Pennington.	1-01-2003	continuing	12-11-2003	8-11-2004	SI844, Amend- ment 1.	Extreme heat, high winds, severe storms, significantly below normal precipitation (drought) resulting in numerous prairie and forest fires.	8	2
MN	1-01-2003	continuing	12-11-2003	8-11-2004	SI844, Amend- ment 1.	Extreme heat, high winds, severe storms, significantly below normal precipitation (drought) resulting in numerous prairie and forest fires.	1
NE	1-01-2003	continuing	12-11-2003	8-11-2004	SI844, Amend- ment 1.	Extreme heat, high winds, severe storms, significantly below normal precipitation (drought) resulting in numerous prairie and forest fires.	1
WY	1-01-2003	continuing	12-11-2003	8-11-2004	SI844, Amend- ment 1.	Extreme heat, high winds, severe storms, significantly below normal precipitation (drought) resulting in numerous prairie and forest fires.	2
SD	Aurora, Clark	1-01-2003	continuing	1-23-2004	9-23-2004	SI844, Amend- ment 2.	Extreme heat, high winds, severe storms, significantly below normal precipitation (drought) resulting in numerous prairie and forest fires.	2	1
NE	(1) Antelope, Cedar, Cuming, Dixon, Madison, Stanton, Wayne, (2) Burt, Knox	7-01-2002	6-02-2004	12-02-2003	8-02-2004	SI845	Drought, high temperatures, grass- hopper infestation. (2) Drought, high temperatures	11	3
IA	7-01-2002	6-02-2004	12-02-2003	8-02-2004	SI845	Drought, high temperatures, grass- hopper infestation. (2) Drought, high temperatures	2
	(3) Dakota						(3)(a) Drought; (b) Continuing rain		
	(4) Pierce						(4)(a) Drought, high temperatures, grasshopper infestation; (b) High winds.		
							Drought, high temperatures, grass- hopper infestation. (2) Drought, high temperatures		
							(3)(a) Drought; (b) Continuing rain		
							(4)(a) Drought, high temperatures, grasshopper infestation; (b) High winds.		

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal Year 2004—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
OR	7-01-2002	6-02-2004	12-02-2003	8-02-2004	S1845	Drought, high temperatures, grasshopper infestation. (2) Drought, high temperatures (3)(a) Drought; (b) Continuing rain (4)(a) Drought, high temperatures, grasshopper infestation; (b) High winds.	5
ID	Bannock, Bear Lake, Benewah, Bingham, Blaine, Bonneville, Butte, Camas, Caribou, Cassia, Clark, Clearwater, Custer, Elmore, Franklin, Fremont, Idaho, Jefferson, Kootenai, Lemhi, Lewis, Lincoln, Madison, Nez Perce, Oneida, Owyhee, Payette, Power, Teton, Twin Falls.	1-01-2003	6-02-2004	12-02-2003	8-02-2004	S1846	(1) Drought (2) Frost/Freeze (3) Inadequate moisture during growing season. (4) Excessive heat (5) Insect infestation (6) Hail	30	13
MT	1-01-2003	6-02-2004	12-02-2003	8-02-2004	S1846	(1) Drought (2) Frost/Freeze (3) Inadequate moisture during growing season. (4) Excessive heat (5) Insect infestation (6) Hail	6
NV	1-01-2003	6-02-2004	12-02-2003	8-02-2004	S1846	(1) Drought (2) Frost/Freeze (3) Inadequate moisture during growing season. (4) Excessive heat (5) Insect infestation (6) Hail	2

OR	1-01-2003	6-02-2004	12-02-2003	8-02-2004	S1846	(1) Drought (2) Frost/Freeze (3) Inadequate moisture during growing season. (4) Excessive heat (5) Insect infestation (6) Hail	2
UT	1-01-2003	6-02-2004	12-02-2003	8-02-2004	S1846	(1) Drought (2) Frost/Freeze (3) Inadequate moisture during growing season. (4) Excessive heat (5) Insect infestation (6) Hail	3
WA	1-01-2003	6-02-2004	12-02-2003	8-02-2004	S1846	(1) Drought (2) Frost/Freeze (3) Inadequate moisture during growing season. (4) Excessive heat (5) Insect infestation (6) Hail	3
WY	1-01-2003	6-02-2004	12-02-2003	8-02-2004	S1846	(1) Drought (2) Frost/Freeze (3) Inadequate moisture during growing season. (4) Excessive heat (5) Insect infestation (6) Hail	2
MO	Dunklin, New Madrid, Pemiscott, Stoddard.	5-04-2003	6-02-2004	12-02-2003	8-02-2004	S1847	(1) Drought (2) Frost/Freeze (3) Inadequate moisture during growing season. (4) Excessive heat (5) Insect infestation (6) Hail	4	6
AR	5-04-2003	6-02-2004	12-02-2003	8-02-2004	S1847	Excessive spring rainfall	4
KY	5-04-2003	6-02-2004	12-02-2003	8-02-2004	S1847	Excessive spring rainfall	1
TN	5-04-2003	6-02-2004	12-02-2003	8-02-2004	S1847	Excessive spring rainfall	2
VA	Annerst, Washington	4-01-2003	8-31-2003	12-02-2003	8-02-2004	S1848	Excessive rain	2	11
TN	4-01-2003	8-31-2003	12-02-2003	8-02-2004	S1848	Excessive rain	2

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal Year 2004—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
MT	Beaverhead, Big Horn, Blaine, Broadwater, Carbon, Carter, Cascade, Daniels, Dawson, Fallon, Fergus, Flathead, Gallatin, Glacier, Golden Valley, Hill, Jefferson, Judith Basin, Lake, Lewis and Clark, Liberty, Madison, Meagher, Musselshell, Park, Phillips, Rosebud, Sanders, Sheridan, Stillwater, Sweetgrass, Teton, Toole, Wheatland, Yellowstone.	1-01-2003	6-02-2004	12-02-2003	8-02-2004	S1849	Drought	35	21
ID		1-01-2003	6-02-2004	12-02-2003	8-02-2004	S1849	Drought		5
ND		1-01-2003	6-02-2004	12-02-2003	8-02-2004	S1849	Drought		5
SD		1-01-2003	6-02-2004	12-02-2003	8-02-2004	S1849	Drought		2
WY		1-01-2003	6-02-2004	12-02-2003	8-02-2004	S1849	Drought		5
ND	Adams, Barnes, Billings, Bottineau, Bowman, Burke, Burleigh, Cass, Cavalier, Dickey, Divide, Dunn, Emmons, Golden Valley, Grand Forks, Grant, Griggs, Hettinger, Kidder, La Moure, Logan, McHenry, McIntosh, McKenzie, McLean, Mercer, Morton, Mountrail, Oliver, Pierce, Ramsey, Ransom, Renville, Rollefe, Sargent, Sheridan, Sioux, Slope, Stark, Steele, Stutsman, Towner, Trail, Walsh, Ward, Wells, Williams.	4-01-2003	6-02-2004	12-02-2003	8-02-2004	S1850	Flooding, ground saturation, storms, winds, tornadoes, high humidity, dry conditions, severe temperatures.	47	6

MN	4-01-2003	6-02-2004	12-02-2003	8-02-2004	SI850	Flooding, ground saturation, storms, winds, tornadoes, high humidity, dry conditions, severe temperatures.	5
MT	4-01-2003	6-02-2004	12-02-2003	8-02-2004	SI850	Flooding, ground saturation, storms, winds, tornadoes, high humidity, dry conditions, severe temperatures.	5
SD	4-01-2003	6-02-2004	12-02-2003	8-02-2004	SI850	Flooding, ground saturation, storms, winds, tornadoes, high humidity, dry conditions, severe temperatures.	8
NE	7-01-2002	5-14-2004	11-14-2003	7-14-2004	SI851	Flooding, ground saturation, storms, winds, tornadoes, high humidity, dry conditions, severe temperatures. Drought, extreme heat, flooding, grasshopper infestation, hail, high winds, tornadoes.	28	12
IA	7-01-2002	5-14-2004	11-14-2003	7-14-2004	SI851	Drought, extreme heat, flooding, grasshopper infestation, hail, high winds, tornadoes.	4
MO	7-01-2002	5-14-2004	11-14-2003	7-14-2004	SI851	Drought, extreme heat, flooding, grasshopper infestation, hail, high winds, tornadoes.	2
KS	7-01-2002	5-14-2004	11-14-2003	7-14-2004	SI851	Drought, extreme heat, flooding, grasshopper infestation, hail, high winds, tornadoes.	6
SC	3-20-2003	11-07-2003	12-09-2003	8-09-2004	SI852	Drought, extreme heat, flooding, grasshopper infestation, hail, high winds, tornadoes. Excessive rainfall	8	16
GA	3-20-2003	11-07-2003	12-09-2003	8-09-2004	SI852	Excessive rainfall	4
NC	3-20-2003	11-07-2003	12-09-2003	8-09-2004	SI852	Excessive rainfall	5
NY	1-01-2003	6-02-2004	continuing	8-02-2004	SI853	Excessive precipitation, disease, insect infestation.	16	3
DE	1-01-2003	6-02-2004	12-02-2003	8-02-2004	SI853	Excessive precipitation	3
NY	1-01-2003	6-02-2004	12-02-2003	8-02-2004	SI853	Excessive precipitation	2

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal Year 2004—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
PA	1-01-2003	6-02-2004	12-02-2003	8-02-2004	S1853	Excessive precipitation	6
TX	Wheeler	1-01-2003	6-12-2004	12-12-2003	8-12-2004	S1854	Drought	1	7
CA	Colusa, Sacramento	7-10-2003	8-26-2003	12-19-2003	8-19-2004	S1855	(1) Excessive rainfall (2) Extreme heat, followed by unseasonable rainfall.	2	11
IL	Boone, Bureau, Carroll, Clay, Edwards, Fayette, Franklin, Gallatin, Hamilton, Hardin, Henderson, Henry, Jackson, Jefferson, Jo Daviess, Johnson, Knox, Lake, Lee, Marion, Marshall, Massac, McHenry, Mercer, Ogle, Perry, Pope, Putnam, Randolph, Saline, St. Clair, Stark, Stephenson, Vermilion, Wabash, Washington, Wayne, White, Whiteside, Williamson, Winnebago, Woodford.	1-01-2003	continuing	12-19-2003	8-19-2004	S1856	Drought	42	28
KY	1-01-2003	continuing	12-19-2003	8-19-2004	S1856	Drought	4
MO	1-01-2003	continuing	12-19-2003	8-19-2004	S1856	Drought	4
WI	1-01-2003	continuing	12-19-2003	8-19-2004	S1856	Drought	5
MO	Audrain, Boone, Callaway, Cape Girardeau, Cole, Crawford, Dade, Franklin, Gasconade, Greene, Howard, Jasper, Knox, Laclede, Lawrence, Lincoln, Macon, Maries, Marion, McDonald, Miller, Moniteau, Monroe, Montgomery, Osage, Perry, Phelps, Pike, Pulaski, Ralls, Randolph, Scotland, Shelby, Warren.	6-01-2002	continuing	12-19-2003	8-19-2004	S1857	Drought	34	21

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
 [Fiscal Year 2004—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
MI	Antrim, Calhoun, Ingham, Jackson, Kent, Mason, Muskegon, Newaygo, Ottawa.	8-01-2003	9-22-2003	1-23-2004	9-23-2004	S1865	Storms that produced hail, high winds, heavy rains.	9	24
MI	Alcona, Alger, Allegan, Alpena, Antrim, Arenac, Baraga, Barry, Bay, Benzie, Berrien, Calhoun, Cass, Charlevoix, Cheboygan, Chippewa, Clare, Clinton, Delta, Dickinson, Eaton, Emmet, Genesee, Gladwin, Gogebic, Grand Traverse, Gratiot, Houghton, Huron, Ingham, Ionia, Iosco, Iron, Isabella, Jackson, Kalamazoo, Kalkaska, Kent, Keweenaw, Lapeer, Leelanau, Livingston, Luce, Mackinac, Macomb, Manistee, Marquette, Mason, Mecosta, Menominee, Midland, Missaukee, Montcalm, Montmorency, Muskegon, Newaygo, Oakland, Oceana, Ogemaw, Ontonagon, Oscoda, Otsego, Ottawa, Presque Isle, Saginaw, Sanilac, Schoolcraft, Shiawassee, St. Clair, St. Joseph, Tuscola, Van Buren, Washtenaw, Wayne, Wexford.	7-01-2003	continuing	1-23-2004	9-23-2004	S1866	Drought	75	8
IN		7-01-2003	continuing	1-23-2004	9-23-2004	S1866	Drought		4
WI		7-01-2003	continuing	1-23-2004	9-23-2004	S1866	Drought		5

MI	Allegan, Antrim, Benzie, Berrien, Cass, Charlevoix, Dickinson, Grand Traverse, Hillsdale, Huron, Ingham, Ionia, Iron, Isabella, Kalamazoo, Kent, Leelanau, Livingston, Macomb, Manistee, Mason, Menominee, Monroe, Montcalm, Muskegon, Newaygo, Oceana, Otsego, Ottawa, St. Clair, Van Buren, Wexford.	(1) 02/28/03 (2) 05/07/03	(1) 07/21/03 (2) 07/21/03	1-23-2004	9-23-2004	S1867	(1) Extreme temperature fluctuations; freezing rain; periods of abnormal warm weather followed by tem- peratures as low as 24 degrees with significant crop damage.. (2) Heavy rains, flooding, hail, high winds.	32	36
IN	(1) 02/28/03 (2) 05/07/03	(2) 07/21/03 (2) 07/21/03	1-23-2004	9-23-2004	S1867	(1) Extreme temperature fluctuations; freezing rain; periods of abnormal warm weather followed by tem- peratures as low as 24 degrees with significant crop damage.. (2) Heavy rains, flooding, hail, high winds.	4
OH	(1) 02/28/03 (2) 05/07/03	(1) 07/21/03 (2) 07/21/03	1-23-2004	9-23-2004	S1867	(1) Extreme temperature fluctuations; freezing rain; periods of abnormal warm weather followed by tem- peratures as low as 24 degrees with significant crop damage.. (2) Heavy rains, flooding, hail, high winds.	3
WI	(1) 02/28/03 (2) 05/07/03	(1) 07/21/03 (2) 07/21/03	1-23-2004	9-23-2004	S1867	(1) Extreme temperature fluctuations; freezing rain; periods of abnormal warm weather followed by tem- peratures as low as 24 degrees with significant crop damage.. (2) Heavy rains, flooding, hail, high winds.	4

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal Year 2004—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
KS	Allen, Anderson, Atchison, Barber, Barton, Bourbon, Chautauqua, Cheyenne, Clay, Cloud, Coffey, Crawford, Decatur, Dickinson, Doniphan, Elk, Ellsworth, Finney, Ford, Geary, Graham, Grant, Gray, Hamilton, Harper, Haskell, Hodgeman, Jefferson, Jewell, Johnson, Kearny, Kingman, Kiowa, Lane, Leavenworth, Lincoln, Linn, Logan, McPherson, Marshall, Meade, Miami, Mitchell, Nemaha, Neosho, Ness, Norton, Osage, Osborne, Ottawa, Phillips, Pottawatomie, Rawlins, Reno, Republic, Rice, Riley, Rooks, Rush, Russell, Saline, Scott, Sheridan, Sherman, Smith, Stafford, Stanton, Thomas, Trego, Wabaunsee, Wallace, Washington, Wyandotte, Douglas, Edwards, Franklin, Gove, Lyon, Morris, Pawnee, Pratt.	1-01-2003	continuing	1-23-2004	9-23-2004	S1868	Drought, excessive wind, insect damage.	81	24
CO	1-01-2003	continuing	1-23-2004	9-23-2004	S1868	Drought, excessive wind, insect damage.	4
MO	1-01-2003	continuing	1-23-2004	9-23-2004	S1868	Drought, excessive wind, insect damage.	11
NE	1-01-2003	continuing	1-23-2004	9-23-2004	S1868	Drought, excessive wind, insect damage.	13

OK	1-01-2003	continuing	1-23-2004	9-23-2004	SI868	Drought, excessive wind, insect damage.	6
OR	10-01-2001	continuing	1-23-2004	9-23-2004	SI869	Drought	2	5
ID	10-01-2001	continuing	1-23-2004	9-23-2004	SI869	Drought	3
WA	10-01-2001	continuing	1-23-2004	9-23-2004	SI869	Drought	4
TX	10-10-2003	10-13-2003	2-10-2004	10-12-2004	SI870	Flash flooding	1	7
TX	1-01-2003	continuing	2-10-2004	10-12-2004	SI871	Excessive rain	1	6
TX	10-10-2003	10-13-2003	2-10-2004	10-12-2004	SI872	Flash flooding	1	5
OK	10-10-2003	10-13-2003	2-10-2004	10-12-2004	SI872	Flash flooding	2
TX	1-01-2003	10-13-2003	2-10-2004	10-12-2004	SI873	Drought, high wind, excessive heat	1	6
TX	4-05-2003	12-08-2003	2-10-2004	10-12-2004	SI874	Hail, tornado, excessive high winds	1	6
TX	1-01-2003	continuing	2-10-2004	10-12-2004	SI875	Drought, high winds	1	5
TX	7-01-2003	continuing	2-10-2004	10-12-2004	SI876	Drought	1	8
TX	7-01-2003	continuing	2-10-2004	10-12-2004	SI877	Drought, excessive temperatures (heat).	1	10
TX	1-01-2003	continuing	2-10-2004	10-12-2004	SI878	Drought, excessive temperatures (heat).	1	7
PA	1-01-2003	12-31-2003	2-13-2004	10-13-2004	SI879	Excessive rainfall, early frost	1	2
NY	1-01-2003	12-31-2003	2-13-2004	10-13-2004	SI879	Excessive rainfall, early frost	1
OH	1-01-2003	12-31-2003	2-13-2004	10-13-2004	SI879	Excessive rainfall, early frost	1
OR	10-01-2001	continuing	2-13-2004	10-13-2004	SI880	Drought	3	4
CA	10-01-2001	continuing	2-13-2004	10-13-2004	SI880	Drought	1
ID	10-01-2001	continuing	2-13-2004	10-13-2004	SI880	Drought	1
MI	8-01-2003	9-30-2003	2-13-2004	10-13-2004	SI881	Abnormally cool, cloudy weather resulting in an increase in aphids, which caused mosaic virus (in vegetable crops).	6	12
IN	8-01-2003	9-30-2003	2-13-2004	10-13-2004	SI881	2
MI	3-01-2003	10-02-2003	2-13-2004	10-13-2004	SI882	Late spring (cool spring weather), combined with early freeze.	4	5
IN	3-01-2003	10-02-2003	2-13-2004	10-13-2004	SI882	Late spring (cool spring weather), combined with early freeze.	3

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
 [Fiscal Year 2004—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
WI	Adams, Ashland, Barron, Bayfield, Buffalo, Burnett, Calumet, Chippewa, Clark, Columbia, Crawford, Dane, Dodge, Douglas, Dunn, Eau Claire, Florence, Fond du Lac, Forest, Grant, Green, Green Lake, Iowa, Iron, Jackson, Jefferson, Juneau, Kenosha, LaCrosse, Lafayette, Langlade, Lincoln, Marquette, Milwaukee, Monroe, Oneida, Ozaukee, Pepin, Pierce, Polk, Portage, Racine, Richland, Rock, Rusk, St. Croix, Sauk, Sawyer, Trempealeau, Vernon, Vilas, Walworth, Washburn, Washington, Waukesha, Waupaca, Waushara, Winnebago, Wood.	5-01-2003	10-31-2003	2-27-2004	10-27-2004	S1883	Drought	59	11
IL		5-01-2003	10-31-2003	2-27-2004	10-27-2004	S1883	Drought		6
IA		5-01-2003	10-31-2003	2-27-2004	10-27-2004	S1883	Drought		3
MI		5-01-2003	10-31-2003	2-27-2004	10-27-2004	S1883	Drought		3
MN		5-01-2003	10-31-2003	2-27-2004	10-27-2004	S1883	Drought		10
MA	Berkshire, Bristol, Franklin, Hampshire, Hampden, Norfolk, Plymouth.	5-01-2003	10-31-2003	3-09-2004	11-09-2004	S1884	Wet weather patterns	7	4
CT		5-01-2003	10-31-2003	3-09-2004	11-09-2004	S1884	Wet weather patterns		2
NH		5-01-2003	10-31-2003	3-09-2004	11-09-2004	S1884	Wet weather patterns		1
RI		5-01-2003	10-31-2003	3-09-2004	11-09-2004	S1884	Wet weather patterns		3
VT		5-01-2003	10-31-2003	3-09-2004	11-09-2004	S1884	Wet weather patterns		1
CA	Fresno, Kern, Merced, Tulare	1-02-2003	9-30-2003	3-09-2004	11-09-2004	S1885	Cool weather followed by extended period of hot weather.	4	15

NY	Albany, Cattaraugus, Chautauqua, Erie, Livingston, Oneida, Orleans, Saratoga, Seneca, Sullivan, Tompkins,	4-01-2003	continuing	3-09-2004	11-09-2004	S1886	Various disasters for each county including: Below normal temperatures, excessive rain, flash flooding, hail, high winds.	11	12
PA	4-01-2003	continuing	3-09-2004	11-09-2004	S1886	Various disasters for each county including: Below normal temperatures, excessive rain, flash flooding, hail, high winds.	3
NY	Wayne	9-23-2003	9-23-2003	3-09-2004	11-09-2004	S1887	Hail	1	4
WA	(1) Clark, Cowlitz, Skamania, Wahkiakum.	5-01-2003	9-06-2003	3-09-2004	11-09-2004	S1888	(1) Drought, excessive heat	7	8
OR	(2) Island, San Juan, Skagit	5-01-2003	9-06-2003	3-09-2004	11-09-2004	S1888	(2) Drought
CA	Sutter, Yuba	8-22-2003	9-15-2003	3-11-2004	11-09-2004	S1889	(1) Drought, excessive heat
CO	Cheyenne, Logan, Phillips	1-01-2004	continuing	3-16-2004	11-16-2004	S1890	(2) Drought	2	8
NE	1-01-2004	1-01-2004	continuing	3-16-2004	11-16-2004	S1890	Drought	3	4
ME	Aroostook, Franklin, Oxford, Penobscot.	6-01-2003	continuing	3-16-2004	11-16-2004	S1891	Excessive rainfall	4	9
NH	6-01-2003	6-01-2003	continuing	3-16-2004	11-16-2004	S1891	Excessive rainfall	2
TX	Hansford	6-05-2003	6-09-2003	3-16-2004	11-16-2004	S1892	Excessive rain, flash flooding, hail, high winds, lightning, tornado.	1	5
OK	6-05-2003	6-05-2003	6-09-2003	3-16-2004	11-16-2004	S1892	Excessive rain, flash flooding, hail, high winds, lightning, tornado.	1
WA	Asotin, Chelan, Columbia, Douglas, Ferry, Garfield, Grays Harbor, King, Kitsap, Lewis, Lincoln, Mason, Pacific, Pend Oreille, Pierce, Spokane, Stevens, Thurston, Walla Walla, Whitman.	1-01-2003	continuing	3-16-2004	11-16-2004	S1893	Drought	20	13
ID	1-01-2003	continuing	3-16-2004	11-16-2004	S1893	Drought	6
OR	1-01-2003	continuing	3-16-2004	11-16-2004	S1893	Drought	2
CI	Entire State	5-01-2003	9-30-2003	3-22-2004	11-22-2004	S1894	Wet weather pattern; high rainfall, insect problems.	8
MA	5-01-2003	9-30-2003	3-22-2004	11-22-2004	S1894	Wet weather pattern; high rainfall, insect problems.	2
NY	5-01-2003	9-30-2003	3-22-2004	11-22-2004	S1894	Wet weather pattern; high rainfall, insect problems.	4

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal Year 2004—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
RI	5-01-2003	9-30-2003	3-22-2004	11-22-2004	S1894	Wet weather pattern; high rainfall, insect problems.	3
HI	Hawaii, Honolulu, Kauai, Maui	1-01-2003	12-31-2003	3-22-2004	11-22-2004	S1895	Drought	4	1
OR	Wasco, Washington	10-01-2001	continuing	3-22-2004	11-22-2004	S1896	Drought	2	8
TX	Hockley	6-30-2003	continuing	3-22-2004	11-22-2004	S1897	Drought	1	8
TX	Fisher	1-01-2003	continuing	3-22-2004	11-22-2004	S1898	Drought, excessive temperatures (heat).	1	7
TX	Lynn	1-01-2003	continuing	4-05-2004	12-06-2004	S1899	(1) Hail, high winds	1	7
NY	Erie, Livingston, Monroe, Onondaga, Ontario, Orleans, Oswego, Schuyler, Tompkins, Brown	10-14-2003	continuing	4-09-2004	12-09-2004	S1900	(2) Drought Excessive rain, high winds	9	20
KS	1-01-2003	continuing	4-21-2004	12-21-2004	S1901	Drought, frost, excessive wind, insect damage.	1
OR	Morrow	9-02-2002	continuing	4-21-2004	12-21-2004	S1902	Drought	1
WA	9-02-2002	continuing	4-21-2004	12-21-2004	S1902	Drought	1
TX	Robertson	10-05-2003	10-09-2003	4-21-2004	12-21-2004	S1903	Excessive rain, flash flooding	1	7
TX	Martin	1-01-2003	12-31-2003	4-23-2004	12-23-2004	S1904	Drought, high winds	1	7
TX	Motley	7-01-2003	continuing	4-23-2004	12-23-2004	S1905	Drought, high winds, static electricity	1	7
TX	San Saba	10-15-2003	continuing	4-23-2004	12-23-2004	S1906	Drought	1	7
TX	Mason	10-01-2003	continuing	4-23-2004	12-23-2004	S1907	Drought, high winds	1	6
TX	Palo Pinto	10-01-2003	continuing	4-23-2004	12-23-2004	S1908	Drought	1	7
TX	Bastrop	3-01-2003	continuing	4-23-2004	12-23-2004	S1909	Drought	1	6
TX	Dickens	8-01-2003	12-18-2003	4-23-2004	12-23-2004	S1910	Drought, excessive temperatures (heat).	1	8
TX	Caldwell	3-15-2003	continuing	4-23-2004	12-23-2004	S1911	Drought	1	6
TX	Kent	8-01-2003	continuing	4-23-2004	12-23-2004	S1912	Drought, excessive temperatures (heat).	1	7
TX	Montague	4-15-2003	continuing	4-23-2004	12-23-2004	S1913	Drought	1	4
OK	4-15-2003	continuing	4-23-2004	12-23-2004	S1913	Drought	2
TX	Crane, Ector, Haskell, Loving, Presidio, Reeves, Ward, Winkler	1-01-2003	continuing	4-23-2004	12-23-2004	S1914	Drought, high winds, excessive heat	8	16
NM	1-01-2003	continuing	4-23-2004	12-23-2004	S1914	Drought, high winds, excessive heat	2

CA	San Luis Obispo, Santa Barbara	4-01-2003	10-31-2003	4-23-2004	12-23-2004	S1915	(1) Insufficient winter chill hours, rainfall, high heat. (2) Insufficient winter chill hours, cool/wet weather, extended hot spell. Drought	2	6
MT	Blackfeet Tribe (Pondera Co.), Confederated Salish Kootenai Tribe (Missoula Co.), Ft. Peck Assisboine & Sioux Tribe; (Valley Co.), Chouteau, Garfield, Granite, Mineral, Prairie, Petroleum, Pondera, Treasure.	1-01-2003	continuing	4-23-2004	12-23-2004	S1916		11	
ID		1-01-2003	continuing	4-23-2004	12-23-2004	S1916	Drought		2
CA	Placer	8-01-2003	10-31-2003	4-23-2004	12-23-2004	S1917	August rain, poor winter chill, high heat-Pistachios.	1	5
NV		8-01-2003	10-31-2003	4-23-2004	12-23-2004	S1917	August rain, poor winter chill, high heat-Pistachios.		3
TX	Crockett, Glasscock, Hardeman, Howard, Irion, Jones, Reagan, Upton, Williamson.	1-01-2003	continuing	4-23-2004	12-23-2004	S1918	Drought	9	32
OK		1-01-2003	continuing	4-23-2004	12-23-2004	S1918	Drought		2
NY	Fulton, Montgomery, Ontario, Otsego.	4-01-2003	continuing	4-27-2004	12-27-2004	S1919	Excessive rain, cool temperatures	4	6
TX	Andrews	1-01-2003	continuing	4-28-2004	12-28-2004	S1920	Drought, high winds	1	5
NM		1-01-2003	continuing	4-28-2004	12-28-2004	S1920	Drought, high winds		1
TX	Donley	9-15-2003	12-31-2003	4-28-2004	12-28-2004	S1921	Drought	1	7
TX	Shackelford, Throckmorton	1-01-2003	11-25-2003	4-28-2004	12-28-2004	S1922	Drought, high winds	2	9
TX	Childress	8-01-2003	continuing	4-28-2004	12-28-2004	S1923	Drought, high winds	1	4
OK		8-01-2003	continuing	4-28-2004	12-28-2004	S1923	Drought, high winds		1
TX	Clay	7-01-2003	continuing	4-28-2004	12-28-2004	S1924	Drought	1	4
OK		7-01-2003	continuing	4-28-2004	12-28-2004	S1924	Drought		2
TX	Wise	7-15-2003	continuing	4-28-2004	12-28-2004	S1925	Drought	1	6
NY	Dutchess	9-01-2003	continuing	5-03-2004	12-28-2004	S1926	Excessive rain, flooding	1	4
CT		9-01-2003	continuing	5-03-2004	1-03-2005	S1926	Excessive rain, flooding		2
MA		9-01-2003	continuing	5-03-2004	1-03-2005	S1926	Excessive rain, flooding		1
CA	Placer, San Luis Obispo	5-01-2003	11-15-2003	5-17-2004	1-18-2005	S1927	(1) Unseasonable rainfall (2) Wheat stripe rust, resulting from unseasonable rainfall.	2	9

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal Year 2004—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
NV	5-01-2003	11-15-2003	5-17-2004	1-18-2005	S1927	(1) Unseasonable rainfall (2) Wheat stripe rust, resulting from unseasonable rainfall.	3
TX	Brooks	4-04-2004	4-04-2004	6-08-2004	2-08-2004	S1928	Excessive rain, flash flooding, flooding, hail, high winds.	1	7
HI	Hawaii, Honolulu, Maui	12-07-2003	3-26-2004	6-21-2004	2-22-2004	S1929	High winds, rain, flooding	3	1
TX	Robertson	4-10-2004	4-10-2004	6-21-2004	2-22-2004	S1930	Hail, high winds	1	7
NE	Arthur, Banner, Chase, Cheyenne, Deuel, Dundy, Frontier, Garden, Hayes, Hitchcock, Keith, Kimball, Lincoln, McPherson, Morrill, Perkins, Red Willow, Scotts Bluff, Sioux.	1-01-2004	continuing	6-21-2004	2-22-2004	S1931	Drought	19	11
SD	1-01-2004	continuing	6-21-2004	2-22-2004	S1931	Drought	1
WY	1-01-2004	continuing	6-21-2004	2-22-2004	S1931	Drought	3
MA	Essex, Franklin, Middlesex	1-05-2004	2-20-2004	7-09-2004	3-09-2004	S1932	Winter damage due to abnormally cold weather patterns.	3	5
NH	1-05-2004	2-20-2004	7-09-2004	3-09-2004	S1932	Winter damage due to abnormally cold weather patterns.	3
VT	1-05-2004	2-20-2004	7-09-2004	3-09-2004	S1932	Winter damage due to abnormally cold weather patterns.	2
TX	Wilson	5-13-2004	5-13-2004	7-20-2004	3-21-2004	S1933	Excessive rain, high winds	1	5
MO	Linn	5-24-2004	5-24-2004	7-29-2004	3-29-2005	S1934	Severe thunderstorms w/ high winds, tornadoes, excessive rain, flooding, lightning, large hail.	1	6
WA	Franklin	1-04-2004	1-07-2004	7-29-2004	3-29-2005	S1935	Sub-zero freezing temperatures	1	6
WA	Yakima	10-29-2003	1-08-2004	7-29-2004	3-29-2005	S1936	Adverse weather conditions; sub-zero freezing temperatures.	1	8
NE	Box Butte, Dawes	1-01-2004	continuing	7-29-2004	3-29-2005	S1937	Drought	2	3
NE	Sheridan	5-13-2004	5-14-2004	7-29-2004	3-29-2005	S1937	Freeze	1	6
SD	Fall River	1-01-2004	continuing	7-29-2004	3-29-2005	S1937	Drought	1
SD	Bennett, Shannon	5-13-2004	5-14-2004	7-29-2004	3-29-2005	S1937	Freeze	2

CA	Butte, Glenn, Yuba	3-12-2004	3-15-2004	8-02-2004	4-04-2005	S1938	Unseasonably high temperatures, low humidity.	1	9
CA	Fresno	3-01-2004	3-31-2004	8-02-2004	4-04-2005	S1938	Unseasonably hot weather during fruit bloom.	1	8
CA	Merced	3-25-2004	3-25-2004	8-02-2004	4-04-2005	S1938	Windy conditions, abnormally high temperatures.	1	6
CA	Sutter	3-09-2004	3-22-2004	8-02-2004	4-04-2005	S1938	Severe high temperatures, low humidity.	1	6
SD	Bennett, Brule, Buffalo, Butte, Campbell, Corson, Custer, Dewey, Fall River, Gregory, Haakon, Hand, Harding, Hughes, Hyde, Jackson, Jones, Lawrence, Lyman, Meade, Mellette, Pennington, Perkins, Shannon, Stanley, Sully, Todd, Tripp, Walworth, Ziebach.	1-01-2004	continuing	8-06-2004	4-06-2005	S1939	Drought, infestation of army cutworms, weevils, and grasshoppers.	30	9
MT		1-01-2004	continuing	8-06-2004	4-06-2005	S1939	Drought, infestation of army cutworms, weevils, and grasshoppers.	2
NE		1-01-2004	continuing	8-06-2004	4-06-2005	S1939	Drought, infestation of army cutworms, weevils, and grasshoppers.	6
ND		1-01-2004	continuing	8-06-2004	4-06-2005	S1939	Drought, infestation of army cutworms, weevils, and grasshoppers.	5
WY		1-01-2004	continuing	8-06-2004	4-06-2005	S1939	Drought, infestation of army cutworms, weevils, and grasshoppers.	3
SD	Charles Mix	1-01-2004	continuing	11-23-2004	7-25-2005	S1939, Amendment 1.	Late spring killing frost, extreme heat, high winds, hail, severe storms, drought, insect infestation.	1	3
NE		1-01-2004	continuing	11-23-2004	7-25-2005	S1939, Amendment 1.	Late spring killing frost, extreme heat, high winds, hail, severe storms, drought, insect infestation.	1

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal Year 2004—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
ND	Adams, Billings, Bottineau, Bowman, Burke, Burleigh, Cavalier, Divide, Dunn, Eddy, Emmons, Foster, Golden Valley, Grand Forks, Grant, Hettinger, McHenry, McKenzie, Mercer, Morton, Mountrail, Nelson, Oliver, Pembina, Pierce, Ramsey, Ransom, Renville, Rolette, Sioux, Slope, Stark, Towner, Walsh, Ward.	1-01-2004	continuing	8-10-2004	4-11-2005	S1940	Drought, late season frost, high winds, flooding, ground saturation, storms, ice, snow, severe temperatures.	35	18
MN	1-01-2004	continuing	8-10-2004	4-11-2005	S1940	Drought, late season frost, high winds, flooding, ground saturation, storms, ice, snow, severe temperatures.	3
MT	1-01-2004	continuing	8-10-2004	4-11-2005	S1940	Drought, late season frost, high winds, flooding, ground saturation, storms, ice, snow, severe temperatures.	5
SD	1-01-2004	continuing	8-10-2004	4-11-2005	S1940	Drought, late season frost, high winds, flooding, ground saturation, storms, ice, snow, severe temperatures.	4
AR	Crawford, Faulkner, Greene, Independence, Jackson, Lawrence, Perry, Pope, Prairie, Pulaski, White, Woodruff, Yell.	4-21-2004	4-27-2004	8-11-2004	4-11-2005	S1941	Excessive rain, flooding	13	29
OK	Crawford, Faulkner, Greene, Independence, Jackson, Lawrence, Perry, Pope, Prairie, Pulaski, White, Woodruff, Yell.	4-21-2004	4-27-2004	8-11-2004	4-11-2004	S1941	Excessive rain, flooding	2

CA	Madera	10-01-2003	5-31-2004	8-11-2004	4-11-2005	S1942	(1) Drought (2) Windy conditions, abnormally high temperatures.	1	5
CA	Colusa	3-12-2004	3-19-2004	8-11-2004	4-11-2005	S1943	Unseasonably high temperatures	1	5
NY	Ontario, Seneca, Steuben, Wayne, Yates.	12-15-2003	2-17-2004	8-11-2004	4-11-2005	S1944	Excessive cold, significant frost	5	11
TX	Lipscomb	4-11-2004	4-12-2004	8-11-2004	4-11-2005	S1945	Freeze	1	3
CA	Alameda	3-01-2004	continuing	8-18-2004	4-18-2005	S1946	Drought, high winds, excessive [record] temperatures.	1	4
CO	Baca, Chaffee, Cheyenne, Custer, Eagle, Fremont, Garfield, Grand, Jackson, Kiowa, Kit Carson, Lake, Lincoln, Phillips, Pitkin, Prowers, Pueblo, Routt, Summit, Yuma.	1-01-2004	continuing	8-18-2004	4-18-2005	S1947	Drought, hail, freeze	20	22
KS		1-01-2004	continuing	8-18-2004	4-18-2005	S1947	Drought, hail, freeze	7
NE		1-01-2004	continuing	8-18-2004	4-18-2005	S1947	Freeze, hail	4
NM		1-01-2004	continuing	8-18-2004	4-18-2005	S1947	Drought	1
OK		1-01-2004	continuing	8-18-2004	4-18-2005	S1947	Drought	1
UT		1-01-2004	continuing	8-18-2004	4-18-2005	S1947	Drought	2
WY		1-01-2004	continuing	8-18-2004	4-18-2005	S1947	Drought	2
KS	Barber, Cloud, Cowley, Decatur, Geary, Gove, Harper, Republic, Scott, Sumner.	4-23-2004	5-29-2004	8-20-2004	4-20-2005	S1948	Hail, high winds, tornadoes, excessive rain, flooding.	10	29
NE		4-23-2004	5-29-2004	8-20-2004	4-20-2005	S1948	Hail, high winds, tornadoes, excessive rain, flooding.	5
OK		4-23-2004	5-29-2004	8-20-2004	4-20-2005	S1948	Hail, high winds, tornadoes, excessive rain, flooding.	5
KS	Cheyenne, Decatur, Ellis, Finney, Gove, Graham, Grant, Greeley, Hamilton, Haskell, Hodgman, Jewell, Kearny, Lane, Logan, Mitchell, Morton, Ness, Norton, Osborne, Phillips, Rawlins, Rooks, Russell, Scott, Seward, Sheridan, Sherman, Stanton, Stevens, Trego, Thomas, Wallace, Wichita.	4-07-2004	5-15-2004	8-20-2004	4-20-2005	S1949	Freezing conditions, drought	34	13
CO		4-07-2004	5-15-2004	8-20-2004	4-20-2005	S1949	Freezing conditions, drought	6

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
 [Fiscal Year 2004—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
NE	4-07-2004	5-15-2004	8-20-2004	4-20-2005	S1949	Freezing conditions, drought	8
OK	4-07-2004	5-15-2004	8-20-2004	4-20-2005	S1949	Freezing conditions, drought	3
OH	Allen, Athens, Carroll, Columbiana, Coshocton, Crawford, Cuyahoga, Fayette, Greene, Guernsey, Hancock, Henry, Hocking, Holmes, Jackson, Logan, Mahoning, Medina, Noble, Perry, Tuscarawas, Union, Wayne—Ashtabula, Defiance, Delaware, Erie, Fairfield, Geauga, Lake, Licking, Logan, Lorain, Lucas, Marion, Morgan, Muskingum, Ottawa, Paulding, Portage, Sandusky, Scioto, Seneca, Summit, Van Wert, Wood, Wyandot.	5-01-2004	continuing	8-27-2004	4-27-2005	S1950	Excessive rain, high winds, flooding, hail, tornado—Excessive moisture.	46	69
IN	5-01-2004	continuing	8-27-2004	4-27-2005	S1950	Excessive rain, high winds, flooding, hail, tornado—Excessive moisture.	3
KY	5-01-2004	continuing	8-27-2004	4-27-2005	S1950	Excessive rain, high winds, flooding, hail, tornado—Excessive moisture.	2
MI	5-01-2004	continuing	8-27-2004	4-27-2005	S1950	Excessive rain, high winds, flooding, hail, tornado—Excessive moisture.	2
PA	5-01-2004	continuing	8-27-2004	4-27-2005	S1950	Excessive rain, high winds, flooding, hail, tornado—Excessive moisture.	5
WV	5-01-2004	continuing	8-27-2004	4-27-2005	S1950	Excessive rain, high winds, flooding, hail, tornado—Excessive moisture.	2
WY	Big Horn, Campbell, Converse, Crook, Goshen, Johnson, Lincoln, Niobrara, Platte, Sheridan, Weston.	1-01-2004	continuing	9-07-2004	5-09-2005	S1951	Drought	11	10
ID	1-01-2004	continuing	9-07-2004	5-09-2005	S1951	Drought	3

MT	1-01-2004	continuing	9-07-2004	5-09-2005	S1951	Drought	4
NE	1-01-2004	continuing	9-07-2004	5-09-2005	S1951	Drought	3
SD	1-01-2004	continuing	9-07-2004	5-09-2005	S1951	Drought	5
UT	1-01-2004	continuing	9-07-2004	5-09-2005	S1951	Drought	1
ID	3-01-2004	4-30-2004	9/14/04	5-16-2005	S1952	Drought	2	14
TX	5-13-2004	5-13-2004	9-14-2004	5-16-2005	S1953	Excessive rain, flash flooding, flooding, high winds, tornado.	3	8
UT	1-01-2004	continuing	9-14-2004	5-16-2005	S1954	Drought, wind, hail, heat, grasshoppers, Mormon crickets.	20	9
AZ	1-01-2004	continuing	9-14-2004	5-16-2005	S1954	Drought, wind, hail, heat, grasshoppers, Mormon crickets.	4
CO	1-01-2004	continuing	9-14-2004	5-16-2005	S1954	Drought, wind, hail, heat, grasshoppers, Mormon crickets.	6
ID	1-01-2004	continuing	9-14-2004	5-16-2005	S1954	Drought, wind, hail, heat, grasshoppers, Mormon crickets.	4
NV	1-01-2004	continuing	9-14-2004	5-16-2005	S1954	Drought, wind, hail, heat, grasshoppers, Mormon crickets.	3
NM	1-01-2004	continuing	9-14-2004	5-16-2005	S1954	Drought, wind, hail, heat, grasshoppers, Mormon crickets.	1
WY	1-01-2004	continuing	9-14-2004	5-16-2005	S1954	Drought, wind, hail, heat, grasshoppers, Mormon crickets.	3
TN	5-01-2004	continuing	9-17-2004	5-17-2005	S1955	Tornadoes, severe thunderstorms, strong winds, excessive rain, flooding, hail.	1	4
AR	5-01-2004	continuing	9-17-2004	5-17-2005	S1955	Tornadoes, severe thunderstorms, strong winds, excessive rain, flooding, hail.	1

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal Year 2004—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
LA	Acadia, Allen, Avoyelles, Beauregard, Bienville, Caldwell, Catahoula, Claiborne, East Carroll, East Feliciana, Evangeline, Franklin, Grant, Iberville, Jackson, Jefferson Davis, La Salle, Lafayette, Lincoln, Madison, Morehouse, Natchitoches, Ouachita, Plaquemines, Pointe Coupee, Rapides, Richland, Sabine, St. Bernard, St. Charles, St. James, St. John the Baptist, St. Landry, Tensas, Union, Vermilion, Vernon, Webster, West Baton Rouge, West Carroll.	5-01-2004	6-30-2004	9-17-2004	5-17-2005	S1956	Excessive rainfall	40	19
AR	5-01-2004	6-30-2004	9-17-2004	5-17-2005	S1956	Excessive rainfall	5
MS	5-01-2004	6-30-2004	9-17-2004	5-17-2005	S1956	Excessive rainfall	7
TX	5-01-2004	6-30-2004	9-17-2004	5-17-2005	S1956	Excessive rainfall	3
IA	Jefferson, Lyon, O'Brien, Taylor	2-01-2004	continuing	9-17-2004	5-17-2005	S1957	Winter snow load, excessive rainfall, high winds, hail, tornadoes.	4	18
MN	2-01-2004	continuing	9-17-2004	5-17-2005	S1957	Winter snow load, excessive rainfall, high winds, hail, tornadoes.	2
MO	2-01-2004	continuing	9-17-2004	5-17-2005	S1957	Winter snow load, excessive rainfall, high winds, hail, tornadoes.	2
SD	2-01-2004	continuing	9-17-2004	5-17-2005	S1957	Winter snow load, excessive rainfall, high winds, hail, tornadoes.	2
TX	Briscoe	6-21-2004	6-22-2004	9-17-2004	5-17-2005	S1958	Excessive rain, hail, high winds, lightning, tornadoes.	1	6
AR	Ashley, Bradley, Calhoun, Drew	5-01-2004	6-30-2004	9-21-2004	5-23-2005	S1959	Hail, high winds	4	7
LA	Ashley, Bradley, Calhoun, Drew	5-01-2004	6-30-2004	9-21-2004	5-23-2005	S1959	Hail, high winds	1

MN	Lake of the Woods, Marshall, Roseau.	5-11-2004	continuing	9-21-2004	5-23-2005	S1960	Excessive rain, flooding	3	5
ND	5-11-2004	continuing	9-21-2004	5-23-2005	S1960	Excessive rain, flooding	2
GA	Appling, Atkinson, Bacon, Baker, Ben Hill, Berrien, Bibb, Bleckley, Brantley, Brooks, Bulloch, Burke, Butts, Calhoun, Camden, Charlton, Chatham, Chat-tahoochee, Clinch, Coffee, Colquitt, Crawford, Decatur, Dodge, Dooly, Dougherty, Echols, Emanuel, Evans, Glascock, Grady, Greene, Hancock, Harris, Henry, Houston, Jeff Davis, Jeffer-son, Jenkins, Johnson, Lamar, Lanier, Laurens, Lee, Long, Lowndes, Macon, Mar-ion, Miller, Mitchell, Monroe, Montgomery, Muscogee, Peach, Pierce, Pike, Pulaski, Schley, Seminole, Spalding, Stewart, Sumter, Talbot, Talladega, Tattnall, Taylor, Telfair, Terrell, Thomas, Tift, Toombs, Treutlen, Turner, Twiggs, Upson, Ware, Wash-ington, Wayne, Webster, Wheeler, Wilcox, Wilkinson, Worth.	9-04-2004	9-07-2004	9-30-2004	6-01-2005	S1961	Hurricane Frances	5
AL	9-04-2004	9-07-2004	9-30-2004	6-01-2005	S1961	Hurricane Frances	9
FL	9-04-2004	9-07-2004	9-30-2004	6-01-2005	S1961	Hurricane Frances	4
SC	9-04-2004	9-07-2004	9-30-2004	6-01-2005	S1961	Hurricane Frances
GA	Candler, Cook, Crisp, Irwin	9-04-2004	9-07-2004	10-28-2004	Amend-ment 1.	Hurricane Frances	4
NC	Camden, Currituck, Hertford, New Hanover, Pender, Pasquotank.	8-14-2004	8-14-2004	9-30-2004	6-01-2005	S1962	Hurricane Charley	6	13

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal Year 2004—Secretarial Designations for Production Losses]

State	Countries requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
VA	8-14-2004	8-14-2004	9-30-2004	6-01-2005	S1962	Hurricane Charley	4
TX	Cameron	5-08-2004	5-08-2004	9-30-2004	6-01-2005	S1963	Excessive rain, flooding	1	2
TX	Bailey	6-16-2004	6-16-2004	9-30-2004	6-01-2005	S1964	Excessive rain, flash flooding, hail high winds, lightning.	1	4
NM	6-16-2004	6-16-2004	9-30-2004	6-01-2005	S1964	Excessive rain, flash flooding, hail high winds, lightning.	2
TOTAL ACTIVE	1,565	2011

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL
[Fiscal Year 2005—Secretarial Designations for Production Losses]

State	Countries requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
ND	Barnes, Benson, Cass, Griggs, Kidder, LaMoure, Logan, McLean, Sheridan, Steele, Sully, Traill, Wells, Williams.	1-01-2004	continuing	1-10-2005	9-12-2005	S1940, Amendment 1.	Drought, late season frost, high winds, excessive rainfall, flooding, ground saturation, early fall frost (August).	14
MN	1-01-2004	continuing	1-10-2005	9-12-2005	S1940, Amendment 1.	2
TX	Zavala	4-04-2004	5-15-2004	10-01-2004	6-01-2005	S1966	Excessive rain, hail	1	7
NV	Entire State	1-01-2004	continuing	10-12-2004	6-13-2005	S1967	Drought, related insect infestations	17
AZ	1-01-2004	continuing	10-12-2004	6-13-2005	S1967	Drought, related insect infestations	1
CA	1-01-2004	continuing	10-12-2004	6-13-2005	S1967	Drought, related insect infestations	10
ID	1-01-2004	continuing	10-12-2004	6-13-2005	S1967	Drought, related insect infestations	3
OR	1-01-2004	continuing	10-12-2004	6-13-2005	S1967	Drought, related insect infestations	3
UT	1-01-2004	continuing	10-12-2004	6-13-2005	S1967	Drought, related insect infestations	7

MN	8-19-2004	8-21-2004	10-12-2004	6-13-2005	S1968	Freezing temperatures	29
Atkin, Becker, Beltrami, Carlton, Cass, Chippewa, Chisago, Clearwater, Cook, Crow Wing, Douglas, Hubbard, Isanti, Itasca, Kanabec, Kittson, Koochiching, Mahanomen, Marshall, Norman, Pennington, Pine, Polk, Red Lake, Roseau, St. Louis, Swift, Todd, Wadena.	8-19-2004	8-21-2004	10-12-2004	6-13-2005	S1968	Freezing temperatures	5
ND	8-19-2004	8-21-2004	10-12-2004	6-13-2005	S1968	Freezing temperatures	3
WI	8-19-2004	8-21-2004	10-12-2004	6-13-2005	S1968	Freezing temperatures	6
TX	4-01-2003	continuing	10-12-2004	6-13-2005	S1969	Drought	1
CA	7-01-2003	6-30-2004	10-12-2004	6-13-2005	S1970	Drought	3
ND	8-19-2004	8-21-2004	10-12-2004	6-13-2005	S1968	Freezing temperatures	5
WI	8-19-2004	8-21-2004	10-12-2004	6-13-2005	S1968	Freezing temperatures	3
TX	4-01-2003	continuing	10-12-2004	6-13-2005	S1969	Drought	6
CA	7-01-2003	6-30-2004	10-12-2004	6-13-2005	S1970	Drought	14
NV	7-01-2003	6-30-2004	10-12-2004	6-13-2005	S1970	Drought	1
KS	1-01-2004	continuing	10-28-2004	6-28-2005	S1971	(1) Drought	1
MT	1-01-2004	continuing	10-28-2004	6-28-2005	S1972	(2) Freezing conditions	18
Beaverhead, Big Horn, Broadwater, Carbon, Carter, Custer, Dawson, Fallon, Glacier, Golden Valley, Jefferson, Judith Basin, Lake, Lewis & Clark, Liberty, Madison, McCone, Meagher, Mineral, Musselshell, Park, Powder River, Powell, Prairie, Rosebud, Sanders, Silver Bow, Stillwater, Sweet Grass, Teton, Treasure, Wheatland, Wibaux, Yellowstone.	1-01-2004	continuing	10-28-2004	6-28-2005	S1972	Drought	6
ID	1-01-2004	continuing	10-28-2004	6-28-2005	S1972	Drought	6
ND	1-01-2004	continuing	10-28-2004	6-28-2005	S1972	Drought	6
SD	1-01-2004	continuing	10-28-2004	6-28-2005	S1972	Drought	2
WY	1-01-2004	continuing	10-28-2004	6-28-2005	S1972	Drought	5
MT	1-01-2004	continuing	2-28-2005	10-28-2005	S1972, Amend-ment 1.	Drought	1
NJ	6-01-2004	continuing	10-28-2004	6-28-2005	S1973	Hail, excessive rain	7
NY	6-01-2004	continuing	10-28-2004	6-28-2005	S1973	Hail, excessive rain	2
PA	6-01-2004	continuing	10-28-2004	6-28-2005	S1973	Hail, excessive rain	2

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal Year 2005—Secretarial Designations for Production Losses]

State	Countries requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
MT	Carter, Fallon, Liberty, Prairie	5-01-2004	6-30-2004	11-08-2004	7-08-2005	S1974	Late Spring Frosts; Frost	4	10
ND		5-01-2004	6-30-2004	11-08-2004	7-08-2005	S1974	Late Spring Frosts; Frost	3
SD		5-01-2004	6-30-2004	11-08-2004	7-08-2005	S1974	Late Spring Frosts; Frost	2
WY		5-01-2004	6-30-2004	11-08-2004	7-08-2005	S1974	Late Spring Frosts; Frost	1
MT	Carter	4-01-2004	continuing	11-08-2004	7-08-2005	S1975	High Winds	1	3
SD		4-01-2004	continuing	11-08-2004	7-08-2005	S1975	High Winds	2
WY		4-01-2004	continuing	11-08-2004	7-08-2005	S1975	High Winds	1
TX	Wilbarger	6-02-2004	6-08-2004	11-08-2004	7-08-2005	S1976	Excessive rain, hail, high winds	1	5
OK		6-02-2004	6-08-2004	11-08-2004	7-08-2005	S1976	Excessive rain, hail, high winds	2
TX	Wise	6-06-2004	6-11-2004	11-08-2004	7-08-2005	S1977	Excessive rain, flash flooding, flooding, high winds, lightning	1	6
TN	Bradley, Cannon, Cocke, Giles, Greene, Hamblen, Hamilton, Lawrence, Lincoln, Loudon, Macon, Marion, McMinn, Meigs, Polk, Rhea, Roane, Rutherford, Sequatchie, Unicoi, Washington, Wayne	9-01-2004	continuing	11-17-2004	7-18-2005	S1978	Storm, including remnants of Hurricanes Frances and Ivan	22	35
AL		9-01-2004	continuing	11-17-2004	7-18-2005	S1978	Storm, including remnants of Hurricanes Frances and Ivan	4
GA		9-01-2004	continuing	11-17-2004	7-18-2005	S1978	Storm, including remnants of Hurricanes Frances and Ivan	6
KY		9-01-2004	continuing	11-17-2004	7-18-2005	S1978	Storm, including remnants of Hurricanes Frances and Ivan	2
NC		9-01-2004	continuing	11-17-2004	7-18-2005	S1978	Storm, including remnants of Hurricanes Frances and Ivan	5
WA	Adams, Benton, Franklin, Grant, Spokane, Walla Walla, Yakima	5-07-2004	6-30-2004	11-17-2004	7-18-2005	S1979	Various disasters, including: Excessive rain, hail, high winds, tornado, lightning, flash flooding	7	13
ID		5-07-2004	6-30-2004	11-17-2004	7-18-2005	S1979	Various disasters, including: Excessive rain, hail, high winds, tornado, lightning, flash flooding	3

OR	5-07-2004	6-30-2004	11-17-2004	7-18-2005	S1979	Various disasters, including: Excessive rain, hail, high winds, tornado, lightning, flash flooding.	2
OK	Grant, Kay	4-21-2004	6-02-2004	11-17-2004	7-18-2005	S1980	Hail, high wind	2	4
KS	Boyd, Brown, Holt, Keya Paha, Rock	4-21-2004	6-02-2004	11-17-2004	7-18-2005	S1980	Hail, high wind	3
NE	1-01-2004	continuing	11-17-2004	7-18-2005	S1981	Drought	5	7
SD	1-01-2004	continuing	11-17-2004	7-18-2005	S1981	Drought	4
NE	Blaine, Cherry, Hayes, Hitchcock, Thomas	(1) 01/01/04	(1) continuing	11-17-2004	7-18-2005	S1982	(1) Drought	1	15
KS	(2) 05/14/04	(2) 05/22/04	11-17-2004	7-18-2005	S1982	(2) Frost	1
SD	(1) 01/01/04	(1) continuing	11-17-2004	7-18-2005	S1982	(1) Drought	4
CA	Solano, Yolo	(2) 05/14/04	(2) 05/22/04	11-17-2004	7-18-2005	S1982	(2) Frost	7
CA	Tulare	(1) 01/01/04	(1) continuing	11-17-2004	7-18-2005	S1982	(1) Drought	4
MT	Fallon, Liberty, Sanders	(2) 05/14/04	(2) 05/22/04	11-17-2004	7-18-2005	S1983	(2) Frost	1	7
ID	3-01-2004	4-30-2004	11-22-2004	7-22-2005	S1983	Record & severe, high temperatures, high winds.	4
ND	3-01-2004	8-31-2004	11-22-2004	7-22-2005	S1984	Excessive heat	1	4
SD	7-01-2004	continuing	11-22-2004	7-22-2005	S1985	Insects	3	13
TN	7-01-2004	continuing	11-22-2004	7-22-2005	S1985	Insects	2
MS	Chester, McNairy, Van Buren, White	7-01-2004	continuing	11-22-2004	7-22-2005	S1985	Insects	3
MS	5-01-2004	continuing	11-22-2004	7-22-2005	S1985	Insects	1
WA	Spokane, Whitman	5-01-2004	continuing	11-22-2004	7-22-2005	S1986	Excessive rain, flooding, high winds, lightning, wet conditions.	4	10
ID	8-02-2004	8-02-2004	11-22-2004	7-22-2005	S1986	Excessive rain, flooding, high winds, lightning, wet conditions.	1
WI	Ashland, Bayfield, Door, Douglas, Iron, Oconto	8-02-2004	8-02-2004	11-22-2004	7-22-2005	S1987	Adverse weather: Severe thunderstorm with high winds, hail, lightning.	2	8
MI	3-01-2004	7-03-2004	11-22-2004	7-22-2005	S1987	Adverse weather: Severe thunderstorm with high winds, hail, lightning.	5
MN	3-01-2004	7-03-2004	11-22-2004	7-22-2005	S1988	Excessive rain, flooding, below normal temperatures.	6	12
TX	Hall	3-01-2004	7-03-2004	11-22-2004	7-22-2005	S1988	Excessive rain, flooding, below normal temperatures.	1
TX	Tarrant	8-12-2004	8-12-2004	11-23-2004	7-25-2005	S1988	Excessive rain, flooding, below normal temperatures.	3
OR	Unatilla	6-01-2004	6-09-2004	11-23-2004	7-25-2005	S1989	Excessive rain, hail, high winds	1	6
WA	5-01-2004	6-15-2004	12-03-2004	8-03-2005	S1990	Excessive rain, flash flooding, flooding, high winds, lightning.	1	6
	5-01-2004	6-15-2004	12-03-2004	8-03-2005	S1991	Excessive rainfall, hail	1	4
	5-01-2004	6-15-2004	12-03-2004	8-03-2005	S1991	Excessive rainfall, hail	3

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal Year 2005—Secretarial Designations for Production Losses]

State	Countries requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
SD	Brookings, Codington, Hamlin	1-01-2004	continuing	12-03-2004	8-03-2005	S1992	Drought, cool growing season, early frost.	3	7
MN		1-01-2004	continuing	12-03-2004	8-03-2005	S1992	Drought, cool growing season, early frost.	2
TX	Uvalde	6-18-2004	6-30-2004	12-03-2004	8-03-2005	S1993	Excessive rain, flash flooding, flooding, hail.	1	8
TX	Deaf Smith	8-12-2004	9-22-2004	12-03-2004	8-03-2005	S1994	(1) Hail	1	5
NM		8-12-2004	9-22-2004	12-03-2004	8-03-2005	S1994	(2) Excessive rain, hail	2
TX	Austin, Washington	6-15-2004	continuing	12-03-2004	8-03-2005	S1995	(2) Excessive rain, flash flooding, flooding, hail, high winds, wind shear.	2	9
TX	Culberson	1-01-2004	continuing	12-03-2004	8-03-2005	S1996	Drought	1	3
NM		1-01-2004	continuing	12-03-2004	8-03-2005	S1996	Drought	2
TX	Bailey	10-05-2004	10-05-2004	12-03-2004	8-03-2005	S1997	Excessive rain, flash flooding, flooding, hail, high winds, lightning.	1	4
NM		10-05-2004	10-05-2004	12-03-2004	8-03-2005	S1997	Excessive rain, flash flooding, flooding, hail, high winds, lightning.	2
WY	Albany, Hot Springs, Natrona, Washakie.	1-01-2004	continuing	12-03-2004	8-03-2005	S1998	Drought	4	1
CO		1-01-2004	continuing	12-03-2004	8-03-2005	S1998	Drought	2
TX	Jeff Davis	1-01-2003	continuing	12-06-2004	8-08-2005	S1999	Drought, high winds, excessive temperatures.	1	6
VA	Northampton	7/15/04	continuing	12-15-2004	8-15-2005	S2000	Excessive Rain	1	1
TX	Swisher	6-21-2004	6-25-2004	12-15-2004	8-15-2005	S2001	High winds, tornado	1	6
MI	Isabella, Mecosta, Otsego	8-19-2004	10-08-2004	12-28-2004	8-29-2005	S2002	Freeze	3	15
MI	Bay, Benzie, Grand Traverse, Isabella, Kakaska, Lake Leelanau, Manistee, Mason, Mecosta, Midland, Missaukee, Oceana, Osceola, Wexford.	7-01-2004	8-17-2004	12-28-2004	8-29-2005	S2003	Drought	15	13

MI	Alcona, Alger, Alpena, Antrim, Baraga, Bay, Benzie, Berrien, Cass, Charlevoix, Cheboygan, Chippewa, Clare, Crawford, Delta, Dickinson, Emmet, Gen- esee, Gladwin, Gogebic, Grand Traverse, Gratiot, Hillsdale, Houghton, Huron, Ingham, Ionia, Iosco, Iron, Isabella, Jackson, Kalamazoo, Kalkaska, Kent, Keweenaw, Lake, Lapeer, Leelanau, Lenawee, Livingston, Luce, Mackinac, Macomb, Manistee, Marquette, Mason, Mecosta, Menominee, Midland, Missaukee, Monroe, Montcalm, Montmorency, Muskegon, Newaygo, Oakland, Oceana, Ogemaw, Ontonagon, Osceola, Oscoda, Otsego, Ottawa, Presque Isle, Roscommon, Saginaw, Sanilac, Schoolcraft, Shiawassee, St. Clair, St. Jo- seph, Tuscola, Van Buren, Washtenaw, Wayne, Wexford.	4-25-2004	continuing	12-28-2004	8-29-2005	S2004	Excessive rainfall, hail, high winds, flooding.	76	7
IN	4-25-2004	continuing	12-28-2004	8-29-2005	S2004	Excessive rainfall, hail, high winds, flooding.	5
OH	4-25-2004	continuing	12-28-2004	8-29-2005	S2004	Excessive rainfall, hail, high winds, flooding.	3
WI	4-25-2004	continuing	12-28-2004	8-29-2005	S2004	Excessive rainfall, hail, high winds, flooding.	5
NE	Adams, Boone, Buffalo, Custer, Sherman, Dawson, Fillmore, Franklin, Furnas, Garfield, Gosper, Harlan, Kearney, Knox, Logan, Loup, Merrick, Nance, Nuckolls, Pawnee, Thayer, Val- ley, Webster, Wheeler.	1-01-2004	continuing	12-28-2004	8-29-2005	S2005	Drought	24	30
KS	1-01-2004	continuing	12-28-2004	8-29-2005	S2005	Drought	9
SD	1-01-2004	continuing	12-28-2004	8-29-2005	S2005	Drought	3

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal Year 2005—Secretarial Designations for Production Losses]

State	Countries requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
TX	Presidio	9-22-2004	9-22-2004	12-28-2004	8-29-2005	S2006	Excessive rain, flash flooding, high winds.	1	3
TX	Cochran	8-19-2004	8-19-2004	12-28-2004	8-29-2005	S2007	Excessive rain, hail, high winds	1	5
NM		8-19-2004	8-19-2004	12-28-2004	8-29-2005	S2007	Excessive rain, hail, high winds		2
CA	Tehama	3-12-2004	3-31-2004	12-28-2004	8-29-2005	S2008	Hot, dry, windy, weather	1	6
CO	Bent, Moffat	1-01-2004	continuing	1-10-2005	9-12-2005	S2009	Bent: High winds, heavy rain Moffat: Drought, freeze (part).	2	7
UT				1-10-2005	9-12-2005	S2009	Drought, freeze		2
WY				1-10-2005	9-12-2005	S2009	Drought, freeze		2
TX	Gonzales	11-15-2004	continuing	1-10-2005	9-12-2005	S2010	Excessive rain, flooding	1	8
MS	Alcorn, Amite, Bolivar, Calhoun, Carroll, Chickasaw, Clarke, Clay, Coahoma, Covington, George, Grenada, Hinds, Holmes, Itawamba, Jackson, Jefferson Davis, Jones, Lamar, Lauderdale, Lawrence, Lee, Marion, Monroe, Montgomery, Oktibbeha, Perry, Pike, Pontotoc, Prentiss, Quitman, Simpson, Smith, Tunica, Union, Walthall, Webster, Wilkinson.	5-01-2004	9-20-2004	1-10-2005	9-12-2005	S2011	Excessive rainfall, flooding, flash flooding, high winds, tornadoes, hail and lightning that occurred from 05/01/04-07/31/04 AND due to Hurricane Ivan 09/13/04-09/20/04	38	39
AL		5-01-2004	10-10-2004	1-10-2005	9-12-2005	S2011	Excessive rainfall, flooding—Hurricane Ivan.		6
AR		5-01-2004	10-10-2004	1-10-2005	9-12-2005	S2011	Excessive rainfall, flooding—Hurricane Ivan.		5
LA		5-01-2004	10-10-2004	1-10-2005	9-12-2005	S2011	Excessive rainfall, flooding—Hurricane Ivan.		6
TN		5-01-2004	10-10-2004	1-10-2005	9-12-2005	S2011	Excessive rainfall, flooding—Hurricane Ivan.		3
TX	Taylor	10-03-2004	11-18-2004	1-10-2005	9-12-2005	S2012	Excessive rain	1	6
TX	Martin	8-01-2004	8-31-2004	1-10-2005	9-12-2005	S2013	Record-breaking cool weather	1	7
TX	Bosque	4-01-2004	continuing	1-10-2005	9-12-2005	S2014	Excessive rain	1	7

TX	Terrell	7-01-2004	continuing	1-10-2005	9-12-2005	S2015	Excessive rain, flash flooding, flooding.	1	4
TX	Caldwell	10-01-2004	continuing	1-10-2005	9-12-2005	S2016	Excessive rain, flash flooding	1	6
TX	Castro	6-01-2004	8-31-2004	1-10-2005	9-12-2005	S2017	Hailstorms	1	6
OR	Coos	1-01-2004	continuing	1-10-2005	9-12-2005	S2018	Drought	1	2
OH	Athens, Belmont, Guernsey, Harrison, Hocking, Jackson, Jefferson, Monroe, Noble, Perry, Scioto, Vinton, Washington.	9-08-2004	9-26-2004	1-10-2005	9-12-2005	S2019	Excessive rain, severe flooding, due to Hurricane remnants.	13	15
KY		9-08-2004	9-26-2004	1-10-2005	9-12-2005	S2019	Excessive rain, severe flooding, due to Hurricane remnants.	2
WV		9-08-2004	9-26-2004	1-10-2005	9-12-2005	S2019	Excessive rain, severe flooding, due to Hurricane remnants.	8
CA	Alpine, Amador, Calaveras, Inyo, Kings, Lake, Lassen, Mariposa, Mendocino, Mono, Monterey, Napa, Nevada, Orange, Plumas, San Benito, Santa Barbara, Santa Clara, Sierra, Sonoma, Tulare, Tuolumne, Yolo, Yuba.	1-01-2004	continuing	1-19-2005	9-19-2005	S2020	Drought	24	29
NV		1-01-2004	continuing	1-19-2005	9-19-2005	S2020	Drought	7
ID	Adams, Benewah, Blaine, Camas, Clearwater, Kootenai, Lewis, Nez Perce, Twin Falls, Washington.	(1) 01/01/04 (2) 07/15/04 (3) 08/01/04	(1) continuing (2) 09/01/04 (3) 09/01/04	1-19-2005	9-19-2005	S2021	(1) Drought (2) Excessive Moisture, (3) High winds	10	18
MT		(1) 01/01/04 (2) 07/15/04 (3) 08/01/04	(1) continuing (2) 09/01/04 (3) 09/01/04	1-19-2005	9-19-2005	S2021	(1) Drought (2) Excessive Moisture, (3) High winds	2
NV		(1) 01/01/04 (2) 07/15/04 (3) 08/01/04	(1) continuing (2) 09/01/04 (3) 09/01/04	1-19-2005	9-19-2005	S2021	(1) Drought (2) Excessive Moisture, (3) High winds	1
OR		(1) 01/01/04 (2) 07/15/04 (3) 08/01/04	(1) continuing (2) 09/01/04 (3) 09/01/04	1-19-2005	9-19-2005	S2021	(1) Drought (2) Excessive Moisture, (3) High winds	3
WA		(1) 01/01/04 (2) 07/15/04 (3) 08/01/04	(1) continuing (2) 09/01/04 (3) 09/01/04	1-19-2005	9-19-2005	S2021	(1) Drought (2) Excessive Moisture, (3) High winds	3
ID	Lincoln	1-01-2004	continuing	2-09-2005	10-11-2005	S2021, Amendment 1.	Drought	1

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal Year 2005—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
TX	Coleman	10-01-2004	continuing	1-19-2005	9-19-2005	S2022	Excessive rain, high winds	1	6
TX	Gaines	9-25-2004	9-30-2004	1-19-2005	9-19-2005	S2023	Excessive rain, flash flooding, high winds, lightning	1	5
NM		9-25-2004	9-30-2004	1-19-2005	9-19-2005	S2023	Excessive rain, flash flooding, high winds, lightning	1	1
TX	Robertson	11-23-2004	11-23-2004	1-19-2005	9-19-2005	S2024	Excessive rain, flash flooding, flooding, hail, high winds, tornado	1	7
TX	Hays	10-01-2004	continuing	1-19-2005	9-19-2005	S2025	Excessive rain, flash flooding	1	5
TX	Borden	9-01-2004	10-15-2004	1-19-2005	9-19-2005	S2026	Excessive rain	1	7
TX	Nolan	10-01-2004	continuing	1-19-2005	9-19-2005	S2027	Excessive rain, flash flooding	1	7
TX	Erath	2-24-2004	continuing	1-19-2005	9-19-2005	S2028	Excessive rain, flooding, flash flooding, high winds, hail	1	7
TX	Howard	10/22/04	10/22/04	1-19-2005	9-19-2005	S2029	(1) Hail	1	7
TX	Dawson	09/25/04	continuing	1-19-2005	9-19-2005	S2030	(2) Excessive rain	1	6
CO	Huerfano, Las Animas, Rio Blanco	06/19/04	08/30/04	2-02-2005	10-03-2005	S2031	(2) Hail	3	11
NM		1-01-2004	continuing	2-02-2005	10-03-2005	S2031	Drought		2
UT		1-01-2004	continuing	2-02-2005	10-03-2005	S2031	Drought		1
TX	Gray	1-01-2004	continuing	2-02-2005	10-03-2005	S2032	Excessive rain	1	7
TX	Hamilton	10-13-2004	10-24-2004	2-02-2005	10-03-2005	S2033	Excessive rain	1	6
TX	Hardin	11-23-2004	11-23-2004	2-02-2005	10-03-2005	S2034	Excessive rain, hail, high winds, tornado	1	6
TX	Bastrop	10-01-2004	11-24-2004	2-02-2005	10-03-2005	S2035	Excessive rain, flooding, tornado	1	6
TX	Garza	10-09-2004	10-09-2004	2-02-2005	10-03-2005	S2036	Hail	1	7
TX	Coryell	1-01-2004	continuing	2-02-2005	10-03-2005	S2037	Excessive rain, flooding, hail	1	5
TX	Jackson	11-20-2004	11/12/04	2-02-2005	10-03-2005	S2038	Excessive rain, flooding	1	6
TX	Gillespie	11-01-2004	11-23-2004	2-02-2005	10-03-2005	S2039	Excessive rain, flooding	1	6
TX	Guadalupe	11-22-2004	11-23-2004	2-02-2005	10-03-2005	S2040	Excessive rain	1	6
TX	Wharton	11-21-2004	11-28-2004	2-02-2005	10-03-2005	S2041	Excessive rain, flash flooding, flooding, hail	1	6
TX	Newton	11-23-2004	11-24-2004	2-02-2005	10-03-2005	S2042	Flash flooding, tornadoes	1	3
LA		11-24-2004	11-24-2004	2-02-2005	10-03-2005	S2042	Flash flooding, tornadoes		4
TX	Terry	6-17-2004	10-05-2004	2-02-2005	10-03-2005	S2043	Hail		7

TX	Wilson	11-18-2004	11-23-2004	2-02-2005	10-03-2005	S2044	Excessive rain	1	5
TX	Yoakum	10-05-2004	10-05-2004	2-02-2005	10-03-2005	S2045	Excessive rain, flash flooding, hail	1	4
NM	Placer	10-05-2004	10-05-2004	2-02-2005	10-03-2005	S2045	Excessive rain, flash flooding, hail	1
CA	San Joaquin	1-01-2004	continuing	2-09-2005	10-03-2005	S2046	Drought	3	1
	Ventura								
NV	Baker, Banks, Bartow, Calhoun,	1-01-2004	continuing	2-09-2005	10-11-2005	S2046	Drought	1
CA	Catrosa, Clay, Coffee, Dade,	9-15-2005	9-17-2005	2-09-2005	10-11-2005	S2047	Tropical Storms Frances, Ivan, Jeanne	32	42
	Decatur, Dougherty, Early,								
	Fannin, Franklin, Gilmer, Grady,								
	Lee, Madison, Miller, Mitchell,								
	Murray, Oconee, Randolph,								
	Schley, Seminole, Stewart,								
	Sumter, Terrell, Thomas, Towns,								
	Union, Webster, Whitfield.								
AL		9-15-2005	9-17-2005	2-09-2005	10-11-2005	S2047	Tropical Storms Frances, Ivan, Jeanne	6
FL		9-15-2005	9-17-2005	2-09-2005	10-11-2005	S2047	Tropical Storms Frances, Ivan, Jeanne	4
NC		9-15-2005	9-17-2005	2-09-2005	10-11-2005	S2047	Tropical Storms Frances, Ivan, Jeanne	2
SC		9-15-2005	9-17-2005	2-09-2005	10-11-2005	S2047	Tropical Storms Frances, Ivan, Jeanne	1
TN		9-15-2005	9-17-2005	2-09-2005	10-11-2005	S2047	Tropical Storms Frances, Ivan, Jeanne	4
NY	Allegany, Cattaraugus, Chau-	11-01-2003	continuing	2-09-2005	10-11-2005	S2048	(1) Multiple disasters related to se-	25	29
	tauqua, Clinton, Columbia,						vere storms, including excessive		
	Erie, Fulton, Genesee, Greene,						rain, hail, flooding, flash flooding,		
	Lewis, Monroe, Montgomery,						high winds.		
	Nassau, Niagara, Oneida, On-						(2) Freeze		
	tario, Orange, Orleans, Sara-								
	toga, Schuyler, Seneca, Tomp-								
	kins, Ulster, Washington,								
MA	Wayne, Wyoming.	11-01-2003	continuing	2-09-2005	10-11-2005	S2048	(1) Multiple disasters related to se-	1
							vere storms, including excessive		
							rain, hail, flooding, flash flooding,		
							high winds.		
NU		11-01-2003	continuing	2-09-2005	10-11-2005	S2048	(2) Freeze	2
							(1) Multiple disasters related to se-		
							vere storms, including excessive		
							rain, hail, flooding, flash flooding,		
							high winds.		
							(2) Freeze		

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal Year 2005—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
PA	11-01-2003	continuing	2-09-2005	10-11-2005	S2048	(1) Multiple disasters related to severe storms, including excessive rain, hail, flooding, flash flooding, high winds. (2) Freeze	5
VT	11-01-2003	continuing	2-09-2005	10-11-2005	S2048	(1) Multiple disasters related to severe storms, including excessive rain, hail, flooding, flash flooding, high winds. (2) Freeze	5
TX	Archer	3-04-2004	continuing	2-09-2005	10-11-2005	S2049	Excessive rain, flooding, high winds, lightning.	1	7
TX	Wichita	3-04-2004	continuing	2-09-2005	10-11-2005	S2050	Excessive rain, flash flooding, flooding, high winds, lightning, insect damage.	1	4
OK	3-04-2004	continuing	2-09-2005	10-11-2005	S2050	Excessive rain, flash flooding, flooding, high winds, lightning, insect damage.	2
TX	Scurry	5-01-2004	10-31-2004	2-09-2005	10-03-2005	S2051	Excessive rain, hail, high winds, tornado.	1	7
TX	Carson	11-01-2004	11-29-2004	2-09-2005	10-03-2005	S2052	Excessive rain, excessive snow, flash flooding.	1	8
TX	Kendall	11-01-2004	11-23-2004	2-09-2005	10-03-2005	S2053	Excessive rain, flash flooding	1	6
TX	Bexar	11-19-2004	11-23-2004	2-09-2005	10-03-2005	S2054	Excessive rain, flooding	1	7
TX	Hudspeth	10-15-2004	10-11-2004	2-09-2005	9-23-2005	S2055	Excessive rain	1	4
NM	10-15-2004	10-11-2004	2-09-2005	9-24-2005	S2055	Excessive rain	1
TX	Colorado	11-21-2004	continuing	2-09-2005	9-25-2005	S2056	Excessive rain, flooding	1	5
TX	Comal	10-01-2004	continuing	2-09-2005	9-26-2005	S2057	Excessive rain, flash flooding	1	5
TX	Wilbarger	11-13-2004	11-22-2004	2-09-2005	9-27-2005	S2058	Excessive rain	1	5
OK	11-13-2004	11-22-2004	2-09-2005	9-28-2005	S2058	Excessive rain	2
WI	Calumet, Clark, Door, Kewaunee, Manitowoc, Marinette, Milwaukee, Oconto, Waukeshia, Waupaca.	3-01-2004	10-08-2004	2-09-2005	9-29-2005	S2059	Excessive rain, flooding, fol. By dry spell, early frost.	10	24

MI	3-01-2004	10-08-2004	2-09-2005	9-30-2005	S2059	Excessive rain, flooding, fol. By dry spell, early frost.	2
CA	Humboldt	3-01-2004	continuing	2-24-2005	10-24-2005	S2060	Drought	1	4
NY	Herkimer, Ontario, Otsego	5-01-2004	10-10-2004	2-24-2005	10-24-2005	S2061	Excessive rain, flash Flooding, flooding.	3	16
CA	Solano	3-01-2004	9-23-2004	2-24-2005	10-24-2005	S2062	Extremely low precipitation (Drought), warm spring temperatures, dry north winds.	1	5
CA	San Luis Obispo	4-23-2004	8-25-2004	2-24-2005	10-24-2005	S2063	Extreme prolonged heat; Subsequent fruit drop, through 08/25/04.	1	4
CA	Marin	1-01-2004	continuing	2-24-2005	10-24-2005	S2064	Sporadic rain, high winds, excessive heat, unseasonable summer winds.	1	1
NY	Broome, Chenung, Chenango, Columbia, Cortland, Delaware, Dutchess, Genesee, Greene, Livingston, Niagara, Onondaga, Orange, Orleans, Oswego, Putnam, Schenectady, Schoharie, Sullivan, Tioga, Ulster, Westchester.	4-01-2004	12-31-2004	2-28-2005	10-28-2005	S2065	Excessive rain, flooding, flash flooding, high winds, hail.	22	20
NY	4-01-2004	12-31-2004	2-28-2005	10-28-2005	S2065	Excessive rain, flooding, flash flooding, high winds, hail.	2
NY	4-01-2004	12-31-2004	2-28-2005	10-28-2005	S2065	1
NY	4-01-2004	12-31-2004	2-28-2005	10-28-2005	S2065	2
NY	4-01-2004	12-31-2004	2-28-2005	10-28-2005	S2065	5
TN	Lawrence, Wayne	10-18-2004	10-19-2004	2-28-2005	10-28-2005	S2066	Storm, with heavy rains, lightning, winds, tornadoes, flooding.	2	6
AL	10-18-2004	10-19-2004	2-28-2005	10-28-2005	S2066	1
TX	Blanco	11-01-2004	11-23-2004	3-07-2005	11-07-2005	S2067	Excessive rain, flash flooding, tornado	1	7
TX	Brown	11-15-2004	continuing	3-07-2005	11-07-2005	S2068	Excessive rain, flash flooding, flooding, hail, high winds, lightning.	1	7
TX	Sherman	11-30-2004	continuing	3-07-2005	11-07-2005	S2069	Excessive rain	1	5
OK	11-30-2004	continuing	3-07-2005	11-07-2005	S2069	Excessive rain	2
TX	Harris	11-20-2004	11-24-2004	3-07-2005	11-07-2005	S2070	Excessive rain, flash flooding, high winds, tornadoes.	1	7
WY	Park	1-01-2004	continuing	3-07-2005	11-07-2005	S2071	Drought	1	2
MT	1-01-2004	continuing	3-07-2005	11-07-2005	S2071	Drought	2

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal Year 2005—Secretarial Designations for Production Losses]

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NY	Albany, Cayuga, Dutchess, Genesee, Livingston, Monroe, Oneida, Orange, Orleans, Rensselaer, Steuben, Sullivan, Ulster, Wayne, Yates.	5-01-2004	continuing	3-08-2005	11-08-2005	S2072	Multiple disasters related to severe storms, including excessive rain, hail, flooding, flash flooding, high winds, lightning, low temperatures.	15	25
CT	5-01-2004	continuing	3-08-2005	11-08-2005	S2072	Multiple disasters related to severe storms, including excessive rain, hail, flooding, flash flooding, high winds, lightning, low temperatures.	2
MA	5-01-2004	continuing	3-08-2005	11-08-2005	S2072	Multiple disasters related to severe storms, including excessive rain, hail, flooding, flash flooding, high winds, lightning, low temperatures.	1
NU	5-01-2004	continuing	3-08-2005	11-08-2005	S2072	Multiple disasters related to severe storms, including excessive rain, hail, flooding, flash flooding, high winds, lightning, low temperatures.	2
PA	5-01-2004	continuing	3-08-2005	11-08-2005	S2072	Multiple disasters related to severe storms, including excessive rain, hail, flooding, flash flooding, high winds, lightning, low temperatures.	4
VT	5-01-2004	continuing	3-08-2005	S2072	Multiple disasters related to severe storms, including excessive rain, hail, flooding, flash flooding, high winds, lightning, low temperatures.	1

AR	Arkansas, Ashley, Chicot, Cleve- land, Columbia, Conway, Crawford, Dallas, Desha, Drew, Franklin, Garland, Grant, Hempstead, Hot Spring, Jack- son, Jefferson, Johnson, Lafay- ette, Lee, Lincoln, Little River, Logan, Lonoke, Marion, Miller, Monroe, Montgomery, Nevada, Phillips, Pope, Prairie, Pulaski, Saline, Scott, Sebastian, Union, White, Woodruff, Yell.	10-01-2004	11-30-2004	3-11-05	11-14-2005	S2073	Excessive rain, flooding	40	25
LA	10-01-2004	11-30-2004	3-11-05	11-14-2005	S2073	Excessive rain, flooding	8	
MO	10-01-2004	11-30-2004	3-11-05	11-14-2005	S2073	Excessive rain, flooding	2	
MS	10-01-2004	11-30-2004	3-11-05	11-14-2005	S2073	Excessive rain, flooding	5	
OK	OK	10-01-2004	11-30-2004	3-11-05	11-14-2005	S2073	Excessive rain, flooding	4	
TX	TX	10-01-2004	11-30-2004	3-11-05	11-14-2005	S2073	Excessive rain, flooding	4	
TX	TX	10-01-2004	11-30-2004	3-11-05	11-14-2005	S2074	Excessive rain	1	7
TX	TX	10-01-2004	continuing	3-15-2005	11-15-2005	S2075	Excessive rain, excessive snow	2	9
ME	Aroostook, Somerset	1-01-2004	12-31-2004	3-15-2005	11-15-2005	S2076	Excessive rain, wet conditions; cold spring, summer.	2	6
TN	Marion, Sequatchie	12-05-2004	continuing	3-17-2005	11-17-2005	S2077	Storms, excessive rain, flooding	2	6
AL	AL	12-05-2004	continuing	3-17-2005	11-17-2005	S2077	Storms, excessive rain, flooding	1	1
GA	GA	12-05-2004	continuing	3-17-2005	11-17-2005	S2077	Storms, excessive rain, flooding	1	1
TX	Waller	5-13-2004	continuing	3-18-2005	11-18-2005	S2078	Excessive rain, flooding	1	6
TX	Jack	6-01-2004	continuing	3-18-2005	11-18-2005	S2079	Excessive rain, hail	1	7
TX	Clark, Lincoln	1-09-2005	1-15-2005	3-18-2005	11-18-2005	S2080	Heavy rain, snow melt; resulting in severe flooding.	2	2
NV	1-09-2005	1-15-2005	3-18-2005	11-18-2005	S2080	Heavy rain, snow melt; resulting in severe flooding.	1	1
AZ	1-09-2005	1-15-2005	3-18-2005	11-18-2005	S2080	Heavy rain, snow melt; resulting in severe flooding.	2	2
CA	1-09-2005	1-15-2005	3-18-2005	11-18-2005	S2080	Heavy rain, snow melt; resulting in severe flooding.	4	4
UT	1-09-2005	1-15-2005	3-18-2005	11-18-2005	S2080	Heavy rain, snow melt; resulting in severe flooding.	1	5
OR	Klamath	10-01-2002	continuing	3-22-2005	11-22-2005	S2081	Drought	2	2
CA	10-01-2002	continuing	3-22-2005	11-22-2005	S2081	Drought	1	3
TX	Williamson	10-01-2004	continuing	3-22-2005	11-22-2005	S2082	Excessive rain, flash flooding	2	3
MA	Hampshire, Hampden	7-15-2004	10-31-2004	3-22-2005	11-22-2005	S2083	Abnormally wet weather conditions	3	3
WA	7-15-2004	10-31-2004	3-22-2005	11-22-2005	S2083	Abnormally wet weather conditions	3	3

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal Year 2005—Secretarial Designations for Production Losses]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
TX	Brewster	7-28-04	7-29-04	3-22-2005	11-22-2005	S2084	Excessive rain, flash flooding	1	4
TX		06-01-04	continuing						
TX	Randall	9-01-2004	12-31-2004	3-25-2005	11-25-2005	S2085	Excessive rain, flash flooding	1	7
TX	Roberts	11-01-2004	continuing	3-25-2005	11-25-2005	S2086	Excessive rain, freeze excessive temperatures	1	8
OH	Ashtabula, Clermont, Delaware, Fairfield, Geauga, Hancock, Holmes, Lake, Licking, Logan, Marion, Morgan, Morrow, Muskingum, Wyandot	12-23-2004	continuing	3-25-2005	11-25-2005	S2087	Extreme weather conditions: Freezing rain, ice, excessive rain, excessive snow, high winds, flash flooding, flooding.	16	36
KY		12-23-2004	continuing	3-25-2005	11-25-2005	S2087	Extreme weather conditions: Freezing rain, ice, excessive rain, excessive snow, high winds, flash flooding, flooding.	3
PA		12-23-2004	continuing	3-25-2005	11-25-2005	S2087	Extreme weather conditions: Freezing rain, ice, excessive rain, excessive snow, high winds, flash flooding, flooding.	2
CT	Fairfield, Hartford, Litchfield, Tolland.	7-01-2004	10-31-2004	3-25-2005	11-25-2005	S2088	Abnormally wet weather conditions	4	4
MA		7-01-2004	10-31-2004	3-25-2005	11-25-2005	S2088	Abnormally wet weather conditions	3
NY		7-01-2004	10-31-2004	3-25-2005	11-25-2005	S2088	Abnormally wet weather conditions	3
UT		1-09-2005	1-11-2005	3-25-2005	11-25-2005	S2089	Severe flooding	2	3
AZ	Iron, Washington	1-09-2005	1-11-2005	3-25-2005	11-25-2005	S2089	Severe flooding	1
NV		1-09-2005	1-11-2005	3-25-2005	11-25-2005	S2089	Severe flooding	1
OH	Franklin, Pickaway, Pike, Ross, Seneca, Shelby, Tuscarawas.	12-23-2004	1-23-2005	4-14-2005	12-14-2005	S2090	Excessive rain, flash flooding, flooding.	7	12
TX		11-15-2004	continuing	4-14-2005	12-14-2005	S2091	Excessive rain	1	6
TX	Hemphill	11-01-2004	continuing	4-14-2005	12-14-2005	S2092	Excessive rain, excessive temperatures, freeze.	1	4
OK		11-01-2004	continuing	4-14-2005	12-14-2005	S2092	Excessive rain, excessive temperatures, freeze.	2
TX	Hunt	11-01-2004	continuing	4-14-2005	12-14-2005	S2093	Excessive rain	1	8
TX	Armstrong, Oldham	11-25-2004	continuing	4-14-2005	12-14-2005	S2094	Excessive rain	2	10

NM	11-25-2004	continuing	4-14-2005	12-14-2005	S2094	Excessive rain	1
TX	Potter	11-25-2004	continuing	4-14-2005	12-14-2005	S2095	Excessive rain	7
TX	Haskell	11-01-2004	continuing	4-28-2005	12-28-2005	S2096	Excessive rain	7
TX	Crosby	5-12-2005	5-13-2005	6-21-2005	2-21-2006	S2097	Excessive rain, flash flooding, flooding, hail, high winds, lightning, tornadoes.	8
CA	Yuba	3-09-2005	3-15-2005	7-18-2005	3-20-2006	S2098	Unseasonably high temperatures, low humidity.	6
MN	Anoka, Benton, Carver, Chisago, Clay, Grant, Hennepin, Isanti, Kanabec, Mille Lacs, McLeod, Morrison, Pine, Pope, Sherburne, Steele, Wabasha, Wilkin, Wright.	11-01-2004	4-30-2005	7-18-2005	3-20-2006	S2099	Winterkill; below freezing temperatures; cool, wet weather.	29
ND	11-01-2004	4-30-2005	7-18-2005	3-20-2006	S2099	Winterkill; below freezing temperatures; cool, wet weather.	2
WI	11-01-2004	4-30-2005	7-18-2005	3-20-2006	S2099	Winterkill; below freezing temperatures; cool, wet weather.	5
TX	Callahan	6-04-2005	6-04-2005	7-18-2005	3-20-2006	S2100	Excessive rain, flash flooding, hail, high winds, lightning.	6
TX	Knox	5-23-2005	5-23-2005	7-18-2005	3-20-2006	S2101	Excessive rain, flash flooding, hail, high winds, lightning.	6
TX	Floyd	6-09-2005	6-09-2005	7-20-2005	3-20-2006	S2102	Excessive rain, flash flooding, hail, high winds, lightning, tornadoes.	7
CA	Fresno, Kern, Madera, Merced, Tulare.	4-28-2005	5-09-2005	7-26-2005	3-27-2006	S2103	Rain, hail storms	14

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal Year 2005—Secretarial Designations for Production Losses]

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OK	Alfalfa, Aloka, Beckham, Blaine, Bryan, Caddo, Canadian, Carter, Choctaw, Cleveland, Coal, Comanche, Cotton, Craig, Creek, Custer, Delaware, Dewey, Ellis, Garfield, Garvin, Grady, Grant, Haskell, Hughes, Jefferson, Johnston, Kingfisher, Latimer, Le Flore, Lincoln, Logan, Love, McClain, McCurtain, McIntosh, Major, Marshall, Mayes, Murray, Muskogee, Okfuskee, Oklahoma, Pawnee, Payne, Pittsburg, Pontotoc, Pottawatomie, Pushmataha, Roger Mills, Rogers, Seminole, Stephens, Tillman, Tulsa, Washita, Woods, Woodward.	1-01-2005	continuing	7-26-2005	3-27-2006	S2104	Drought	58	17
AR	1-01-2005	continuing	7-26-2005	3-27-2006	S2104	Drought	6
KS	1-01-2005	continuing	7-26-2005	3-27-2006	S2104	Drought	6
MO	1-01-2005	continuing	7-26-2005	3-27-2006	S2104	Drought	1
TX	1-01-2005	continuing	7-26-2005	3-27-2006	S2104	Drought	14
TX	Crosby	6-09-2005	6-10-2005	7-26-2005	3-27-2006	S2105	Excessive rain, flash flooding, flooding, hail, high winds, lightning, tornadoes.	1	8

IL	Adams, Boone, Brown, Bureau, Calhoun, Carroll, Cass, Cham- paign, Clark, Clay, Clinton, Coles, Cook, Crawford, Cum- berland, De Kalb, De Witt, Douglas, Du Page, Edgar, Ed- wards, Effingham, Fayette, Ford, Fulton, Gallatin, Greene, Grundy, Hamilton, Hardin, Hen- derson, Henry, Iroquois, Jack- son, Jasper, Jefferson, Jersey, Jo Davies, Johnson, Kane, Kan- kakee, Kendall, Knox, La Salle, Lake, Lawrence, Lee, Living- ston, Logan, Macoupin, Madi- son, Marion, Marshall, Mason, Massac, McDonough, McHenry, McLean, Menard, Mercer, Mon- roe, Morgan, Moultrie, Ogle, Pe- oria, Perry, Piatt, Pike, Pope, Putnam, Randolph, Richland, Rock Island, Saline, Sangamon, Schuyler, Scott, Shelby, St. Clair, Stark, Stephenson, Taze- well, Vermilion, Wabash, War- ren, Washington, Wayne, White, Whiteside, Will, Williamson, Winnebago, Woodford.	1-01-2005	continuing	7-27-2005	3-27-2006	S2106	Drought	93	8
IN	1-01-2005	continuing	7-27-2005	3-27-2006	S2106	Drought	10
IA	1-01-2005	continuing	7-27-2005	3-27-2006	S2106	Drought	8
KY	1-01-2005	continuing	7-27-2005	3-27-2006	S2106	Drought	4
MO	1-01-2005	continuing	7-27-2005	3-27-2006	S2106	Drought	11
WI	1-01-2005	continuing	7-27-2005	3-27-2006	S2106	Drought	6
TX	Duval	12-01-2004	continuing	7-29-2005	3-29-2006	S2107	Drought, high winds	1	7
TX	Baylor	5-31-2005	5-31-2005	7-29-2005	3-29-2006	S2108	Excessive rain, flash flooding, hail, high winds, lightning.	1	8
TX	Jones	5-31-2005	5-31-2005	7-29-2005	3-29-2006	S2109	Excessive rain, flash flooding, hail, high winds, lightning.	1	7
TX	Brooks, Jim Hogg	3-01-2005	continuing	7-29-2005	3-29-2006	S2110	Drought, high winds, excessive tem- peratures.	2	8

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal Year 2005—Secretarial Designations for Production Losses]

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CA	Tehama	3/01/05 03/23/05	05/01/05 3/15/05 03/23/05	8-12-2005	4-12-2006	S2111	Hot, dry, windy weather Severe hailstorm Rain, wind, unusually cool temperatures.	1	6
TX	Gillespie Sutter	6-01-2005 3-05-2005	06/08/05 6-01-2005 3-15-2005	8-12-2005 8-18-2005	4-12-2006 4-18-2006	S2112 S2113	High winds Severe high temperatures, low humidity, strong winds.	1	6
CA	Mendocino	5-15-2005	5-19-2005	8-22-2005	4-24-2006	S2114	Rain, hail	1	6
CA	Stanislaus	4-30-2005	5-01-2005	8-22-2005	4-24-2006	S2115	Rains	1	7
CA	Butte	4-25-2005	5-20-2005	8-22-2005	4-24-2006	S2116	Hail, late rains	1	6
CA	Lake	5-18-2005	6-16-2005	8-22-2005	4-24-2006	S2117	Unseasonable heavy rainfall	1	6
TX	Burleson	5-01-2005	6-30-2005	8-22-2005	4-24-2006	S2118	Drought	1	5

MO	Adair, Andrew, Audrain, Barry, Barton, Bates, Benton, Bolinger, Boone, Buchanan, Butler, Caldwell, Callaway, Camden, Cape Girardeau, Carroll, Carter, Cass, Cedar, Charlton, Christian, Clark, Clay, Clinton, Cole, Cooper, Crawford, Dade, Dallas, Daviess, Dekalb, Dent, Douglas, Dunklin, Franklin, Gasconade, Gentry, Greene, Grundy, Harrison, Henry, Hickory, Howard, Howell, Iron, Jackson, Jasper, Jefferson, Johnson, Knox, Laclede, Lafayette, Lawrence, Lewis, Lincoln, Linn, Livingston, Macon, Madison, Maries, Marion, McDonald, Mercer, Miller, Mississippi, Monteau, Monroe, Montgomery, Morgan, New Madrid, Newton, Nodaway, Oregon, Osage, Ozark, Pemiscot, Perry, Pettis, Phelps, Pike, Platte, Polk, Putnam, Ralls, Randolph, Ray, Reynolds, Ripley, Saline, Schuyler, Scotland, Scott, Shannon, Shelby, St Charles, St Clair, St Francois, St Louis, Ste Genevieve, Stoddard, Stone, Sullivan, Taney, Texas, Vernon, Warren, Washington, Wayne, Webster, Worth, Wright.	1-01-2005	continuing	8-23-2005	4-24-2006	S2119	Drought	112	3
AR		1-01-2005	continuing	8-23-2005	4-24-2006	S2119	Drought	12	
IL		1-01-2005	continuing	8-23-2005	4-24-2006	S2119	Drought	12	
IA		1-01-2005	continuing	8-23-2005	4-24-2006	S2119	Drought	9	
KS		1-01-2005	continuing	8-23-2005	4-24-2006	S2119	Drought	10	
OK		1-01-2005	continuing	8-23-2005	4-24-2006	S2119	Drought	4	
TN		1-01-2005	continuing	8-23-2005	4-24-2006	S2119	Drought	2	
		1-01-2005	continuing	8-23-2005	4-24-2006	S2119	Drought	2	

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal Year 2005—Secretarial Designations for Production Losses]

State	Countries requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
CA	Sutter	5-08-2005	5-19-2005	8-25-2005	4-25-2006	S2120	Unseasonable rain	1	6
KS	Butler, Ford, Gove, Grant, Meade, Sedgwick, Trego, Wabaunsee.	6-03-2005	6-16-2005	8-25-2005	4-25-2006	S2121	Hail, high winds, lightning, tornadoes, excessive rain, flash flooding, flooding.	8	37
OK		6-03-2005	6-16-2005	8-25-2005	4-25-2006	S2121			1
MN	Atkin, Beltrami, Benton, Clearwater, Dakota, Grant, Itasca, Kittson, Koochiching, Lake of the Woods, Marshall, Mille Lacs, Pennington, Roseau, Traverse, Washington, Wilkin.	5-07-2005	continuing	8-25-2005	4-25-2006	S2122	Excessive rain, hail, high winds	17	28
ND		5-07-2005	continuing	8-25-2005	4-25-2006	S2122	Excessive rain, hail, high winds		4
SD		5-07-2005	continuing	8-25-2005	4-25-2006	S2122	Excessive rain, hail, high winds		1
WI		5-07-2005	continuing	8-25-2005	4-25-2006	S2122	Excessive rain, hail, high winds		3
OR	Polk, Yamhill	3-24-2005	4-30-2005	8-31-2005	5-01-2006	S2123	Heavy winds, rains	2	7
TX	Wilbarger	3-01-2005	7-05-2005	8-31-2005	5-01-2006	S2124	Drought, high winds, excessive temperatures.	1	5
TX		3-01-2005	7-05-2005	8-31-2005	5-01-2006	S2124	Drought, high winds, excessive temperatures.		2
VA	Fauquier	4-01-2005	6-30-2005	8-31-2005	5-01-2006	S2125	Drought, high temperatures	1	7

MS	Adams, Amite, Attala, Choctaw, Claiborne, Clarke, Copiah, Cov- ington, Forrest, Franklin, George, Greene, Hancock, Har- rison, Hinds, Jackson, Jasper, Jefferson, Jefferson Davis, Jones, Kemper, Lamar, Lauder- dale, Lawrence, Leake, Lincoln, Lowndes, Madison, Marion, Neshoba, Newton, Noxubee, Oktibbeha, Pearl River, Perry, Pike, Rankin, Scott, Simpson, Smith, Stone, Walthall, Warren, Wayne, Wilkinson, Winston, Yazoo.	8-29-2005	continuing	9-9-2005	5-9-2006	S2126	Hurricane Katrina	31	4
AL	8-29-2005	continuing	9-9-2005	5-9-2006	S2126	Hurricane Katrina	3
AR	8-29-2005	continuing	9-9-2005	5-9-2006	S2126	Hurricane Katrina	6
LA	8-29-2005	continuing	9-9-2005	5-9-2006	S2126	Hurricane Katrina	2
TN	8-29-2005	continuing	9-9-2005	5-9-2006	S2126	Hurricane Katrina	3
IA	Cedar, Clinton, Davis, Des Moines, Henry, Iowa, Jackson, Jefferson, Johnson, Keokuk, Lee, Louisa, Muscatine, Scott, Van Buren, Washington.	1-01-2005	continuing	9-13-2005	5-15-2006	S2127	Drought	16	10
IL	1-01-2005	continuing	9-13-2005	5-15-2006	S2127	Drought	7
MO	1-01-2005	continuing	9-13-2005	5-15-2006	S2127	Drought	3
KS	Ellsworth, Geary, Gove, Greeley, Jewell, Osage, Riley, Russell, Trego, Wabaunsee.	1-01-2005	continuing	9-13-2005	5-15-2006	S2128	Freeze, drought, excessive heat, high winds.	10	34
CO	1-01-2005	continuing	9-13-2005	5-15-2006	S2128	Freeze, drought, excessive heat, high winds.	3
NE	1-01-2005	continuing	9-13-2005	5-15-2006	S2128	Freeze, drought, excessive heat, high winds.	2

EMERGENCY PREPAREDNESS AND PROGRAMS BRANCH (EPPB) DISASTER DESIGNATION REQUESTS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal Year 2005—Secretarial Designations for Production Losses]

State	Countries requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
OH	Ashtland, Ashtabula, Athens, Auglaize, Belmont, Brown, Butler, Carroll, Champaign, Clermont, Clinton, Columbiana, Coshocton, Crawford, Cuyahoga, Darke, Defiance, Erie, Fairfield, Fayette, Franklin, Fulton, Gallia, Geauga, Guernsey, Hamilton, Hancock, Hardin, Henry, Highland, Hocking, Huron, Jackson, Knox, Lake, Lawrence, Licking, Logan, Lorain, Lucas, Madison, Mahoning, Medina, Meigs, Mercer, Miami, Monroe, Montgomery, Morgan, Muskingum, Noble, Ottawa, Paulding, Perry, Pickaway, Pike, Preble, Putnam, Richland, Ross, Sandusky, Scioto, Seneca, Shelby, Trumbull, Tuscarawas, Union, Van Wert, Vinton, Warren, Washington, Wyandot.	5-25-2005	continuing	9-20-2005	5-22-2006	S2129	Extreme weather conditions	72	16
IN	5-25-2005	continuing	9-20-2005	5-22-2006	S2129	Extreme weather conditions	9
KY	5-25-2005	continuing	9-20-2005	5-22-2006	S2129	Extreme weather conditions	9
MI	5-25-2005	continuing	9-20-2005	5-22-2006	S2129	Extreme weather conditions	3
PA	5-25-2005	continuing	9-20-2005	5-22-2006	S2129	Extreme weather conditions	5
WV	5-25-2005	continuing	9-20-2005	5-22-2006	S2129	Extreme weather conditions	11
TX	Bowie, Hunt, Rains	4-01-2005	continuing	9-19-2005	5-19-2006	S2130	Drought	3	11
AR	4-01-2005	continuing	9-19-2005	5-19-2006	S2130	Drought	2
OK	4-01-2005	continuing	9-19-2005	5-19-2006	S2130	Drought	1
TX	Foard	3-01-2005	continuing	9-19-2005	5-19-2006	S2131	Drought	1	6
TX	Jim Wells	10-01-2004	continuing	9-19-2005	5-19-2006	S2132	Drought, high winds	1	6

TX	Kieberg	10-01-2004 ...	continuing ...	9-19-2005 ...	5-19-2006 ...	S2133	Drought, excessive temperatures	1	4
TX	Red River	4-01-2005 ...	continuing ...	9-19-2005 ...	5-19-2006 ...	S2134	Drought, excessive temperatures	1	7
OK	4-01-2005 ...	continuing ...	9-19-2005 ...	5-19-2006 ...	S2134	Drought, excessive temperatures	2
TOTAL ACTIVE	1,126	2048

DISASTER ASSISTANCE BRANCH/EMERGENCIES SECTION (DAB/ES) DISASTER DECLARATIONS: FINAL TOTALS SECRETARIAL
[Fiscal year 2006]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
IL	Alexander, Franklin, Hancock, Pulaski, Union.	1-01-05	continuing ...	10-04-05 ...	6-05-06	S2106, Amendment 1.	Drought	5	12
IA	1-01-05	continuing ...	10-04-05 ...	6-05-06	S2106, Amendment 1.	Drought	1
KY	1-01-05	continuing ...	10-04-05 ...	6-05-06	S2106, Amendment 1.	Drought	2
MO	1-01-05	continuing ...	10-04-05 ...	6-05-06	S2106, Amendment 1.	Drought	6
MS	Alcorn, Lee, Tippah, Tishomingo	8-29-05	continuing ...	10-31-05 ...	7-03-06	S2126, Amendment 1.	Hurricane Katrina	4
AL	8-29-05	continuing ...	10-31-05 ...	7-03-06	S2126, Amendment 1.	Hurricane Katrina	2
TN	8-29-05	continuing ...	10-31-05 ...	7-03-06	S2126, Amendment 1.	Hurricane Katrina	2
CA	Glenn	5-01-05	6-10-05	10-04-05 ...	6-05-06	S2135	Rain, wind, unusually cool temperatures.	1	5
CA	Yuba	5-09-05	5-19-05	10-04-05 ...	6-05-06	S2136	Unseasonably heavy rains	1	6
MT	Fergus	1-01-05	continuing ...	10-04-05 ...	6-05-06	S2137	Drought	1	8
TX	Fannin	4-01-05	continuing ...	10-04-05 ...	6-05-06	S2138	Drought	1	5
OK	4-01-05	continuing ...	10-04-05 ...	6-05-06	S2138	Drought	1

DISASTER ASSISTANCE BRANCH/EMERGENCIES SECTION (DAB/ES) DISASTER DECLARATIONS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal year 2006]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
TX	Webb	3-01-05	continuing	10-04-05	6-05-06	S2139	Drought, high winds, excessive temperatures.	1	7
SD	Bon Homme, Clay, Lincoln, Turner	1-01-05	continuing	10-07-05	6-07-06	S2140	Drought, high winds, spring frosts, excessive heat, flash flooding, hail, excessive rainfall.	4	6
IA		1-01-05	continuing	10-07-05	6-07-06	S2140	Drought, high winds, spring frosts, excessive heat, flash flooding, hail, excessive rainfall.		2
NE		1-01-05	continuing	10-07-05	6-07-06	S2140	Drought, high winds, spring frosts, excessive heat, flash flooding, hail, excessive rainfall.		3
UT	Washington	6-26-05	8-01-05	10-07-05	6-07-06	S2141	Fires caused by lightning	1	2
AZ		6-26-05	8-01-05	10-07-05	6-07-06	S2141	Fires caused by lightning		1
NV		6-26-05	8-01-05	10-07-05	6-07-06	S2141	Fires caused by lightning		1
AR	Entire State	5-01-05	continuing	10-13-05	6-13-06	S2142	Drought, extremely high temperatures.	75	
AR		5-01-05	continuing	10-13-05	6-13-06	S2142	Drought, extremely high temperatures.		8
AR		5-01-05	continuing	10-13-05	6-13-06	S2142	Drought, extremely high temperatures.		6
AR		5-01-05	continuing	10-13-05	6-13-06	S2142	Drought, extremely high temperatures.		11
AR		5-01-05	continuing	10-13-05	6-13-06	S2142	Drought, extremely high temperatures.		5
AR		5-01-05	continuing	10-13-05	6-13-06	S2142	Drought, extremely high temperatures.		4
AR		5-01-05	continuing	10-13-05	6-13-06	S2142	Drought, extremely high temperatures.		2
OR	Lane	3-01-05	5-15-05	10-18-05	6-19-06	S2143	Excessive rains	1	6
TX	Comanche	8-09-05	8-10-05	10-18-05	6-19-06	S2144	Flooding	1	5
TX	Haskell	8-09-05	8-15-05	10-18-05	6-19-06	S2145	Excessive rain, flash flooding	1	7
TX	Haskell	8-09-05	continuing	12-21-05	8-21-06	S2145, Amendment 1.	Excessive rain, flash flooding	1	7

TX	Jones, Knox	8-14-05	continuing	10-18-05	6-19-06	S2146	Excessive rain, flash flooding	2	11
TX	Camp, Franklin, Hopkins, Lamar, Morris, Titus	4-01-05	continuing	10-18-05	6-19-06	S2147	Drought	6	10
OK	Adair, Allen, Anderson, Ballard, Barren, Bath, Bell, Boone, Bourbon, Boyd, Boyle, Bracken, Breckinridge, Bulitt, Butler, Caldwell, Calloway, Campbell, Carlisle, Carroll, Carter, Casey, Clark, Clinton, Crittenden, Cumberland, Daviess, Edmonson, Elliott, Estill, Fayette, Fleming, Floyd, Franklin, Gallatin, Garrard, Grant, Graves, Grayson, Green, Johnson, Kenton, Knott, Larue, Lawrence, Lee, Leslie, Letcher, Lewis, Lincoln, Livingston, Logan, Lyon, Madison, Magoffin, Marion, Marshall, Martin, Mason, McCracken, McCreary, Meade, Menifee, Mercer, Metcalfe, Monroe, Montgomery, Morgan, Muhlenberg, Nelson, Nicholas, Ohio, Oldham, Owen, Owsley, Pendleton, Perry, Pike, Powell, Pulaski, Robertson, Rockcastle, Rowan, Russell, Scott, Shelby, Simpson, Spencer, Taylor, Todd, Trimble, Union, Warren, Washington, Wayne, Webster, Whitley, Wolfe, Woodford	4-01-05	continuing	10-18-05	6-19-06	S2147	Drought	2
KY		2-01-05	continuing	10-25-05	6-26-06	S2148	Drought	109	10
IL		2-01-05	continuing	10-25-05	6-26-06	S2148	Drought	6
IN		2-01-05	continuing	10-25-05	6-26-06	S2148	Drought	12
MO		2-01-05	continuing	10-25-05	6-26-06	S2148	Drought	1
OH		2-01-05	continuing	10-25-05	6-26-06	S2148	Drought	6
TN		2-01-05	continuing	10-25-05	6-26-06	S2148	Drought	2
VA		2-01-05	continuing	10-25-05	6-26-06	S2148	Drought	4
WV		2-01-05	continuing	10-25-05	6-26-06	S2148	Drought	2
TX	Fisher	8-01-05	8-16-05	10-20-05	6-20-06	S2149	Flooding	1	7

DISASTER ASSISTANCE BRANCH/EMERGENCIES SECTION (DAB/ES) DISASTER DECLARATIONS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal year 2006]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contig-uous
LA	Acadia, Allen, Avoyelles, Beauregard, Bienville, Bossier, Caddo, Calcasieu, Caldwell, Cameron, Catahoula, Claiborne, Concordia, De Soto, East Carroll, Evangeline, Franklin, Grant, Jackson, Jefferson Davis, La Salle, Lafayette, Lincoln, Madison, Morehouse, Natchitoches, Ouachita, Rapides, Red River, Richland, Sabine, St. Landry, St. Martin, Tensas, Union, Vermilion, Vernon, Webster, West Carroll, Winn.	4-26-05	continuing	10-24-05	6-26-06	S2150	Drought, Hurricane Katrina, Hurricane Rita.	40	6
AR		4-26-05	continuing	10-24-05	6-26-06	S2150	Drought, other disasters		6
MS		4-26-05	continuing	10-24-05	6-26-06	S2150	Drought, other disasters		6
TX		4-26-05	continuing	10-24-05	6-26-06	S2150	Drought, other disasters		9
NE	Holt	5-24-05	6-10-05	10-24-05	6-26-06	S2151	Cool, wet weather	1	8
OR	Linn	Early spring	5-15-05	10-24-05	6-26-06	S2152	Excessive ongoing rains	1	6
OR	Wasco	3-01-05	5-31-05	10-24-05	6-26-06	S2153	Severe frosts, rain events	1	7
WA		3-01-05	5-31-05	10-24-05	6-26-06	S2153	Severe frosts, rain events		1
TX	Delta	4-01-05	continuing	10-24-05	6-26-06	S2154	Drought	1	6
TX	Coryell	7-15-05	7-17-05	10-31-05	7-03-06	S2155	High winds	1	
ND	Adams, Benson, Bottineau, Bowman, Burke, Cavalier, Dickey, Divide, Emmons, Grand Forks, Grant, Griggs, Hettinger, Kidder, LaMoure, McHenry, McIntosh, McLean, Mercer, Mountrail, Nelson, Oliver, Pembina, Pierce, Ramsey, Ransom, Renville, Richland, Rolette, Sargent, Sheridan, Slope, Steele, Towner, Traill, Walsh, Ward.	1-01-05	continuing	10-31-05	7-03-06	S2156	Freeze, damage, late spring snow storms, overland flooding, torrential, rainfall, standing water, hail, high winds, tornadoes.	37	16
MN		1-01-05	continuing	10-31-05	7-03-06	S2156	Freeze, damage, late spring snow storms, overland flooding, torrential, rainfall, standing water, hail, high winds, tornadoes.		

MT	1-01-05	continuing	10-31-05	7-03-06	S2156	Freeze, damage, late spring snow storms; overland flooding, torrential, rainfall, standing water, hail, high winds, tornadoes.
SD	1-01-05	continuing	10-31-05	7-03-06	S2156	Freeze, damage, late spring snow storms; overland flooding, torrential, rainfall, standing water, hail, high winds, tornadoes.
WI	Clark, Marinette, Milwaukee, Outagamie, Walworth, Waukesha, Waushara.	1-01-05	5-31-05	10-31-05	7-03-06	S2157	Winterkill, due to unusually warm weather; followed by below freezing temperatures, and ice.	7	25
IL	1-01-05	5-31-05	10-31-05	7-03-06	S2157	Winterkill, due to unusually warm weather; followed by below freezing temperatures, and ice.	2
MI	1-01-05	5-31-05	10-31-05	7-03-06	S2157	Winterkill, due to unusually warm weather; followed by below freezing temperatures, and ice.	2
OR	Douglas	1-01-05	continuing	10-24-05	6-26-06	S2158	Severe weather conditions	1	6
NE	Chase, Cheyenne, Deuel, Dundy, Fumas, Garden, Hayes, Hitchcock, Morrill, Perkins, Red Willow, Scotts Bluff, Sheridan, Sioux.	1-01-05	continuing	11-03-05	7-03-06	S2159	Freeze incidents; hail, disease, ongoing drought.	13	13
NE	1-01-05	continuing	11-03-05	7-03-06	S2159	Freeze incidents; hail, disease, ongoing drought.	4
NE	1-01-05	continuing	11-03-05	7-03-06	S2159	Freeze incidents; hail, disease, ongoing drought.	5
NE	1-01-05	continuing	11-03-05	7-03-06	S2159	Freeze incidents; hail, disease, ongoing drought.	1
NE	1-01-05	continuing	11-03-05	7-03-06	S2159	Freeze incidents; hail, disease, ongoing drought.	2
CO	Delta, Kit Carson	1-01-05	continuing	11-07-05	7-07-06	S2160	(1) Freezing temperatures (2) Drought	2	7
KS	1-01-05	continuing	11-07-05	7-07-06	S2160	Drought	3
TX	Wood	4-01-05	continuing	11-07-05	7-07-06	S2161	Drought	1	7
WI	Dane, Vernon	8-18-05	8-18-05	11-07-05	7-07-06	S2162	Tornadoes, severe storms	2	12
IA	8-18-05	8-18-05	11-07-05	7-07-06	S2162	Tornadoes, severe storms	1
MN	8-18-05	8-18-05	11-07-05	7-07-06	S2162	Tornadoes, severe storms	1
TX	Collin	4-01-05	continuing	11-02-05	7-03-06	S2163	Drought	1	6

DISASTER ASSISTANCE BRANCH/EMERGENCIES SECTION (DAB/ES) DISASTER DECLARATIONS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal year 2006]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
MI	Calhoun, Huron, Jackson, Kalamazoo, Mecosta, Sanilac, St. Joseph, Tuscola, Van Buren.	6-05-05	7-24-05	11-14-05	7-14-06	S2164	Storms with excessive rain, localized flooding, high winds, hail.	9	22
IN		6-05-05	7-24-05	11-14-05	7-14-06	S2164	Storms with excessive rain, localized flooding, high winds, hail.		2
IA	Clay, Dubuque, Harrison, Monona	1-01-05	continuing	11-14-05	7-14-06	S2165	Drought	4	17
IL		1-01-05	continuing	11-14-05	7-14-06	S2165	Drought		1
NE		1-01-05	continuing	11-14-05	7-14-06	S2165	Drought		3
WI		1-01-05	continuing	11-14-05	7-14-06	S2165	Drought		1
MI	Alger, Allegan, Antrim, Baraga, Berrien, Calhoun, Cass, Charlevoix, Cheboygan, Chippewa, Delta, Dickinson, Emmet, Gogebic, Grand Traverse, Houghton, Ionia, Iron, Kalamazoo, Kalkaska, Kent, Keweenaw, Leelanau, Luce, Mackinac, Manistee, Marquette, Mason, Mecosta, Menominee, Missaukee, Muskegon, Newaygo, Oceana, Ontonagon, Osceola, Otsego, Ottawa, Presque Isle, Schoolcraft, Van Buren.	4-01-05	continuing	11-14-05	7-14-06	S2166	Drought		3
IN		4-01-05	continuing	11-14-05	7-14-06	S2166	Drought		5
WI		4-01-05	continuing	11-14-05	7-14-06	S2166	Drought		2
TX	Cameron	7-19-05	7-20-05	11-14-05	7-14-06	S2167	Flooding, high winds, hurricane, lightning.	1	
CA	El Dorado	(1) 05-16-05 (2) 04-15-05	(1) 06-16-05 (2) 05-15-05	11-14-05	7-14-06	S2168	(1) Unseasonable rains (2) Hail, freezing conditions	1	4
NV		(1) 05-16-05 (2) 04-15-05	(1) 06-16-05 (2) 05-15-05	11-14-05	7-14-06	S2168	(1) Unseasonable rains (2) Hail, freezing conditions		1
TX	Hidalgo	1-01-05	6-30-05	11-14-05	7-14-06	S2169	Drought, excessive temperatures	1	5
TX	Kenedy	10-01-04	continuing	11-14-05	7-14-06	S2170	Drought, excessive temperatures	1	4
CA	San Joaquin	3-01-05	5-31-05	11-14-05	7-14-06	S2171	Spring rains	1	6
CA	Nevada	3-01-05	6-15-05	11-14-05	7-14-06	S2172	Rains	1	3
NV		3-01-05	6-15-05	11-14-05	7-14-06	S2172	Rains		1

TN	Clay, Fentress, Giles, Greene, Hancock, Hawkins, Jackson, Morgan, Overton, Pickett, Scott, Smith, Sumner, Unicoi, Van Buren, Washington, White, Williamson, Wilson.	5-01-05	continuing	11-23-05	7-24-06	S2173	Extreme drought, higher than normal temperatures.	19	28
AL		5-01-05	continuing	11-23-05	7-24-06	S2173	Extreme drought, higher than normal temperatures.	2
KY		5-01-05	continuing	11-23-05	7-24-06	S2173	Extreme drought, higher than normal temperatures.	7
NC		5-01-05	continuing	11-23-05	7-24-06	S2173	Extreme drought, higher than normal temperatures.	3
VA		5-01-05	continuing	11-23-05	7-24-06	S2173	Extreme drought, higher than normal temperatures.	2
TX	Bailey	8-27-05	8-27-05	11-23-05	7-24-06	S2174	Excessive rain, flash flooding, hail, high winds, lightning.	1	4
NM		8-27-05	8-27-05	11-23-05	7-24-06	S2174	Excessive rain, flash flooding, hail, high winds, lightning.	2
TX	Coryell	8-08-05	8-10-05	11-23-05	7-24-06	S2175	Excessive rain, flooding, high winds	1	5
TX	Garza	8-27-05	8-27-05	11-23-05	7-24-06	S2176	Excessive rain, hail, high winds	1	7
TX	Lee	4-01-05	continuing	11-23-05	7-24-06	S2177	Drought	1	6
TX	Nacogdoches	3-01-05	continuing	11-23-05	7-24-06	S2178	Drought, excessive heat, high winds.	1	5
TX	Willacy	1-01-05	continuing	11-23-05	7-24-06	S2179	Drought, high winds	1	3
MI	Alger, Allegan, Antrim, Berrien, Cass, Delta, Dickinson, Hillsdale, Ingham, Iron, Jackson, Kalamazoo, Kent, Livingston, Marquette, Mecosta, Menominee, Muskegon, Newaygo, Ottawa, St. Joseph, Schoolcraft, Shiawassee, Van Buren.	4-01-05	5-05-05	11-21-05	7-21-06	S2180	Above average temperatures, followed by frost, freeze, excessive snow, hail.	24	30
IN		4-01-05	5-05-05	11-21-05	7-21-06	S2180	Above average temperatures, followed by frost, freeze, excessive snow, hail.	5
OH		4-01-05	5-05-05	11-21-05	7-21-06	S2180	Above average temperatures, followed by frost, freeze, excessive snow, hail.	2
WI		4-01-05	5-05-05	11-21-05	7-21-06	S2180	Above average temperatures, followed by frost, freeze, excessive snow, hail.	4
TX	Hockley	8-27-05	8-28-05	11-14-05	7-14-06	S2181	Hail	1	8

DISASTER ASSISTANCE BRANCH/EMERGENCIES SECTION (DAB/ES) DISASTER DECLARATIONS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal year 2006]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
NY	Chenango, Columbia, Dutchess, Ontario, Rensselaer, Ulster, Wayne, Westchester.	4/01/05 05/05/05	4/04/05 05/17/05	11-23-05	7-24-06	S2182	(1) Excessive rain, flooding, flash flooding. (2) Extreme and unseasonably cold temperatures, frost, freezes.	8	22
CT		4/01/05 05/05/05	4/04/05 05/17/05	11-23-05	7-24-06	S2182	(1) Excessive rain, flooding, flash flooding. (2) Extreme and unseasonably cold temperatures, frost, freezes.	2
MA		4/01/05 05/05/05	4/04/05 05/17/05	11-23-05	7-24-06	S2182	(1) Excessive rain, flooding, flash flooding. (2) Extreme and unseasonably cold temperatures, frost, freezes.	1
NU		4/01/05/05/05	4/04/05/17/05	11-23-05	7-24-06	S2182	(1) Excessive rain, flooding, flash flooding. (2) Extreme and unseasonably cold temperatures, frost, freezes.	1
VT		4/01/05 05/05/05	4/04/05 05/17/05	11-23-05	7-24-06	S2182	(1) Excessive rain, flooding, flash flooding. (2) Extreme and unseasonably cold temperatures, frost, freezes.	1
CA	Sutter	2-14-05	2-24-05	12-13-05	8-14-06	S2183	(2) Extreme and unseasonably cold temperatures, frost, freezes.	1	6
OK	Benton, Yarnhill	3-01-05	6-30-05	12-13-05	8-14-06	S2184	Cold, wet weather Excessive ongoing rains, cool temperatures.	2	8
OR	Wasco	1-01-05	continuing	12-13-05	8-14-06	S2185	Drought	1	7
WA		1-01-05	continuing	12-13-05	8-14-06	S2185	Drought	1
TX	Coryell	4-01-05	8-04-05	12-13-05	8-14-06	S2186	Drought	1	5
TX	Lamb	9-12-05	9-12-05	12-13-05	8-14-06	S2187	Hail	1	7
CO	Crowley, El Paso, Lincoln, Otero, Park, Phillips, Pueblo, Teller, Washington, Yuma.	1-01-05	continuing	12-19-05	8-21-06	S2188	Various disasters: Drought, wind, hail, heavy rains.	10	20
KS		1-01-05	continuing	12-19-05	8-21-06	S2188	Various disasters: Drought, wind, hail, heavy rains.	1
NE		1-01-05	continuing	12-19-05	8-21-06	S2188	Various disasters: Drought, wind, hail, heavy rains.	3

NY	Chemung, Dutchess, Essex, Jefferson, Oneida, Onondaga, Oswego, Saratoga, Schuyler, Seneca, Tioga, Ulster.	4-02-05	continuing	12-19-05	8-21-06	S2189	Drought & various disasters	12	33
CT	MA	4-02-05	continuing	12-19-05	8-21-06	S2189	Drought & various disasters	2	2
PA	PA	4-02-05	continuing	12-19-05	8-21-06	S2189	Drought & various disasters	1	1
VI	VI	4-02-05	continuing	12-19-05	8-21-06	S2189	Drought & various disasters	3	3
TX	Taylor	4-02-05	continuing	12-19-05	8-21-06	S2189	Drought & various disasters	2	2
TX	Bosque, Grayson, Henderson, Houston, Johnson, Leon, Navarro, Tarrant, Van Zandt, Waller.	8-03-05	8-29-05	12-19-05	8-21-06	S2190	Excessive rain	1	6
TX		4-01-05	continuing	12-19-05	8-21-06	S2191	Drought	10	36
OK	Livingston, Madison	4-01-05	continuing	12-19-05	8-21-06	S2191	Drought	3	3
NY		5-12-05	6-17-05	12-27-05	8-28-06	S2192	Various disasters : Excessive rain, flash flooding, frost.	2	12
TX	Calhoun	4-15-05	9-30-05	12-27-05	8-28-06	S2193	Drought	1	5
TX	Llano, Mason	8-25-05	continuing	12-27-05	8-28-06	S2194	Drought	2	7
VA	Anella, Bland, Brunswick, Buckingham, Campbell, Charlotte, Chesterfield, Cumberland, Dinwiddie, Essex, Floyd, Fluvanna, Franklin, Frederick, Giles, Greensville, Halifax, Isleight, King Lee, Louisa, Lunenburg, Mecklenburg, Montgomery, Nelson, Nottoway, Page, Patrick, Pittsylvania, Powhatan, Prince Edward, Pulaski, Scott, Shenandoah, Smyth, Southampton, Tazewell, Wythe.	6-01-05	8-31-05	12-27-05	8-28-06	S2195	Drought, high temperatures	38	51
KY		6-01-05	8-31-05	12-27-05	8-28-06	S2195	Drought, high temperatures	2	2
NC		6-01-05	8-31-05	12-27-05	8-28-06	S2195	Drought, high temperatures	11	11
TN		6-01-05	8-31-05	12-27-05	8-28-06	S2195	Drought, high temperatures	4	4
WV		6-01-05	8-31-05	12-27-05	8-28-06	S2195	Drought, high temperatures	9	9
KS	Cheyenne, Edwards, Harper, Haskell, Linn, Rush, Stanton.	6-03-05	6-13-05	12-21-05	8-21-06	S2196	Severe storms	7	29
CO		6-03-05	6-13-05	12-21-05	8-21-06	S2196	Severe storms	4	4
MO		6-03-05	6-13-05	12-21-05	8-21-06	S2196	Severe storms	2	2
NE		6-03-05	6-13-05	12-21-05	8-21-06	S2196	Severe storms	1	1
OK		6-03-05	6-13-05	12-21-05	8-21-06	S2196	Severe storms	2	2
NY	(1) Columbia, Ontario (2) Fulton, Hamilton, Herkimer, Madison, Montgomery, Ontario, Orange, Rensselaer, Suffolk, Sullivan.	(1) 06-09-05 (2) 05-01-05	(1) 07-27-05 (2) continuing	12-21-05	8-21-06	S2197	(1) Excessive rain, hail, flash flooding. (2) Drought, heat, high temperatures.	11	31

DISASTER ASSISTANCE BRANCH/EMERGENCIES SECTION (DAB/ES) DISASTER DECLARATIONS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal year 2006]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
CT	(1) 06-09-05	(1) 07-27-05	12-21-05 ...	8-21-06	S2197	(1) Excessive rain, hail, flash flooding.	1
MA	(1) 06-09-05 (2) 05-01-05	(1) 07-27-05 (2) continuing	12-21-05 ...	8-21-06	S2197	(1) Excessive rain, hail, flash flooding. (2) Drought, heat, high temperatures.	1
NU	(2) 05-01-05 (2) continuing	12-21-05 ...	8-21-06	S2197	(2) Drought, heat, high temperatures.	2	
PA	(2) 05-01-05	(2) continuing	12-21-05 ...	8-21-06	S2197	(2) Drought, heat, high temperatures.	2
VT	(2) 05-01-05	(2) continuing	12-21-05 ...	8-21-06	S2197	(2) Drought, heat, high temperatures.	1
SD	Aurora, Bon Homme, Butte, Charles Mix, Douglas, Harding, Hughes, Hutchinson, Hyde, Perkins, Potter, Stanley, Sully, Yankton.	1-01-05	continuing	12-21-05 ...	8-21-06	S2198	Drought, late spring frosts, extreme heat, high winds, hail, prairie fires.	14	22
MT	1-01-05	continuing	12-21-05 ...	8-21-06	S2198	Drought, late spring frosts, extreme heat, high winds, hail, prairie fires.	2
ND	1-01-05	continuing	12-21-05 ...	8-21-06	S2198	Drought, late spring frosts, extreme heat, high winds, hail, prairie fires.	3
NE	1-01-05	continuing	12-21-05 ...	8-21-06	S2198	Drought, late spring frosts, extreme heat, high winds, hail, prairie fires.	3
WY	1-01-05	continuing	12-21-05 ...	8-21-06	S2198	Drought, late spring frosts, extreme heat, high winds, hail, prairie fires.	1
TX	Cooke	3-01-05	continuing	12-21-05 ...	8-21-06	S2199	Drought, late spring frosts, extreme heat, high winds, hail, prairie fires.	1	4
OK	3-01-05	continuing	12-21-05 ...	8-21-06	S2199	Drought, excessive temperatures	1

TX	Falls	2-01-05	10-21-05	12-21-05	8-21-06	S2200	Drought	1	5
TX	McLennan	3-01-05	continuing	12-21-05	8-21-06	S2201	Drought	1	6
MS	All MS Counties, except Pontotoc & Union	1-01-05	continuing	1-09-06	9-11-06	S2202	Hurricane Rita Drought	80	2
AL		1-01-05	continuing	1-09-06	9-11-06	S2202	Hurricane Rita Drought		10
AR		1-01-05	continuing	1-09-06	9-11-06	S2202	Hurricane Rita Drought		5
LA		1-01-05	continuing	1-09-06	9-11-06	S2202	Hurricane Rita Drought		10
TN		1-01-05	continuing	1-09-06	9-11-06	S2202	Hurricane Rita Drought		5
NU	Atlantic, Bergen, Burlington, Camden, Cape May, Cumberland, Essex, Gloucester, Hunterdon, Mercer, Middlesex, Monmouth, Morris, Ocean, Passaic, Salem, Somerset, Sussex, Warren.	6-01-05	10-06-05	1-09-06	9-11-06	S2203	Drought, high humidity, excessive heat.	19	2
DE		6-01-05	10-06-05	1-09-06	9-11-06	S2203	Drought, high humidity, excessive heat.		1
NY		6-01-05	10-06-05	1-09-06	9-11-06	S2203	Drought, high humidity, excessive heat.		6
PA		6-01-05	10-06-05	1-09-06	9-11-06	S2203	Drought, high humidity, excessive heat.		7
NY	(1) Allegany, Cattaraugus, Cayuga, Orleans, Rensselaer, Steuben, Yates. (2) Dutchess, Putnam, Rensselaer, Suffolk, Ulster, Westchester.	4-01-05 10-07-05	continuing continuing	1-09-06	9-11-06	S2204	(1) Drought; drought related disasters. (2) Excessive rain, flooding; related disasters.	12	26
CT		4-01-05 10-07-05	continuing continuing	1-09-06	9-11-06	S2204	(1) Drought; drought related disasters. (2) Excessive rain, flooding; related disasters.		2
MA		4-01-05 10-07-05	continuing continuing	1-09-06	9-11-06	S2204	(1) Drought; drought related disasters. (2) Excessive rain, flooding; related disasters.		1
PA		4-01-05 10-07-05	continuing continuing	1-09-06	9-11-06	S2204	(1) Drought; drought related disasters. (2) Excessive rain, flooding; related disasters.		4
VT		4-01-05 10-07-05	continuing continuing	1-09-06	9-11-06	S2204	(1) Drought; drought related disasters. (2) Excessive rain, flooding; related disasters.		1
TX	Duval	10-27-05	10-27-05	1-09-06	9-11-06	S2205	Excessive rain, hail, high winds, lightning, tornado.	1	7

DISASTER ASSISTANCE BRANCH/EMERGENCIES SECTION (DAB/ES) DISASTER DECLARATIONS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal year 2006]

State	Countries requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
TX	Ellis	2-01-05	continuing	1-09-06	9-11-06	S2206	Drought	1	7
TX	Frio	5-01-05	10-24-05	1-09-06	9-11-06	S2207	Drought	1	7
TX	Gregg, Smith, Upshur	4-01-05	continuing	1-09-06	9-11-06	S2208	Drought, excessive heat	3	9
TX	Hill	2-01-05	10-24-05	1-09-06	9-11-06	S2209	Drought	1	6
TX	Jim Wells	10-27-05	10-27-05	1-09-06	9-11-06	S2210	Excessive rain, flooding, hail, high winds, lightning, tornado.	1	6
TX	Kimble	9-01-05	continuing	1-09-06	9-11-06	S2211	Drought	1	7
TX	Lynn	8-28-05	9-14-05	1-09-06	9-11-06	S2212	Excessive rain, hail, high winds, lightning.	1	7
TX	Mills, San Saba	9-01-05	continuing	1-09-06	9-11-06	S2213	Drought	2	7
TX	Parker, Wharton	6-01-05	continuing	1-09-06	9-11-06	S2214	Drought	2	12
WA	Benton, Clark, Columbia, Cowlitz, Douglas, Franklin, Kittitas, Klickitat, Lincoln, Skamania, Wahkiakum, Walla Walla, Yakima.	1-01-05	continuing	1-09-06	9-11-06	S2215	Drought	13	13
OR		1-01-05	continuing	1-09-06	9-11-06	S2215	Drought		10
WA	(1) Garfield, Whitman	1-01-05	continuing	1-09-06	9-11-06	S2216	(1) Drought	3	9
	(2) Pacific	09-09-05	09-09-05				(2) Hailstorm		
ID		1-01-05	continuing	1-09-06	9-11-06	S2216	Drought		3
		09-09-05	09-09-05						
OR		1-01-05	continuing	1-09-06	9-11-06	S2216	Drought		1
		09-09-05	09-09-05						
CO	Logan	1-01-05	continuing	1-09-06	9-11-06	S2217	Drought, crop diseases	1	6
NE		1-01-05	continuing	1-09-06	9-11-06	S2217	Drought, crop diseases		2
TX	Wilson	3-20-05	11-14-05	1-09-06	9-11-06	S2218	Drought	1	5
TX	Denton, Kaufman, Robertson, Rockwall, Shelby, Wise.	3-01-05	continuing	1-17-06	9-18-06	S2219	Drought	6	24
LA		3-01-05	continuing	1-17-06	9-18-06	S2219	Drought		2
TX	Gillespie	5-01-05	continuing	1-17-06	9-18-06	S2220	Drought	1	6

IN	Bartholomew, Clark, Crawford, Dearborn, Elkhart, Floyd, Harrison, Jackson, Jasper, Jefferson, Kosciusko, Lake, LaPorte, Newton, Ohio, Orange, Porter, Posey, Scott, St. Joseph, Starke, Switzerland, Warrick, Washington.	6-01-05	8-31-05	1-17-06	9-18-06	S2221	Drought	24	25
IL		6-01-05	8-31-05	1-17-06	9-18-06	S2221	Drought	6	
KY		6-01-05	8-31-05	1-17-06	9-18-06	S2221	Drought	11	
MI		6-01-05	8-31-05	1-17-06	9-18-06	S2221	Drought	3	
OH		6-01-05	8-31-05	1-17-06	9-18-06	S2221	Drought	2	
SD	Lawrence	1-01-05	continuing	1-17-06	9-18-06	S2222	Drought, late spring frosts, extreme heat, high winds, hail, prairie fires	1	3
WY		1-01-05	continuing	1-17-06	9-18-06	S2222	Drought, late spring frosts, extreme heat, high winds, hail, prairie fires	2	
TX	Bee, De Witt, Hood, Somervell	6-01-05	continuing	1-17-06	9-18-06	S2223	Drought	4	14
TX	Brazos, Dimmitt, Freestone, Guadalupe, La Salle, Madison, Stephens, Zavala.	4-01-05	continuing	1-17-06	9-18-06	S2224	Drought	8	31
TX	Edwards, Hamilton	9-01-05	continuing	1-17-06	9-18-06	S2225	Drought	2	13
TX	Hall	10-10-05	10-10-05	1-17-06	9-18-06	S2226	Excessive rain, hail, high winds	1	6
TX	Hardenan	1-01-05	continuing	1-17-06	9-18-06	S2227	Drought	1	4
OK		1-01-05	continuing	1-17-06	9-18-06	S2227	Drought	2	
TX	Medina	4-01-05	continuing	1-17-06	9-18-06	S2228	Drought, excessive heat	1	6
TX	Montague	8-01-05	continuing	1-17-06	9-18-06	S2229	Drought	1	4
OK		8-01-05	continuing	1-17-06	9-18-06	S2229	Drought	2	
TX	Runnels	5-01-05	continuing	1-17-06	9-18-06	S2230	Drought, excessive temperatures	1	6
TX	Williamson	4-15-05	continuing	1-17-06	9-18-06	S2231	Drought	1	6
TX	Zapata	1-01-05	continuing	1-17-06	9-18-06	S2232	Drought	1	3
MT	Hill Co. & Rocky Boy Indian Reservation	8-10-05	8-10-05	1-27-06	9-27-06	S2233	(1) Severe hail, windstorm	1	3
TX	Austin, Cass, Eastland, Palo Pinto	01-01-05	continuing	1-23-06	9-25-06	S2234	(2) Drought	4	19
AR		8-01-05	continuing	1-23-06	9-25-06	S2234	Drought	1	
LA		8-01-05	continuing	1-23-06	9-25-06	S2234	Drought	1	
TX	Caldwell, Comal, Hays	8-01-05	continuing	1-23-06	9-25-06	S2235	Drought	3	8
TX	Goliad, McMullen	7-01-05	continuing	1-23-06	9-25-06	S2236	Drought	2	11
KS	Cheyenne	1-01-05	continuing	2-01-06	10-02-06	S2237	Drought, excessive heat, high winds	1	2
CO		1-01-05	continuing	2-01-06	10-02-06	S2237	Drought, excessive heat, high winds	2	

DISASTER ASSISTANCE BRANCH/EMERGENCIES SECTION (DAB/ES) DISASTER DECLARATIONS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal year 2006]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
NE	1-01-05	continuing	2-01-06	10-02-06	S2237	Drought, excessive heat, high winds	1
KS	Sherman, Wallace	6-19-05	continuing	2-01-06	10-02-06	S2238	Severe storms	2	6
CO	6-19-05	continuing	2-01-06	10-02-06	S2238	Severe storms	2
NY	Cayuga, Ontario, Tompkins, Wayne	12-20-04	12-20-04	2-01-06	10-02-06	S2239	Freeze, excessive cold temperatures	4	11
TX	Anderson, Dallas	3-01-05	continuing	2-01-06	10-02-06	S2240	Drought	2	12
TX	Blanco	5-01-05	continuing	2-01-06	10-02-06	S2241	Drought	1	7
TX	Gonzales	7-01-05	continuing	2-01-06	10-02-06	S2242	Drought	1	8
TX	Haskell	9-30-05	9-30-05	2-01-06	10-02-06	S2243	Excessive rain, hail, high winds	1	7
TX	Karnes	7-25-05	continuing	2-01-06	10-02-06	S2244	Drought, abnormally high temperatures	1	7
TX	Kinney	3-15-05	continuing	2-01-06	10-02-06	S2245	Drought, excessive heat	1	5
TX	Limestone	4-01-05	continuing	2-01-06	10-02-06	S2246	Drought	1	7
TX	Live Oak	7-01-05	continuing	2-01-06	10-02-06	S2247	Drought	1	7
TX	Starr	1-01-05	continuing	2-01-06	10-02-06	S2248	Drought, excessive heat	1	4
AR	Conway	11-27-05	11-27-05	2-07-06	10-09-06	S2249	Excessive rainfall, high winds, tornadoes, lightning	1	5
AR	Arkansas, Ashley, Chicot, Conway, Crittenden, Desha, Drew, Jefferson, Lee, Lincoln, Little River, Lonoke, Monroe, Phillips, Pope, Prairie, St. Francis, Woodruff	9-24-05	9-24-05	2-07-06	10-09-06	S2250	Excessive rainfall, high winds, tornadoes, lightning, due to Tropical Storm Rita	18	22
LA	9-24-05	9-24-05	2-07-06	10-09-06	S2250	Excessive rainfall, high winds, tornadoes, lightning, due to Tropical Storm Rita	4
MS	9-24-05	9-24-05	2-07-06	10-09-06	S2250	Excessive rainfall, high winds, tornadoes, lightning, due to Tropical Storm Rita	6
OK	9-24-05	9-24-05	2-07-06	10-09-06	S2250	Excessive rainfall, high winds, tornadoes, lightning, due to Tropical Storm Rita	1
TN	9-24-05	9-24-05	2-07-06	10-09-06	S2250	Excessive rainfall, high winds, tornadoes, lightning, due to Tropical Storm Rita	2

TX	9-24-05	2-07-06	10-09-06	S2250	Excessive rainfall, high winds, tornadoes, lightning, due to Tropical Storm Rita.	1
MA	6-01-05	2-09-06	10-09-06	S2251	Drought	2	3
RI	6-01-05	2-09-06	10-09-06	S2251	Drought	3
OR	6-30-05	2-09-06	10-09-06	S2252	Severe Weather events	1	3
WA	6-01-05	2-09-06	10-09-06	S2252	Severe Weather events	2
TX	8-01-05	continuing	2-09-06	10-09-06	S2253	Drought	1	6
TX	6-01-05	continuing	2-09-06	10-09-06	S2254	Drought, excessive heat, high winds.	1	5
TX	4-01-05	continuing	2-09-06	10-09-06	S2255	Drought	2	14
TX	5-01-05	continuing	2-09-06	10-09-06	S2256	Drought	1	6
OR	1-01-05	continuing	2-09-06	10-09-06	S2257	Drought	1	2
WA	1-01-05	continuing	2-09-06	10-09-06	S2257	Drought	1
TX	12-26-05	12-27-05	2-09-06	10-09-06	S2258	Fire, high winds	1	6
TX	12-26-05	continuing	2-09-06	10-09-06	S2259	Fire, high winds	1	6
CT	6-01-05	10-15-05	2-13-06	10-13-06	S2260	Drought	8
MA	6-01-05	10-15-05	2-13-06	10-13-06	S2260	Drought	3
NY	6-01-05	10-15-05	2-13-06	10-13-06	S2260	Drought	3
RI	6-01-05	10-15-05	2-13-06	10-13-06	S2260	Drought	3
NY	5-01-05	9-30-05	2-13-06	10-13-06	S2261	Drought, heat	2	8
PA	5-01-05	9-30-05	2-13-06	10-13-06	S2261	Drought, heat	2
NY	10-06-05	10-06-05	2-13-06	10-13-06	S2262	High winds	1	2
VT	10-06-05	10-06-05	2-13-06	10-13-06	S2262	High winds	2
NY	10-25-05	10-25-05	2-13-06	10-13-06	S2263	Excessive rain, excessive snow	2	4
VT	10-25-05	10-25-05	2-13-06	10-13-06	S2263	Excessive rain, excessive snow	3
NY	10-07-05	10-24-05	2-13-06	10-13-06	S2264	Excessive rain Freeze	1	4
NY	10-20-05	10-22-05	2-13-06	10-13-06	S2265	Excessive rain	1	5
NY	9-01-05	10-31-05	2-13-06	10-13-06	S2266	Excessive rain	1	6
NY	9-15-05	continuing	2-13-06	10-13-06	S2266	Excessive rain	23
TN	5-01-05	continuing	2-13-06	10-13-06	S2267	Drought, high temperatures	8
GA	5-01-05	continuing	2-13-06	10-13-06	S2267	Drought, high temperatures	4
KY	5-01-05	continuing	2-13-06	10-13-06	S2267	Drought, high temperatures	2
NC	5-01-05	continuing	2-13-06	10-13-06	S2267	Drought, high temperatures	4
VA	5-01-05	continuing	2-13-06	10-13-06	S2267	Drought, high temperatures	2
TX	8-29-05	9-30-05	2-13-06	10-13-06	S2268	Hurricane related wind and storms	2	4
GA	8-29-05	9-30-05	2-13-06	10-13-06	S2268	Hurricane related wind and storms	4
NC	8-29-05	9-30-05	2-13-06	10-13-06	S2268	Hurricane related wind and storms	1
TX	3-01-05	continuing	2-13-06	10-13-06	S2269	Drought, frost	1	7

DISASTER ASSISTANCE BRANCH/EMERGENCIES SECTION (DAB/ES) DISASTER DECLARATIONS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal year 2006]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Continuing
TX	Cooke	12-27-05	12-27-05	2-13-06	10-13-06	S2270	Fire	1	4
OK		12-27-05	12-27-05	2-13-06	10-13-06	S2270	Fire	1	1
TX	Fayette	4-15-05	continuing	2-13-06	10-13-06	S2271	Drought	1	8
TX	Lavaca	9-13-05	continuing	2-13-06	10-13-06	S2272	Drought, excessive temperatures, high winds	1	6
TX	Palo Pinto	1-01-06	1-01-06	2-13-06	10-13-06	S2273	High winds, wildfire	1	7
TX	Rusk	3-01-05	continuing	2-13-06	10-13-06	S2274	Drought	1	7
WI	Adams, Brown, Burnett, Calumet, Dodge, Door, Fond du Lac, Kenosha, Kewaunee, Manitowoc, Marinette, Marquette, Oconto, Racine, Sheboygan, Walworth, Washburn, Waupaca.	3-01-05	continuing	2-13-06	10-13-06	S2275	Drought	18	28
IL		3-01-05	continuing	2-13-06	10-13-06	S2275	Drought	3	3
MI		3-01-05	continuing	2-13-06	10-13-06	S2275	Drought	2	2
MN		3-01-05	continuing	2-13-06	10-13-06	S2275	Drought	2	2
PA	Armstrong, Bedford, Bradford, Centre, Clearfield, Clinton, Elk, Fayette, Fulton, Greene, Jefferson, Lackawanna, Lehigh, Luzerne, McKean, Pike, Potter, Susquehanna, Sullivan, Tioga, Washington, Wayne, Wyoming.	5-01-05	continuing	2-21-06	10-23-06	S2276	Drought	23	27
MD		5-01-05	continuing	2-21-06	10-23-06	S2276	Drought	3	3
NY		5-01-05	continuing	2-21-06	10-23-06	S2276	Drought	1	1
NY		5-01-05	continuing	2-21-06	10-23-06	S2276	Drought	10	10
OH		5-01-05	continuing	2-21-06	10-23-06	S2276	Drought	1	1
WV		5-01-05	continuing	2-21-06	10-23-06	S2276	Drought	7	7
TX	Sterling	1-01-06	1-01-06	2-21-06	10-23-06	S2277	Fire	1	6
TX	Tom Green	1-01-06	continuing	2-23-06	10-23-06	S2278	Grass fires	1	8
VA	Bedford, Hanover, Russell, Wise	6-01-05	continuing	2-23-06	10-23-06	S2195, Amendment 2.	Drought, high temperatures	4	24
KY		6-01-05	continuing	2-23-06	10-23-06	S2195, Amendment 2.	Drought, high temperatures	3	3

VA	Culpeper, Goochland, Grayson, King William, Surry, Washington.	6-01-05	continuing ...	2-28-06	10-30-06 ...	S2195, Amendment 1. S2195, Amendment 1. S2195, Amendment 1. S2279	Drought, high temperatures	6	30
NC	6-01-05	continuing ...	2-28-06	10-30-06 ...	S2195, Amendment 1. S2195, Amendment 1. S2195, Amendment 1. S2279	Drought, high temperatures	3
TN	6-01-05	continuing ...	2-28-06	10-30-06 ...	S2195, Amendment 1. S2195, Amendment 1. S2195, Amendment 1. S2279	Drought, high temperatures	2
OK	Entire State	7-01-05	continuing ...	2-28-06	10-30-06 ...	S2279	Drought, high temperatures, high winds, fire.	77
AR	7-01-05	continuing ...	2-28-06	10-30-06 ...	S2279	Drought, high temperatures, high winds, fire.	8
CO	7-01-05	continuing ...	2-28-06	10-30-06 ...	S2279	Drought, high temperatures, high winds, fire.	1
KS	7-01-05	continuing ...	2-28-06	10-30-06 ...	S2279	Drought, high temperatures, high winds, fire.	14
MO	7-01-05	continuing ...	2-28-06	10-30-06 ...	S2279	Drought, high temperatures, high winds, fire.	2
NM	7-01-05	continuing ...	2-28-06	10-30-06 ...	S2279	Drought, high temperatures, high winds, fire.	1
TX	7-01-05	continuing ...	2-28-06	10-30-06 ...	S2279	Drought, high temperatures, high winds, fire.	20

DISASTER ASSISTANCE BRANCH/EMERGENCIES SECTION (DAB/ES) DISASTER DECLARATIONS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal year 2006]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
GA	Appling, Bacon, Banks, Barrow, Bartow, Ben Hill, Bibb, Bleckley, Bryan, Bulloch, Butts, Carroll, Catoosa, Chattooga, Cherokee, Clarke, Clayton, Clinch, Cobb, Columbia, Coweta, Crawford, Crisp, Dade, Dawson, Decatur, De Kalb, Dodge, Dooly, Douglas, Elbert, Emanuel, Evans, Fannin, Fayette, Floyd, Forsyth, Franklin, Fulton, Gilmer, Glascock, Gordon, Grady, Gwinnett, Habersham, Hall, Haralson, Harris, Hart, Heard, Henry, Houston, Irwin, Jackson, Jeff Davis, Jefferson, Johnson, Lamar, Lanier, Laurens, Lincoln, Long, Lumpkin, McDuffie, Macon, Madison, Marion, Meriwether, Miller, Mitchell, Monroe, Montgomery, Murray, Muscogee, Oconee, Oglethorpe, Paulding, Peach, Pickens, Pike, Polk, Pulaski, Rabun, Richmond, Rockdale, Screven, Seminole, Spalding, Stephens, Sumter, Talbot, Tattnall, Taylor, Telfair, Thomas, Towns, Treutlen, Troup, Turner, Twiggs, Union, Upson, Walker, Walton, Warren, Washington, Wayne, Wheeler, White, Whitfield, Wilkes, Wilkinson.	8-01-05	continuing	3-07-06	11-07-06	S2280	Drought	112	39
AL	8-01-05	continuing	3-07-06	11-07-06	S2280	Drought	9
FL	8-01-05	continuing	3-07-06	11-07-06	S2280	Drought	6
NC	8-01-05	continuing	3-07-06	11-07-06	S2280	Drought	4
SC	8-01-05	continuing	3-07-06	11-07-06	S2280	Drought	8
TN	8-01-05	continuing	3-07-06	11-07-06	S2280	Drought	4

TX	Angelina, Aransas, Archer, Armstrong, Atascosa, Bailey, Bastrop, Baylor, Bell, Bexar, Borden, Briscoe, Brown, Burnet, Callahan, Cameron, Carson, Castro, Childress, Clay, Cochran, Coke, Coleman, Collingsworth, Comanche, Concho, Coryell, Cottle, Crockett, Crosby, Dawson, Deaf Smith, Dickens, Donley, Erath, Fisher, Floyd, Fort Bend, Gaines, Garza, Glasscock, Gray, Grimes, Hale, Hall, Hansford, Harris, Harrison, Haskell, Hemphill, Hockley, Howard, Hutchinson, Iron, Jackson, Jasper, Jones, Kent, Kerr, King, Knox, Lamb, Lampasas, Lipscomb, Lubbock, Lynn, Marion, Maverick, McCulloch, Menard, Milam, Mitchell, Montgomery, Moore, Motley, Newton, Nolan, Nueces, Ochiltree, Oldham, Panola, Parmer, Polk, Potter, Randall, Reagan, Real, Refugio, Roberts, Sabine, San Augustine, San Jacinto, San Patricio, Schleicher, Scurry, Shackelford, Sherman, Sterling, Stonewall, Sutton, Swisher, Taylor, Terry, Throckmorton, Tom Green, Travis, Trinity, Tyler, Upton, Uvalde, Val Verde, Victoria, Walker, Wheeler, Wichita, Yoakum, Young	4-01-05	continuing ...	3-07-06	11-07-06 ...	S2281	Drought, above normal temperatures, wildfires.	117	87
LA	4-01-05	continuing ...	3-07-06	11-07-06 ...	S2281	Drought, above normal temperatures, wildfires.	6
NM	4-01-05	continuing ...	3-07-06	11-07-06 ...	S2281	Drought, above normal temperatures, wildfires.	4
OK	4-01-05	continuing ...	3-07-06	11-07-06 ...	S2281	Drought, above normal temperatures, wildfires.	10
NY	Cortland, Tompkins	10-20-05 ...	11-20-05 ...	3-10-06	11-10-06 ...	S2282	Excessive rain	2	9
TN	Anderson, Campbell, Cannon, Carter, Knox, Sullivan	5-01-05	continuing ...	3-10-06	11-10-06 ...	S2283	Drought, higher than normal temperatures.	6	19
KY	5-01-05	continuing ...	3-10-06	11-10-06 ...	S2283	Drought, higher than normal temperatures.	2

DISASTER ASSISTANCE BRANCH/EMERGENCIES SECTION (DAB/ES) DISASTER DECLARATIONS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal year 2006]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
NC	5-01-05	continuing	3-10-06	11-10-06	S2283	Drought, higher than normal temperatures.	2
VA	5-01-05	continuing	3-10-06	11-10-06	S2283	Drought, higher than normal temperatures.	3
TX	Jack	1-12-06	1-12-06	3-10-06	11-10-06	S2284	Wildfire, high winds	1	7
TX	Erath	1-01-06	1-01-06	3-29-06	11-29-06	S2285	Wildfire	1	7
WV	Barbour, Berkeley, Boone, Brooke, Cabell, Grant, Hampshire, Hancock, Hardy, Jefferson, Lincoln, Logan, Marion, Marshall, Mason, Mineral, Mingo, Monongalia, Morgan, Ohio, Pendleton, Preston, Putnam, Randolph, Taylor, Tucker, Tyler, Wayne, Wetzel.	3-01-05	11-30-05	3-29-06	11-29-06	S2286	Drought	29	12
KY	3-01-05	11-30-05	3-29-06	11-29-06	S2286	Drought	4
MD	3-01-05	11-30-05	3-29-06	11-29-06	S2286	Drought	3
OH	3-01-05	11-30-05	3-29-06	11-29-06	S2286	Drought	8
PA	3-01-05	11-30-05	3-29-06	11-29-06	S2286	Drought	4
VA	3-01-05	11-30-05	3-29-06	11-29-06	S2286	Drought	8
CO	Huerfano, Kiowa, Las Animas, Sedgwick	3-01-05	continuing	4-05-06	12-05-06	S2287	Drought, related disasters	4	14
KS	3-01-05	continuing	4-05-06	12-05-06	S2287	Drought, related disasters	1
NE	3-01-05	continuing	4-05-06	12-05-06	S2287	Drought, related disasters	4
TX	3-01-05	continuing	4-05-06	12-05-06	S2287	Drought, related disasters	2
TX	Frio	1-01-06	continuing	4-18-06	12-18-06	S2288	Drought, high temperatures	1	7
TX	Wheeler	3-12-06	3-15-06	4-18-06	12-18-06	S2289	Fire, high winds	1	5
OK	3-12-06	3-15-06	4-18-06	12-18-06	S2289	Fire, high winds	2
TX	Collingsworth	3-12-06	continuing	4-20-06	12-20-06	S2290	Fire, high winds	1	5
OK	3-12-06	continuing	4-20-06	12-20-06	S2291	Fire, high winds	2
TX	Gray	3-12-06	3-12-06	4-20-06	12-20-06	S2291	Fire, extreme wind	1	7
TX	Roberts	3-12-06	3-12-06	4-20-06	12-20-06	S2292	Fire	1	8
TX	Taylor	1-01-06	continuing	4-20-06	12-20-06	S2293	Drought	1	6
HI	Honolulu, Kauai	2-20-06	3-26-06	4-24-06	12-27-06	S2294	Rain, flooding	2
TX	Cottle	3-12-06	continuing	5-03-06	1-03-07	S2295	Fire, high winds	1	7
AZ	All counties except La	1-01-06	continuing	5-09-06	1-09-07	S2296	Drought	14	1
CA	z	1-01-06	continuing	5-09-06	1-09-07	S2296	Drought	2

CO	1-01-06	continuing	5-09-06	1-09-07	S2296	Drought	1
NM	1-01-06	continuing	5-09-06	1-09-07	S2296	Drought	6
NV	1-01-06	continuing	5-09-06	1-09-07	S2296	Drought	2
UT	1-01-06	continuing	5-09-06	1-09-07	S2296	Drought	3
TX	1-01-06	continuing	5-15-06	1-16-07	S2297	Drought, high winds	1	7
TX	1-01-06	continuing	5-15-06	1-15-07	S2298	Fire, high temperatures	1	7
TX	1-01-06	continuing	5-15-06	1-15-07	S2299	Fire	1	7
TX	3-12-06	3-12-06	5-15-06	1-15-07	S2300	Fire	1	6
NM	1-01-06	continuing	5-15-06	1-15-07	S2301	Drought	31	2
AZ	1-01-06	continuing	5-18-06	1-18-07	S2301	Drought, high winds	3
CO	1-01-06	continuing	5-18-06	1-18-07	S2301	Drought, high winds	7
OK	1-01-06	continuing	5-18-06	1-18-07	S2301	Drought, high winds	1
TX	1-01-06	continuing	5-18-06	1-18-07	S2301	Drought, high winds	16
UT	1-01-06	continuing	5-18-06	1-18-07	S2301	Drought, high winds	1
TX	3-12-06	3-12-06	5-18-06	1-18-07	S2302	Drought, high winds	1	4
OK	3-12-06	3-12-06	5-18-06	1-18-07	S2302	Fire	2
TX	3-24-06	3-24-06	5-22-06	1-22-07	S2303	Fire	5
TX	1-01-06	continuing	5-22-06	1-22-07	S2304	Freeze	1	6
TX	4-11-06	4-11-06	5-22-06	1-22-07	S2305	Drought	1	3
OK	4-11-06	4-11-06	5-22-06	1-22-07	S2305	Wildfires	2
TX	1-01-06	continuing	5-30-06	1-30-07	S2306	Wildfires	2	7
TX	1-01-06	continuing	5-30-06	1-30-07	S2306	Drought, high winds	1
TX	1-01-06	continuing	5-30-06	1-30-07	S2307	Drought, high winds	1
TX	3-05-06	3-11-06	5-31-06	1-31-07	S2308	Wildfires	1	7
TX	4-28-06	4-28-06	5-31-06	1-31-07	S2309	Drought	2	11
OK	3-24-06	3-25-06	5-31-06	1-31-07	S2310	Flash flooding, hail, high winds	1	4
TX	1-01-06	continuing	6-05-06	2-05-07	S2311	Flash flooding, hail, high winds	1
TX	3-12-06	3-12-06	6-05-06	2-05-07	S2312	Freeze	1	6
NM	3-12-06	3-12-06	6-05-06	2-05-07	S2312	Drought, high winds	1	4
AR	4-07-06	4-07-06	6-12-06	2-12-07	S2313	Wildfires	1	5
LA	4-07-06	4-07-06	6-12-06	2-12-07	S2313	Hail, high winds	2	5
KS	8-01-05	continuing	6-12-06	2-12-07	S2314	Hail, high winds	2
CO	8-01-05	continuing	6-12-06	2-12-07	S2314	Drought, high winds, wildfires, above-normal temperatures.	2	4
MO	8-01-05	continuing	6-12-06	2-12-07	S2314	above-normal temperatures.	2
OK	8-01-05	continuing	6-12-06	2-12-07	S2314	Drought, high winds, wildfires, above-normal temperatures.	1
	8-01-05	continuing	6-12-06	2-12-07	S2314	Drought, high winds, wildfires, above-normal temperatures.	4

DISASTER ASSISTANCE BRANCH/EMERGENCIES SECTION (DAB/ES) DISASTER DECLARATIONS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal year 2006]

State	Countries requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
CA	Alameda, Amador, Butte, Calaveras, Contra Costa, El Dorado, Fresno, Glenn, Humboldt, Kings, Lake, Madera, Mendocino, Merced, Nevada, Plumas, Sacramento, San Joaquin, San Mateo, Shasta, Sierra, Solano, Sonoma, Stanislaus, Sutter, Tehama, Tulare, Yolo, Yuba.	12-17-06	4-26-06	6-15-06	2-15-07	S2315	Storms: Excessive rainfall, hail, high winds, Frost, freeze, fluctuating temperatures.	29	21
NV		12-17-06	4-26-06	6-15-06	2-15-07	S2315	Storms: Excessive rainfall, hail, high winds, Frost, freeze, fluctuating temperatures.		2
TX									
TX	Bosque, Johnson, McLennan	1-01-06	continuing	6-15-06	2-15-07	S2316	Drought	3	12
TX	Terrell	1-01-06	continuing	6-15-06	2-15-07	S2317	Drought, high winds	1	4
TX	Collin	5-09-06	5-09-06	6-19-06	2-19-07	S2318	Tornado	1	6
TX	Kleberg	1-01-06	continuing	6-19-06	2-19-07	S2319	Drought, excessive temperatures, high winds.	1	4
TX	McLennan	5-06-06	5-06-06	6-19-06	2-19-07	S2320	Excessive rain, hail, high winds, tornado.	1	6
VT									
MA	Entire State	5-01-06	continuing	6-23-06	2-23-07	S2321	Severe weather; excessive rainfall	14	
NH		5-01-06	continuing	6-23-06	2-23-07	S2321	Severe weather; excessive rainfall		2
NY		5-01-06	continuing	6-23-06	2-23-07	S2321	Severe weather; excessive rainfall		4
CA	Placer	3-01-06	4-30-06	6-26-06	2-26-07	S2321	Severe weather; excessive rainfall		4
NV		3-01-06	4-30-06	6-26-06	2-26-07	S2322	Excessive rainfall, hail	1	5
CA	Placer	3-01-06	4-30-06	6-26-06	2-26-07	S2322	Excessive rainfall, hail		3
TX	McLennan	3-24-06	3-25-06	6-29-06	3-01-07	S2323	Excess rainfall [sic], hail	1	
TX	Mitchell	5-02-06	5-02-06	6-29-06	3-01-07	S2324	Flash flooding, hail, tornado	1	6
									7

AL	Baldwin, Coffee, Barbour, Bibb, Bullock, Butler, Chambers, Cherokee, Choctaw, Clarke, Clay, Etowah, Colbert, Conecuh, Coosa, Covington, Crenshaw, Cullman, Dale, Elmore, Escambia, Lee, Franklin, Geneva, Greene, Hale, Henry, Houston, Jackson, Lauderdale, Lawrence, Randolph, Macon, Madison, Marengo, Mobile, Monroe, Montgomery, Morgan, Perry, Pike, Russell, St. Clair, Sumter, Tallapoosa, Tuscaloosa, Washington, Wilcox.	1-01-06	continuing ...	6-30-06	3-02-07	S2325	Drought, high temperatures	48	18
MS	1-01-06	continuing ...	6-30-06	3-02-07	S2325	Drought, high temperatures	6
TN	1-01-06	continuing ...	6-30-06	3-02-07	S2325	Drought, high temperatures	15
AL	1-01-06	continuing ...	6-30-06	3-02-07	S2325	Drought, high temperatures	10
AL	1-01-06	continuing ...	6-30-06	3-02-07	S2325	Drought, high temperatures	7
CA	Lassen	1-01-06	4-30-06	7-05-06	3-05-07	S2326	Excessive rainfall, flooding, cooler than normal temperatures.	1	4
NV	1-01-06	4-30-06	7-05-06	3-05-07	S2326	Excessive rainfall, flooding, cooler than normal temperatures.	1
CO	Adams, Alamosa, Broomfield, Baca, Chaffee, Cheyenne, Conejos, Costilla, Custer, Denver, Dolores, Douglas, Elbert, Fremont, Hinsdale, Huerfano, Kit Carson, Lake, Las Animas, Mineral, Montezuma, Morgan, Prowers, Pueblo, Rio Grande, Saguache, San Miguel, Weld.	1-01-06	continuing ...	7-10-06	3-12-07	S2327	Drought	28	24
AZ	1-01-06	continuing ...	7-10-06	3-12-07	S2327	Drought	1
KS	1-01-06	continuing ...	7-10-06	3-12-07	S2327	Drought	7
NE	1-01-06	continuing ...	7-10-06	3-12-07	S2327	Drought	1
NM	1-01-06	continuing ...	7-10-06	3-12-07	S2327	Drought	5
OK	1-01-06	continuing ...	7-10-06	3-12-07	S2327	Drought	1
UT	1-01-06	continuing ...	7-10-06	3-12-07	S2327	Drought	1
WY	1-01-06	continuing ...	7-10-06	3-12-07	S2327	Drought	1
NY	Cattaraugus, Chautauqua, Erie	4-25-06	4-27-06	7-10-06	3-12-07	S2327	Frost	3	4
PA	4-25-06	4-27-06	7-10-06	3-12-07	S2328	Frost	3

DISASTER ASSISTANCE BRANCH/EMERGENCIES SECTION (DAB/ES) DISASTER DECLARATIONS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal year 2006]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
CO	Arapahoe, Archuleta, Bent, Boulder, Crowley, Delta, El Paso, Gunnison, Jefferson, Kiowa, La Plata, Montrose, Ouray, Park, Phillips, Teller, Washington.	1-01-06	continuing	7-11-06	3-12-07	S2329	Drought	17	37
KS		1-01-06	continuing	7-11-06	3-12-07	S2329	Drought	11
NE		1-01-06	continuing	7-11-06	3-12-07	S2329	Drought	2
NM		1-01-06	continuing	7-11-06	3-12-07	S2329	Drought	2
UT		1-01-06	continuing	7-11-06	3-12-07	S2329	Drought	2
CO	Dolores, Montezuma, San Miguel	5-09-06	5-30-06	7-13-06	3-13-07	S2330	Freeze	3	4
AZ		5-09-06	5-30-06	7-13-06	3-13-07	S2330	Freeze	1
NM		5-09-06	5-30-06	7-13-06	3-13-07	S2330	Freeze	1
UT		5-09-06	5-30-06	7-13-06	3-13-07	S2330	Freeze	1
NE	Boyd, Brown, Buffalo, Garfield, Howard, Kearney, Kaya, Paha, Loup, Rock, Sherman, Valley, Webster, Wheeler.	1-01-06	continuing	7-13-06	3-13-07	S2331	High winds, excessive heat a late freeze, drought.	13	18
KS		1-01-06	continuing	7-13-06	3-13-07	S2331	High winds, excessive heat a late freeze, drought.	2
SD		1-01-06	continuing	7-13-06	3-13-07	S2331	High winds, excessive heat a late freeze, drought.	4
NE	Arthur, Banner, Blaine, Box Butte, Chase, Cherry, Cheyenne, Custer, Dawes, Dawson, Deuel, Dundy, Franklin, Frontier, Furnas, Garden, Gosper, Grant, Harlan, Hayes, Hitchcock, Holt, Hooker, Keith, Kimball, Lincoln, Logan, McPherson, Morrill, Perkins, Phelps, Red Willow, Scotts Bluff, Sheridan, Sioux, Thomas.	1-01-06	continuing	7-13-06	3-13-07	S2332	High winds, excessive heat [high temperatures], drought.	36	15
CO		1-01-06	continuing	7-13-06	3-13-07	S2332	High winds, excessive heat [high temperatures], drought.	5
KS		1-01-06	continuing	7-13-06	3-13-07	S2332	High winds, excessive heat [high temperatures], drought.	6

SD	1-01-06	continuing	7-13-06	3-13-07	S2332	High winds, excessive heat [high temperatures], drought.	5
WY	1-01-06	continuing	7-13-06	3-13-07	S2332	High winds, excessive heat [high temperatures], drought.	3
OR	Malheur	3-29-06	5-10-06	7-13-06	3-13-07	S2333	Flooding, cooler temperatures, abnormally high precipitation.	1	3
ID	3-29-06	5-10-06	7-13-06	3-13-07	S2333	Flooding, cooler temperatures, abnormally high precipitation.	4
NV	3-29-06	5-10-06	7-13-06	3-13-07	S2333	Flooding, cooler temperatures, abnormally high precipitation.	1
AR	Jefferson	5-10-06	5-10-06	7-13-06	3-13-07	S2334	Excessive rainfall, high winds, tornadoes, lightning.	1	6
AR	Little River	5-04-06	5-04-06	7-13-06	3-13-07	S2335	Excessive thunderstorms, rainfall, high winds, hail, lightning.	1	4
OK	5-04-06	5-04-06	7-13-06	3-13-07	S2335	Excessive thunderstorms, rainfall, high winds, hail, lightning.	1
TX	5-04-06	5-04-06	7-13-06	3-13-07	S2335	Excessive thunderstorms, rainfall, high winds, hail, lightning.	1
TX	Lee	4-20-06	4-20-06	7-13-06	3-13-07	S2336	High winds	1	6
TX	Kenedy	1-01-06	continuing	7-13-06	3-13-07	S2337	Drought, excessive temperatures, high winds.	1	4
TX	Colorado, Pecos	1-01-06	continuing	7-20-06	3-20-07	S2338	Drought	2	12
TX	Dimmit	1-01-06	continuing	7-20-06	3-20-07	S2339	Drought	1	5
TX	Duval	1-01-06	continuing	7-20-06	3-20-07	S2340	Drought, high winds, high temperatures.	1	7
TX	Mason	1-01-06	continuing	7-20-06	3-20-07	S2341	Drought, excessive heat	1	6
TX	Nolan	1-01-06	continuing	7-20-06	3-20-07	S2342	Drought, fire, high winds	1	7
OK	Entire State	1-01-06	continuing	7-27-06	3-27-07	S2343	Drought, extreme heat, high winds, stressful moisture conditions.	77
AR	1-01-06	continuing	7-27-06	3-27-07	S2343	Drought, extreme heat, high winds, stressful moisture conditions.	8
CO	1-01-06	continuing	7-27-06	3-27-07	S2343	Drought, extreme heat, high winds, stressful moisture conditions.	1
KS	1-01-06	continuing	7-27-06	3-27-07	S2343	Drought, extreme heat, high winds, stressful moisture conditions.	14
MO	1-01-06	continuing	7-27-06	3-27-07	S2343	Drought, extreme heat, high winds, stressful moisture conditions.	2
NM	1-01-06	continuing	7-27-06	3-27-07	S2343	Drought, extreme heat, high winds, stressful moisture conditions.	1

DISASTER ASSISTANCE BRANCH/EMERGENCIES SECTION (DAB/ES) DISASTER DECLARATIONS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal year 2006]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
TX	1-01-06	continuing	7-27-06	3-27-07	S2343	Drought, extreme heat, high winds, stressful moisture conditions.	20
SD	Brule, Buffalo, Campbell, Corson, Custer, Dewey, Edmunds, Fall River, Faulk, Hughes, Hyde, Jackson, Jerald, Jones, Lyman, Meade, Pennington, Perkins, Potter, Stanley, Sully, Walworth, Ziebach.	1-01-06	continuing	7-27-06	3-27-07	S2344	Spring killing frost, extreme heat, high winds, hail, insect damage, drought.	23	18
ND	1-01-06	continuing	7-27-06	3-27-07	S2344	Spring killing frost, extreme heat, high winds, hail, insect damage, drought.	4
NE	1-01-06	continuing	7-27-06	3-27-07	S2344	Spring killing frost, extreme heat, high winds, hail, insect damage, drought.	2
WY	1-01-06	continuing	7-27-06	3-27-07	S2344	Spring killing frost, extreme heat, high winds, hail, insect damage, drought.	2
SD	Brule, Buffalo, Campbell, Corson, Custer, Dewey, Edmunds, Fall River, Faulk, Hughes, Hyde, Jackson, Jerald, Jones, Lyman, Meade, Pennington, Perkins, Potter, Stanley, Sully, Walworth, Ziebach.	1-01-06	continuing	8-15-06	4-16-07	S2344, Amendment 1.	ADDs: prairie fires caused by dry lightning to disasters for 23 counties.	23	18
ND	1-01-06	continuing	8-15-06	4-16-07	S2344, Amendment 1.	ADDs: prairie fires caused by dry lightning to disasters for 23 counties.	4
NE	1-01-06	continuing	8-15-06	4-16-07	S2344, Amendment 1.	ADDs: prairie fires caused by dry lightning to disasters for 23 counties.	2
WY	1-01-06	continuing	8-15-06	4-16-07	S2344, Amendment 1.	ADDs: prairie fires caused by dry lightning to disasters for 23 counties.	2
SD	Turner	6-16-06	6-16-06	7-27-06	3-27-07	S2345	High winds, heavy rain, hail	1	6

TN	Rutherford	5-11-06	5-25-06	7-27-06	3-27-07	S2346	Hail, excessive rain	1	7
TX	Live Oak, McMullen	1-01-06	continuing	7-27-06	3-27-07	S2347	Drought	2	9
TX	Calhoun	6-20-06	6-20-06	7-31-06	4-02-07	S2348	Excessive rain, flash flooding, flooding	1	5
TX	Hartley, La Salle, Presidio	1-01-06	continuing	8-02-06	4-02-07	S2349	Drought	3	14
NM		1-01-06	continuing	8-02-06	4-02-07	S2349	Drought	2	2
TX	Robertson	4-18-06	4-20-06	8-07-06	4-09-07	S2350	Hail, high winds	1	7
CO	Eagle, Fremont, Garfield, Larimer, Logan, Otero, Pitkin, Rio Blanco, Yuma	1-01-06	continuing	8-08-06	4-09-07	S2351	Drought, heat, high winds	8	21
KS		1-01-06	continuing	8-08-06	4-09-07	S2351	Drought, heat, high winds	1	1
NE		1-01-06	continuing	8-08-06	4-09-07	S2351	Drought, heat, high winds	4	4
UT		1-01-06	continuing	8-08-06	4-09-07	S2351	Drought, heat, high winds	2	2
WY		1-01-06	continuing	8-08-06	4-09-07	S2351	Drought, heat, high winds	2	2
CO	Fremont	7-05-06	7-05-06	8-08-06	4-09-07	S2352	Flooding	1	7
CO	Yuma	4-28-06	6-10-06	8-08-06	4-09-07	S2353	Hail	1	4
KS		4-28-06	6-10-06	8-08-06	4-09-07	S2353	Hail	1	1
NE		4-28-06	6-10-06	8-08-06	4-09-07	S2353	Hail	2	2
TX	Llano	1-01-06	continuing	8-08-06	4-09-07	S2354	Drought, excessive heat	1	5
TX	Lubbock	1-01-06	continuing	8-08-06	4-09-07	S2355	Drought, high winds, extreme temperatures	1	8
TX	Victoria	1-01-06	6-01-06	8-08-06	4-09-07	S2356	Drought	1	6
SD	Aurora, Beadle, Bennett, Butte, Clark, Codington, Douglas, Haakon, Hand, Harding, Hutchinson, Mellette, McPherson, Sanborn, Shannon, Spink, Todd, Tripp	1-01-06	continuing	8-08-06	4-09-07	S2357	Late spring killing frost, extreme heat, high winds, hail, insect damage, insufficient subsoil moisture, prairie fires caused by dry lightning, ongoing drought.	18	35
MT		1-01-06	continuing	8-08-06	4-09-07	S2357	Late spring killing frost, extreme heat, high winds, hail, insect damage, insufficient subsoil moisture, prairie fires caused by dry lightning, ongoing drought.	2	2
NE		1-01-06	continuing	8-08-06	4-09-07	S2357	Late spring killing frost, extreme heat, high winds, hail, insect damage, insufficient subsoil moisture, prairie fires caused by dry lightning, ongoing drought.	4	4

DISASTER ASSISTANCE BRANCH/EMERGENCIES SECTION (DAB/ES) DISASTER DECLARATIONS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal year 2006]

State	Countries requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
ND	1-01-06	continuing	8-08-06	4-09-07	S2357	Late spring killing frost, extreme heat, high winds, hail, insect damage, insufficient subsoil moisture, prairie fires caused by dry lightning, ongoing drought.	4
WY	1-01-06	continuing	8-08-06	4-09-07	S2357	Late spring killing frost, extreme heat, high winds, hail, insect damage, insufficient subsoil moisture, prairie fires caused by dry lightning, ongoing drought.	1
CT	Entire State	4-01-06	continuing	8-15-06	4-16-07	S2358	Cool spring, excessively wet weather pattern.	8
MA	4-01-06	continuing	8-15-06	4-16-07	S2358	Cool spring, excessively wet weather pattern.	3
NY	4-01-06	continuing	8-15-06	4-16-07	S2358	Cool spring, excessively wet weather pattern.	3
RI	4-01-06	continuing	8-15-06	4-16-07	S2358	Cool spring, excessively wet weather pattern.	3
NJ	Atlantic, Bergen, Burlington, Camden, Cape May, Cumberland, Gloucester, Hunterdon, Mercer, Middlesex, Monmouth, Morris, Ocean, Salem, Somerset, Sussex, Warren.	6-01-06	continuing	8-15-06	4-16-07	S2359	Excessive precipitation, high winds, hail, high humidity.	17	4
DE	6-01-06	continuing	8-15-06	4-16-07	S2359	Excessive precipitation, high winds, hail, high humidity.	1
NY	6-01-06	continuing	8-15-06	4-16-07	S2359	Excessive precipitation, high winds, hail, high humidity.	3
PA	6-01-06	continuing	8-15-06	4-16-07	S2359	Excessive precipitation, high winds, hail, high humidity.	6
RI	Entire State	4-01-06	continuing	8-15-06	4-16-07	S2360	Excessive precipitation, high winds, hail, high humidity, unusually cool spring, excessively wet weather pattern (excessive rainfall).	5

CT	4-01-06	continuing	8-15-06	4-16-07	S2360	unusually cool spring, excessively wet weather pattern (excessive rainfall).	2
MA	4-01-06	continuing	8-15-06	4-16-07	S2360	unusually cool spring, excessively wet weather pattern (excessive rainfall).	3
TX	Dallam, Hardeman, Jim Wells, Kinney, San Patricio, Wilson, Zavala.	1-01-06	continuing	8-15-06	4-16-07	S2361	Drought	7	28
NM	1-01-06	continuing	8-15-06	4-16-07	S2361	Drought	1
OK	1-01-06	continuing	8-15-06	4-16-07	S2361	Drought	3
TX	Foard, Stephens, Wilbarger	1-01-06	continuing	8-15-06	4-16-07	S2362	Drought, high winds	3	12
OK	1-01-06	continuing	8-15-06	4-16-07	S2362	Drought, high winds	2
CA	Tulare	5-01-06	5-15-06	8-21-06	4-23-07	S2363	Unseasonable heat spell	1	4
GA	All counties except Fannin, Gilmer, Towns, Union.	3-01-06	continuing	8-21-06	4-23-07	S2364	Drought, excessive heat	155	4
AL	3-01-06	continuing	8-21-06	4-23-07	S2364	Drought, excessive heat	11
FL	3-01-06	continuing	8-21-06	4-23-07	S2364	Drought, excessive heat	9
NC	3-01-06	continuing	8-21-06	4-23-07	S2364	Drought, excessive heat	3
SC	3-01-06	continuing	8-21-06	4-23-07	S2364	Drought, excessive heat	10
TN	3-01-06	continuing	8-21-06	4-23-07	S2364	Drought, excessive heat	4
NH	Entire State	5-01-06	continuing	8-21-06	4-23-07	S2365	Flooding, excessive rain	10
ME	Entire State	5-01-06	continuing	8-21-06	4-23-07	S2365	Flooding, excessive rain	2
MA	Entire State	5-01-06	continuing	8-21-06	4-23-07	S2365	Flooding, excessive rain	4
VT	Entire State	5-01-06	continuing	8-21-06	4-23-07	S2365	Flooding, excessive rain	5
NY	Albany, Schoharie	5-01-06	6-30-06	8-21-06	4-23-07	S2366	Excessive rain, cold temperatures	2	8
NY	Columbia, Greene	4-01-06	5-31-06	8-21-06	4-23-07	S2367	Freeze, frost, hail, excessive rain	2	6
CT	4-01-06	5-31-06	8-21-06	4-23-07	S2367	Freeze, frost, hail, excessive rain	1
MA	4-01-06	5-31-06	8-21-06	4-23-07	S2367	Freeze, frost, hail, excessive rain	1
NY	Cortland, Jefferson, Washington	4-01-06	continuing	8-21-06	4-23-07	S2368	Tree tent caterpillar infestation due to unusually mild winter weather.	3	14
VT	4-01-06	continuing	8-21-06	4-23-07	S2368	Tree tent caterpillar infestation due to unusually mild winter weather.	3
NY	Dutchess, Ulster	6-24-06	continuing	8-21-06	4-23-07	S2369	Excessive rain, flooding, flash flooding, high winds.	2	6
CT	6-24-06	continuing	8-21-06	4-23-07	S2369	Excessive rain, flooding, flash flooding, high winds.	2
MA	6-24-06	continuing	8-21-06	4-23-07	S2369	Excessive rain, flooding, flash flooding, high winds.	1
NY	Wayne	5-11-06	continuing	8-21-06	4-23-07	S2370	Hail, high winds, excessive rain	1	4
TX	Fannin, Hopkins, Hunt, Jeff Davis, Lavaca	1-01-06	continuing	8-21-06	4-23-07	S2371	Drought	5	24

DISASTER ASSISTANCE BRANCH/EMERGENCIES SECTION (DAB/ES) DISASTER DECLARATIONS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal year 2006]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contig-uous
OK	1-01-06	continuing	8-21-06	4-23-07	S2371	Drought	1
TX	Knox	7-11-06	7-11-06	8-21-06	4-23-07	S2372	Hail	1	6
TX	Red River	1-01-06	continuing	8-21-06	4-23-07	S2373	Drought, excessive heat	1	7
OK	Red River	1-01-06	continuing	8-21-06	4-23-07	S2373	Drought, excessive heat	2
TX	Willacy	1-01-06	continuing	8-21-06	4-23-07	S2374	Drought, high temperatures, high winds.	1	3
WI	Adams, Ashland, Barron, Bayfield, Burnett, Douglas, Dunn, Iron, Langlade, Lincoln, Marquette, Polk, Price, Rusk, St. Croix, Sawyer, Taylor, Washburn, Waushara.	4-01-06	continuing	8-25-06	4-25-07	S2375	Drought	19	20
MI	4-01-06	continuing	8-25-06	4-25-07	S2375	Drought	1
MN	4-01-06	continuing	8-25-06	4-25-07	S2375	Drought	5
VA	Pittsylvania, Rappahannock	3-01-06	continuing	8-28-06	4-30-07	S2376	Drought, high temperatures	2	11
NC	3-01-06	continuing	8-28-06	4-30-07	S2376	Drought, high temperatures	2
TX	Glasscock	1-01-06	continuing	8-28-06	4-30-07	S2377	Drought, heat, high winds, low humidity.	1	6
MN	Aitkin, Anoka, Beltrami, Benton, Carlton, Cass, Chisago, Clearwater, Cook, Crow Wing, Hennepin, Hubbard, Itasca, Kanabec, Kittson, Koochiching, Lake, Lake of the Woods, Mahnommen, Marshall, Mille Lacs, Morrison, Norman, Pennington, Pine, Polk, Pope, Red Lake, Roseau, St. Louis, Sherburne, Stearns, Todd, Wadena, Wright.	5-10-06	continuing	8-31-06	5-01-07	S2378	Drought	36	15
ND	5-10-06	continuing	8-31-06	5-01-07	S2378	Drought	5
WI	5-10-06	continuing	8-31-06	5-01-07	S2378	Drought	3
TX	Karnes	1-01-06	continuing	8-31-06	5-01-07	S2379	Drought	1	7

WA	Adams, Benton, Chelan, Douglas, Grant, Lincoln, Okanogan, Spokane, Franklin, Walla Walla, Whitman, Yakima.	5-01-06	continuing ...	8-31-06	5-01-07	S2380	Adverse weather conditions: Excessive rain, excessive heat, hail, high winds, severe thunderstorms, lightning, flash flooding, freezing weather.	12	15
ID	5-01-06	continuing ...	8-31-06	5-01-07	S2380	Adverse weather conditions: Excessive rain, excessive heat, hail, high winds, severe thunderstorms, lightning, flash flooding, freezing weather.	5
OR	5-01-06	continuing ...	8-31-06	5-01-07	S2380	Adverse weather conditions: Excessive rain, excessive heat, hail, high winds, severe thunderstorms, lightning, flash flooding, freezing weather.	2
AL	Autauga, Blount, Calhoun, Chilton, Cleburne, Dallas, De Kalb, Fayette, Jefferson, Lamar, Limestone, Lowndes, Marion, Marshall, Pickens, Shelby, Talladega, Walker, Winston.	1-01-06	continuing ...	8-31-06	5-01-07	S2381	Adverse weather conditions: Excessive rain, excessive heat, hail, high winds, severe thunderstorms, lightning, flash flooding, freezing weather.	19	24
GA	1-01-06	continuing ...	8-31-06	5-01-07	S2381	Drought, high temperatures	6
MS	1-01-06	continuing ...	8-31-06	5-01-07	S2381	Drought, high temperatures	4
TN	1-01-06	continuing ...	8-31-06	5-01-07	S2381	Drought, high temperatures	2
CO	Jackson, Lincoln, Mesa, Moffat	1-01-06	continuing ...	8-31-06	5-01-07	S2382	Drought	4	18
MS	1-01-06	continuing ...	8-31-06	5-01-07	S2382	Drought	4
TN	1-01-06	continuing ...	8-31-06	5-01-07	S2382	Drought	3
IA	Cerro Gordo, Cherokee, Clay, Crawford, Des Moines, Dickinson, Harrison, Humboldt, Ida, Lee, Lucas, Madison, Monona, Monroe, Montgomery, Plymouth, Sac, Sioux, Woodbury, Worth.	1-01-06	continuing ...	8-31-06	5-01-07	S2383	Drought, severe weather	20	44
IL	1-01-06	continuing ...	8-31-06	5-01-07	S2383	Drought, severe weather	3
MN	1-01-06	continuing ...	8-31-06	5-01-07	S2383	Drought, severe weather	3
MO	1-01-06	continuing ...	8-31-06	5-01-07	S2383	Drought, severe weather	1
NE	1-01-06	continuing ...	8-31-06	5-01-07	S2383	Drought, severe weather	4
SD	1-01-06	continuing ...	8-31-06	5-01-07	S2383	Drought, severe weather	2
MA	Barnstable, Berkshire, Bristol, Essex, Franklin, Hampden, Hampshire, Middlesex, Norfolk, Plymouth, Worcester.	5-01-06	6-30-06	8-31-06	5-01-07	S2384	Cool temperatures, excessive rain, floods.	11	2

DISASTER ASSISTANCE BRANCH/EMERGENCIES SECTION (DAB/ES) DISASTER DECLARATIONS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal year 2006]

State	Counties requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
CT	5-01-06	6-30-06	8-31-06	5-01-07	S2384	Cool temperatures, excessive rain, floods.	4
NH	5-01-06	6-30-06	8-31-06	5-01-07	S2384	Cool temperatures, excessive rain, floods.	3
NY	5-01-06	6-30-06	8-31-06	5-01-07	S2384	Cool temperatures, excessive rain, floods.	3
RI	5-01-06	6-30-06	8-31-06	5-01-07	S2384	Cool temperatures, excessive rain, floods.	3
VT	5-01-06	6-30-06	8-31-06	5-01-07	S2384	Cool temperatures, excessive rain, floods.	2
TN	Fentress, Franklin, McMinn, Meigs, Morgan, Scott.	5-01-06	6-30-06	8-31-06	5-01-07	S2385	Drought, extreme heat	6	18
TN	5-01-06	continuing	8-31-06	5-01-07	S2385	Drought, extreme heat	2
TN	5-01-06	continuing	8-31-06	5-01-07	S2385	Drought, extreme heat	2
CA	Butte, Calaveras, Fresno, Glenn, Imperial, Kern, Kings, Madera, Merced, San Bernardino, Solano, Sonoma, Stanislaus, Sutter, Tehama, Tulare.	7-15-06	7-31-06	9-07-06	5-07-07	S2386	Record setting HEAT WAVE	16	31
AZ	# N/A	# N/A	# N/A	# N/A	S2386	Record setting HEAT WAVE	3
NV	# N/A	# N/A	# N/A	# N/A	S2386	# N/A	1
NY	Cayuga, Chenango, Clinton, Columbia, Cortland, Essex, Franklin, Fulton, Greene, Herkimer, Jefferson, Lewis, Montgomery, Orange, Otsego, Rensselaer, St. Lawrence, Saratoga, Suffolk, Sullivan, Washington.	4-01-06	continuing	9-12-06	5-14-07	S2387	Excessive rain, flooding, flash flooding.	21	20
CT	# N/A	# N/A	# N/A	# N/A	S2387	# N/A	1
MA	# N/A	# N/A	# N/A	# N/A	S2387	# N/A	1
NI	# N/A	# N/A	# N/A	# N/A	S2387	# N/A	2
PA	# N/A	# N/A	# N/A	# N/A	S2387	# N/A	2
VT	4-01-06	continuing	9-12-06	5-14-07	S2387	Excessive rain, flooding, flash flooding.	5
ND	Entire State	1-01-06	continuing	9-12-06	5-14-07	S2388	Drought, drought-related disasters	53
MN	1-01-06	continuing	9-12-06	5-14-07	S2388	Drought, drought-related disasters	7

DISASTER ASSISTANCE BRANCH/EMERGENCIES SECTION (DAB/ES) DISASTER DECLARATIONS: FINAL TOTALS SECRETARIAL—Continued
[Fiscal year 2006]

State	Countries requested	Beginning Date of disaster	Ending Date of disaster	Approved by Secretary	Termination Date	Designation Number	Description of disaster	Primary	Contiguous
TX	Bee, Blanco, Clay, Delta, DeWitt, Hood, Jack, Navarro, Palo Pinto, Somervell, Tom Green.	1-01-06	continuing	9-27-06	5-28-07	S2397	Drought	11	46
OK		1-01-06	continuing	9-27-06	5-28-07	S2397	Drought		2
TX	Bowie	4-01-06	continuing	9-27-06	5-28-07	S2398	Drought	1	3
AR		4-01-06	continuing	9-27-06	5-28-07	S2398	Drought		2
OK		4-01-06	continuing	9-27-06	5-28-07	S2398	Drought		1
TX	Brooks, Jim Hogg	1-01-06	continuing	9-27-06	5-28-07	S2399	Drought, excessive temperatures, high winds.	2	8
TX	Gregg, Upshur	4-01-06	continuing	9-27-06	5-28-07	S2400	Drought, excessive heat	2	7
TX	Haskell, Jones, Knox	1-01-06	continuing	9-27-06	5-28-07	S2401	Drought, high winds, excessive heat.	3	10
TX	Lynn	1-01-06	continuing	9-27-06	5-28-07	S2402	Drought, high winds	1	7
TOTAL ACTIVE								2,301	3,861

AGRICULTURAL CREDIT INSURANCE FUND

Question. For each of the years 2003, 2004, 2005 and 2006, please document in detail for the record exactly how the funds provided through the Agricultural Credit Insurance Fund account were actually obligated and used by the Agency.

Answer. The information on obligation of ACIF funds by loan category for fiscal year 2003 through fiscal year 2006 will be provided for the record.
[The information follows:]

AGRICULTURAL CREDIT INSURANCE FUND OBLIGATIONS BY FISCAL YEAR

[In thousands of dollars]

	Fiscal year 2003	Fiscal year 2004	Fiscal year 2005	Fiscal year 2006
Direct Loans:				
Ownership	168,575	142,404	271,929	274,604
Operating	689,849	609,565	556,008	640,742
Emergency	95,698	29,789	23,570	51,525
Indian Land Acquisition	110	1,586	360
Boll Weevil	99,000	97,695	83,070	22,000
Guaranteed Loans:				
Ownership	1,231,167	1,099,052	1,027,016	949,122
Operating Unsubsidized	1,012,926	951,314	884,523	937,655
Operating Subsidized	418,379	271,217	283,423	271,589

Question. Also please provide a detailed accounting of any S&E funds, such as the IT budget or others, that were obligated and used in support of Farm Loans. In each year, what was the percentage of the total FSA S&E appropriation actually obligated and used to support Farm Loans in the Field, in the State Offices, at the IT or Finance Office level, and at the National Office level?

Answer. As generally required by the Federal Credit Reform Act (FCRA) and by OMB Circular A-11, administrative expenses in support of the ACIF loan programs are appropriated to the ACIF program account. These funds are then transferred to Farm Service Agency (FSA) Salaries and Expenses (S&E) account. Per the A-11, “administrative expenses means all costs that are directly related to credit program operations, including payments to contractors. The FCRA generally requires that administrative expenses for both pre-1992 and post-1991 direct loans and loan guarantees be included in program accounts.”

Therefore, there is relative transparency in the amount of funding in the FSA S&E account that is used in support of ACIF, since these funds are originally budgeted in and appropriated to ACIF. The table below provides the amounts of ACIF administrative funds that are transferred to the FSA S&E account, and the relative percentage of ACIF administrative expenses to total S&E funding.

[The information follows:]

AGRICULTURAL CREDIT INSURANCE FUND OBLIGATIONS AS A PERCENT OF FSA S&E OBLIGATIONS

	Fiscal year 2003	Fiscal year 2004	Fiscal year 2005	Fiscal year 2006
ACIF Administrative Expenses	\$277,361	\$281,350	\$291,414	\$301,545
Total Salaries and Expenses	\$1,249,900	\$1,267,428	\$1,318,733	\$1,309,028
ACIF Admin as percent of Total S&E	22.19	22.20	22.10	23.04

FARM LOAN PROGRAM STAFFING

Question. FSA has a formal training and testing procedure in place for Farm Loan Officers and Farm Loan Officer Trainees. It is module type training—complete a module and take a test. This training takes about a year to complete and covers loan making and loan servicing. Then before an FLO is granted loan approval authority they must submit 5 loan dockets they have prepared and the loans pass a review. In addition to the formal training, senior management officials state that it requires at least another year or two of on the job training for a FLO to attain the experience needed to fully and independently perform the loan officer duties. For a FLO to attain the knowledge skills and ability to become a Farm Loan Manager, Farm Loan Specialist or advance to a Farm Loan Chief position will require additional years of experience.

According to a Strategic Human Capital Management study, many Farm Loan employees will be retiring very soon. The Farm Loan employees are in the GS-1165 series. On average, 1,165 employees are retiring within 3 months of their retirement eligibility date. 50 percent of supervisory 1,165 employees are eligible to retire between now and 2008. Twenty-eight percent of all FSA 1,165 employees are eligible to retire between now and 2008.

What is FSA's plan to replace these experienced Farm Loan employees, and how much will Congress need to invest to make sure there is no crisis in the ability of FSA to deliver the Farm Loan programs?

Answer. FSA Farm Loan Officers functions are critical to the effective delivery and service of Agency Farm Loan Programs (FLP). Because the GS-1165 series within FLP requires specialized training, it is essential that resources to support the Farm Loan Officer Training program be allocated prior to announced retirements.

FSA plans to fund additional loan officer trainee positions from within existing resources. In fiscal year 2006, FSA funded 30 loan officer trainee positions and plans on an additional 15 positions available for fiscal year 2007. The fiscal year 2008 budget assumes 45 trainee positions. Analysis of available Human Resources data indicates that from fiscal year 2006 through fiscal year 2009, 26 percent of currently employed loan officers will be eligible to retire.

QUESTIONS SUBMITTED BY SENATOR SAM BROWNBACK

NATIONAL VETERINARY MEDICAL SERVICES ACT

Question. In the 2006 Agriculture Appropriations hearings, you stated that the implementation of the full National Veterinary Medical Service Act would take 18 months. One year later, we are informed that you have not yet submitted for public comments a proposed rule and we are concerned that the National Veterinary Medical Service Act may not be implemented within the timeframe you initially provided.

What steps do you have planned that will assure implementation of the NVMSA by October 2007 (18 months from the testimony in which you estimated 18 months would be necessary to complete the rules)?

Answer. Although there are additional administrative steps that must be completed prior to the distribution of funds, a framework for the program has been proposed by CSREES. This proposal has recently been reviewed by the appropriate legal and regulatory entities. On March 12, 2007, the Final Rule was approved. The Final Rule was published in the Federal Register on March 19, 2007, and permits CSREES to implement a NVMSA program. The Department recognizes the importance of this Act to both the veterinary community as well as the supporters of the Act. You can be assured that we have communicated with agency personnel responsible for moving this program forward to ensure that it is implemented appropriately and as quickly as possible.

Question. Section 2 of NVMSA, Public Law 108-161, reads "The National Agricultural Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3101 et seq.) is amended by inserting after section 1415 the following new section:" Given that 3101 of the 7 U.S.C. is entitled "Purposes of agricultural research, extension, and education" and that the money appropriated for NVMSA has been allocated to CSREES's Research and Education Activities, why has the USDA not formally designated CSREES as the administering agency for NVMSA?

Answer. A Final Rule will be published in the Federal Register on March 19, 2007 delegating NVMSA to CSREES.

Question. A study of Food Supply Veterinary Medicine released in June 2006 quantified existing and projected shortages of veterinary practitioners in various practice areas. How has this study helped the NVMSA implementation process?

Answer. CSREES has utilized the 2006 Kansas State University study on Food Supply Veterinary Medicine to identify an area of critical need in veterinary medicine. Results of this study indicate that among the highest forecasted future shortages in veterinary practice between 2004 and 2016 will be the Federal-animal health career and Federal-food safety and security sectors. The finding of the study correlates with the large number of difficult-to-fill vacancies for veterinarians in FSIS.

Question. I do not consider the short-term pilot FSIS program, currently being developed by CSREES, to be an acceptable substitute for progress on the intended NVMSA program, especially the parts of NVMSA that would address rural practice and emergency response shortages. Furthermore, I do not approve of CSREES's intention to reprogram the NVMSA funds into a different loan repayment program

within FSIS. Is your work on the FSIS pilot program diverting resources that could otherwise be used to implement the rural and emergency response portions of NVMSA?

Answer. CSREES has entered into a reimbursable agreement to implement the loan repayment provisions of the Act. The FSIS-oriented implementation strategy represents an approach that enables the initiation of the use of NVMSA funds as loan repayments to eligible veterinarians in the shortest possible time frame. Funding is not sufficient to implement the emergency portion of the Act.

Question. Your colleague, former HHS Secretary Tommy Thompson, was quoted to have said, "I, for the life of me, cannot understand why terrorists have not attacked our food supply because it is so easy to do." Given that the risks of bioterrorism are high, that the Federal Government has been criticized for its preparedness for and response to recent disasters, and that you have in the form of NVMSA a program within the USDA that would create a "Veterinary National Guard" available for immediate mobilization in the event of a zoonotic or major food animal disease outbreak and improve disease surveillance in the form of escalated geographic veterinary coverage, why are you not expediting the implementation of NVMSA?

Answer. Implementation of the loan repayment sections of NVMSA are being expedited through the use of a reimbursable agreement with FSIS, which was developed in order to take advantage of current student loan regulations. Funding is not sufficient to implement the emergency portion of the Act. Moreover, eligibility for service to the Federal Government in emergency situations is dependent on first establishing eligibility for the loan repayment program. The current strategy, therefore, helps to establish a population of veterinarians eligible to serve as emergency responders.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

STATEMENT OF HON. ANDREW VON ESCHENBACH, COMMISSIONER,
FOOD AND DRUG ADMINISTRATION

ACCOMPANIED BY:

JOHN DYER, DEPUTY COMMISSIONER FOR OPERATIONS, FOOD
AND DRUG ADMINISTRATION

RICHARD TURMAN, DEPUTY ASSISTANT SECRETARY FOR BUDGET,
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator KOHL. Our next panel will include the FDA Commissioner, Dr. Andrew von Eschenbach; Mr. John Dyer, who is the FDA Chief Operating Officer; and also Mr. Richard Turman of the Department of Health and Human Services Budget Office.

Dr. von Eschenbach, whenever you are ready, we'll take your testimony.

STATEMENT OF DR. ANDREW VON ESCHENBACH

Dr. von ESCHENBACH. Good morning, Mr. Chairman. I am very honored to present to you and the members of the subcommittee the President's fiscal year 2008 budget request for the Food and Drug Administration. I am joined this morning by Mr. John Dyer, the FDA's Deputy Commissioner for Operations, and Mr. Richard Turman, the Deputy Assistant Secretary for Budget at the Department of Health and Human Services.

Mr. Chairman, at the outset may I emphasize our extraordinary gratitude for your support and the support of the committee that was provided by Congress in fiscal year 2007. Soon after the President proposed our budget on February 5, Congress enacted a revised continuing resolution for fiscal year 2007, and we are in the midst of developing the operating plan for fiscal year 2007 that we will be forwarding to you within the very near future, in the 30-day time commitment.

But, taken together, the fiscal year 2007 and the fiscal year 2008 budgets are components of an ongoing investment strategy needed to create a modern Food and Drug Administration capable of addressing the challenges and the opportunities of the 21st century. We recognize how precious these assets are to the administration and the Congress, and we will be good stewards of the funds you provide.

For fiscal year 2008, the President's budget represents a 5.3 percent increase above the fiscal year 2007 President's budget, and the requested \$2.08 billion consists of \$1.64 billion in budget authority, \$428 million in current law user fees, and \$42.7 million for three new user fees. The additional dollars that are requested in fiscal year 2008 are principally directed to support the work force of the FDA and to enhance our programs of food safety, enhanced drug

and medical product safety, and to accelerate the approval of generic drugs.

At its core, FDA is a scientific data analysis, information management, and decision-making organization, and as such we are critically dependent upon the expertise of a strong, diverse work force that is using modern information technologies and state-of-the-art scientific equipment. Eighty percent of the FDA budget funds payroll and related personnel costs, and these costs have been increasing yearly. For fiscal year 2008 we request \$64.7 million to cover nondiscretionary increased costs for pay raises, rent, utilities, and security, and our relocating to our White Oak, Maryland campus.

Food safety is an important cornerstone of the FDA mission. During recent years there have been changes in our food supply that create new challenges to the FDA to enhance food safety.

Consumption of fresh produce, particularly ready-to-eat products that include raw and fresh foods, has increased dramatically. Products are harvested from the vine, stem, and from the soil, and then are delivered rapidly to our tables, with an increasing proportion coming from outside our domestic borders.

We propose a \$10.7 million increase for a food safety initiative that's focused on fresh produce. FDA is taking a multitiered risk management approach to the product life cycle of food that will build enhanced quality into the food chain from farm to fork. This will include development and dissemination of new and refined Good Agricultural Practices for prevention, the deployment of scientific tools for the detection of intentional and unintentional contamination, and accelerated processes to detect, trace, and more rapidly contain outbreaks.

A few examples of how we would use FDA resources include conducting research to develop new methods to detect foodborne pathogens; conducting advanced training for our partners in State and local agencies that we will work with to prevent outbreaks; and employing new microbiological techniques to identify ways to improve the safety of produce. We will also enhance our traceback teams and mechanisms, and deploy IT decision systems to detect high risk food imports.

In addition to food, we will focus on drug and device safety. Last month FDA released its commitment to drug safety which outlined 41 initiatives that will cover the life cycle of a drug from its development to its delivery. The \$11.2 million increase for modernizing drug safety supports FDA's response to the report by the Institute of Medicine on drug safety.

With these resources, FDA will strengthen the science and tools we use to ensure drug safety. We will improve communication and information flow among all stakeholders involved in the safe use of drugs. And we will restructure our operations and management systems to ensure optimum review, analysis, consultation, and communication to achieve a stronger drug safety system.

With regard to medical devices, we will build on the programs already in place by directing an additional \$7.2 million to enhance active surveillance of devices in the post-market area that employs modern information technology for data mining and analysis.

In addition to safer and more effective medical products, the public also needs more cost-effective choices, and to that end the President's budget for fiscal year 2008 requests \$5.6 million in budget authority and \$15.7 million in user fees that are dedicated to enhancing the approval of generic drugs. We expect to be able to, with the \$5.6 million increase in BA, to approve an additional 50 applications during fiscal year 2008.

The proposed user fee program ensures that FDA can measurably improve generic drug review performance over the next 4 to 8 years, and this investment will return many billions in savings to consumers and government-sponsored health plans.

PREPARED STATEMENT

We recognize that all these dollars we are requesting are in fact precious assets of the American taxpayer, and yet the programs they will make possible are essential to protecting and promoting the health of all Americans. There are critical challenges to be addressed, but there are enormous opportunities, such as accelerating the development and delivery of lifesaving interventions. Meeting these challenges and seizing these opportunities are only made possible by your support, for which we are very incredibly grateful.

Thank you, Mr. Chairman.

Senator KOHL. Thank you very much, Dr. von Eschenbach.

[The statement follows:]

PREPARED STATEMENT OF ANDREW C. VON ESCHENBACH, M.D.

Introduction

Chairman Kohl and members of the Subcommittee, this year as a confirmed Commissioner I am honored to present for your consideration and approval the President's fiscal year 2008 budget request for FDA. I am joined by Mr. John Dyer, my recently appointed Deputy Commissioner and Chief Operating Officer and Mr. Richard Turman, Deputy Assistant Secretary for Budget at the Department of Health and Human Services. I also have members of FDA's senior leadership with me, who at your discretion can respond to any specific questions you may have.

We live in an era of rapid science, technology, and individualized medicine that is changing the products FDA regulates and the environment for FDA regulation. Congress and the Administration recognize the challenges we face and have responded with the resources in fiscal year 2007 that will allow FDA to begin addressing these challenges.

As you consider our fiscal year 2008 request, please do so mindful of the extraordinary gratitude of the FDA for your support in fiscal year 2007. The budgets for these two fiscal years represent important steps in an ongoing effort to create a modern FDA capable of responding to the challenges and opportunities to protect and promote public health in the 21st century. We will be good stewards of the funds you provide and we will search for efficient and effective solutions to the problems we are working to solve.

The resources requested in the President's budget for fiscal year 2008 will allow FDA to respond to emerging challenges, advance the gold standard for regulating food and drugs, and strengthen America's confidence in the work of our important agency.

Our achievements during the past year reflect our service to the American public and our dedication to their health and safety. These achievements also justify the trust you placed in us with your support in fiscal year 2007. Using funds that you appropriated, FDA:

- approved a new test to diagnose avian influenza virus in humans
- issued guidelines to expedite seasonal and pandemic flu vaccine development
- approved new vaccines for shingles and to prevent HPV infections
- approved new treatments for cancer, HIV, diabetes, Parkinson's, schizophrenia, and macular degeneration
- issued more than 510 generic drug approvals or tentative approvals
- approved the first totally implanted artificial heart

- embraced many of the Institute of Medicine findings on *The Future of Drug Safety*
- launched a program to achieve the optimum safety system for drugs and other medical products
- developed proposals to renew prescription drug and medical device user fee programs
- conducted drug reviews and issued approvals under the President's Emergency Plan for Aids Relief
- conducted enforcement actions to protect consumers against unapproved drugs and devices, to safeguard the blood supply, and to protect consumers from dietary supplements containing ephedrine alkaloids
- worked with Federal, State, and local partners to respond to Salmonella, E. coli O157:H7, and other foodborne threats
- issued a final rule on health claims for barley products and issued guidance on whole grain content in food
- protected consumers with food allergies by publishing guidance documents for industry on food allergen labeling and soy derived products
- conducted a CARVER + vulnerability assessment in eight food products to distinguish between real and perceived food vulnerabilities.

FDA's 2008 President's Budget Request

For fiscal year 2008, the President's budget request builds on success of fiscal year 2007 to maintain the trajectory, by proposing a 5.3 percent increase above the fiscal year 2007 President's budget. This will provide FDA with \$2.085 billion, which consists of \$1.641 billion in discretionary budget authority and \$428 million in current law user fees. Our budget also includes \$42.7 million for three proposed user fees related to reviewing generic drugs, reinspecting facilities, and issuing export certificates for food and animal feed.

Strengthening Food Safety

FDA is committed to ensuring that America's food supply continues to be among the safest in the world, but we face challenges. For example, consumption of produce, particularly ready-to-eat products, has increased dramatically during the past decade. Americans often consume these products in their raw state, harvested from the vine, stem, or soil without processing to reduce or eliminate pathogens that may be present. Consequently, the manner in which these products are grown, harvested, packed, processed, and distributed is crucial to ensuring that microbial contamination is minimized, thereby reducing the risk of illness to consumers. Even if a small amount of what is harvested is contaminated, it can result in severe illness. FDA is taking a "farm-to-fork" systematic risk management approach to food safety to reduce the risk of food illness at all points in the food chain.

FDA's ability to prevent and respond to outbreaks of foodborne illness needs to be strengthened. For fiscal year 2008, we propose a \$10.7 million increase for a food safety initiative focused on fresh produce. FDA will develop methods to prevent food outbreaks from occurring by rapidly detecting contamination that leads to illness, more quickly tracking contamination to its source, and more effectively conducting root cause analysis of contamination. We will also provide training to our State and local partners and develop a geographic information mapping system for faster emergency response. Finally, we will develop a decision-making system to detect high-risk imports before they enter U.S. commerce, so they can be evaluated by FDA.

Access to Safe and Effective Medical Products

On January 30, 2007, FDA released a report, *The Future of Drug Safety—Promoting and Protecting the Health of the Public*, that presents our comprehensive commitment to the safety of drugs and other medical products throughout their lifecycle. The report addresses issues referred to FDA by the 2006 Institute of Medicine report. The report details initiatives FDA will take to achieve the best possible safety systems for medical products, and ensures that FDA processes and scientific methods keep pace with, and harness the benefits of, the rapid evolution of science, technology, and health care.

At FDA, we use a systems approach to ensure drug quality and maintain the right balance between the benefits and risks of the drugs we approve. An \$11.2 million increase for modernizing drug safety allows FDA to advance a lifecycle approach to regulating drugs and managing drug risks. Using the fiscal year 2008 increase and base resources in the drug program, FDA will revolutionize our ability to identify safety issues and rapidly and effectively communicate safety concerns to health professionals, patients, and the public. These efforts will improve drug safety both before FDA grants approval and after drugs reach the market. We will also

strengthen our organizational culture to further foster an environment dedicated to the safety of drugs and biologics.

As the complexity and utility of medical devices increases by virtue of advances in electronics and engineering, FDA maintains the same commitment to the safety of medical devices. Our budget contains a \$7.2 million increase to strengthen medical device safety and improve FDA's ability to identify, analyze, and act on postmarket safety information and use this information to improve the quality of new devices coming to market.

Generic drugs are an important part of our health care system. The Congressional Budget Office estimates that generic drug use results in savings of \$10 billion per year. During the next few years, \$60 to \$70 billion in brand name drugs will lose their patent protection, and FDA must be poised to respond to the growing number of generic drug applications. To help ensure that consumers enjoy a wide selection of lower-cost generic drugs, FDA requests an additional \$5.6 million in budget authority and \$15.7 million in new user fees to accelerate the review and approval of generic drugs. With the \$5.6 million budget authority increase, FDA expects to approve an additional 50 applications during fiscal year 2008. The new user fee program ensures that FDA can measurably improve generic drug review performance over the next 4 to 8 years. With this new program in place, by 2014 FDA expects to approve 90 percent of generic drug applications within 180 days. These investments will return many billions of dollars in savings to consumers and government-sponsored health plans.

Our budget includes long-standing user fee programs. These programs provide supplemental resources that not only allow FDA to provide services in response to manufacturers' product applications but also ensure that Americans have access to safe and effective medical products. Two of these programs, the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee Modernization Act (MDUFMA) expire on September 30, 2007. We have engaged with stakeholders to develop proposals to extend these programs for an additional 5 years. In the case of PDUFA, FDA published a draft proposal for PDUFA IV in the Federal Register and conducted a public meeting with stakeholders on February 16, 2007. In the case of MDUFMA, FDA is nearing the end of discussions on the reauthorization of MDUFMA. FDA will notify Congress of our results when we complete this process.

Ensure a Strong FDA

To successfully perform its broad mission, FDA must hire and retain a world-class workforce that can respond to complex and escalating public health challenges. Our workforce is FDA's most important asset, and securing the resources to support our workforce is a top priority in our fiscal year 2008 budget. We have nearly 10,000 employees, consisting of medical officers, consumer safety officers, food and drug safety experts, medical product reviewers, and other scientists and professionals with specialized education, training, and experience to address complex public health challenges. Eighty percent of the FDA budget funds payroll or costs related to personnel, such as rent, utilities, and security. These are operational costs, and the amount we pay rises each year. For fiscal year 2008, we propose a \$64.7 million initiative to ensure that increased costs for the pay raise, infrastructure costs, and the cost of relocating to our new White Oak, Maryland campus do not erode core FDA programs.

Closing

FDA's request of \$2.085 billion is essential to the success of our mission—established by Congress—to protect and promote the health and safety of the American public. These resources are an essential step in building a 21st century FDA that responds to the new opportunities and new challenges of science and technology. Our budget allows FDA to strengthen the tools we use to ensure the safety of foods, evaluate new products, and better predict—earlier and more accurately—the safety and efficacy of drugs, biologics and medical devices. With these resources, we will work to ensure that Americans enjoy the benefits of personalized medicine, a safe and wholesome food supply, and the promise of a better, healthier future. Our goal is to enable all Americans to go to bed each night confident that the food they ate is safe, the medical devices they used are reliable, and the drugs that they gave to their children and grandchildren are safe and effective.

Thank you.

Senator KOHL. I'd like to start by asking you to comment on the generic situation, generic drug situation at FDA, and the recent funding resolution. We provided an increase of \$5 million for generic drug review. The increase provided in this resolution should

allow for 10 additional approvals or tentative approvals per month, which would be a 25 percent increase above the current average of 40 approvals per month. If we can do that, it would be very beneficial in bringing more generic drugs to market.

You stated in the requested increase in fiscal year 2008 that it would allow FDA to approve just 50 additional applications per year. Now, that would average about \$112,000 per application, which seems very high, and it doesn't come close, the 50 doesn't come close to what we estimated would be an additional 10 per month, which would be more than double the 50 that you are talking about. How do you explain this discrepancy?

Dr. VON ESCHENBACH. Well, Mr. Chairman, first of all let me point out that in addition to hiring the additional reviewers, which is an important part of the allocation to then be able to increase capacity, we also intend to increase capacity by the efficiencies that we're building into the review process.

One particular example is to be able to do cluster analysis, where we can take groups of generic drugs that are of a similar nature and be able to deal with them in a cluster type of analysis, so that we can increase the number of outputs per the number of people and reviewers that we have. So it's not just a matter of the 50 that is allocated to the increased reviewers; it's also what we can do by virtue of how we increase the systems we're using for generic drug review.

Senator KOHL. So the number that we thought we heard from your department, 50 additional applications to be approved for this year with the increased budget allocation that we gave you, that number of 50 is really not what we should be focusing on?

Dr. VON ESCHENBACH. Well, again I apologize for not explaining to you clearly. What I indicated was, we would go in an incremental way to increasing the total output. And so what we're expecting is, as we bring reviewers on, as we train them up, there will be a gap and then we will pick up on the outputs as we go forward over time by virtue of, one, the fact that we're bringing the reviewers on, training them up, getting outputs from them and, two, adjusting our systems. So I think what we're indicating is what is initial and then there will be a ramp-up beyond that.

Senator KOHL. Okay. I just point out that the increase in generic drug applications submitted to FDA has increased from 307 applications in 2002 to almost 800 in 2006, and as you know, we are all very intent on bringing more and more generics to market in an effort to reduce the cost of drugs to our population, particularly our senior population. Generic is key to that, as you know. My understanding is that you are most sympathetic to that attempt, want to do everything you can to facilitate it and to increase the number of approvals that we annually can give through the FDA to the generic market. Is that a fair statement?

Dr. VON ESCHENBACH. Yes, sir, that is a fair statement and I think, as we have spoken before, we're doing this not only in terms of increasing numbers but trying to do this strategically as well. So we're looking at opportunities to make sure that we have a broad portfolio of options across that portfolio, and so we're expediting, if you will, the process to get first generics out.

We're educating the industry to get better applications in the first place. So as the application numbers increase, if they're better applications, that will enhance the review process and the likelihood of success. So we're taking a multipronged approach to being able to accomplish the goal that you have felt so strongly about and have proposed to us.

Senator KOHL. That's good. As you know, we're planning a hearing in Madison, Wisconsin, on I believe it's March 12, and I'm looking forward to that hearing on food safety. And I don't want to get into too much detail about that because we'll deal with it at that time, but there is a report that you may want to comment on, that between 2003 and 2006 FDA food safety inspections have dropped by 47 percent. This was reported yesterday by the Associated Press.

Now, clearly with all the concern about food safety in our country, dropping the number of inspections by nearly half, according to that report, is I am sure something that concerns you greatly, to the extent that it is accurate. And what we are allocating in your budget for strengthening food safety is an increase of less than 3 percent for food safety, to include food inspections.

Now we have all these ongoing recalls. Just this morning I was informed, as this hearing unfolded, there is a recall on cantaloupes. I don't know any details on it, but it's out there. Perhaps you've heard about it, maybe you haven't heard about it, but it came over the press this morning.

But people are going to be very concerned when they read in the paper that the number of food safety inspections has declined by 47 percent over a 3-year period. Do you wish to say something to them and to us at this time?

FOOD SAFETY INSPECTIONS

Dr. VON ESCHENBACH. Well, Mr. Chairman, let me first of all address the issue with regard to the magnitude of the decline. The data that I have available indicates that the number of inspections in 2004 was 21,876, and in 2006 it was 17,730. Now, that's a reduction of about 23 percent.

The issue there is the realization that we have been implementing a risk management approach to inspections, and so rather than a blanket inspection, we are targeting particular facilities that propose a particular high risk or probable high risk. That makes the inspection much more intense, and so the inspection itself is increasing in its magnitude and scale and scope.

Now, the numbers have gone down but the intensity and the targeting of the inspections have actually increased, and we're doing that because we recognize that there are differences among these various facilities, depending upon what they're producing, as to how likely they might result in a food outbreak. For example, facilities that are producing bread have very low probabilities of problems, whereas those that are processing seafood have a much higher risk. So we want to target the inspections to those areas, rather than just simply look across at the numbers.

As far as expanding our capability and our capacity to do this, that's an important part of what has been an ongoing effort to look at our field operations and to make strategic decisions as to what

type of field investigators we need going forward and how we can most effectively utilize our resources.

So as we have recognized that we have less need for laboratory investigators, and more need for field investigators, who have the tools of modern science available to them to be deployed and dispersed at the site of inspection, we're shifting our work force over the next few years to that goal, and that will in itself bring another 75 to 100 investigators into that work force to enhance our inspection capability. But it is a systems approach to the problem, rather than just simply a matter of counting facilities that we inspect.

Senator KOHL. According to this same report that I'm holding, which I got from Senator Harkin, who could not remain but wanted to have these issues raised with you this morning, safety tests for U.S.-produced food have dropped nearly 75 percent, from 9,748 in 2003 to 2,455 last year, according to your agency's own stats, which are being used on this report that I got from Senator Harkin this morning. It's from [cnn.com/Associated Press](http://cnn.com/AssociatedPress).

Now, I think those numbers, at least on their face, would be of great concern to you, certainly of great concern to the American public. Do you have any comment on that?

Dr. VON ESCHENBACH. Well, as I indicated, what we are attempting to do is really maximize our ability to have impact with regard to these inspections. In some degree that is a matter of increasing the kind of—the number of investigators and their unique skill sets, and that is a process that we have engaged in and are committed to.

In addition to that, I think the real opportunity is to realize that there are 60,700 food firms that are out there that we must inspect, and where we have the opportunity to really make major inroads is to place the inspection process on a sound foundation of risk management. And so by targeting those facilities that we think are at the highest risk and maximizing our efforts there, it really gives us an opportunity to protect the public health, I think in a more effective way. So it's not just a matter of numbers, it's a matter of how we are doing the inspections and how we're deploying our work force, and I think both of those are important.

PANDEMIC FLU

Senator KOHL. All right. I'd like to turn to Mr. Turman now and ask you this question. In Dr. von Eschenbach's opening statement he talked about some of the FDA accomplishments over the past year. The first two of those had to do with pandemic flu.

Could you talk about efforts at the department level on pandemic flu? We had discussed this earlier with Secretary Johanns. How are the various agencies at HHS, where you occupy a very high ranking position, working together and with the USDA in order to make sure that we have a streamlined and coordinated plan for dealing with any potential outbreaks of avian flu, Mr. Turman?

Mr. TURMAN. Thank you, Mr. Chairman. I can affirm that indeed Secretary Leavitt is working very closely with his Cabinet colleagues such as Secretary Johanns, as part of the President's plan which the Congress funded last year at \$5.6 billion through supplemental funding for avian flu and being prepared for it. And within the Department of Health and Human Services, we work very

closely together with the FDA, with the CDC, with the NIH, with our other partners in the Office of the Secretary, we work very closely together to make sure that we can be protected as best we can for that which we see and foresee coming.

And the areas where the funding has gone, they have been primarily to work both on purchasing those antivirals which we can get and stockpile, and also developing vaccines which would be of use against some of the strains that could be coming in terms of avian influenza. And in that regard FDA has a very key role and has been playing an important role on helping us try and speed the development of those vaccines.

That is a key position that FDA has relative to their expertise, and their counsel and their efforts have been well integrated with the department's plans, and they have been making a key contribution in that regard. And so they used the funding provided from the Congress in the initial supplemental, and indeed our 2008 budget request has additional funds over current investments to not only help deepen those efforts but also work on engaging in some tools which would help detect foodborne transmission potentially of any of these virus items.

So it's an area where Dr. von Eschenbach may want to amplify in terms of FDA's piece, but they are an integral partner of the department's plans.

WOMEN'S HEALTH

Senator KOHL. All right. Dr. von Eschenbach, fiscal year 2007 House and Senate bills included \$4 million for the Office of Women's Health. In fiscal year 2008 the President's budget request includes a decrease of \$350,000 for that office. According to FDA, this funding will be transferred to the National Center for Toxicological Research, for research pertaining to women's health that is ongoing. However, this is the first time that women's health funding has been decreased in the budget.

I was disappointed to see the decrease in that budget of \$350,000 for women's health, and in today's Washington Post there was a report that FDA is intending to cut the fiscal year 2007 level down to \$2.8 million from the \$4 million requested by the President and provided by Congress. Now, I know that your spending plan has not yet been finalized, but this information must have come from somewhere. Can you assure us that the budget for fiscal year 2007 is going to be \$4 million and not something less?

Dr. VON ESCHENBACH. Well, Mr. Chairman, at the outset let me assure you and other members of the committee that I personally, and the FDA is absolutely committed to enhancing the issues of women's health within the agency. We are, as you pointed out, in the process of developing our plan for 2007, and will be bringing that to you within the next few weeks.

With regard to the issue of the 2008 budget, I think it's important to put this entire issue into context. When I say that we are committed to women's health, this is a comprehensive effort.

One of the most important aspects of it is the critically important research that's going on in the National Center for Toxicologic Research, that is helping us identify genetic and molecular differences that are related to gender and how we can begin to really address

many of the challenges that have been presented by the Women's Health Initiative. Actually, Women's Health has been using dollars to fund that research in NCTR all along, and what this is essentially is a transfer of that \$350,000, to get them integrated into the NCTR's research base so that we can really amplify that portfolio.

So it's not in any stretch of the imagination a diminishing of our commitment to women's health. It's actually enhancing our ability to create a research base that will address critically important scientific issues in women's health, as well as provide that foundation for other similar questions, including the kind of challenges we're seeing in personalized medicine that not only recognize gender differences but even potentially differences that come about beyond gender, including racial differences.

Senator KOHL. That toxicological research is for 2008, but in today's paper it was reported that the FDA is intending to cut the fiscal year 2007 budget for Women's Health down from \$4 million to \$2.8 million. Now, I would like you to say that that's an inaccurate report, it's not operable, that for fiscal year 2007, which is not fiscal year 2008 and targeting this \$350,000, but for fiscal year 2007 the number of \$4 million remains intact and is not going to be reduced.

Dr. VON ESCHENBACH. Well, Mr. Chairman, the answer to your question is, we haven't made that decision yet as to what the 2007 final plan would be. I'm looking at the entire portfolio, so that we're responsive across the entire budget, and have not at this point made any final decision about any particular component of that budget.

Senator KOHL. Are you, just let me ask the question, are you familiar with any consideration for a reduction in fiscal year 2007 of the Office of Women's Health to something below the \$4 million?

Dr. VON ESCHENBACH. Well, we have been looking across the entire Office of the Commissioner, of which the Office of Women's Health is a component, and we're looking to bring that entire office into fiscal balance, if you will, with regard to our overall budget. Now, with regard to the specific details of what's happening with each of those compartments within the Office of the Commissioner, I can't speak to, but I'll be happy to get back to you on that for the record. But the fact of the matter is, we haven't made a final decision, so I can't commit to any particular number at this point, until that is done.

Senator KOHL. All right. We'll continue to work on that number and get some report, as you have indicated, as soon as you can. I thank you.

[The information follows:]

WOMEN'S HEALTH

We are currently working on our fiscal year 2007 operating plan, as required under section 113 of Public Law 110-5, the Revised Continuing Resolution for fiscal year 2007. We expect to fund the Office of Woman's Health at not less than last year's level. FDA is committed to activities sounding women's health. The concerns of women are a priority at FDA, and the Office of Women's Health serves as a champion for women's health issues.

Senator KOHL. At this time I would like to turn to Senator Reed.

SUNSCREEN MONOGRAPH

Senator REED. Thank you very much, Mr. Chairman.

Thank you, doctor. Just a point, not a question. But since 1997 the agency has been struggling to get a UVA/UVB labeling protocol, monograph, together. I'm going to follow up with a written question and ask you, bottom line, when it might happen.

TOBACCO

Turning to another topic of interest, I just left the HELP hearing on the regulation of tobacco, and it raises serious questions. You have extensive experience as a former director of the National Cancer Institute. I believe personally that authority for FDA is long overdue, to have some role in the regulation of tobacco, and I'm hopeful we can get the legislation through. What are your views with respect to FDA's role in potentially the regulation of tobacco products?

Dr. VON ESCHENBACH. Well, Senator, as you point out, from my perspective and my career at the National Cancer Institute, like you and everyone, I recognize the serious public health threat that occurs as a result of smoking and tobacco.

From the perspective of the Food and Drug Administration, as Commissioner, one of the things I think is extremely important is to realize the complexity of this issue and the complexity of the kind of issues that it presents, on one hand looking at it from the perspective of what has emerged with regard to the science and our understanding of addiction as it's related to nicotine, all the other way to the other end of the continuum, where we're looking at a cigarette which is a complex product. It has tobacco that has additives of one type or another, wrapped in paper and set on fire, and someone breathes in smoke.

And from that perspective, with all that complexity, I think it's extremely important that we engage in a careful assessment of how we might address that complexity as a way of then beginning to address what role FDA should or should not have in that process.

Senator REED. But the complexity itself is not such that you would be incapable as an agency of dealing with the issue. The question would be what you could do effectively. I think that would be the first question.

Dr. VON ESCHENBACH. Well, as I look at it and the question, framing it within the mission of the FDA to protect and promote the public health, I think it's an issue of being able to determine how we could regulate whether a product was in fact safe under any circumstances or in any possible way, and what potential benefit or value it might have to health in any possible circumstance or any possible way.

So that is what I believe is at the core and the base of a regulatory decision, the complexity of a regulatory process as it relates to tobacco. And I think those are discussions and issues that need to occur and are going on.

Senator REED. At a threshold level you certainly could identify the ingredients and publicize those, of a cigarette.

Dr. VON ESCHENBACH. I think that's one of the questions that we have to address.

Senator REED. That you could or could not do that?

Dr. VON ESCHENBACH. Correct.

Senator REED. How difficult is it to identify the ingredients of a cigarette?

Dr. VON ESCHENBACH. If you're talking about the ingredients in the inhaled smoke, that, which is what in fact would have the public health impact, not what's in the product prior to it being smoked, that is the kind of scientific challenge and question that I think underscores the complexity of the problem.

Senator REED. Do you think that the companies themselves have that information or do that research?

Dr. VON ESCHENBACH. I honestly don't know the answer to that question, Senator.

USER FEES

Senator REED. Turning to another issue, and that is the issue of user fees, so many of your programs have user fees attached to them, which raises a question of what percentage of your total budget is covered by annual appropriations, what percentage is paid for through user fees.

Dr. VON ESCHENBACH. As far as the absolute percentage, I'm going to turn to my right to ask Mr. Dyer to quickly calculate that for you. But while he's doing that, let me state specifically that I view the user fees as exactly that. They are a fee for service, so that they do not impact upon the overarching mission of the agency, but allow us to provide a service that is of value or benefit to the industry in terms of their ability to move applications more efficiently and more rapidly through the system, by having the resources with which to do that.

And so I know that issues have been raised about whether the fact that we have user fees is in some way creating problems with regard to the mission and focus of the agency, and let me assure you, Senator, that is not the case and will not be the case.

Having said that, I think that they provide for us the opportunity to enhance resources, infrastructure, personnel to address issues like our ability to accelerate drug approvals, our ability to bring new products, whether they be devices or drugs or biologics, to patients as rapidly as possible, while we still at the same time assure the safety and the efficacy of those products.

Senator REED. Mr. Dyer.

Mr. DYER. Sir, the budget proposes \$444 million in fiscal year 2008 for user fees in total, out of a total program level of about \$2.1 billion, which makes about 20 percent.

Senator REED. Twenty percent? And how has that number changed, that percentage changed, over the last 5 years? Has it increased, decreased, remained stable?

Mr. DYER. I don't have the exact numbers. We'll provide them for the record. But it has been increasing.

[The information follows:]

USER FEES

From fiscal year 2002 to fiscal year 2006, the percent of FDA user fees compared to the total FDA budget increased from 12 to 20 percent. During this time, FDA established two new user fees for Medical Devices and Animal Drugs. FDA began to collect fees under these two user fee programs in fiscal year 2003 and fiscal year

2004, respectively. These new user fees account for nearly one fifth of the total fee increase from fiscal year 2002 to fiscal year 2006.

Senator REED. Has been increasing. And as you project forward, do you project an increase in the fees, this 20 percent getting bigger and bigger?

Mr. DYER. The amount of fees will go up, but again it depends on what percentage of the overall budget, depending on how much budget authority this committee gives us.

Senator REED. And, doctor, you have assured us that these fees in no way distort your approach to your duties, i.e., because you're being paid but with fees you have to do certain things, where other appropriated functions are not tended to. That's your statement.

Dr. VON ESCHENBACH. What I was speaking to, Senator, was where the concerns that have been raised about user fees in the press and et cetera allow me the opportunity to assure you that as far as the regulatory process is concerned, the integrity of that process is not in any way impacted or adulterated by the fact that user fees make up a portion of our resource base. They are strictly, as I have indicated, a fee for service.

With regard to our ability to manage our portfolio of resources, I think it's an issue that we are addressing, to make certain that we are able to deploy resources as efficiently and as effectively across that entire continuum. And so I am committed to putting all components of the agency on that sound foundation, whether they have user fees or not.

Senator REED. Are there new user fees in this budget, proposed budget?

Dr. VON ESCHENBACH. Yes, sir. There are three particular user fees that are proposed in the fiscal year 2008 budget. One of them has to do with generic drugs, and the other ones are user fees that have previously been presented, having to do with reinspection fees and export certificate fees.

Senator REED. And will we receive a formal proposal to enact these fees?

Dr. VON ESCHENBACH. Yes, sir. That, as far as the proposal for authorization of these fees, the two that I mentioned, the reinspection fees and the export certificates, they have previously been introduced and we will reintroduce them again. The generic drug user fee is a new fee, and we are in the process of developing that proposal for authorization.

Senator REED. It seems, the impression, at least, that because of constraints on your appropriated budget there is a strong tendency to ask for user fees. Is that what seems to be happening here?

Dr. VON ESCHENBACH. I think they present an option with regard to continuing to increase our ability to provide services. And in addition to the appropriations, we have looked for a variety of ways to be able to do that, including our ability to collaborate and co-operate in relationships, for example, with the NIH.

So the approach I'm taking, Senator, is to build a resource base and a business plan that supports our overall mission, recognizing that there is a critically important part of that that is the appropriation; there are user fees that can contribute to that; and then there may be other opportunities as well. And the point of all of that is to enhance our ability to serve the American people by

bringing safe and effective products and food to them as rapidly and as efficiently as possible, while still assuring the safety and the efficacy of those products.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator REED. A final question, doctor. It's my understanding that other agencies like the National Science Foundation don't have to go through all of the hoops and the hurdles that you do through HHS and OMB, that they have much more direct engagement with Congress on their budget. Would a more direct engagement help you?

Dr. VON ESCHENBACH. Well, I have found that the process that I have at this point, since I've been in this position, has really worked quite well, Senator. I think as we looked at the 2007 budget and the 2008 budget, the collaboration and cooperation within the department, within the administration, and with Congress is working quite well at this point.

Senator REED. Thank you, Mr. Chairman.

Senator KOHL. Thank you, Senator Reed. And we would like to thank you. Dr. von Eschenbach, as well as Mr. Dyer and Mr. Turman, for helping us to conduct an informative hearing, and we look forward to continuing to work with you.

ADDITIONAL COMMITTEE QUESTIONS

We want to thank all of our witnesses, yourself and the Secretary of Agriculture, for being here. Members should provide us with questions for the record by Tuesday, March 6. And we look forward to continuing our dialogue and our collaboration together on behalf of the American people. Thank you so much.

Dr. VON ESCHENBACH. Thank you.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR HERB KOHL

OVERALL FUNDING

Question. Please provide a crosswalk table, in the same format as was provided on page 68 of FDA's fiscal year 2008 Budget Summary, that shows how FDA will allocate requested increases from the fiscal year 2007 spending plan level to the fiscal year 2008 President's budget request. If possible, please do not include any "redeployments".

Answer. FDA is in the process of finalizing the fiscal year 2007 spending plan and developing the bridge between the spending plan and the fiscal year 2008 President's budget.

Question. Please provide updated performance data based on this information.

Answer. The performance data submitted in the President's budget may change. The fiscal year 2008 President's Budget uses the fiscal year 2007 President's Budget as a baseline, which is different from the fiscal year 2007 enacted appropriation. We appreciate that the fiscal year 2007 enacted appropriations fully funded our pay and infrastructure needs, allowing FDA to keep more staff on board to maintain our current performance levels throughout the Agency.

Question. If the Committee provided FDA with all increases requested in the President's budget, totaling \$95,439,000, would the performance data submitted by FDA still be accurate, even though these increases would be based on a number that is higher than the original level FDA budgeted from?

Answer. The performance data submitted in the President's budget may change. The fiscal year 2008 President's Budget uses the fiscal year 2007 President's Budget as a baseline, which is different from the fiscal year 2007 enacted appropriation. We

appreciate that the fiscal year 2007 enacted appropriations fully funded our pay and infrastructure needs, allowing FDA to keep more staff on board to maintain our current performance levels throughout the Agency.

FOOD SAFETY

Question. Please provide information on how additional funding provided for food safety activities at FDA above the President's request would be allocated. Please provide this information in \$5 million increments up to \$50 million.

Answer. FDA is committed to ensuring that America's food supply continues to be among the safest in the world, but we face challenges. For example, consumption of produce, particularly "ready-to-eat" products, has increased dramatically during the past decade. Americans usually consume these products in their raw state, harvested from the vine, stem, or soil without processing to reduce or eliminate pathogens that may be present. Consequently, the manner in which these products are grown, harvested, packed, processed, and distributed is crucial to ensuring that microbial contamination is minimized, thereby reducing the risk of illness to consumers. Even if a small percentage of what is harvested is contaminated, it can result in severe illness. FDA is taking a "farm-to-fork" systematic risk management approach to food safety to reduce the risk of food illness at all points in the food chain.

For fiscal year 2008, we propose a \$10.644 million increase for a food safety initiative focused on fresh produce. FDA will develop methods to prevent food outbreaks from occurring by rapidly detecting contamination that leads to illness, more quickly tracking contamination to its source, and more effectively conducting root cause analysis of the contamination. We will also provide training to our State and local partners and develop a geographic information mapping system for faster emergency response. Finally, we will develop a decision-making system to detect high-risk imports before they enter U.S. commerce, so they can be evaluated by FDA.

Due to the increased consumption of fresh produce and the current outbreaks of contamination, FDA would allocate additional funding for specific areas where we could expand the food safety program in order to promote and improve the public health. FDA has identified the following five critical areas as targets for future growth:

- preventing contamination and produce safety research
- preventing outbreaks and mitigating outbreak impact
- monitoring antibiotic usage and antibiotic resistance in bacteria from farm-raised aquatic animals and their environments
- developing efficient techniques for identifying foodborne pathogens that cause outbreaks
- providing additional field support for the Foods and Animal Drugs and Feed Programs.

Question. Please provide information on how the rapid response teams in the Strengthening Food Safety initiative would be set up and what activities they would undertake. Please provide an estimate of how much it will cost to create and support each rapid response team.

Answer. The \$3.5 million requested in the fiscal year 2008 Congressional Justification, Strengthening Food Safety Initiative, will support FDA costs for 12 staff members, and provide equipment and training for each team member. The Office of Regulatory Affairs, or ORA, will be able to develop teams trained in traceback technologies and incident command. ORA will strategically position these teams in areas with large produce-growing regions. In addition, ORA will provide training, equipment, and other assistance to States so that they can be full partners with FDA in responding to and preventing produce-related outbreaks. After the first year, ORA will have 12 fully equipped and trained FTEs with traceback equipment, such as handheld GPS devices that can be used with geographic information systems to facilitate investigations of outbreaks.

These teams will be modeled on the California Food Emergency Response Team, or CalFERT, which investigated the recent E. coli outbreak in spinach. CalFERT is a joint FDA and California Department of Health Services' Food and Drug Branch, or FDB, Rapid Response Team trained and ready to respond within hours of the verification of a food borne outbreak. That team, consisting of ORA Investigators and Microbiologists and State of California FDB personnel, demonstrated the importance of FDA collaboration with State regulatory partners. Team members can immediately start the outbreak investigation because they have clearly defined roles and responsibilities, a previously identified chain of command and a known procedure to keep other involved parties informed, such as the Incident Command Center

of FDA's Office of Crisis Management. These teams will benefit the entire food program, not just produce safety.

Question. Does CFSAN have an overall "produce safety" plan? If so, please provide this to the Committee, including all cost estimates to implement this plan, even if they were not include in the President's budget request.

Answer. In October 2004, FDA issued a Produce Safety Action Plan (the PSAP) designed to target microbial and other food safety hazards, such as bacteria, viruses, and parasites, in or on produce consumed in the United States, whether produced in the United States or abroad. The PSAP extends to all parts of the food chain from farm through retail or consumer preparation and consumption and has four general objectives: 1—to prevent contamination of fresh produce with pathogens; 2—to minimize the public health impact when contamination of fresh produce occurs; 3—to improve communication with producers, preparers, State and local government entities, and consumers about fresh produce; and 4—to facilitate and support research relevant to fresh produce. For each objective, the PSAP identifies steps that could contribute to the achievement of the objective.

The fiscal year 2008 President's Budget Request contributed to these objectives.

GENERIC DRUGS

Question. As you know, in the JR, we also provided an increase of \$5 million for generic drug review at FDA. It is my understanding that the increase provided in the JR will allow for ten additional approvals or tentative approvals per month, which is a 25 percent increase above the current average of 40 approvals per month. What is the current backlog of generic drugs? Do you expect it to increase this year, even with the additional funds provided, because of an increase in applications submitted?

Answer. The current backlog is around 1,300 abbreviated new drug applications (ANDAs) as of the end of February 2007. However, not all ANDAs are available to be approved currently due to patent protection and exclusivities. There are currently about 600 abbreviated new drug applications that do not have patent or exclusivity protection. Because we are still not at a point where we can process (approve or tentatively approve) the number of applications that we receive, the backlog will continue to increase. The rate of increase, however, will not be as steep with the provision of additional funds. Our goal is to use the FTEs obtained with the \$5 million to address certain review areas to increase the number of approvals and tentative approvals. Through additional efficiency initiatives, we will still endeavor to approach the projected percent increase in approvals.

Question. What will the \$5.5 million increase requested in the budget buy? How many additional approvals will you get with this money?

Answer. It is expected that an additional \$5.5 million will provide 13 FTEs. Although it is difficult to predict the number of additional approvals due to the increasing scientific and legal complexity of the applications being received, the escalating workload involved with responding to Citizen Petitions received, and the growing number of requests for information received by the office, the Office of Generic Drugs or OGD, will strive to increase the yearly number of approvals and tentative approvals by 50. It is important to note that each Abbreviated New Drug Application, or ANDA, represents a product intended to be marketed in this country and contains a full scientific data package that must be carefully evaluated. The increasing complexity of many of the applications received is increasing the review time needed to fully and comprehensively review these applications.

Question. Please provide information on how many additional approvals could be provided with increases of up to \$20 million, in \$5 million increments.

Answer. We estimate that we would be able to increase the number of approvals in fiscal year 2009 (from 60 to 135) more than fiscal year 2008 (from 50 to 125), taking into account that 10–15 percent of the increase used for IT investment and time to hire all the reviewers and train them to conduct reviews could affect the projected number of approvals:

[The information follows:]

NUMBER OF APPROVALS ¹

Increment	Fiscal year 2008	Fiscal year 2009
\$5 million	50	60
\$10 million	80	90
\$15 million	110	120

NUMBER OF APPROVALS¹—Continued

Increment	Fiscal year 2008	Fiscal year 2009
\$20 million	125	135

¹ Note we assume that the full \$20 million is received in fiscal year 2008 and fiscal year 2009.

Question. Please provide a breakdown of the pending generic drug applications by the four paragraphs of the Hatch Waxman Act.

Answer. The current breakdown is as follows:

Paragraph I: patent information has not been filed—418

Paragraph II: patent has already expired;—186

Paragraph III: date on which the patent will expire (generic drug will not seek final approval until that date passes);—344

Paragraph IV: patent is challenged as invalid or not infringed.—347

Question. How many pending applications would be “first” generics? Of those, how many could immediately be marketed if approved?

Answer. It is difficult to determine what you intend to include in the term “first” generic. There may be a number of pending applications for the same product that does not currently have generic competition. They could not all be counted as the “first” generic and we will not know which will be the “first” generic until we issue an approval. For this reason, applications are not classified as “first” generics upon receipt in the office, making the tracking of “first” generics in the list of pending applications difficult.

Regarding the pending applications in OGD, 344 applications have been submitted with paragraph 3 patent certifications (will wait until a patent in force expires) and 347 applications have been submitted with paragraph 4 certifications (are challenging a listed patent as invalid or not infringed). Since products to which these applications refer still have patents in force which may have prevented previous generic approvals, many of these 691 applications have the potential to be “first” generic applications. The majority, of course, will be approved subsequent to the first generic approval, and, until the time of approval, we will not be able to determine which product will be THE first generic for a particular reference listed drug.

Of the remaining applications, 445 were submitted with paragraph 1 certifications (no listed patents) and 187 were submitted with paragraph 2 certifications (patents have expired). Because many of the products referenced in these applications already have generic competition, only a few of these are likely to be “first” generics when approved. To address the products in this category for which no generic has been previously approved, the Office of Generic Drugs, or OGD, instituted a revision in its first-in, first-reviewed policy last October (10/06). Instead of reviewing these products in the order of receipt, OGD will now expedite any application for a “first” generic product for which there are no listed patents on the reference product at the time of the generic application’s submission. We believe that this will allow critically needed “first” generics of products without patent protection to reach the market place faster.

Question. Please provide specific productivity outputs should the proposed generic drug user fee program be authorized.

Answer. Following the first full implementation year, during which time additional staff will be hired and trained, the Generic Drug User Fee will result in a 50 percent increase in approvals/tentative approvals compared to the current average of 40 approvals/tentative approvals per month. During the next 5 years, the goal is to meet the statutory requirement for generic drug review by acting on 90 percent of original Abbreviated New Drug Application, or ANDA, and amendments to unapproved applications within 180 days.

IMPORT INSPECTION

Question. How many import lines did FDA review from 2002–2007, by year? How many import lines does FDA anticipate reviewing in 2008?

Answer. I will be happy to provide that information for the record
[The information follows:]

IMPORT LINES FOR FISCAL YEAR 2002–2006

	Fiscal year				
	2002	2003	2004	2005	2006
TOTALS	7,838,956	9,336,735	11,616,348	13,819,402	14,977,795

ESTIMATED IMPORT LINES BY FISCAL YEAR 2007–2008

	Fiscal year	
	Estimate 2007	Estimate 2008
TOTALS	16,323,947	17,893,795

Question. What percentage of imports were physically inspected by FDA in 2006? What percentage does FDA anticipate inspecting in fiscal year 2007 and 2008?

Answer. Approximately .89 percent of all imports were physically inspected by FDA in fiscal year 2006. FDA estimates it will physically inspect .73 percent in fiscal year 2007 and .66 percent in fiscal year 2008.

It is important to note that FDA electronically screens imports through the Operational and Administrative System for Import Support, or OASIS. OASIS is an automated system for processing and making admissibility determinations for FDA regulated products that are offered for import. FDA also performs laboratory analysis on products offered for import into the United States; conducts foreign inspections to evaluate manufacturing conditions of products before they are offered for import; and, performs periodic filer evaluations to ensure that the import data being provided to FDA is accurate.

The Prior Notice Center, or PNC, is another important part of FDA's import strategy. The mission of FDA's PNC is to identify imported food and feed products that may be intentionally contaminated with biological, chemical or radiological agents, or which may pose significant health risks to the American public, and intercept them before they enter the United States. FDA will continue to focus resources on Intensive Prior Notice Import Security Reviews of products that pose the highest potential bioterrorism risks. By using a risk based approach, the PNC can intercept potentially hazardous products before they enter the United States.

The benefit of these reviews comes from the quality and targeting of review activities; not from the volume of imports inspected. Thus the quality of import screening is a better measure of FDA's import strategy rather than simply focusing on the items physically examined.

I will be happy to provide information on the percentage of imports physically inspected in table form for the record.

[The information follows:]

	Import Lines	Physical Exam Subtotal	Percent Physically Examined
Fiscal year 2006	14,977,795	132,594	0.89
Fiscal year 2007 estimates	16,323,947	118,400	0.73
Fiscal year 2008 estimates	17,893,795	118,370	0.66

Question. Please provide information regarding total field staff working on import inspections? How has this number changed in the last 5 years?

Answer. FDA estimates that 611 FTE will perform import investigative work in fiscal year 2008 and 643 FTE in fiscal year 2007. This number compares to 674 FTE in fiscal year 2006; 666 FTE in fiscal year 2005; 653 FTE in fiscal year 2004; and, 807 FTE in fiscal year 2003. These resources include FTE who perform import laboratory analyses.

I am happy to provide the information in table form for the record.

[The information follows:]

Fiscal year	Import Investiga- tive FTE (in- cludes import lab analyses re- sources)
2008 estimate	611
2007 actual	643
2006 actual	674
2005 actual	666
2004 actual	653
2003 actual	807

Question. What percentage of fresh produce was physically inspected in fiscal year 2006? What percentage does FDA anticipate inspecting in fiscal year 2007 and 2008?

Answer. Approximately .82 percent of fresh produce was physically inspected by FDA in fiscal year 2006. FDA estimates it will physically inspect .69 percent in fiscal year 2007 and .67 percent in fiscal year 2008. An FDA physical inspection of an import line is defined as either having had a field exam conducted or a sample of the import line collected and analyzed in the laboratory. A field examination is simply an on-the-spot examination or field test performed on a product to support a specific decision. A physical inspection does not include import lines that were detained at entry without a physical exam, or DWPE, based upon an Import Alert.

I will be happy to provide that information in table form for the record. The information follows. The following tables reflect the estimated percentage of fresh produce imports that were physically inspected in fiscal year 2006, and the estimated percentage of fresh produce that will be physically inspected in fiscal year 2007 and fiscal year 2008.

[The information follows:]

	Fresh Produce Import Lines	Physical Exam Subtotal	Percent Phys- ically Examined
Fiscal year 2006	1,553,401	12,668	0.82
Fiscal year 2007 estimates	1,591,345	10,980	0.69
Fiscal year 2008 estimates	1,630,216	10,922	0.67

Question. Is the FDA's Prior Notice Center fully staffed and operational? Please provide a breakdown of staff makeup, including permanent staff, temporary staff, detailees, etc.

Answer. The Prior Notice Center is opened and operating on a 24/7 basis. The current composition of the permanent PNC staff includes one Director, one Deputy Director; eight Watch Commanders; and, 22 Reviewers. In addition, the PNC presently has one Watch Commander and three Reviewers on detail to the PNC.

FDA is currently advertising a vacancy announcement for 2 additional reviewers. Ideally, the PNC would like to hire 1 additional Watch Commander, 3 additional reviewers, one support staff person, and 1 statistician. This would bring the total staff at the PNC to 1 Director, 1 Deputy Director, 9 Watch Commanders, 27 reviewers, 1 support staff person and 1 statistician.

AERS II

Question. Please provide a copy of the November 2006 report of the Breckinridge Institute on AERS II.

Answer. I would be happy to provide that for the record. Please note that although the reports has a confidential heading FDA has cleared the document for public disclosure

[The information follows:]



Breckenridge Institute
HARNESSING THE POWER OF CULTURE™

Independent Verification and Validation of AERS II Requirements Process

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TABLE OF CONTENTS

1.0 Executive Summary.....	3
2.0 Summary of Observations	5
3.0 Organizational Culture and Background	8
3.1 Background, Timeline, and Key Events	
3.2 From the SRS to AERS	
3.3 The Initial Assessment in March 2003	
3.4 Conflict between OIT Managers, Working Level Technical Staff, and Contractors	
3.5 Creating an Essential Tension between OPaSS and OIT	
3.6 The AERS II Project Manager Is Unilaterally Reassigned	
3.7 The Turning Point for AERS II Despite the Protest of OPaSS	
3.8 The 2005 AERS Users Satisfaction Survey	
3.9 OIT Unilaterally Sets IT Direction Despite the Protests of AERS Users	
3.10 Unanswered Questions	
4.0 Use of Appropriate IT Methodology.....	34
4.1 The Six Tiered Method	
4.2 OIT's People Design	
4.3 Analysis of the High-Level Requirements Document	
4.4 Analysis of the Detailed Requirements Document and User Needs	
4.5 A Quantitative Analysis of the AERS Requirements Process	
5.0 The Impact of Not Having AERS II Operational in 2005	54
5.1 Financial Impact of <i>Not</i> Having AERS II Operational in 2005	
6.0 The Path Forward	57
APPENDIX A: Requirements Analysis Database and Method	58
APPENDIX B: Mapping the 1996 BAH Document to the 2003 RTM.....	61
APPENDIX C: Mapping the 2006 BAH Document to the 2003 RTM.....	99
APPENDIX D: Report of Findings on OIT by Linda Rule.....	153
APPENDIX E: AERS User's Satisfaction Survey	154

1.0 Executive Summary

The self assessment that is summarized in this report was conducted by the Breckenridge Institute™ and is an independent verification and validation of the AERS II Requirements Process. It describes AERS-related activities that are currently on-going as of October 2006 and is the final step in a process initiated in 2003 by Dr. Paul Seligman to replace the dysfunctional AERS system. The work that resulted in this report was initiated by the AERS Program Office prior to its being disbanded, and prior to the reorganization of the Office of Pharmacoeconomics and Statistical Science (OPaSS) into the current Office of Surveillance and Epidemiology (OSE). Based on the information and data evaluated, the Breckenridge Institute assessment team has identified one root-cause finding (shown below) and 12 supporting observations that are found in Section 2.0. The assessment team has included three recommendations for corrective action.

Root Cause Finding: CDER's culture can be characterized as one in which managers at all organizational levels fail to move from the *awareness* of organizational problems, to the kind of *action* that will produce positive change. When some CDER managers do attempt to make positive change as with the AERS II system described in this report, their attempts are frustrated and undermined by an "invisible bureaucracy" that they don't really understand. In the case covered in this report, the AERS II system could have been completed in 2005, but was delayed and ultimately shelved, by: a) a change in project scope from replacing the dysfunctional AERS system to building an FDA-wide adverse event reporting system, and b) unilateral decisions and questionable procurement practices on the part of CDER's Office of Information Technology (OIT). These actions were taken despite the documented needs of AERS users, and the documented objections of CDER managers and scientists. The consequences of these actions include:

- Conducting an AERS II requirements process led by CDER OIT that: a) was unnecessary and cost \$1,500,000; b) did not follow proper IT methodology; c) selected and utilized contractors that have a known and documented track record of inadequate or poor performance; d) ineffectively utilized the time of dozens of AERS users in requirements development meetings because OIT lacked personnel who could execute the Business Systems Analyst function; and e) culminated in a High-Level Requirements Document, a Technical Alternatives Analysis Document, and a Detailed Requirements document that makes FDA less prepared today to replace the dysfunctional AERS system than it was in 2004.
- A total estimated cost of \$25,000,000 and a four-to-five year delay in replacing the AERS system, which will not be operational until 2009 or 2010.
- The frustrating and undermining of the post-marketing drug safety work of Safety Evaluators, epidemiologists, and personnel in the Offices of Compliance and FOI because they lack some of the basic tools they need to perform their jobs, e.g. a computing system that meets their requirements.

One of the most difficult tasks of characterizing the culture in an organization like CDER is to tease apart the difference between: a) the beliefs, assumptions, and ways of working of individual managers and key personnel, and b) beliefs, assumptions, and ways of working that are held collectively by the organization as a social phenomenon, e.g. culture. Perhaps the key indicator that an issue is "cultural" is the existence of long-term patterns of organizational behavior that span long-periods of time. In the case of AERS, this study documents a pattern of organizational behavior on the part of CDER's OIT that spans ten years, two Center Directors, at least two different configurations of CDER's organizational structure, and multiple Directors of CDER's OIT. Given the data presented in this report, the Breckenridge Institute assessment team is convinced that the root cause of the problems associated with the AERS II requirements processes is cultural and can only be addressed by a significant change in CDER's culture.

Recommendation 1: In an atmosphere in which IT management and contracting practices are coming under increased scrutiny, and in the wake of the recent report from the Institute of Medicine (IOM) that identifies organizational culture as a root cause of issues in FDA, the senior managers in CDER should conduct a thorough investigation into the leadership, management, and contracting practices of OIT.¹ In addition to characterizing the tacit, underlying patterns of organizational beliefs and behavior in CDER's organizational culture, they should investigate: a) how effectively CDER's portfolio of IT projects is being led and managed; b) the selection criteria by which contractors like the one mentioned above are screened and selected; c) and the way in which financial resources are being combined into larger and larger categories in CDER's OMB Exhibit 300. This *increases* the extent to which OIT can reprogram the IT funds of CDER's science-technical units like OSE, award those funds to contractors they select without the approval of science-technical managers, and *decreases* the level of traceability and overall accountability for doing so.²

Recommendation 2: The senior managers in CDER should take immediate action to correct the problems in CDER's OIT as described in this report. In addition, under the auspices of the IT consolidation, organizations such as OSE that contain AERS users should have the opportunity to select a team of IT professionals from the consolidated FDA IT organization that have a proven track record of technical performance and providing outstanding service to end users like the Safety Evaluators who use AERS.

Recommendation 3: FDA should execute an updated version of the software acquisition plan that was developed by the CDER OIT AERS II Project Manager and AERS Program Manager in 2004 and begin the process of acquiring a replacement for AERS I immediately. The AERS II system has been absorbed into an FDA-wide IT system that includes multiple FDA Centers. This is a much more complex and daunting task than simply replacing the AERS system, and consequently making such a system functional is probably four-to-five years away – minimum. This forces Safety Evaluators in CDER and CBER and other FDA units such as the Offices of Compliance and FOI, to work with the dysfunction AERS I system for yet another extended period of time, thus further undermining their ability to effectively carry out FDA's mission of post-marking surveillance and drug safety. Based on the information contained in this report, a replacement for AERS could be operational in less than two years at a cost of about \$5 million dollars. More importantly, this fully functioning AERS II system could then be used as a solid foundation for an FDA-wide system. It is important to note, that recently in the wake of the IOM report, there seems to be a renewed interest on the part of CDER's OIT and OSE in replacing the dysfunctional AERS I system as a necessary first step in developing an Agency wide system, despite the fact that funding for AERS II has been zeroed out in FY 2006 and FY 2007.

¹ See the Institute of Medicine's report entitled, *The Future of Drug Safety: Promoting and Protecting the Health of the Public*, published on Sept 26, 2006.

² For example, see the audit and investigation into the \$170 million IT system developed for the FBI that was unusable. See, "The FBI's Upgrade That Wasn't," by Dan Eggen and Griff Witte in, *The Washington Post*, August 18, 2006 (<http://www.washingtonpost.com/wp-dyn/content/article/2006/08/17/AR2006081701485.htm>).

2.0 Summary of Observations

The conclusions that emerged from the research and analysis process conducted by the Breckenridge Institute have been codified into twelve observations. The supporting evidence for each observation in the text is linked to the observations below by reference in the text.

OB 1-2006: There has been a pattern of unilateral decision-making about the AERS II system on the part of CDER OIT despite the documented needs of AERS users, and the documented objections of CDER managers and scientists. This pattern of unilateral decision-making has been evidenced by the Directors of OIT since 2003 (see supporting data in the text below).

OB 2-2006: The requirements activity from 2005 on was unnecessary, did not add value to what had already been done, cost \$1,500,000, and did not follow proper IT methodology as defined by FDA and industry standards such as Oracle – the FDA standard for IT systems. More specifically, no new information on user requirements emerged from the HL Requirements Document that would have supported taking a different direction, yet this was used as the basis for a second “technical” alternatives analysis and a Detailed Requirement’s Document that took the AERS II project in an entirely different direction than the one established prior to July 2004. In addition, the AERS II requirements process violated procedures specific in the FDA’s Life Cycle Systems Document (LCSD) and standard industry methodologies like those developed by Oracle – the FDA standard for IT systems (see supporting data in the text below).

OB 3-2006: Over the three years covered by this assessment, the Directors of OIT have demonstrated a lack of effective leadership and management of AERS II as evidenced by continued turnover of AERS II Project Managers - there were five Project Managers during the three year period. On November 8th 2006, another former AERS Project Manager resigned his position with OIT and the government (see supporting data in the text below).

OB 4-2006: Over the period of time covered by this assessment, CDER’s OIT has been combining the Center’s IT financial resources into larger and larger pools in the OMB Exhibit 300, making it increasingly difficult to have accountability for the spending of large amounts of money. This increases the extent to which OIT can: a) reprogram the IT funds of CDER’s science-technical units like OSE, b) award those funds to contractors OIT selects without the approval of science-technical managers, and c) decrease the level of traceability and overall accountability for doing so (see supporting data in the text below).

OB 5-2006: The original AERS system was released on November 1, 1997, taken off-line because it was largely unusable by AERS users, and then re-released on 1998. Despite known and documented inadequacies in their performance, this same contractor was hired by CDER’s OIT to do the High-Level Requirements Document that is methodologically flawed and makes FDA less able to replace the dysfunctional AERS system now than it was in 2004. When the hiring of the contractor was questioned by senior FDA managers and AERS users, OIT obfuscated the situation and did not justify their decision based on the contractor’s previous performance (see supporting data in the text below).

OB 6-2006: The AERS II requirements process and CDER’s OIT and OIM lacked an effective *liaison* between: a) AERS users, b) the working level technical people within OIT who functioned as AERS Project Managers, and c) the IT designers in the AERS software maintenance contractor organization. This liaison function is normally described as a business systems analyst (BSA). Until recently, the AERS Program Manager tried to fulfill this role, but this position has been abolished (see supporting data in the text below).

OB 7-2006: Neither the 2004 High-Level Requirements Document, nor the 2006 Detailed Requirements Document specifies what methodology and/or tools were used to manage the AERS II requirements process or to produce the models in the final documents, e.g. a requirements repository like Oracle Designer. Standard IT methodology requires that such methods and tools be used as the basis of a requirements process and that they be clearly documented in the final requirements document. In the case of the AERS II requirements process, it appears that lists of requirements that were available prior to July 2004 were edited, and then cut and pasted into the two documents using MS Word or Excel rather than using a requirements repository/tool to manage the overall requirements process. In 2003, FDA paid Oracle over \$300,000 to reverse engineer the AERS I system into Oracle Designer, an automated tool widely used by Oracle customers and consultants to design new systems and document existing systems.³ It appears that this information was ignored by CDER's OIT and its contractors during the AERS II requirements process (see supporting data in the text below).

OB 8-2006: Neither the 2004 High-Level Requirements Document, nor the 2006 Detailed Requirements Document took a "top down" Business Process Analysis approach to the AERS II requirements process, e.g. the AERS II requirements process was not linked to CDER's mission and goals in any meaningful way. More specifically, CDER mission and goals were not incorporated in the 2004 High-Level Requirements Document. Although the document contains a section entitled, *Business Vision and Objectives*, this contains a cursory discussion of the objectives for the AERS II system, but does not tie AERS II back to CDER's mission or goals. In addition, the 2004 High-Level Requirements Document does not contain (or reference) a properly conducted Business Process Analysis using methods such as workflow analysis, Swimlane diagrams, or IDEF0 process analysis. There is no "as-is" or "to-be" analysis of CDER's enterprise-wide business process of Drug Safety, or its enabling processes, e.g. conducting safety analyses, epidemiological studies, or the tasks performed by the Offices of Compliance and FOI. The form of analysis that was included in the document was inappropriate for a high level requirements phase, e.g. using Use Cases that would typically be used at the Presentation-User Interface to break down CDER's enterprise-wide business process and enabling processes, both of which should reside at the higher-level Enterprise-Wide Business Processes (see supporting data in the text below).

OB 9-2006: The back-engineering of the AERS I system using Oracle Designer in 2003 provided a solid foundation upon which to build AERS II in terms of an Entity Relationship (ER) model and underlying data structure. The 1996 AERS I document contained a Data Requirements section, complete with a dictionary report. Although this information is stored in the Oracle Designer container maintained by CDER's OIT, it appears to have been ignored by OIT and its contractors in the AERS II requirements work conducted from July 2004 on, resulting in a *very serious* lack of definition at the most fundamental level of Data Management. If, by leaving the Data Management tier out of both the 2004 HLR Document and the 2006 SRS Document, the intention was to rely on the ER Model and Data Management

³ Oracle Designer, formerly called Oracle CASE (Computer Aided Systems Engineering), is a tool that can be used from day one of the systems development life cycle to document and analyze system requirements. Richard Barker's book, *Case Method: Tasks and Deliverables*, describes how to use the tool for every step of the life cycle. The Designer repository captures increasingly detailed information obtained during the life cycle, without the need for re-entry of requirements. For example, during the Strategy (High Level Requirements) phase, information about conceptual data entities is stored. During the Analysis (Detailed Requirements) phase, these same entities are documented in more detail, and a complete Entity Relationship model is completed. Then during the Design phase, a utility within the repository can be run to generate a default database design, which subsequently can be used to automatically generate SQL syntax and create the necessary tables in Oracle.

tier in AERS I, then serious deficiencies in AERS II functionality will be unavoidable, as indicated by the comments and data gathered in the 2005 AERS Users Satisfaction Survey. This also indicates that a higher priority was placed on the ER Model and Data Management Tier ten years ago than today. The lack of an ER Model and well-defined underlying data structure presents a *serious risk* to the potential success of AERS II because without these elements, user needs will not be met again as was the case with the AERS I system. Without an ER Model and underlying data structure, it is not possible to evaluate the degree to which the Presentation and Application Logic levels of the design actually contain complete functionality. Regardless of whether one is developing a custom software application where information deliverables are used to build a sound database structure, or evaluating the extent to which a COTS or COTS integration package will meet user needs, a well-defined foundation of an ER Model and information deliverables is required by standard industry practice (see supporting data in the text below).

OB 10-2006: The unilateral decision by CDER's OIT Director to begin the AERS II requirements process all over again post-July 2004 had an enormous negative impact on AERS users by delaying the replacement of the dysfunctional AERS I system by at least five years. This decision was made despite the objections of: a) technical staff in CDER's OIT, b) CDER's OIT AERS II Project Manager, c) AERS users in multiple FDA Centers, d) the OPaSS AERS Program Manager, and e) numerous CDER managers and scientists. But this unilateral decision also had an enormous financial impact that will ultimately cost FDA more than \$25,000,000 in a time when funding for computing is increasingly scarce. In other words, had FDA moved forward on the CDER OIT-OPaSS approved plan in July-2004 rather than unilaterally changing direction, FDA would have: a) had a functioning AERS II system in 2005, and b) avoided spending more than \$25,000,000 in contracts and services - many of which were not value-added to FDA or its mission (see supporting data in the text below).

OB 11-2006: The AERS users in CDER, CBER and other organizational units throughout the FDA have been forced to use the dysfunctional AERS I system for more than 10 years which has frustrated and undermined their ability to perform their jobs effectively (see User Survey comments). The additional 4-5 year delay caused by the AERS II requirements process being unnecessarily repeated have perpetuated and exacerbated the functionality problems identified in the AERS User Satisfaction Survey conducted in 2005 (see supporting data in the text below).

OB 12-2006: An analysis of the 2003 Requirements Traceability Matrix (RTM) that used the 1996 and 1998 Requirements Documents as a baseline revealed that almost 48% of the functionality of the AERS I system was removed from the original AERS system requirements (381 out of 795 requirements).⁴ Even after discussions with CDER's OIT, it was unclear *why* these pieces of functionality were removed, *when* they had been removed, or *who* authorized their removal, yet many of the problems faced by users today in FY07 are *directly caused* by these missing pieces of functionality.⁵ Further analysis has shown that at least 150 (40%) of the requirements that were removed from AERS I were *added back in* to the Detailed Requirements Document delivered by BAH in June of 2006, indicating that FDA will have to pay for this functionality a second time (see supporting data in the text below).

⁴ See the Booz Allen Hamilton, *FDA Center for Drug Evaluation and Research, AERS Requirements Traceability Matrix*, Task No. T06 – Contract No. 223-97-5513, September 8, 2003.

⁵ See Booz Allen Hamilton, *AERS II System Requirements Specification*, Version 1.1, April 6, 2006, and Booz Allen Hamilton, *AERS II Safety Evaluator, FOI, & Compliance Requirements (with Changes Tracked Based on Input from Safety Evaluators Received on May 17, 2006)*, June 2006.

3.0 Organizational Culture and Background

The purpose of this section is to establish the overall historical context for the Independent Verification and Validation of the AERS II Requirements Process, and to evaluate the rationale and consequences of critical decisions that were made by CDER's OIT, AERS users, and CDER managers and scientists that have brought the AERS II project to the point it is today in FY07. It is meant to answer two fundamental questions.

- How did the project scope for AERS II get radically shifted from replacing the dysfunctional AERS I system, to building an Agency-wide adverse event report system?⁶
- What are the end-effects and consequences for taking this path on FDA's and CDER's ability to carry out its mission of protecting and promoting public health through safety evaluations, epidemiological studies, and the functions executed by the Offices of Compliance and FOI.

The long-term patterns of decision-making and organizational behavior described in this section of the report are strong indicators that CDER's culture is one in which managers at all organizational levels fail to move from the *awareness* of organizational problems, to the kind of *action* that will produce positive change. When some CDER managers do attempt to make positive change as with the AERS II system, their attempts are frustrated and undermined by an "invisible bureaucracy" that they don't really understand. An example of an attempt to make positive change described in this section was Dr. Paul Seligman's plan to create an "essential tension" (interdependency) between the scientific-technical elements within OPaSS and CDER's IT function, where OIT would be *accountable* for giving AERS users what they needed to do their jobs by replacing the dysfunctional AERS I system. As the evidence presented below indicates, this move was counter-cultural and created a deep-seated power-struggle between OPaSS and CDER's OIT for control of the AERS system because it meant that the IT-tail would no longer be able to wag the dog of FDA's scientific, programmatic and business needs. The fact that senior FDA managers have known about the ineffective performance of CDER's OIT for over ten years and have not corrected this situation is an example of CDER's failure to move from *awareness* of these organizational problems, to the kind of *action* that would have produced positive change.

As mentioned previously, one of the most difficult tasks of characterizing the culture in an organization like CDER is to tease apart the difference between: a) the beliefs, assumptions, and ways of working of individual managers and key personnel, and b) beliefs, assumptions, and ways of working that are held collectively by the organization as a social phenomenon, e.g. culture. Perhaps the key indicator that an issue is "cultural" is the existence of long-term patterns of organizational behavior that span long-periods of time. In the case of AERS, this study documents a pattern of organizational behavior on the part of CDER's OIT that spans ten years, two Center Directors, at least two different configurations of CDER's organizational structure, and multiple Directors of CDER's OIT. Given the data presented in this report, the Breckenridge Institute assessment team is convinced that the root cause of the problems associated with the AERS II requirements processes is cultural and can only be addressed by a significant change in CDER's culture.

⁶ It is important to note, that recently in the wake of the IOM report, there seems to be a renewed interest on the part of CDER's OIT and OSE in replacing the dysfunctional AERS I system as a necessary first step in developing an Agency wide system, despite the fact that funding for AERS II has been zeroed out in FY2006 and FY 2007.

3.1 Background

The FDA is responsible for pre-market and post-marketing safety and efficacy assessments of human drugs and certain biologics through its Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER), respectively. Clinical trials, which represent the pre-market process that leads to formal marketing approval, only begin to quantify the safety and efficacy of a given pharmaceutical compound or biological product. The post-market assessment of safety and efficacy is conducted largely by means of reviewing and monitoring of adverse event reports.

An adverse event is any undesirable event associated with the use of a drug or biologic in humans. Given the approach of spontaneous or “passive” surveillance, the collection and analysis of adverse event data must be reported to FDA in order for the agency to carry out its mission of performing post-marketing drug safety (PMDS) throughout the entire life cycle of the product. The Adverse Event Reporting System (AERS) is a computing system that FDA staff uses to carry out the PMDS function. The Office of Pharmacoepidemiology and Statistical Science (OPaSS) AERS Program Office is the organizational unit in FDA that *orchestrates* the needs of users in all FDA Centers who perform the PMDS function and the technical support of CDER’s Office of Information Technology (OIT) and Office of Information Management (OIM).

The genesis of the FDA spontaneous reporting system for drugs dates to the 1962 Kefauver-Harris Amendment to the Food, Drug, and Cosmetic Act that required drug manufacturers to report all adverse reactions for any product marketed under an approved New Drug Application (NDA). FDA began computerizing adverse drug reaction reports in the mid-1960s. The automated Spontaneous Reporting System (SRS) was initially designed in 1969 to serve as a means for FDA to detect rare, unexpected adverse drug and biologics reactions, where biologics included blood, allergenics, cellular tissue and gene products and therapies. In 1986, prescription drugs on the market without an approved application (i.e., those drugs and biologics marketed before 1938) became subject to adverse event reporting requirements. In 1993, the FDA initiated the MedWatch program to increase public awareness about the importance of reporting adverse reactions, to educate health professionals on reporting requirements, to standardize reporting formats, and to provide an agency-wide single point of entry for adverse reaction reports submitted by the public and health professionals.

The SRS worked well when CDER and CBER were receiving a total of 10,000 reports a year. But by the mid-1990s, the increasing scope of FDA’s requirements for spontaneous reporting of adverse events combined with the agency’s desire to increase public awareness about reporting adverse events increased the number of reports to over 150,000 per year. The enormous volume of reports pushed the SRS to its operational and technical limits. It also hampered the agency’s ability to effectively perform PMDS. The Adverse Events Reporting System (AERS I) replaced the SRS in 1997 and became the primary post-marketing spontaneous reporting system for human drugs and biologic therapeutics. It was designed to utilize state-of-the-art technology to facilitate the collection, analysis, and dissemination of post-marketing spontaneous reporting information.

Since that time the number of adverse event reports has grown to over 400,000 per year, and the FDA’s commitment to gathering larger data samples, communicating risks to the public and encouraging reporting of adverse events will drive this number even higher. While FDA’s efforts were successful in increasing the amount of data that the agency could use to protect public health and safety, this success has created an enormous IT challenge that the current AERS I computer system can no longer handle. The OPaSS AERS Program Office tried to *orchestrate* the needs of

users in all FDA Centers and the technical support of CDER's OIT and OIM to ensure that a new AERS computer system (AERS II) served the needs of users who carry out FDA's PMDS mission.⁷

3.2 From the SRS to AERS

The contract for AERS was established in September 1995, and the original AERS system requirements document was issued in 1996.⁸ The development of AERS was part of a larger re-engineering project to revitalize the human drug post-marketing surveillance program and AERS was described as being a vital component of FDA's comprehensive Pharmacovigilance Program. The contractor who was designing the AERS system described it as being the "gold standard" of adverse event reporting systems that would implement international agreements and increase FDA's operational efficiency.⁹ More specifically, they claimed that the AERS system would:

- Build an adverse event reporting system capable of supporting a revitalized Pharmacovigilance Program at FDA
- Improve the operational efficiency, effectiveness, and quality control of the processes for handling adverse events reports
- Improve the accessibility of adverse event information
- Integrate AERS with other agency information system
- Implement and maintain compatibility with ICH standards
- Build the capability to receive electronic submissions of adverse event reports
- Provide automated signal generation capabilities and improved tools for the efficient and effective analysis of adverse event signals

The AERS system was designed to address specific problems that FDA was having at that time, more specifically the process flow for handling adverse events was problematic. There was redundant effort, with multiple organizations performing the same reviews. There was also fragmentation of systems and data, making it difficult to integrate data for effective risk assessment and monitoring drug safety. The time required to process individual safety reports was lengthy sometimes taking several months before a report was fully accessible to risk assessors.

In addition, the system that was in use prior to the advent of AERS, the Spontaneous Reporting System (SRS), provided only limited automated support for processing and assessing drug safety risk. Designed in 1969 when information technology was much less sophisticated, the SRS consisted of on-line data entry screens, a database of all reports submitted since 1969, approximately 20 canned reports, and an ad hoc query facility. Only a few of the data elements on a typical adverse reaction report were entered into the database because the SRS was viewed as a system that would signal potentially serious and unexpected reactions, rather than as a full-text

⁷ Since that time, FDA has formed the Office of Surveillance and Epidemiology (OSE) that has replaced many of the functions that OPaSS performed.

⁸ See the overheads from Sandra Valencia's presentation at the ODP Session entitled, *Adverse Event Reporting System Configuration Control Board Process (CCB) Overview*, July 15, 2003, and Booze-Allen & Hamilton, *Adverse Event Reporting System (AERS) Requirements Document, Draft Version II*, Contract No: 223-94-5528/F01), September 23, 1996.

⁹ See Booze-Allen & Hamilton, *AERS Requirements Document*, (1996), p. 1-5.

retrieval system. At that time, if reviewers needed the full text of the report to confirm a potential signal, they had to go back to the original paper form or to an image retrieval system. Although the SRS was migrated to an Oracle relational database in 1983, its core functions were largely untouched. At the time AERS was being designed, there were over one million records stored in the SRS database that included over 25 years of spontaneous reporting.

The contractor who was designing AERS promised to remedy many or all of these problems and provide a system that was a quantum advance over the SRS system and would equip FDA Safety Evaluators to better protect the public health. But the AERS system described in the 1996 Requirements Document that was released on November 1, 1997 was so flawed by a non-normalized database that created data integrity, functionality, and user problems that FDA's AERS Project Manager Bob Nelson aborted the release and he and the former Director of CDER's Office of Information Technology (OIT), Ralph Lillie, *demand*ed that the contractor fix the system and deliver what they had promised in the 1996 requirements documents.¹⁰ In the mean time, the CDER and CBER Safety Evaluators along with other FDA units like FOI and the Office of Compliance continued using the antiquated SRS to conduct their work. A revised AERS Requirements document was issued in August 1998 and the AERS system was also re-released, but the system was still plagued by data integrity, functionality, and user problems as evidenced by the fact that there were over 1,000 Change Control Requests (CCRs) for fixes to the AERS system.¹¹

As this report indicates, one of the root causes of the *confusion* and *delay* surrounding the AERS II system from 2003 onward is a lack of effective leadership and management on the part of CDER's Office of Information Technology (OIT), despite the on-going protests of FDA's Office of Pharmacoeconomics and Statistical Science (OPaSS) and OPaSS' on-going efforts to make AERS II functional as quickly as possible. More specifically, given the documented ineffective performance of this contractor and their inability to provide the deliverables of the original AERS system, it's unclear why CDER's OIT continued to use them to produce the detailed requirements for the AERS II system well into 2006. As this report shows, the work that this contractor is currently conducting on AERS II is even more methodologically flawed than the work that culminated in the original AERS system.¹²

3.3 The Initial Assessment in March 2003

User frustration with work-arounds, lack of functionality, data integrity and the overall ineffectiveness of the AERS system had reached an all time high when Dr. Paul Seligman, Director of CDER's Office of Pharmacoeconomics and Statistical Science (OPaSS), first contacted the Breckenridge Institute in February, 2003.¹³ Seligman told the Breckenridge Institute staff that most users were very unhappy with the performance of the AERS system and he identified three primary issues that needed to be addressed.

- Making better public health use of AERS data
- Improving the AERS database and its performance
- Better management of the AERS program

¹⁰ Based on an interview conducted by the Breckenridge Institute with Ralph Lillie on March 12, 2003.

¹¹ See Booze-Allen & Hamilton, *The Adverse Event Reporting System (AERS) Draft Version 2*, Contract No: 223-97-5513, August 14, 1998.

¹² See the Methodology Matrix in Section 4.0 that shows that the 1996 requirements document used more standard methodology than the current document dated June 2006.

¹³ The Breckenridge Institute was formally called the Breckenridge Consulting Group, which conducted this work for FDA.

Seligman said that some kind of “strategic planning” might be needed to sort out the issues involved and to develop a path forward toward improving the AERS situation once and for all. Seligman’s three issues were used as the focus of an initial set of exploratory interviews of users and other FDA personnel conducted on March 11 and 12, 2003. About 25 people were interviewed from ODS, DSRCS, DMETS, CBER, DDRE, OB, CDER OIT, CDER OIM. In addition to Seligman’s observations on AERS, the current version of the CDER OIT/OIM Strategic Plan (February 2003), provided to the Breckenridge Institute by Linda Burek, current Director of CDER’s OIT, was used as a guide for what the FDA needed from the AERS system.¹⁴

The purpose of the exploratory interviews was: a) to determine what the salient issues were, and b) whether “strategic planning” or some other form of organization development activity might remedy the situation. The data that resulted from the interviews resulted in eleven Initial Observations for Improvement. The list of these observations (shown below) helped focus the subsequent Organizational Design and Planning process undertaken by Seligman and the OPaSS organization.

- **Observation 1 (Description and Purpose):** The issues associated with AERS cannot be addressed by a “strategic planning” effort because strategic planning assumes that there is an organization that is doing the planning. The organizational flux of OIT, OIM, a temporary home for the AERS system in OPaSS, and the move to its eventual home in OIM is more like a business process reengineering project (BPR) combined with a strategic planning effort.¹⁵
- **Observation 2 (Project Management):** The management oversight of the software maintenance contract has been frustrating to OIT and users alike.¹⁶ This needs to be corrected. OIT is taking many positive steps to do what can be done now by moving the contractor’s people on-site so they will be more accountable and OIT can download information that they now have sole possession of. OIT is also having Oracle come in and back-engineer the existing AERS system to get as much documentation as is possible. The consensus of the people interviewed was that the structure of this contract, the CCB, and the CCR systems all need to be reengineered.
- **Observation 3 (Communication):** As is so often the case, the IT people and the users have different professional paradigms and talk past each other. Although the OIM plans to hire business analysts to “mediate” between these groups, this is a function that has been and continues to be missing, thus complicating communications.
- **Observation 4: Poor System Design:** The discussions with technical people in OIT and in OPaSS indicated that the back-end of the AERS system built by the existing software maintenance contractor was not designed properly and would not be a suitable foundation for a future system. For example, the data were not normalized and many data tables were designed using embedded information. In addition, the system is extremely complicated (much more than it needs to be) with a multiplicity of tables that were kludged together without an overall guiding data model. This probably eliminates the possibility of just putting a new front end on the existing AERS system to increase functionality, but one of the initial tasks is for an OIT/OIM working group to determine. Interviews from technical people in OIT and OPaSS indicated that what was presented by the contractor as being a

¹⁴ See the *CDER OIT/OIM Strategic Plan*, February 2003.

¹⁵ These Observations also appear as a follow-up baseline in the AERS User’s Satisfaction Survey conducted in 2005. See Appendix E for details.

¹⁶ The software maintenance contractor for this work was Booz Allen Hamilton (BAH).

well-designed relational database, became a kind of two-dimensional flat file system that produces lists of information and lacks even the analytical capabilities of an Excel spread sheet. While systems like the Data Mart, CBEAR, etc have been able to increase analytical capabilities on a user-group, by user-group basis, and while the data-mining project appears to be a more complete solution, these are expensive and time consuming work-arounds that would not have been necessary if the contractor had delivered the system described in the 1996 and 1998 AERS Requirements Documents.

- **Observation 5 (Lack of Documentation and Training):** The difficulties of back-engineering the AERS system because of a lack of documentation, pale in the light of trying to reconstruct the history of what the original specifications and system functionality were and developing up-to-date user documentation and training. This is important because it defines a) what functionality was promised but not delivered, from b) "functionality creep" where users want more and more bells and whistles after the fact - beyond the scope of the original system. The documentation on how to use the system that does exist is badly out of date and currently there is no formal training on how to use the system.
- **Observation 6 (Electronic Submissions):** Electronic submissions will increasingly become a serious problem (especially given the requirement in the recent rulemaking). Interviews suggest that the main problem with increasing the number of electronic submission from its current rate of about 25% is on FDA's end. If everyone went to electronic submissions tomorrow (let's say as a result of rule making), the IT structure at the agency could not handle it because of limitations of the gateway (data lines) into the central IT structure (mainly due to attachments). Interviews also indicated that this limiting aperture could be eliminated with about a \$200K upgrade to FDA systems. Of the \$8M per year spent on AERS, about \$6M goes to data input. One approach might be to invest the \$200K in enlarging the capacity of the gateway and encourage electronic input from submitters to radically reduce the amount of data input needed, then leverage up to \$5M out of \$6M per year by using it to pay for the design and construction of a new AERS system.¹⁷
- **Observation 7 (AERS Ownership):** Ownership of the AERS system is a problem. If everyone is responsible, then no one is responsible (see comments below for Observation 9 on IT Consolidation).
- **Observation 8 (AERS Activity):** Estimates of the "usability" of the system by users range from 60-90% depending on who was asked. What seemed clear was that the system is useable, but there are multiple work-arounds that users must do in order to make it usable (cleaning up data, depending on their memory and knowledge for heuristics and analysis, etc). Given this level of usability, all revisions might be frozen, and this time and energy could be invested in looking toward a new system.
- **Observation 9 (IT Consolidation):** The role of the IT consolidation effort within FDA needs to be taken into consideration regardless of whatever path is taken, especially if this results in a 3-5 year strategic plan. The centralization of IT/IM resources and line management responsibility to the CIO must be factored into any future AERS system.
- **Observation 10 (System Interfaces):** The possibility of interfacing with other systems inside the FDA (Drug Quality Reporting System, Clinical Trials system), and outside the FDA (AHRQ safety net, etc) needs to be seriously considered.

¹⁷ This Gateway finally became operational three years later in April 2006 with a delay cost of about \$15 million related to the cost of having to re-key data into the AERS I system.

- **Observation 11 (Identify All Users):** All users' needs and requirements must be taken into account including, safety evaluators in OPSS, biologics, medical errors, epidemiologists, compliance people, FOI, and the 15 Review Divisions. The consensus on system requirements must be part of the written documentation of the next AERS system so that the baseline of functionality and user requirements can be teased apart from the normal course of functionality creep of systems of this size.

In addition to the above observations, information gathered during the March 2003 interviews revealed that there were three Change Control Boards (CCBs) overseeing AERS, with one dedicated to electronic submissions, a second focused on data entry issues, and a third CCB related to issues effecting CDER and CBER Safety Evaluators, and over 220 outstanding CCRs - many of which were long-standing. In addition, problems that FDA users had with functionality, downtime, or peripheral parts of the system (for example batch printing) were sent directly to the BAH AERS help desk, where BAH added to or deleted from the CCR list, with little or no oversight from CDER OIT personnel.¹⁸

3.4 Conflict between OIT Managers, Working Level Technical Staff, and Contractors

Another key issue that was revealed in the exploratory interviews conducted in March 2003 was serious organizational problems within the CDER OIT organization itself. Linda Burek had only been Director of OIT for about six months and had inherited a problematic situation where the previous OIT management, OIT's technical people at the working level, and the AERS software maintenance contractor (BAH) were seriously misaligned.¹⁹ Shortly after becoming the Director of CDER's OIT in the fall of 2002, Burek undertook an internal assessment of the projects being conducted by OIT staff. On January 24, 2003 she made a presentation to OIT staff entitled, "OIT Findings" and laid out her observations about the status of what was called the Big Four effort. Some of these issues included in the slides of that presentation are included below.²⁰

- Lack of good budget and resource planning
- Insufficient resources
- Management must commit resources to projects by being realistic about workloads
- Hire additional project managers, security experts, software engineers, and database personnel
- Significant issues do not reach resolution
- No significant system success in about three years
- No clear lines of authority
- Lack of closure on management positions causing confusion
- Staff has good technical skills
- Lack of permanent project management causing confusion
- Lack of resources dedicated to systems engineering
- Lack of clarity on user requirements

¹⁸ See the overheads from Sandra Valencia's presentation at the ODP Session entitled, *Adverse Event Reporting System Configuration Control Board Process (CCB) Overview*, July 15, 2003.

¹⁹ Based on interviews with Linda Burek, Tina Hamilton, Sandra Valencia, and CCB members on March 12-13, 2003.

²⁰ The issues discussed during the March 12, 2003 interview with Burek were later documented in detail in the *Report of Findings on CDER-OIT, Tasks One through Four*, by Linda Rule, October, 2003.

From an historical perspective, these issues had plagued CDER's OIT for at least five years prior to her coming, e.g. back to the initial November 1, 1997 release of the AERS system. However, the presentation had a profoundly negative effect on the working level technical staff and project managers in OIT.

At the time of Breckenridge Institute's March 2003 exploratory interviews, Burek explained how she was attempting to address this long history of miscommunication; interpersonal conflicts; misalignment about roles, responsibilities, and authorities; missed goals and objectives; and a dysfunctional AERS system – all within a climate of interpersonal conflict, a lack of trust, and fear of retribution. This on-going conflict between OIT management and the working level technical people has manifested itself over the timeframe covered by this report as a continual turnover of AERS Project Managers. More specifically, there have been five different AERS Project Managers between 2003 and 2006, with the recent resignation of George Jett's creating a sixth vacancy.²¹ Burek was aware of the negative impact that this lack of project management continuity had had on AERS and was trying to establish a long-term direction for CDER's OIT and AERS in the *CDER OIT/OIM Strategic Plan* document, given the realignment of all IT functions under CDER's Chief Information Officer, Jim Renaldi.²²

Subsequently, in an OIT all-hands meeting on April 1, 2003 Burek announced a unilateral decision to simply *halt* all work on the Big Four effort pending a reevaluation. Although many of the people involved in the Big Four effort expressed admiration for her courage in trying to set clear direction, a number of working level technical people were devastated by the surprise announcement. As was later recounted, senior CDER management felt overwhelmingly that the way in which the project was halted was insensitive, uninformed, had seriously damaged morale, and was indicative of making snap decisions and acting on them without time for reflection and consensus building.²³ What is important to note, is that there has been a *pattern* of this type of unilateral decision-making by OIT management in regard to their staff and despite the protests of senior CDER management about AERS II and the affect of delays on the Safety Evaluators' ability to conduct effective post-marking surveillance, questions from pharmaceutical companies about the status of AERS II, and interest on the part of the Institute of Medicine in using AERS as an example of a data-driven approach to patient safety (OB 1-2006).²⁴

As noted above in Observation 3 of the exploratory interviews conducted in March 2003, one of the most problematic issues with AERS was the lack of an effective *liaison* between: a) AERS users, b) the working level technical people within OIT who functioned as AERS Project Managers, and c) the IT designers in the AERS software maintenance contractor organization. This liaison function is normally described as a business systems analyst (OB 6-2006). More specifically, working level IT professionals with computing backgrounds and end users who are Safety Evaluators have different professional paradigms and often talk past each other with different professional languages. During her March 12, 2003 interview with the Breckenridge Institute, Burek recognized this problem and described how this missing function was going to be performed by CDER's new OIM organization that was being headed by Randy Levin - also described in the *CDER OIT/OIM Strategic Plan*. The plan was for OIM to hire business analysts to "mediate" between AERS users, the OIT's AERS Project Manager, and the AERS software maintenance contractors for the development of AERS II. Our research showed no evidence for the fact that these business systems analysts were ever hired by OIM or that OIT or OIM provided this function during the AERS II requirements development

²¹ The five different AERS Project Managers were Tina Hamilton, Sandra Valencia, Tim Rigg, Kathleen Keats, and George Jett who recently left FDA.

²² See the *CDER OIT/OIM Strategic Plan*, February 2003.

²³ See *Report of Findings on CDER-OIT, Tasks One through Four*, by Linda Rule, October, 2003, p. 6.

²⁴ See <http://www.strategy-business.com/press/enewsarticle/22314>.

process. As a result, over the three-year period covered by this report AERS users were forced into a role where they repetitively listed and described IT system functionality at the application logic and data management levels in meetings, rather than simply mapping out the day-to-day work process of conducting post-marketing surveillance for drug safety.

In early 2003, Tina Hamilton was the acting OIT AERS Project Manager because the permanent OIT AERS Project Manager, Sandra Valencia, was on leave. Hamilton and Valencia were the latest in a series of AERS Project Managers to inherit AERS and their biggest challenge was finding a way to get a handle on (and fix) the methodologically flawed AERS system when the same contractor that built it still had the AERS software maintenance contract. As working level technical people, both Hamilton and Valencia were very concerned that this contractor: a) had sole possession of the vast majority of AERS information, b) had moved off of the FDA site, making them much less accessible, c) had only produced ten AERS releases between the years 1997-2003, and d) OIT management seemed unable to correct these problems.²⁵

This misalignment between OIT management, the working level technical staff in OIT who functioned as AERS Project Managers, and the AERS software maintenance contractor is an on-going *theme* that runs throughout the entire period reviewed by this report, and is a *root cause* of the delays and unnecessary costs incurred to the AERS II project. More specifically, information from interviews and written documents seem to indicate that the working level technical people in OIT have been committed to satisfying the needs of AERS users as quickly as possible and working effectively with the “business” side of FDA. It’s not clear what the objectives or goals of CDER’s OIT management have been during this time period, but the documented result of their decisions as described below have resulted in: a) a four-five year delay in the replacement of the dysfunctional AERS I system released in 1997 which has (and will continue to) negatively impact the ability of Safety Evaluators to effectively conduct post-marketing surveillance, b) the unnecessary maintenance and operating cost of about \$25 million for not replacing AERS I in FY 2005, and c) the risk of trying to develop an agency-wide adverse events reporting system without a fully functioning AERS II system as a foundation (see section entitled, *The Impact of Not Having AERS II Operational in 2005* for details).²⁶

After returning as AERS Project Manager in the summer of 2003, Sandra Valencia decided to take five steps to remedy the situation.

- First she planned to move the contractor people back onto the FDA site so they could be more accountable.
- Second, she planned to begin the process of downloading information about the AERS system from the contractor to OIT developers.²⁷
- Third, she arranged for Laura Eden (an Oracle consultant who was under contract to OIT) to back-engineer the AERS system and try to gather as much information as possible about the structure, design, and operation of the AERS system.²⁸

²⁵ As a point of comparison, between 2003-2006 there have been over 20 releases, along with substantial reduction in software maintenance costs.

²⁶ Based on interviews with Tina Hamilton, Sandra Valencia, and CCB members on March 12-13, 2003, and a subsequent interview with Laura Eden on April 18, 2006. The cost to back-engineer the system was about \$300K.

²⁷ See June 27, 2003 email from Valencia to Stone on this topic.

²⁸ Interview with Laura Eden on April 18, 2006 revealed that the AERS project personnel from Booz Allen Hamilton person refused to give her access to the forms for the AERS system, despite being directed to do

- Fourth, she had the information from the back-engineered AERS system placed into the CDER Oracle Designer/2000 Repository so it could be used as a CDER-wide resource on the structure, design, and operation of the AERS system, but subsequent analysis shows that this valuable resource was never used by any of contractors that worked on the AERS II requirements process under study in this report. More importantly, the failure to use a data repository as the basis of the process of developing detailed requirements is a *root cause* of the methodologically flawed approach used in the entire process.
- Fifth, Valencia conducted some preliminary analysis of a Commercially Off The Shelf (COTS) adverse event reporting software package that was available from Oracle and had done some initial exploration of this option.

In the August 13, 2003 OMB 300, Valencia reported that CDER's OIT staff had conducted two meetings with Oracle Representatives. The focus of the first meeting was to discuss the investment scope, while the second meeting focused on a Demo of the COTS. The estimate was based on an individual license cost of \$15,000 and \$3,000 per seat for about 500 users for a total of \$1,515,000 for a new AERS system.²⁹ Given the pressing needs of the AERS users and the existence of a fully back-engineered AERS I system in the CDER Oracle Designer/2000 Repository, Valencia viewed the Oracle AERS COTS option as the most cost-effective solution to quickly remedying the ineffectiveness of the AERS system.³⁰

3.5 Creating an Essential Tension between OPaSS and OIT

As mentioned above, user frustration with the overall ineffectiveness of the AERS system had reached an all time high when Seligman first contacted the Breckenridge Institute in February 2003. Seligman knew that the contractor that designed and built the original AERS system had submitted a "white paper" to FDA proposing that the AERS system be "consolidated" with other adverse event reporting systems across the agency.³¹ Seligman also knew that AERS was too *mission critical* to be delegated to IT professionals in CDER's OIT who lacked the clinical, pharmaceutical, and epidemiological expertise required to understand FDA's overall purpose and goals. More importantly, the lack of project management continuity for AERS on the part of CDER's OIT was of great concern, as evidenced by the continuing turnover of AERS project managers. Seligman decided to remedy these situations by bringing responsibility for OPaSS-related AERS activity within his organization – a move that was counter to FDA's culture.

His *first* step toward accomplishing this was to conduct a series of Organizational Design and Planning (ODP) meetings that began in June 2003. His *second* step was to create an organizational unit within OPaSS and direct it to give all AERS users the computing resources needed to effectively perform their jobs. Just prior to the first ODP meeting, Seligman brought Charlie Stone into OPaSS on a detail as the AERS Program Manager and tasked him: a) to assume responsibility

so by CDER OIT. This forced her to use the data repository (Oracle Designer) to try to reconstruct the forms.

²⁹ See the *OMB Exhibit 300* prepared by Sandra Valencia, August 13, 2003, p. 14. The cost estimate of \$3,000 per seat was discussed with Breckenridge Institute staff during the interviews with Tina Hamilton and Sandra Valencia.

³⁰ Almost two years later, forty percent of the vendors that proposed a total solution to the RFI issued in February 2005 included Oracle AERS as a part of their solution. They also said it would take about 30 months and over \$10 million – over twice the estimated cost identified only months earlier. See CDER Drug Safety Team, *AERS II Alternatives Analysis Report*, version 1.3, June 2005, p. 19-20.

³¹ Booz Allen Hamilton, *FDA Adverse Event Consolidation*, January 29, 2003.

for all OPaSS-related AERS activity, and b) to build an AERS Program Office.³² The new AERS Program Office within OPaSS created an “essential tension” between the programmatic and IT functions within CDER that had long been missing – the kind of interdependency and accountability that is a *signature* for how IT infrastructure is designed in high-performing organizations.³³ Seligman’s plan to make OIT *accountable* for giving AERS users what they needed to do their jobs, created a deep-seated power-struggle between OPaSS and CDER’s OIT for control of the AERS system because it meant that the IT-tail would no longer be able to wag the dog of FDA’s scientific, programmatic and business needs.

The ODP sessions that began in June 2003 were formed and operated around a written charter and involved people from OPaSS, OIT, OIM, ODS, DSRCS, DMETS, DDRE, OND, OC, CBER, CFSAN, CDRH, CVM, FOI, DRLS, FURLS, OTC and others. Linda Burek, Sandra Valencia, and other personnel from CDER’s OIT and OIM actively participated in these meetings, with Valencia making a detailed presentation on AERS at most of the five meetings. Five working groups were formed to address the issues that had plagued the AERS system since its first release in November 1997. The five working groups covered the following issues:

- Data Input
- Data Structure
- Data Queries and Retrieval
- Contract Management
- Training

There were five ODP sessions in which the issues associated with AERS and many of the requirements and missing functionality were discussed and documented.³⁴ Seligman actively participated in every session, and helped guide the new AERS Program Manager (Charlie Stone) in the direction he wanted the initiative and the AERS Program Office in OPaSS to take.

Under direction from Seligman to move forward, Stone formalized the strengths and areas for improvement that emerged from the ODP sessions into the first *OPaSS AERS Program Strategic Plan* that outlined a path forward for AERS II.³⁵ This document described how the OPaSS AERS Program Office that was newly formed by Seligman would be an organizational unit internal OPaSS that would be the “voice of the user.” As such it would *orchestrate* the needs of users and the technical support of CDER’s OIT and OIM to ensure that AERS II would enable OPaSS to operate an effective post marketing surveillance program. In the wake of the failed AERS I system, Seligman charged the OPaSS AERS Program Office with ensuring that the new AERS II be designed to serve the needs of all users.

Stone began to work closely with Sandra Valencia in OIT to improve communications between OIT and AERS users and to develop a path forward for what had become AERS II. As a follow-up to Valencia’s meeting with Oracle in August 2003, Stone and Valencia attended a second meeting in September with representatives of Oracle who offered to conduct a pilot program with an AERS COTS package that would take four weeks to conduct and would include a requirements analysis, a database migration, and ten pilot user licenses for a cost of \$84,000. As a result, CDER’s OIT recommended this approach as a path forward for AERS II in the August 2003 OMB Exhibit 300

³² A preliminary outline of what the new AERS Program Office organizational structure would look like is found in the first *AERS Program Strategic Plan* document issued in December 2003.

³³ The Clinger-Cohen Act of 1996 requires federal agencies to follow corporate America’s best practices for managing IT, see Alan Holmes, “Federal IT Flunks Out” in, *CIO Magazine*, May 15, 2006.

³⁴ The June 24-25, 2003, July 15-16, 2003, August 5-6, 2003, September 15-17, 2003, December 2003.

³⁵ See the *CDER OPaSS AERS Program Strategic Plan (FY 2003-2008)*, issued on December 9, 2003.

prepared by Sandra Valencia and CDER's OIT began the process of planning a formal alternatives analysis for the new AERS II system.³⁶

What is important to note is that the information produced by the back engineering of the AERS system that was (and still is) stored in CDER's Oracle Designer Case tool was more than sufficient to have AERS II up and running in FY 2004. More specifically, the information about AERS that OIT possessed since October of 2003 included:

- A Requirements Document Updated by the Back Engineering of the Oracle Designer CASE Tool and a Strategy/Vision Document³⁷
- Entity Relationship Models and Definitions
- Physical Data Model and Definitions
- Module Definitions (for screens, XML, C++, JAVA, Webscreens, etc)
- Requirements Traceability

The above list of information would have been sufficient to enable CDER's OIT to: a) conduct a gap/fit analysis between AERS and COTS products like Oracle AERS to determine how well they map to the FDA Technical Reference Model, b) define the degree of customization of a COTS package, c) determine the degree to which a COTS fits with the overall Application Architecture of the agency, e.g. Net, J2EE, d) define whether a COTS is 2-tier, n-tier and whether it supported the overall architecture objectives of the agency, including moving to Service Oriented Architecture (SOA), e) define the extent to which a COTS supported a concept of services that fit within the overall FDA architecture, f) develop a work break down structure for actually customizing the COTS, data migration, and initializing the new system and finally g) providing the basis for developing a firm fixed price contract for the new AERS system.³⁸

In other words, the AERS II system that was envisioned during the ODP sessions and was subsequently recommended by Valencia in the August 2003 OMB Exhibit 300 could have been in operation and being used by FDA personnel sometime in FY 2005 had OIT management accepted the recommendations of the AERS Project Manager and Paul Seligman and Charlie Stone in OPaSS. As a result of decisions by CDER's OIT, the AERS users in CDER, CBER and other organizational units throughout the FDA have been forced to use the dysfunctional AERS I system for more than 10 years which has frustrated and undermined their ability to perform their jobs effectively as identified in the 2005 Users Satisfaction Survey found in Appendix E (OB 11-2006). The additional 4-5 year delay caused by the AERS II requirements process being unnecessarily repeated have perpetuated and exacerbated the functionality problems identified in the AERS User Satisfaction Survey conducted in 2005.

3.6 The AERS Project Manager Is Unilaterally Reassigned

From April 21 through June 17, 2003 Linda Rule continued to conduct interviews with over 30 OIT employees about the halting of the Big Four effort, and her final report was issued in October

³⁶ See *OMB Exhibit 300*, August 13, 2004, completed by Sandra Valencia, p. 14. Tim Rigg took over for Valencia as AERS Project Manager in November 2003.

³⁷ See Booze-Allen & Hamilton, *The Adverse Event Reporting System (AERS) Draft Version 2*, Contract No: 223-97-5513, August 14, 1998, October 7, 2003 revision.

³⁸ The notion of "agility" (the ability to change IT quickly to fit business needs) and the latest strategy for doing this called Service Oriented Architecture (SOA) is described in, Christopher Koch, "The Truth about SOA" in, *CIO Magazine*, June 15, 2006, volume 19, number 17, p. 49-60. The key to SOA is to mirror chunks of business processes in modules of technology that can be mixed and matched to create automated business processes.

2003.³⁹ The view of the OIT staff described in her report was that OIT management could not be relied upon to review issues factually and make decisions based on objective technical criteria and user needs. Rather, decisions were made in a forum called *Senior Staff* without the input of working level technical people, organizations like OPaSS, or AERS users. Staff indicated that OIT management made decisions in a vacuum based on personality and favoritism, rather than with an openness to new ideas, new technologies, listening to the advice of OIT's technical people, or the voice of users in OPaSS and across the agency. When "action" meetings were held within OIT, no minutes were kept or distributed, and every participant came away with a different view of what had happened, and then proceeded to act based on their own views of what they thought had been decided.

The report by Linda Rule also stated that OIT staff viewed OIT management as trying to create the *perception* that they required high standards of performance and held people accountable when "dealing up" to senior CDER management. But in terms of "managing down" within the OIT organization, staff viewed OIT management as arrogant, making constant references to the "absolute trust and freedom" granted them by senior CDER management to do as *they* saw fit regarding CDER-related IT decisions.⁴⁰ From the perspective of many of the thirty-three people who were interviewed by Rule, OIT management acted as if they had a "license" to run over the Staff's ideas and needs as well as the ideas and needs of the end users of CDER's IT systems. More specifically, interviews with senior CDER managers like Seligman, CCB members, Safety Evaluators, and other FDA scientists revealed that when Burek and Burnette were questioned about the negative impacts on users of a unilateral decision they had made, the "business" side was told, "Just trust us – this is a 'technical' matter. We're the IT experts."

This pattern of creating the *perception* that OIT was working closely with senior CDER management and AERS users while acting *unilaterally* without building consensus with: a) OIT staff like Valencia, b) AERS users and the CCBs, c) OPaSS' AERS Program Manager (Charlie Stone), or even d) senior CDER management is a root cause of the four-five year delay in AERS II and unnecessary costs totaling \$25 million (see section entitled, *Financial Impact and Value-Added of OIT Activities Post-July 2004* for details (OB 10-2006).

Margo Burnette joined the FDA as Deputy Director of CDER's OIT on August 11, 2003 at a time when the AERS II project was making great progress and was in the final stages of obtaining the AERS II system.⁴¹ A fully back-engineered AERS I system existed in the CDER Oracle Designer/2000 Repository, the Oracle AERS COTS option had been proposed as a cost-effective solution to quickly remedying the ineffectiveness of the AERS I system, and Sandra Valencia was planning on conducting an alternatives analysis. Consequently, Seligman and Stone were seriously concerned that the project would lose momentum when OIT management suddenly announced in September 2003 that Sandra Valencia was going to be "reassigned" to another project.

Seligman and Stone questioned Burek's and Burnette's decision to reassign Valencia given the fact that OIT was ready to move forward on AERS II, with the final step being the completion of an alternatives analysis. But OIT management assured Seligman and Stone that the project would stay on track because Valencia would remain involved at some reduced level until October 31, 2003 and Tim Rigg would be acting AERS Project Manager until Valencia's replacement, Kathleen Keats, arrived in December of that year. OIT management assured Seligman and Stone that one of Keats'

³⁹ See *Report of Findings on CDER-OIT, Tasks One through Four*, by Linda Rule, October, 2003, p. 11-13 and 20-21.

⁴⁰ See *Report of Findings on CDER-OIT, Tasks One through Four*, by Linda Rule, October, 2003, p. 24.

⁴¹ Burnette's prior position was as a network administrator for the State of Maryland where she worked with Linda Burek who was formerly the CIO of the State of Maryland.

first tasks would be to conduct the alternatives analysis so that AERS II would not be delayed. As follow-up to these discussions Burek emailed a draft DHHS policy on alternatives analysis to Stone that stated that it was not necessary to spend a lot of time gathering detailed requirements prior to conducting an alternative analysis.⁴²

Given the pressing needs of the AERS users, the existence of a fully back-engineered AERS I system in the CDER Oracle Designer/2000 Repository, and OIT's endorsement of the Oracle AERS COTS option in the August 13, 2003 OMB Exhibit 300 as the most cost-effective solution to quickly remedying the ineffectiveness of the AERS system, Keats informed Stone in an email in January 2004 that all she needed to proceed with the alternatives analysis was a set of high-level requirements. It appears that no one in CDER's OIT organization informed Keats or Stone that the information produced by back engineering the AERS system six months earlier would have been more than sufficient to conduct an alternatives analysis of various COTS, and then purchase the new AERS II system. Had they known about the existence of a complete set of requirements for the AERS I system, they could have proceeded down the path of obtaining an AERS II system even more quickly.

This lack of communication about valuable information that FDA had purchased at a cost of \$300,000 was symptomatic of the deeply troubled situation within the OIT organization where the left-hand did not know what the right hand was doing. So in the absence of this information, two months later on March 12, 2004 Stone delivered a high-level requirements document to Keats. Our analysis shows that the set of requirements produced by Stone was taken from the AERS I 1996 Detailed Requirements document and the RTM that he requested in 2003 and was more than enough information to conduct an alternatives analysis because it contained all (100%) of the requirements listed in the AERS I Detailed Requirement Document and new user requirements contained in the 2003 Requirements Traceability Matrix.

The AERS II proposal was *reviewed and approved* by Linda Burek, Margo Burnette and the CDER IMSC on March 26, 2004. With the IMSC approval in hand, Keats began the alternatives analysis and stated in the March 2004 OMB Exhibit 300 that although detailed requirements would have to be developed, that the requirements found in Stone's March 2004 document were sufficient to evaluate COTS packages like Oracle AERS as viable alternatives for AERS II. The OMB Exhibit also stated that given all the progress made, that *the new AERS II system would probably be up and running in FY2005*.⁴³ Keats also noted in the OMB 300 that despite the fact that there was a lack of *new* funding for AERS II, that the system could be brought on-line using the cost savings from the AERS maintenance contract, plus savings from reducing the cost of AERS I data entry. More specifically, the OPaSS AERS Program Office had instituted improvements and efficiencies that: a) reduced the AERS maintenance contract from \$2.5 to \$1.9 million per year, then ultimately to \$1.2 million per year, plus b) AERS II would reduce the cost of data entry by another \$500K per year. This was more than enough to have AERS II up and running in FY 2005 as was indicated two years earlier in Observation 6 of the initial report developed by the Breckenridge Institute staff.

OIT's Kathleen Keats arranged a presentation by Oracle on May 4, 2004 so users could make a preliminary evaluation about whether the functionality provided by a COTS product like Oracle AERS was worthwhile pursuing from the perspective of AERS users. The following people attended the presentation:

- Charlie Stone (OPaSS)
- Kathleen Keats (CDER OIT)

⁴² See the *HHS IRM Policy for Conducting Information Technology Alternatives Analysis*, HHS-IRM-2003-0002.002, October, 2003.

⁴³ See *OMB Exhibit 300*, March 24, 2004, completed by Kathleen Keats, p. 16-17.

- Tina Hamilton (CDER OIT)
- Toni Piazza-Hepp (DSRCS)
- Min Chen (DDRE)
- Jim Wilson
- Lynette Swartz (DMETS-IT)
- Charlene Flowers (DDRE)
- Ann Gaines (CBER)
- Jerry Yokoyama (CDER OIT)
- Krishna Chary
- Tim Rigg (CDER OIT)
- Lise Stevens (CBER)
- Roger Goetsch (DSRCS)
- Kathleen Farhart-Sabet (DMETS-IT)
- Andrea Feight (OPaSS)
- Carol Krueger (OC)
- Sarah Singer (DDRE)
- Harold Stepper (OC)

Because it was an initial demonstration, AERS users who attended were instructed not to reveal their requirements to Oracle, so as not to give them an unfair advantage. The general consensus of the attendees was that the Oracle AERS product would meet almost all of the AERS users' needs. As a follow-up to the meeting, Oracle sent a proposal to Charlie Stone on July 12, 2004 to conduct an Oracle AERS Pilot that would answer any lingering questions that the Safety Evaluators had about whether the Oracle AERS product was a viable alternative to AERS I and would provide functionality they were missing. The five phase pilot program would include: a) requirements gathering and scope definition, b) setup of initial AERS pilot instance, c) design and setup of data capture of final AERS pilot instance, d) user training and implementation of pilot, and e) complete documentation. The total cost of the pilot program with Oracle's 80% DHHS-wide discount was about \$85,000.⁴⁴ As a follow on to the pilot, Oracle gave Stone a fixed-price proposal that would turn the Oracle AERS COTS package into a fully functioning AERS II system for \$4.5 million. As a final step, Kathleen Keats completed the AERS II alternatives analysis on June 3, 2004.

The AERS II system had past one of the last hurdles and was on its way to becoming a reality. But over the next few months, a complicated series of events and *unilateral* decisions on the part of OIT management would: a) *slow down* and ultimately *shelve* the AERS II project, b) change the project scope from replacing the dysfunctional AERS system to an agency-wide adverse event reporting system championed by Margo Burnette and the Bioinformatics Board (BIB), and c) create the perception that this radical change of project scope would have little or no negative impact on AERS users in CDER and across the agency (OB 1-2006).

- On April 30, 2004 Linda Burek became the Director of CDER's Office of Information Management (OIM) and Margo Burnette became the Director of CDER's OIT.
- On June 30, Burnette began to champion the idea of a consolidated, FDA-wide adverse event reporting system (FAERS) like the one proposed by BAH in a white paper they issued in January 2003.⁴⁵

⁴⁴ For details on Oracle's 80% discount to Federal agencies see, John More, *Feds Get Smart with Oracle*, April 26, 2005, (<http://www.fcw.com/article88699-04-26-05-Web>).

⁴⁵ Booz Allen Hamilton, *FDA Adverse Event Consolidation*, January 29, 2003.

- Originally systems such as AERS had their own OMB Exhibit 300, but these documents started to be combined into more and more generic packages of budget and work (from AERS, to Drug Safety, to Post-Marketing, etc.) with the result that it became increasingly difficult to identify the exact budget allocation for a system like AERS II, which gave OIT much less accountability and traceability for how money was spent or “reprogrammed.”
- The OMB Exhibit 300 issued on July 6, 2004 with Burnette as the new Director of OIT stated that the AERS system would not be replaced until 2007 - two full years later than the date Keats recorded just three months earlier in the March 2004 OMB Exhibit 300. The only explanation given was that OIT had conducted a market research study that had showed that there were several other AERS COTS packages on the market other than the Oracle AERS package and that these packages would be investigated. This decision was not based on changes in user needs.
- Seligman’s July 30, 2004 email to Steven Galson and Douglas Throckmorton about Stone’s AERS II meeting with Jim Rinaldi (CDER’s CIO), Ray Russo, and Don Lipkey in Business Process Planning Office (BPP), and Rinaldi’s interest in using the AERS II, Oracle AERS system as a basis for the next generation of FDA-wide adverse events reporting system (FAERS) and his willingness to present this concept to FDA’s management council indicates gathering support for an agency-wide system at the very highest levels of FDA. This was the beginning of the change in project scope from replacing AERS I to building an Agency-wide adverse event reporting system.

As mentioned previously, these actions have resulted in: a) a four-five year delay in the replacement of the dysfunctional AERS I system released in 1997 which has (and will continue to) negatively impact the ability of Safety Evaluators to effectively conduct Drug Safety surveillance, b) the unnecessary maintenance and operating cost of about \$25 million for not replacing AERS I in FY 2005, and c) the risk of trying to develop an agency-wide adverse events reporting system without a fully functioning AERS II system as a foundation (see section entitled, *The Impact of Not Having AERS II Operational in 2005* for details).

3.7 The Turning Point for AERS II Despite the Protest of OPaSS

Seligman, Stone, and the community of AERS users were shocked when AERS II took a sudden change in direction under Burnette’s leadership as she *unilaterally* informed them that they would have to begin the process of gathering requirements and conducting an alternatives analysis *all over again* (OB 1-2006). More specifically, OIT would: a) produce yet another high-requirements document, b) conduct a second alternatives analysis, c) issue a Request for Information (RFI), and d) produce another set of detailed requirements. These activities would cost \$778,769 and not be completed until April 2006 - almost two years later.⁴⁶ Other than having conducted a market research study that identified potential COTS packages other than the Oracle AERS system, OIT management gave no reason for this abrupt change in direction. Not only were there no changes in user requirements that would have necessitated this change, OIT had more than enough information to evaluate these other COTS packages and/or COTS integration solutions for AERS without going through another requirements gathering process, including the ability to:

- Conduct a gap/fit analysis between AERS and the newly identified COTS products to determine how well they map to the FDA Technical Reference Model.
- Define the degree of customization of a given COTS package, e.g. 20%, 50% or more

⁴⁶ See *OMB Exhibit 300*, July 6, 2004, completed by Kathleen Keats, p. 16.

- Determine the degree to which a given COTS package fit with the overall Application Architecture of the agency, e.g. Net, J2EE
- Define whether a given COTS package is 2-tier, n-tier and whether it supported the overall architecture objectives of the agency, including moving to Service Orientated Architecture (SOA)
- Define the extent to which a given COTS package supported a concept of services that fit within the overall FDA architecture
- Develop a work break down structure for actually customizing a given COTS package, data migration, and initializing the new system and finally
- Providing the basis for developing a firm fixed price contract for the new AERS system

In an email dated August 26, 2004, Stone and Seligman told OIT management that OPaSS and the broader community of AERS users across FDA *could not wait* two more years and spend almost \$800,000 to repeat the process they had just completed because OIT already had all the information they needed to move ahead on AERS II. The email also noted that the Oracle proposal of \$85,000 to conduct the pilot program within four weeks looked a lot better than the prospect of slowing down the AERS II project by more than two years. Stone also reminded Burnette that he had a written fixed price from Oracle for the entire AERS II with a total cost of \$4.5 million. Seligman questioned the value-added of what she had decided and instead wanted to leverage the existing documentation and have the final requirements completed prior to the Presidential election and they specifically asked OIT not to obligate any funds or move forward on this plan. Those funds were obligated despite the objections of Seligman and Stone.

On August 27, 2004 Burnette replied to Stone in an email stating, "Oracle is selling you a bill of goods – it's called low-balling." She also reminded Stone, Seligman, and the AERS users that, "As you well know, the business side of FDA isn't to be building IT systems."⁴⁷ But given the time delays and unnecessary costs incurred over the course of the next two years it would become clear that it was OIT that was selling OPaSS and the AERS users "a bill of goods" about how long it would take to replace the dysfunctional AERS I system while telling them - "Just trust us – this is a 'technical' matter. We're the IT experts" (OB 1-2006).

The September 2004 OMB Exhibit 300 issued by CDER's OIT stated that OIT was now going to conduct a "technical" alternatives analysis and consequently that AERS II had been pushed off until 2007. Given the fact that there had been no changes or additions to the AERS user requirements, this was a serious departure from what Kathleen Keats had recorded in the OMB Exhibit 300 just a few months earlier. To the surprise of Stone and Seligman, Kathleen Keats left OIT in September 2004 after staying only nine months and George Jett became the next AERS II Project Manager on October 18, 2004. The new HL-Requirements Document started after Keats' departure was delivered to OIT on December 15, 2004 at a cost of \$169,910.⁴⁸ As discussed in the section of this report entitled, *Use of Appropriate IT Methodology*, analysis of this document revealed that it only partially followed appropriate IT methodology and the resulting document actually contains *less* "technical" information about AERS user requirements than the baseline that existed in July 2004.

OIT published a Request for Information (RFI) about the AERS II system in February 2005 using a base of user requirements that included the 1996 and 1998 AERS Requirements Documents developed by BAH; the 2003 RTM requested by Stone and two later versions of the RTM; and the High-Level Requirements Document that was completed in June 2005 by ISSA at a cost of \$210,000.⁴⁹ There were 43 responses and the top eleven stated that it would take 24-30 months

⁴⁷ See August 27, 2004 e-mail from Burnette to Stone.

⁴⁸ See *FDA CDER Adverse Event Reporting System II (AERS II) High Level Requirements (HLR)*, Version 1.03, by ISSA, December 15, 2004.

⁴⁹ See *Request for Information, OSS/OAGS/DSCI/ITCT RFI Number: FDA2005-001*, February 2005.

from this time and cost between 5-10 million dollars.⁵⁰ George Jett's presentation on the Alternatives Analysis states, "It can now be stated that the AERS II development effort should be a COTS integration effort. While it is possible that a significant portion of the AERS core functionality can be supplied by a COTS Adverse Events product, other major functionality must be supplied by other best-of-breed COTS products."⁵¹

But it is important to note that this change in direction means that new information should have emerged as part of the HL-Requirements and RFI processes, because in George Jett's summary presentation on the Alternatives Analysis presented on August 4, 2005 he stated that the *user requirements could not be satisfied* by a single COTS package so consequently AERS II would require a systems integrator or software developer to oversee a COTS integration process.⁵² This was a very different conclusion than OIT's Sandra Valencia and Kathleen Keats and OPaSS' Charlie Stone had reached only a few months earlier following the June 2004 completion of Keats' alternatives analysis. In fact, the Breckenridge Institute's evaluation of the HL-Requirements Document indicates that the level of detail of the AERS user requirements included in the December 2004 HL-Requirements Document is *substantially less* than the level of detail of the requirements used to complete Keats' June 2004 alternatives analysis (OB 2-2006). This indicates OIT's decision to change directions on AERS II must have been predicated on something other than changes in AERS user requirements or other technical details (see section entitled, *Use of Appropriate IT Methodology*).

More specifically, the following things remain unchanged from Keats' alternatives analysis following the issuance of the HL-Requirements, RFI results, and OIT's conclusions about the alternatives analysis. *First*, as described above, a gap/fit analysis would have had to been conducted on any COTS package or COTS integration package to identify the percent of customization because it's almost never the case that a COTS fully satisfies user needs. *Second*, the user requirements remained unchanged and our analysis shows that there is a many-to-one relationship where multiple requirements were rolled up into a single high-level summary requirement that provided *substantially less* information about AERS user requirements than the body of requirements used by Keats. In fact, even things like moving away from a client server approach toward a web application for AERS II and interfacing with other FDA and government-wide systems were included in the requirements used by Keats and the Strategic Plan developed by Stone in 2003. *Third*, Oracle was still the accepted FDA standard in terms of computing applications and 80% of the respondents to the RFI specified that they would use Oracle products, with a number specifying that they would use Oracle AERS (OB 2-2006).

What does appear to have changed is the following:

- Who was leading the effort, e.g. the "essential tension" that Seligman had established between CDER's OIT and AERS users in OPaSS and across the agency was dismantled
- A technological shift towards a Service-Oriented-Architecture (SOA) that: a) *was not* driven by user requirements, and b) was unilaterally decided in the absence of the detailed CDER-CBER business process mappings needed to create the components of an SOA architecture.⁵³

⁵⁰ See CDER Drug Safety Team, *AERS II Alternatives Analysis Report*, version 1.3, June 2005

⁵¹ See *FDA Adverse Events Reporting System (AERS) II Alternatives Analysis Report*, Version 1.3, June, 2005, p. 3

⁵² See George Jett's presentation, *Adverse Events Reporting System (AERS) II Alternative Analysis Report*, August 4, 2005.

⁵³ The notion of "agility" (the ability to change IT quickly to fit business needs) and the latest strategy for doing this called Service Oriented Architecture (SOA) is described in, Christopher Koch, "The Truth about

- A radical shift in project scope from replacing the dysfunctional AERS I system to an agency-wide adverse event reporting systems that would take on a number of different names, e.g. FAERS, MedWatch Plus, etc.

3.8 The 2005 AERS Users Satisfaction Survey

Had OIT management moved forward on the plan developed by Keats and Stone, the AERS II system would have probably been up and running by the fall of 2005. Instead, the AERS II system was far from even beginning and AERS users were more unhappy than ever about the dysfunctional AERS I system, as evidenced in the June 2005 users survey – summarized below. Using the 11 Observations for Improvement identified in the 2003 interviews as a baseline, users were asked to evaluate performance of AERS related activities over the last 18 months (see Appendix E for the complete result of the AERS Users Survey).

- *Project Management:* BAH is no longer the contractor and interviews and other data show that the current contractor (SAIC/PSI) is doing a great job. In addition, the AERS Program Office is doing an excellent job providing oversight for all contractors working on the AERS Program by holding them to task and closely monitoring the number of tasks being completed and the contractor's performance on those tasks. The three CCBs have been combined into a single, more effective entity, the number of outstanding CCRs has been substantially reduced, CCRs for organizations such as DMETS and CBER that were outstanding for years have been completed, and the number of CCRs addressed per new release of AERS I has increased dramatically.
- *Communication:* Interviews and other data indicate that the AERS Program Office has effectively filled the role of liaison (business systems analyst) between CDER's OIT/OIM organizations and the spectrum of users in OPaSS, CBER and throughout the Agency. The level, kind, frequency, and quality of communication provided to AERS I users about the system has improved substantially over the last 18 months.
- *AERS Ownership:* Prior to Seligman's establishment of the AERS Program Office, organizational responsibility for the AERS I system was unclear. According to Seligman and AERS users, the AERS Program Office owns and is responsible for the effective operation of the AERS Program. But this is increasingly difficult because the AERS Program Office has the *responsibility* for effectively running the program, without the funding *authority* needed to make this happen.
- *Identify All AERS Users:* Over the last 18 months, the AERS Program Office has systematically included and tried to meet the needs of all AERS users including other safety evaluators in OPaSS (DMETS), CBER, epidemiologists, Office of Compliance, FOI, and the Review Divisions in the Office of New Drugs (OND).

The data from the AERS User's Satisfaction Survey also showed the following issues remain extremely problematic.

- *Poor System Design:* Seligman and the AERS Program Office have made a conscious decision not to invest resources in fixing problems in AERS I that would be fixed by AERS II and instead spent their time and resources trying to get AERS II into production.

SOA" in *CIO Magazine*, June 15, 2006, volume 19, number 17, p. 49-60. The key to SOA is to mirror chunks of business processes in modules of technology that can be mixed and matched to create automated business processes.

Interviews with AERS users indicated, that if the AERS II system is substantially delayed, resources *must* be dedicated to increasing the functionality of the AERS I system. Analysis showed that AERS I users spent on average about 3/4 of an hour per day on AERS I-related inefficiencies, with some users spending as much as four hours per day on such inefficiencies. For the 75 users who participated in the survey, spending 3/4 of an hour per day amounted to about \$700,000 per year in lost salary and is the equivalent of about 6 FTEs (see Appendix E for details).

- *Lack of Documentation and Training:* The documentation and User's Manual for the AERS I system that exists is badly out of date and was originally written in 1999, with none of the system upgrades or enhancements up through 2005 being included in this 1999 version. In addition, there was no regularly offered formal training on how to use the AERS system provided to existing or even new users. Increased change in AERS I and employee turnover among Safety Evaluators has made the training and documentation problems worse over the last 18 months.
- *Electronic Submissions:* This issue was scheduled to be completed as part of the AERS II process as listed in the AERS Program Office Strategic Plan but had not been acted upon as of June 2005 (Note: This was actually completed in April 2006).
- *IT Consolidation:* The "essential tension" consciously established by Seligman when he established the AERS Program Office placed OPaSS in direct conflict with CDER's OIT because OPaSS has the *responsibility* for effectively running the AERS program, without the funding *authority* needed to make this happen. For example, in May 2005 CDER's OIT informed the AERS Program Manager that AERS I would have to take a 25% cut in funding. What is most problematic was that the Director of OIT (Burnette) knew about this reduction in funding since January 2005, but failed to inform the AERS Program Manager until five months later when options for dealing with the cut were far fewer.
- *System Interfaces:* The need for interfacing with other systems inside the FDA (Drug Quality Reporting System, Clinical Trials system), and outside the FDA (AHRQ safety net, etc) was slated for completion as part of the AERS II process but had not been addressed at the time of the survey.

3.9 OIT Unilaterally Sets IT Direction Despite the Protests of AERS Users

In an email to Seligman on June 16, 2005, Burnette described how she and representatives from the CIO's Office and IT representatives from CBER, ORA, and CFSAN had met on the FAERS project and had decided to initiate the FAERS project as a formal Agency-wide project, with the first phase being AERS II. The group had also agreed that CDER's OIT and BPP group, not the AERS Program Office in OPaSS, would lead the initiative.⁵⁴ In effect the "essential tension" that Seligman had created with the AERS Program Office to make OIT accountable to AERS users would no longer exist and the liaison (business systems analyst) function that Stone had provided would erode, as technically oriented OIT staff and consultants would once again interact directly with AERS users. Burnette's email was to inform Seligman about this unilateral decision and to ask him for his support and concurrence in dismantling what he had created in OPaSS (OB 1-2006). In addition, other senior level FDA managers like Janet Woodcock and Steven Galson also gave their support and concurrence to the FAERS project with the stipulation that it did not negatively impact AERS II and/or CDER – a condition to which Burnette agreed.

⁵⁴ See June 16, 2005 e-mail from Burnette to Seligman.

On November 22, 2005, FEDSIM announced that BAH had been awarded the AERS II Detailed Requirements (SRS) contract at a price of \$389,000 and two weeks later on December 8, 2005 Burnette began a 120 day detail to CDER's BPP group, with Jim Shugars becoming acting Director of CDER's OIT. It is important to note that the pattern of *unilateral* decision-making on the part of OIT management described by Linda Rule's Report continued even after Burnette joined the BPP group and Jim Shugars became acting Director of CDER's OIT. More specifically, interviews and evidence from documents and emails indicate a pattern of Burnette and OIT: a) *telling* senior FDA and CDER management that the FAERS project would not negatively impact AERS II or AERS users, but b) making decisions that in fact resulted in a negative impact on the timely replacement of the dysfunctional AERS I system and the ability of AERS II users to adequately do their jobs of protecting the public health.

For example, during a FAERS meeting in December 2005, FDA's Deputy Commissioner Janet Woodcock began to question why BAH had been hired to do the Detailed Requirements Document for AERS II given their track record on AERS I – a project that was done while she was Center Director of the CDER. Woodcock specifically asked that *BAH make a presentation to her* and the FAERS Executive Committee describing their current strategy for developing the detailed requirements, and to specifically describe what they were going to do differently now than they did for AERS I. The presentation by BAH was never given because of unilateral decision-making on the part of CDER's OIT, now led by Jim Shugars (OB 1-2006).

- First, on January 10, 2006 Stone sent an email to George Jett and Tim Rigg informing them that the FAERS Executive Committee, and Janet Woodcock in particular, wanted BAH to make a 20 minute presentation on January 18, 2006 covering: a) their approach to data gathering and documenting the detailed requirements for AERS II, and b) what they plan on doing differently this time.
- Second, on January 12, 2006, Burnette sent an email to Jim Shugars, Tim Rigg, Tim Mahoney, and George Jett stating, "I've talked with some of you individually, but (if time permits) it would be good for us to talk together so that OIT CDER and BAH can be best prepared to present how the AERS II requirements are being done. The underlying purpose behind Dr. Woodcock's request is that the Executive Committee has a degree of distrust in BAH. You will be able to show (1) you made a valid selection, and (2) what is different this time in the methodology, structure and management involved.
- Third, on January 12, 2006, Mahoney sent an email to Rigg, Jett, and Shugars stating, "Tim/George, I don't think BAH should be giving a presentation; it should be us (OIT-CDER). I think we should propose to Charlie that he recommend a presentation like this..."
- Fourth, on January 13, 2006, Shugars sent an email to Mahoney, Rigg, and Jett stating, "I agree also. Tim R – can you grease the skids with the committee? We should have a quick dry run before the brief."

Woodcock never got what she asked for, but instead, Margo Burnette, George Jett and Tim Rigg from OIT gave the presentation on February 15, 2006 and defended their decision to hire BAH once again. They also reiterated to Woodcock and what had become the MedWatch Plus Executive Committee (formerly FAERS) that the newly expanded scope of the FAERS project *would have no negative impact on AERS II or CDER*.

Consequently, Stone and Seligman were shocked to learn on February 23, 2006 that the AERS II project schedule had gone from green to yellow on the CDER OIT status report, where a "green" status meant that the project was on track, and a "yellow" status means that there are definite

concerns about funding, cost, and schedule (OB 1-2006). In response to Stone's inquiry about the change to yellow status, George Jett replied in his February 24, 2006 email,

"Actually Charlie I'm the one who changed the status for the schedule from green to yellow. This is a report coming from OIT-CDER and my opinion is that this report was intended to convey risks as we perceive them. I feel that by changing this schedule area to yellow it shows that the AERS II schedule *will be* impacted by a change in scope to accommodate MedWatch Plus. In all of the discussions we've had about expanding the scope I have always taken the position that scope change would, in fact, impact our plans. The schedule, contract and cost will change. So to me this is a risk to the current AERS II project schedule. This status change was vetted through the OIT-CDER management chain.

"With respect to cost we collectively (OIT-CDER) decided to change the status to yellow. This is intended to reflect the simple fact that it's almost March and there is still no FY06 budget for AERS II development. I've already lost a team member and am in danger of losing another in a week or so. Also, not knowing if there will be enough funds to move into the next phase represents a huge risk to the schedule. Actually when I think about it I believe I could make a case for the cost area being red, but at the very least it seems to me that this area should be yellow. Others in OIT-CDER agree."

Where had the funding for AERS II gone and why hadn't Stone and the AERS users been consulted about it? Who reprogrammed the money and to where had it been moved? These are questions that could not be determined within the scope of our study but need to be further explored (OB 1-2006).

The gathering of the detailed requirements had been underway since November 2005, and representatives from OIT and BAH had formed five working groups for AERS users to participate in:

- Data Input
- Dictionaries
- Interfaces
- Security
- User Needs

As the Safety Evaluators and other users participated in meeting after meeting with the CDER OIT staff and BAH contractors, the AERS users became more and more frustrated and eventually called an emergency meeting of the largest user group (User Needs) on February 21, 2006. The following is a summary of the major concerns expressed by AERS users that were captured in an email by AERS Program Office personnel.

- The contractor and OIT are not prepared; they don't understand our needs.
- We spend ours completing tables; to what end?
- The contractor and OIT should help us better understand features available in other AE system
- The contractor and OIT should use the existing AERS requirements, AERS II high level requirements, list of CCRs, and ODP session notes as a baseline (those that existed as of July 2004)
- We are very uncomfortable with the process of one contractor gathering requirements, and another contractor doing design and build

- The process of splitting the project into requirements and design/build means we will need to spend more time to train the next contractor
- We want to see other AE products so we know what is already available to other and to help stimulate better ways of doing our jobs
- What happens between the draft copy on March 21, 2006 and the final document on April 12, 2006?
- What happens if the final detailed requirements document delivered on April 12, 2006 is unsatisfactory? Who fixes? Will it cost more? Who pays?
- Why don't we have representatives from FOI; why don't we have Medical Officers and Epidemiologists attending? What about their requirements?

The AERS users suggested that OIT *stop work* on the requirements gathering process until they could be sure that the process would be done correctly, but OIT seemed to ignore their request. Had the AERS II process gone forward in July 2004 rather than being delayed by OIT management, the AERS II system would have been up and running for six months to a year.

Oblivious to the needs of AERS users to replace the dysfunctional AERS I system, Burnette and the Business Process Planning group continued pushing toward the new project scope of building an FDA-wide system and contracted with IBM to conduct a high-level business process analysis. Given the scale and complexity of FDA and its Centers, and the fact that the scope of the IBM project was only \$43,000, it's unclear what BPP was expecting to accomplish with this project other than to create more support for accelerating the FDA-wide system at the expense of an AERS I replacement by revealing the obvious, e.g. that there was a large degree of commonality of processes across the agency in the areas listed below.

- Developing instructions and guidance for adverse event reporter use
- Methods for collecting adverse event information (i.e., phone, fax, mail)
- Activities for registering a received adverse event (i.e., logging, sorting)
- Data Entry
- Identifying importance to address adverse event, typically termed "Triage"
- Steps for coding
- Quality control (data entry, coding, other handling)
- Conducting archiving (paper and electronic)
- Privacy Act Redaction
- Reviewer Notification
- Obtaining additional information, typically termed "Follow-up"

The IBM study in combination with an increasing pressure for an agency-wide adverse events reporting system propelled the MedWatch Plus project to the forefront and increasingly slowed the AERS II project. In an email dated March 13, 2006, Burnette transmitted a copy of the draft Addendum to the AERS II Boundary Document that incorporated FDA-wide needs to Paul Seligman, Charlie Stone, Tim Rigg, Tim Mahoney Jim Shugars, Mary Ann Slack, Don Lipkey, Malcolm Bertoni, and Nancy Stanisic.⁵⁵ Burnette stated that CDER's OIT was preparing a high level analysis of the impact that these changes would have on the CDER/CBER AERS II initiative, when in fact OIT already knew the extent of the negative impact as would be indicated by George Jett's changing of the AERS II status from green to yellow.

⁵⁵ See Addendum AERS II Boundary Document, March 13, 2006.

In her March 15, 2006 email to Seligman, Burnette stated that the MedWatch Plus Executive Committee had reviewed the proposed addendum to the AERS II Boundary Document and had agreed on it subject to two key points:

- Janet Woodcock stated and it was agreed/endorsed by all that any changes to AERS II scope to include agency-wide functions *could not negatively impact CDER*
- It was unanimously accepted that additional functionality would be phased in

This was another example of the pattern of *saying* that there would be no negative impact on AERS users or CDER, when in fact the project was (and would continue to be) negatively impacted (OB 1-2006). Burnette learned that Steven Galson was also worried about the negative impact that an agency-wide system would have on AERS users and CDER, so she sent him an email on March 15, 2006 trying to ease his concerns and smooth the situation over. In the email Burnette states,

“Steven, I expect you have some concern about whether the MedWatch plus activities might negatively impact AERS II. I just want to let you know that it was specifically mentioned by Janet and agreed and endorsed by all at the MedWatch Plus Executive Committee meeting that any changes to AERS II scope to include agency wide functions could not negatively impact CDER. OIT-CDER has some good suggestions for how to proceed from a technical perspective.

“You’ll see some meeting notices in the next week or so (I expect) that talks about changes to the AERS II boundary document. What we’ve done is made the changes as an addendum, so basically AERS II continues as planned, and the agency wide components will be “add ons.” This is similar to what we did with SPL, where the first phase was CDER only, but there were options in the contract to do additional components. There will have to be agreement to the ‘add ons,’ so it will be important to have the right people from CDER there to have the official CDER voice.”

But it became increasingly difficult to see how CDER and AERS users *would not* be negatively impacted by an agency-wide system, given the fact that its funding for AERS II for FY 2006 had been zeroed out and reprogrammed to OIT (OB 1-2006). In fact, in the March 23, 2006 ODS Budget Sheet, AERS II funding for FY 2006 was listed as being \$1.528 million and two weeks later in the April 10, 2006 ODS Budget Sheet the funding for AERS II had been zeroed out and reprogrammed from the “business side” in ODS to OIT. The current funding for AERS II in FY07 has also been zeroed out. Based on the information available to the assessment team, it is unclear exactly who reprogrammed the AERS II funding to OIT. But what is clear is that reprogramming AERS II funding to OIT *almost guaranteed* an enormous negative impact on AERS users and CDER by even more delays in replacing the dysfunctional AERS I system and unnecessary costs incurred by not moving on the AERS II system two years earlier in July 2004. More specifically, reprogramming AERS II funding to MedWatch Plus activities would give BIB and CDER’s OIT a one year lead over the financially stalled AERS II project, allowing them to “leap frog” the MedWatch Plus project over AERS II, then argue that the AERS II project had been overcome by events, e.g. it had simply been absorbed into the yet to be developed agency-wide system, without ever becoming an operational IT system. Given the performance of OIT on AERS I and throughout the time period covered by this study, this is an enormous risk to FDA and AERS users in all Centers.

3.10 Unanswered Questions

What is most confusing about the current status of the AERS II project is that the COTS and/or COTS Integration solution that was shown in July 2004 to be the preferred solution for replacing

the dysfunctional AERS I system is still one of the solutions currently being considered, yet FDA has not acted on this plan. More specifically, on May 18, 2006 Margo Burnette sent an email to OIT staff members Tim Rigg, Tim Mahoney, and George Jett stating that she had just seen a presentation by a company that specializes in adverse event case management business processes that indicated there were only a few products that were widely used as adverse events reporting systems.⁵⁶ She asked OIT to conduct *yet another* alternative analysis on the following four products mentioned in the presentation:

- Phase Forward – Clintrace
- Relsys – Argus
- Aris Global – ARISg
- Oracle – Oracle AERS

The fourth option, Oracle AERS, is the same system that was recommended by OIT's AERS Project Managers Sandra Valencia Kathleen Keats in the July 2004 OMB Exhibit 300. Had this proposal been implemented in 2004, the AERS II system would have been fully operational in FY 2005 at a cost of about \$4.5 million, most of which would have been paid for by cost efficiencies from the existing AERS I system.

As mentioned above, the purpose of this section is to establish the overall historical context for the Independent Verification and Validation of the AERS II Requirements Process, and to evaluate the rationale and consequences of critical decisions that were made by CDER's OIT, AERS users, and CDER managers and scientists that have brought the AERS II project to the point it is today in FY07. It is meant to answer two fundamental questions.

- How did the project scope for AERS II get radically shifted from replacing the dysfunctional AERS I system, to building an Agency-wide adverse event report system?
- What are the end-effects and consequences for taking this path on FDA's and CDER's ability to carry out its mission of protecting and promoting public health through safety evaluations, epidemiological studies, and the functions executed by the Offices of Compliance and FOI?

But a close examination of the events surrounding the AERS II requirements development process raises as many questions as it answers, especially about the pattern of questionable decisions and practices used by CDER's OIT. For example, July 7, 2006 was George Jett's last day as CDER's OIT AERS II Project Manager because he accepted a job at Aris Global - one of the four adverse event reporting companies that Burnette asked him to evaluate only two months earlier in her May 16, 2006 e-mail. During the last week of September 2006, Jett made a presentation about adverse event reporting at the FDA sponsored ePrompt meeting as the Director of Strategic Initiatives for ARIS Global. On October 4, 2006 Jett e-mailed FDA's Roger Goetsch apologizing for missing Goetsch's presentation at the ePrompt meeting and asking him for a copy of his presentation slides. When Goetsch questioned this as a conflict of interest, OIT's Tim Rigg responded by e-mail, "I told George he had to talk to FDA Ethics about it."⁵⁷

In an atmosphere in which IT management and contracting practices are coming under increased scrutiny, and in the wake of the recent report from the Institute of Medicine (IOM), the senior managers in CDER should conduct a thorough investigation into the leadership, management, and

⁵⁶ See May 18, 2006 e-mail from Burnette to Tim Rigg, Tim Mahoney, and George Jett.

⁵⁷ See e-mail from Roger Goetsch to Tim Rigg, with copies to Charlie Stone and Jim Wilson.

contracting practices of OIT.⁵⁸ More specifically, they should investigate: a) how effectively CDER's portfolio of IT projects is being led and managed; b) the selection criteria by which contractors like the one mentioned above are screened and selected; and c) the way in which financial resources are being combined into larger and larger categories in CDER's OMB Exhibit 300 which *increases* the extent to which OIT can reprogram the IT funds of CDER's science-technical units like OSE, award those funds to contractors they select without the approval of science-technical managers, and *decreases* the level of traceability and overall accountability for doing so.

⁵⁸ For example, see the audit and investigation into the \$170 million IT system developed for the FBI that was unusable. See, "The FBI's Upgrade That Wasn't," by Dan Eggen and Griff Witte in, *The Washington Post*, August 18, 2006 (<http://www.washingtonpost.com/wp-dyn/content/article/2006/08/17/AR2006081701485.html>). Also see the Institute of Medicine's report entitled, *The Future of Drug Safety: Promoting and Protecting the Health of the Public*, published on Sept 26, 2006.

4.0 Use of Appropriate IT Methodology⁵⁹

This section of the report evaluates whether standard IT Methodology was used for the AERS II system's design and requirements development process. By way of general introduction, enterprise-wide knowledge management requires that leaders and managers put their organization's "whole brain" to work. This means viewing "knowledge-as-knowledge" whether it is stored and manipulated in a silicon-based system like a computer, or a carbon-based system like an FDA Safety Evaluator's brain. In today's information intensive environment, FDA's human and computing resources need to work together like a cross-functional work team to achieve the Agency's objectives and goals. A mission-oriented approach to the AERS II system that embodies an effective IT infrastructure should have four high-level functionalities:

- Move information about adverse events from the *external environment* outside FDA to the correct place in the organization so it can be analyzed, digested and acted on.
- Move information from *internal processes* within FDA to the correct place in the organization so it can be analyzed, digested and acted on, for example from OSE to the appropriate review divisions in OND.
- Move information about the *status* of goals, milestones, deliverables, and budgets in operations plans to the correct place within FDA so it can be analyzed, digested and acted on.
- *Structure and manage data storage* so it is a resource that's available to AERS II users in all FDA Centers, e.g. data isn't isolated in data silos or shadow systems.

All too often, an organization's IT infrastructure is designed and maintained by IT professionals who give line managers what they think is needed to operate the business. This is one of the root causes in the derailed development of the AERS II system. Savvy senior managers know that a high-performing IT infrastructure is a key element of accomplishing their purpose, mission and goals, and consequently systems like AERS II are much too mission-critical to be delegated to IT professionals who often lack an intimate knowledge of an organization's purpose, goals, structures, systems, and organizational culture.

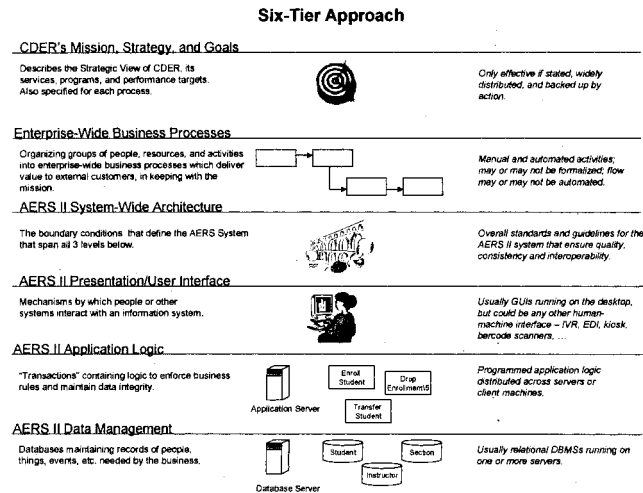
Whether an organization is designing custom software like AERS I, or piecing together a COTS integration package like AERS II, there are specific foundational principles and IT methodologies that must be included. This section of the report compares the processes used in the development of the AERS II High-Level Requirements Document and Detailed Requirements Document

⁵⁹ The following references were used to define our assumptions of what constitutes an appropriate IT Methodology: a) Alec Sharp & Patrick McDermott, *Workflow Modeling*, (Boston: Artech House Inc., 2001). Sharp and McDermott provide proven techniques for identifying, modeling, and redesigning business processes, implementing workflow improvement, and developing software that effectively implements business processes. The techniques described enable requirements definition for either systems development or acquisition. The techniques include Workflow Modeling (Swimlane diagrams), Use Cases, and Entity Relationship Diagrams; and b) Richard Barker, *CASE*Method Tasks and Deliverables*, (New York: Oracle – Addison-Wesley, 1991). This is the gold-standard text that defines the structured development methodology used by Oracle Corporation for either systems development or acquisition. It describes how to utilize Oracle's repository system, Oracle Designer (formerly Oracle CASE), to document and automate the software development process. The CASE methodology may be used either to custom-build an application or to evaluate the suitability of off-the-shelf "COTS" applications or "COTS" integration.

(SRS) to IT software development methodology and practices that are commonly accepted in industry.⁶⁰

4.1 The Six Tiered Method

A commonly used framework in the world of business process automation and information Technology is the six tiered framework.⁶¹ The six tiered framework clearly defines all of the layers that are essential to building successful IT systems. The six tiers are shown in the diagram below:



Adapted from Alec Sharp and Patrick McDermott, *Workflow Modeling: Tools for Process Improvement and Application Development*, (Boston, MA: Artech House, 2001), p. 43

The Six Tiered Method is a common sense approach to understanding the interdependent layers (tiers) that constitute an IT development project and how those tiers should interact over the course of an entire project. The Breckenridge Institute used this framework to evaluate the AERS II requirements process conducted by OIT and its contractors. A more detailed description of each of the six tiers appears below along with commentary on how the AERS II process either did or did not address these areas.

Tier One: CDER's Mission, Strategy, and Goals

⁶⁰ The Clinger-Cohen Act of 1996 requires federal agencies to follow corporate America's best practices for managing IT, see Alan Holmes, "Federal IT Flunks Out" in, *CIO Magazine*, May 15, 2006.

⁶¹ The bulk of the information in this section was taken from Alec Sharp and Patrick McDermott, *Workflow Modeling: Tools for Process Improvement and Application Development*, (Boston, MA: Artech House, 2001), p. 39 ff.

An organization's Mission, Strategy, and Goals are the driving force behind everything that it does, including its IT systems – business processes and IT systems do not exist in isolation. With clear mission, strategy, and goals in place, the business processes that support them can be described and analyzed. It is at this level that senior CDER managers must ensure that the lifecycle phases and the activities therein are kept in alignment with the organization's mission. FDA's overall mission is to protect and promote the public health and safety and organizational units like CDER and CBER contribute to this mission in various ways. The following kinds of documentation for Tier 1 should have been kept in the forefront of IT development by CDER's OIT and its contractors throughout the AERS II requirements process:

- Mission for FDA, Centers, and Organizational Units like the Office of Surveillance and Epidemiology (OSE)
- Strategic Plan for FDA, Centers, and Organizational Units like OSE
- Goals and Objectives for FDA, Centers, and Organizational Units like OSE

The assessment team found no evidence that the AERS II requirements process meaningfully analyzed FDA's or CDER's mission, strategy, and goals, or the mission, strategy, or goals of any of the organizational units that utilize the AERS system in CDER, CBER, or elsewhere across the Agency. Neither the 2004 High-Level Requirements Document, nor the 2006 Detailed Requirements Document took a "top down" approach to the AERS II requirements process, e.g. the AERS II requirements process was not linked to CDER's mission and goals in any meaningful way (OB 8-2006). More specifically, CDER mission and goals (Tier One) were not incorporated in the 2004 High-Level Requirements Document. Although the document contains a section entitled, *Business Vision and Objectives*, this contains a cursory discussion of the objectives for the AERS II system, but does not tie AERS II back to CDER's mission or goals at Tier One.

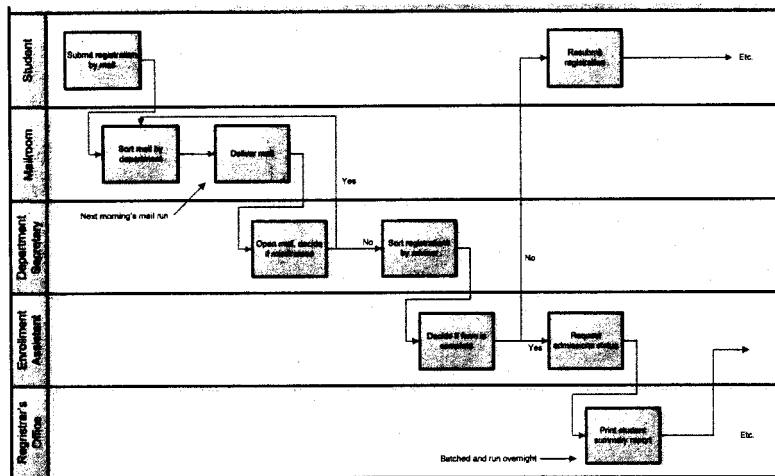
Tier Two: Enterprise-Wide Business Processes

The Business Process tier analyzes the enterprise-wide business processes and enabling processes (manual and automated) that allow an organization to conduct its business. Tier Two analysis typically occurs during the High-Level Requirements phase of a software development or COTS integration project. With respect to AERS II, this tier would consist of the end-to-end process of drug safety and enabling processes such as conducting safety evaluations, epidemiological studies, and the tasks associated with the Offices of Compliance and FOI.

When analyzing an organization's enterprise-wide business processes and enabling processes as part of software development, it is important to lay the groundwork by first analyzing the processes "as-is", or as they occur "today". This provides the perspective that is necessary for looking for process improvement and designing the "to-be" workflow. When designing software or evaluating the components of a COTS integration package, the "as-is" and "to-be" processes can be developed and analyzed using a repository tool like Oracle Designer. A diagramming technique frequently used for documenting the workflows is called a swimlane diagram. This diagram demonstrates both the process flow as well as the handoffs from one user or organization to another. The following kinds of documentation should be included in Tier 2:

- Overall Process Map
- As-is workflow (swimlane diagrams)
- To-be workflow (swimlane diagrams)

The following diagram demonstrates a sample swimlane diagram, and it can be seen from this diagram how easily a workflow can be understood by using this technique:



As mentioned above, the assessment team found no evidence that the AERS II requirements process analyzed either CDER's enterprise-wide process of drug safety, or any of the enabling process like conducting safety evaluations and epidemiological studies or the tasks associated with the Offices of Compliance or FOI. As mentioned earlier in the report, CDER's Office of Business Process Planning contracted with IBM to conduct a high-level business process analysis after the AERS II requirements process was almost complete. Given the scale and complexity of FDA and its Centers, and the fact that the scope of the IBM project was only \$43,000, it's unclear what BPP was expecting to accomplish with this project other than to create more support for accelerating the FDA-wide system at the expense of an AERS I replacement by revealing the obvious, e.g. that there was a large degree of commonality of processes across the agency (see Section 3.9 of this report for details).

Neither the 2004 High-Level Requirements Document, nor the 2006 Detailed Requirements Document took a "top down" Business Process Analysis approach to the AERS II requirements process (OB 8-2006). The 2004 High-Level Requirements Document does not contain (or reference) a properly conducted Tier Two Business Process Analysis using methods such as workflow analysis, swimlane diagrams, or IDEF0 process analysis, e.g. there is no "as-is" or "to-be" analysis of CDER's enterprise-wide business process of Drug Safety, or its enabling processes, e.g. conducting safety analyses, epidemiological studies, or the tasks performed by the Offices of Compliance and FOI. The form of analysis that was included in the document (Use Cases) was inappropriate for a high level requirements phase. More specifically, the detailed levels of swimlane diagrams of CDER's Tier Two enterprise-wide business processes and enabling processes (safety evaluations and epidemiological studies) should have been linked to

and then Use Cases should have been used to link the Presentation-User Interface to Tier Five (Application Logic). The assessment team found that *there is no meaningful connection between the High-Level Requirements Document and the Detailed Requirements Document (SRS)*. Alec Sharp comments on the incorrect application of Use Cases in IT system design:

“Whenever a technique is successful, someone will try to take it too far, and use cases are no exception. A notable example: they have been proposed as the core technique of a process reengineering methodology in which a process is viewed as a use case – a very large use case – that is progressively decomposed until it arrives at task-level use cases. This approach simply hasn’t taken off, so if you’re considering it, don’t bother. Process framing and swimlane diagramming are better for dealing with complete business processes, just as use cases are better for determining how actors and systems will interact to complete tasks.”⁶²

The 2004 High-Level Requirements Document appears to assume that the CDER’s current business and enabling processes (that are currently in operation and undefined) would remain unchanged, and simply summarized available lists of requirements that existed prior to 2004 and added some new features primarily in the area of technology (for example web-based interface). As operating experience with the dysfunctional AERS I system has painfully shown, the effect of functionality problems on users tends to magnify, the further into the IT systems development life cycle one progresses. More specifically, it is inexpensive and relatively easy to identify and analyze missing or incorrect Business Process functionality early on in the process, but very expensive and time consuming to add or fix functionality in the later stages of the development process (for example, while programming or integrating multiple COTS packages).

Tier Three: AERS System-Wide Architecture

The System-Wide Architecture Tier defines the overarching framework within which the AERS II system should be developed and operated. It spans the 3 tiers below it, and is necessary in order to define, build, and maintain a consistent, quality technical solution. The following kinds of documentation should be included in Tier 3:

- Project Schedule and Work Breakdown Structure
- Technical Architecture – Hardware platform, Operating system, Database Management System, etc.
- Standards – Naming, coding, look and feel
- Test Plan
- User Acceptance Criteria
- Migration Plan
- Constraints and Assumptions
- Quality Assurance Plan
- Security Plan
- Configuration Management Plan
- User Documentation
- User Training

Although some of these areas were mentioned in the requirements documents, they were not addressed in the depth required for a system of the scope and complexity of AERS II. For

⁶² Alec Sharp, *Workflow Modeling: Tools for Process Improvement and Application Development*. (Artech House, Inc., 2001), p. 299

example, there were requirements that stated that data would be migrated from AERS I, but how could a Migration Plan be included when there was no Data Model included?

Tier Four: AERS Presentation/User Interface Level

The Presentation/User Interface Tier can be considered the “gateway” into and out of the AERS system. It represents the mechanisms by which people or other systems interact with the system and is the appropriate place for Use Cases to be used to model these interfaces. For end-users, this tier appears as the Presentation-User Interface, e.g. what they see on their desktop computer screen, Blackberry, reporting facilities, or other media/devices. Also included in this tier are other types of interfaces into and out of the system such as electronic data submission, bar code scanners, and public web sites. Some examples of documentation that should be generated at this tier include:

- Screen designs and specifications for their behavior
- Report layouts and specifications for their search capabilities
- Interface specifications
- Reporting tool requirements for specialized tools and advanced analytics (e.g. SAS, SPSS, Excel, etc.)
- Download/Upload requirements

Although over 50% of the requirements in the 2006 SRS are geared to defining this tier, they do so primarily through lists of requirement text, most of which existed prior to 2004, and some Use Cases that are *unconnected* to the other tiers, especially the Data Management tier. There are only a few sample screen designs and no report layouts contained in the 2006 AERS II SRS developed by BAH. These incomplete and/or disconnected requirements were interspersed throughout the document, making the 2006 AERS II SRS of questionable value.

In addition, the assessment team found that neither the 2004 High-Level Requirements Document, nor the 2006 Detailed Requirements Document specifies what methodology and/or tools were used to manage the AERS II requirements process or to produce the models in the final documents, e.g. a requirements repository like Oracle Designer (OB 7-2006). Standard IT methodology requires that such methods and tools be used as the basis of a requirements process and that they be clearly documented in the final requirements document.

In the case of the AERS II requirements process, it appears that lists of requirements that were available prior to July 2004 were edited, and then cut and pasted into the two documents using MS Word or Excel rather than using a requirements repository/tool to manage the overall requirements process. In 2003, FDA paid the Oracle Corporation over \$300,000 to reverse engineer the AERS I system into Oracle Designer, an automated tool widely used by Oracle customers and consultants to design new systems and document existing systems.⁶³ This information appears to have been ignored by CDER’s OIT and its contractors during the AERS II

⁶³ Oracle Designer, formerly called Oracle CASE (Computer Aided Systems Engineering), is a tool that can be used from day one of the systems development life cycle to document and analyze system requirements. Richard Barker’s book describes how to use the tool for every step of the life cycle. The Designer repository captures increasingly detailed information obtained during the life cycle, without the need for re-entry of requirements. For example, during the Strategy (High Level Requirements) phase, information about conceptual data entities is stored. During the Analysis (Detailed Requirements) phase, these same entities are documented in more detail, and a complete Entity Relationship model is completed. Then during the Design phase, a utility within the repository can be run to generate a default database design, which subsequently can be used to automatically generate SQL syntax and create the necessary tables in Oracle.

requirements process. The existing AERS I data model was completely reverse engineered (loaded into the Designer repository using an Oracle utility that captures all information about the existing database), with additional documentation added regarding the description and size of every table in the database. This “physical” database design was then further analyzed and reversed engineered into a logical Entity Relationship model. Although BAH would not allow Oracle access to reverse engineer the Oracle programs (forms, reports, etc.), Oracle manually input information into the repository regarding the functional design of AERS I as well. This repository could have saved enormous amounts of time and money had it been used for the following purposes:

- Understanding and further documenting the “as-is” business processes during the High Level Requirements phase.
- Automating the analysis of the “to-be” processes, building upon the wealth of information already in the repository.
- Understanding the current AERS I Entity Relationship model.
- Based on the analysis of “to-be” processes, modifying and enhancing the AERS I Entity Relationship model to represent the data requirements for AERS II.
- Tracking the evolution of requirements from AERS I (1996) to the present day, without having to re-analyze, re-number, and re-document these requirements.
- Manage the current AERS I environment by having a single place for complete documentation needed for the maintenance of the system. This can include training new OIT (or contractor) employees on AERS I and doing impact analysis of changes.
- During the future COTS integration process, the Repository could be used for automated generation of any components of the system that must be custom developed, whether it be database components, such as database tables, or application components.

As a result of not using the appropriate methodology or tool, the requirement numbering schemes from the 1996 document to the 2006 requirements document changed multiple times, with very little traceability of requirements from one document to the next. For example, in the 2006 SRS document there is a column indicating the source of a requirement. In some cases, this source may indicate a specific requirement in the RTM. In many other cases, it may indicate a Work Group or another document, but that requirement still mapped back exactly to a requirement in the RTM. Because these requirements were not controlled and tracked in a data repository that recorded a given requirement’s change history, users were forced to discuss the same requirements over and over again. What is even more problematic is that CDER’s OIT actually owns and maintains CDER’s Oracle Designer repository that contains a full back-engineered AERS I system, but failed to use it for the AERS II requirements process despite the fact that AERS is situated on an Oracle platform. The OIT did use an IBM-based repository called RequisitePro *after-the-fact* to generate a requirements traceability matrix. But the cost and work associated with this entire step would have been unnecessary had OIT and its contractors used Oracle Designer from the beginning of the process.

Tier Five: AERS Application Logic

The Application Logic Tier contains the business rules and process logic that must be implemented in order for the Presentation/User Interface Tier to interact with the Data

Management Tier. This application logic is programmed into the application, and may exist at any layer of the system (e.g. database server, web server, etc.). In addition to automating the logic of the application, it ensures that the application data can be maintained. Some examples of documentation that should be contained at this tier include:

- Use Case Diagrams with associated logic
- Life-cycle logic for maintenance of data entities (create, update, delete)
- Logic to support searching and analysis requirements

Tier Five is the most complex of the Six Tiers to analyze and requires a number of well established techniques: a) event identification, b) state transition modeling, and c) transaction specification, none of which were found in the 2006 AERS II SRS document produced by BAH.

There are numerous requirements associated with Tier Five in the 2006 AERS II SRS in the form of lists of requirements that existed prior to 2004 and Use Cases. However, it is difficult to assess their completeness and whether the requirements of AERS users have actually been included in the SRS because of: a) the aforementioned lack of a top-down approach that connects all six tiers, and b) the complete lack of a data model at Tier Six which is described below.

Tier Six: AERS Data Management

The Data Management Tier is the foundation of the system – the ability to store and retrieve data. Building a software system without a well-designed data management structure is like building a house without a foundation. As has been painfully evident with AERS I, without a quality database design and database management system, the quality and usefulness of the information provided to the users via the Application Logic and User Interface is of questionable value. The Data Management Tier must take into account both the day-to-day operational data as well as the data warehouse where the data will be used for analysis and reporting. Some examples of documentation that should be included at this tier include:

- Entity Relationship Model (ER Model). The ER Model starts out at a very high level during the High-Level Requirements phase, is refined to greater levels of detail during Detailed Requirements phase, and should be described in detail in the High-Level Requirements and Detailed Requirements Documents. Typically, this documentation would be comprised of:
 - The *things* that the organization must record information about (entities) – for example, the data contained in an adverse event report.
 - The connections or associations between one entity and another (relationships). For example, *one or more adverse events* about a specific drug.
 - The facts that describe an entity (attributes) – for example, drug ingredients, labeling information, etc.
- ER Model Dictionary Report – Contains definitions of entities and attributes as well as other detailed information about them.
- Entity usages – function/entity matrices and business unit/entity matrices.
- Data volumes – projected quantities of entities (e.g. there will be 10,000 customers).

- Detailed Database Design – takes the detailed ER Model and defines how it will be implemented in the database management system of choice (defined in Tier Three, Architecture). This is accomplished during the Design/Build phase, taking into account both the operational (transaction processing) needs and the data warehousing (reporting and analysis) needs of the application and its users.
- Data quality and data integrity logic.

The assessment team found this tier to be seriously deficient due to the complete lack of *all* of the components mentioned above – no ER model or dictionary, entity usages, detailed database design, or data quality and data integrity logic. The only Tier Six requirements contained in the HLR or SRS were lists of statements regarding types of data that needed to be included in the database, e.g., dictionaries.

In addition, it is important to note that the back-engineering of the AERS I system using Oracle Designer in 2003 would have provided a solid foundation upon which to build AERS II in terms of an Entity Relationship (ER) model and underlying data structure (OB 9-2006). The 1996 AERS I document contained a Data Requirements section, complete with a dictionary report. Although this information is stored in the Oracle Designer container maintained by CDER's OIT, it was ignored by OIT and its contractors in the AERS II requirements work conducted from July 2004 on, resulting in a *very serious* lack of definition in Tier Six, Data Management. If, by leaving the Data Management tier out of the 2006 SRS Document, the intention was to rely on the ER Model and Data Management tier in AERS I, then serious deficiencies in AERS II functionality will be unavoidable, as indicated by the comments and data gathered in the 2005 AERS Users Satisfaction Survey. This also indicates that a higher priority was placed on the ER Model and Data Management Tier ten years ago than today.

The lack of an ER Model and well-defined underlying data structure presents a *serious risk* to the potential success of AERS II because without these elements, user needs will not be met again as was the case with the AERS I system. Without an ER Model and underlying data structure, it is not possible to evaluate the degree to which Tier Four (Presentation) and Tier Five (Application Logic) actually contain complete functionality. One of the techniques for cross-checking that these requirements are complete is to evaluate each data entity in the ER Model to see if its complete life cycle is represented in them. For example, is there a Use Case for the creation, maintenance, and deletion of each entity, and is there a user interface (e.g. screen) or imbedded application logic to perform this function? Since there is no ER Model and no definition of entities, there is also most likely a *large hole* in the application logic requirements of the 2006 SRS document. Regardless of whether one is developing a custom software application where information deliverables are used to build a sound database structure or evaluating the extent to which a COTS or COTS integration package will meet user needs, a well-defined foundation of an ER Model underlying data structure and information deliverables is required.

4.2 OIT's People Design

There are a number of roles that must be filled in order to ensure that an organization like CDER's OIT can deliver a system that meets the needs of AERS II users. A close assessment of the AERS II requirements process conducted by OIT reveals that OIT did not have the appropriate "people design" to carry out the AERS II requirements process and that AERS users and CDER managers were not involved in appropriate roles. In addition, proper guidance for requirements gathering was not provided to AERS users by OIT or its contractors.

More specifically, the AERS II requirements process lacked an effective *liaison* between: a) AERS users, b) the working level technical people within OIT who functioned as AERS Project

Managers, and c) the IT designers in the AERS software maintenance contractor organization. This liaison function is normally described as a Business Analyst. Until recently, the AERS Program Manager tried to fulfill this role, but this position has since been abolished (OB 6-2006).

The roles listed below detail the roles that would typically be involved in the early stages (high level requirements, detailed requirements) of an IT project like AERS II. Some commentary related to the approach taken by OIT for AERS II is provided with each bullet, with more detailed descriptions presented below.

- *Sponsoring User:* The senior manager in the users' organization who is responsible for ensuring the quality of user input to the project, for resolving scientific and technical issues, and for signing off at the end of each phase. For AERS II, this role is filled by senior CDER managers who understand the scientific and medical issues involved in carrying out CDER's post-marketing Drug Safety function. It is important to note that this role should not be delegated to the OIT organization or to a staff-support organization like CDER's Business Process Planning Office (BPP).
- *User Management:* This role should be fulfilled by a formal steering committee to oversee the project to ensure that the new software system will meet users' needs, is cost-justified, and well run from a project management perspective. For AERS II, this function was carried out by the OPaSS AERS Program Office, the Change Control Board (CCB), and the AERS Project Manager in the OIT organization.
- *Business Analyst:* This is a key role, responsible for straddling the boundary between the OIT organization and the scientific and technical aspects of the processes used to conduct safety evaluations and epidemiological studies. The Business Analyst is the interface between the working level technical people/project managers in OIT, and the users and should be involved in all phases of development (2004 HLR and 2006 SRS). In this case, they must be able to speak the language of IT systems, *and* the language of Safety Evaluators, Epidemiology, and the Offices of Compliance and FOI. This function was, and remains, missing in CDER's OIT and OIM which forced AERS users to focus on issues of IT functionality rather than the processes involved in conducting safety evaluations and epidemiological studies.
- *User:* A person who will be the eventual user of a system. Users should provide input during all stages of a development project. They may be interviewed, participate in feedback sessions, work together with Business Analysts and designers, participate in the system acceptance tests, etc. In this case, Safety Evaluators, Epidemiologists and the Offices of Compliance and FOI are the primary users of AERS II.
- *Designers:* Responsible for producing the program specifications and database design, or *how* the requirement is to be met, as well as identifying and resolving design issues at any stage in the project. This role was filled by OIT who outsourced this work to contractors, e.g. High Performance Technologies Inc. for the High Level Requirements Document, and BAH for the Detailed Requirements Document. Although they outsourced the work, OIT remains responsible for this role throughout the life of the project. As the data presented in this report show, OIT selected contractors that had a known and documented history of marginal performance and then failed to exercise adequate oversight over their performance.
- *Project Manager:* The OIT person who was responsible for all application work, project planning and control, putting the plan into action, keeping all parties informed of plans,

progress, and issues, managing the project team, and ensuring the quality of the deliverables. There were six different project managers over the three year time period covered by this study.

- **Data Administrator:** Responsible for monitoring business models, advising on data issues, defining standards for data security and naming conventions, and accepting the data models. This is typically a senior person with extensive knowledge of the business. It is not clear to what extent a Data Administrator role was filled for AERS II by OIT personnel.

The absence of the role of the Business Analyst in the AERS II process left a gap between the technical working level and project staff in OIT, the Program Office staff in OPaSS, and the users in CDER, CBER and other FDA units. As a result, AERS users were forced to fill the vacuum of the Business Analyst role by attending myriad requirements gathering meetings where they were asked to list and re-list their requirements at an overly detailed level, rather than focusing on the process-oriented aspects of conducting safety evaluations and epidemiological studies. Many of these meetings would have been unnecessary had OIT provided staff members to function in the Business Analyst role. An even more serious problem is that it is unclear to AERS user who participated in these meeting and CDER managers and scientists whether the requirements need to replace the dysfunctional AERS I system are actually contained in the SRS delivered to FDA by BAH in June 2006.

4.3 Analysis of the High-Level Requirements Document

The High-Level Requirements (HLR) Document dated December 14, 2004, was reviewed and compared to standard Life Cycle Development Methodologies for completeness. The 2004 High Level Requirements document contains *almost nothing* regarding Data Management. There is no conceptual ER Model or documentation, only a few requirements in list format that refers to the dictionaries needed (OB 8-2006). This lack of an ER Model violates *FDA's own System Development Life Cycle*, as can be seen in the Methodology Summary – Detailed Requirements table below.

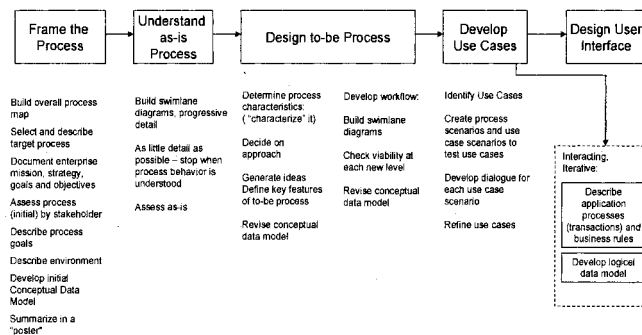
METHODOLOGY SUMMARY - STRATEGY (HIGH LEVEL) PHASE					
Doc Type	Document Content	AERS II HLR 12/15/04	Barker	Sharp	Comments
System-Wide	Statement of Organization mission, strategy, goals, objectives, and vision	P	X	X	Brief vision and objectives for system, not at organizational level.
	Organizational, technology, or other issues		X		
	System Boundary definition	P	X		As defined by Functionality Domains
	Phased development plan		X		
	Optional feasibility reports and vendor proposals		X		
	Glossary of terms	P	X		List of acronyms, but not a complete glossary of terms
	Proposed system architecture/approach (recommended and alternative system architectures, by application system area, with priorities, dependencies, assumptions, etc.)	P	X	X	Contains some diagrams showing architecture and interfaces; no alternatives presented.
Functional	Function Hierarchy (high level)		X		There are 2 workflow diagrams, covering only a very small part of the functionality.
	As-Is Work Process - Swimlane diagrams			X	The rest of the functional requirements are depicted by Use Case Diagrams.
	To-Be Work Processes - Swimlane diagrams	P		X	
Data	Entity Relationship Model (high level)		X	X	

This matrix shows expected components of a high level requirements document in green, as compared to the actual AERS II HLR contents in red. An "X" would indicate that the component is fairly completely represented, while a "P" indicates that it is only partially represented.

The FDA SDLC requires a Logical Data Model (ER Model), Logical Model Dictionary Report, and Data Volumes to be included with the Requirements Phase, comparable to the 2006 SRS document. None of these are included in this document. The three methodologies reviewed in this document, FDA's SDLC, Richard Barker, and Alec Sharp, are consistent in their approach to Tier 6 Data Management – they all require an ER Model. It would be difficult, if not impossible to find a sound IT development methodology that does not require data modeling and a solid Tier 6 foundation and specification. As mentioned in the above section on the Six Tier Approach, the HLR is the phase when “as-is” and “to-be” business processes should be analyzed. The standard technique is as shown in the diagram above and is incorporated in a repository tool like Oracle Designer.

The High-Level Requirements phase should cover the first 3 steps of the Business Process Analysis model shown below – Frame the Process, Understand the “as-is” Process, and Design the “to-be” Process. The framing step clearly sets the expectations and boundaries from the start regarding the target processes to be improved by developing an overall process map. It also ties the business processes to the organization's mission, strategy and goals. Understanding the “as-is” process provides a starting point for determining what needs to be “fixed” in AERS I and why it needs to be fixed. Then the designing of the to-be process takes a fresh look the businesses processes, identifying areas for improvement. The matrix summarizes the documentation that typically would be included in a High-Level Requirements Document and compares this to the December 15, 2004 AERS II HLR that was delivered to CDER's OIT.

Business Process Analysis



As mentioned above, the assessment team found the 2004 HLR to be seriously lacking in terms of a) having a top-down business process analysis approach and b) the data requirements specification. By not including an ER Model or performing “as-is” and “to-be” business process analysis, the stage for AERS II is not set upon a firm foundation, and the value of the entire HLR document is questionable.

4.4 Analysis of the Detailed Requirements Document and User Needs

The AERS II System Requirements Specification (SRS) dated April 6, 2006 and amended May 17, 2006 was also reviewed and compared to standard Life Cycle Development Methodologies for completeness (see chart below).⁶⁴ With reference to the Six-Tier Approach, this detailed requirements phase is when all four bottom tiers should be addressed from a business (not technical) perspective: System-Wide Architecture, Presentation/User Interface, Application Logic, and Data Management.

METHODOLOGY SUMMARY - ANALYSIS (DETAILED) PHASE						
Doc Type	Document Content	AERS I SDO 8/1998 (1)	AERS II SRS 5/1706 (2)	FDA SDLC	Barker	Sharp
System-Wide	Current System Analysis Document		X	X		2 - Appendices include 1998 regs and subsequent RTMs
	Project Management Plan			X		
	Project Schedule			X		
	Purchase Request/Request for Proposal			X		
	Function/Entity Matrices			X		
	Function/Business Unit Matrices			X		
	Entity/Business Unit Matrices			X		
	Models for Dataflow, Funct. Dependency, & State Transition			X		
	Outline of Manual Procedures			X		
	User Acceptance Criteria			X		
	Constraints and Assumptions	X	X	X		
	Methodology	X				1 - Describes methodology used, which is similar to Barker
	Software Development Plan			X	X	
	Software Preliminary Design Document			X		
Functional	Software Quality Assurance Plan		X	X		
	System Requirements Specification		X	X		
	Functional Hierarchy with Function Detail	X		X		
	Function Frequencies			X		
	To-Be Process Workflows (Swimlane Diagrams)	P			X	1 - Contains some process flows (not in the format of swimlane diagrams, don't show user hand-offs)
	Use Case Scenarios (dev. from Detailed Swimlane Diagrams)		P		X	2 - Use Cases with no Workflows
Data	Logical Data Model (Entity Relationship Diagram)	X		X	X	
	Logical Model Dictionary Report	X		X		
	Database Preliminary Design Document			X		
	Data Volumes	X		X		2 - Extremely high level volumes, not entity level
Architecture	Database Naming Standards			X		
	Software Coding Standards			X		
	Technical Architecture	X				1 - High-level diagram of systems architecture
	Software Configuration Management Plan			X		
	System Quality Assurance Plan			X		
	System Security Plan	X	P	X		2 - List of security requirements, not a plan
	User Performance Expectations		X	X		
	Working Style Definition			X		

The AERS II SRS, the matrix shown above evaluates the 1998 AERS System and Design document, against standard components of a detailed requirements document, including the standard process and criteria for developing software found in FDA's System Development Life Cycle document (SDLC). This matrix shows expected components of a detailed level requirements document in green, as compared to the actual AERS II HLR contents in red. An

⁶⁴ Although the AERS II document is entitled "System Requirements Specification", matching the name of one line item from the FDA SDLC, the purpose as defined in section 1.1 found on p. 6 is "The purpose of this document is to capture detailed requirements regarding the Adverse Event Reporting System (AERS) II and to communicate these requirements to the CDER business community who will review and validate the requirements prior to the system design and development phase of this project." This purpose implies that the document addresses the broader scope of the SDLC Requirements Analysis Phase. In fact, a System Requirements Specification as defined by the SDLC would not be sufficient to enter the system design and development phase for the project.

“X” would indicate that the component is fairly completely represented, while a “P” indicates that it is only partially represented. The comments are labeled to indicate which document they refer to – AERS I SDD (1) or AERS II SRS (2).

The 2006 System Requirements Specification document also contains almost nothing regarding Tier Six (Data Management). There is no detailed ER Model or documentation other than a list of the dictionaries needed (OB 8-2006). This lack of an ER Model violates *FDA's own System Development Life Cycle*, as can be seen in the Methodology Summary – Detailed Requirements table below. The FDA SDLC requires a Logical Data Model (ER Model), Logical Model Dictionary Report, and Data Volumes to be included with the Requirements Phase, comparable to the 2006 SRS document. None of these are included in this document. The three methods used as the basis of this assessment report (FDA's SDLC, Richard Barker, and Alec Sharp) are consistent in their approach to Tier Six Data Management – they all require an ER Model. It would be difficult, if not impossible to find a sound IT development methodology that does not require data modeling and a solid Tier Six foundation and specification. Building a software application or COTS integration package without a well-defined data model at Tier Six is like building a house without a foundation.

As mentioned previously, the assessment team found the 2006 SRS to be seriously lacking in both: a) a follow through of the top-down process that should have been started in the HLR (but wasn't) – there was no apparent connection between the HLR and the SRS and b) the complete lack of data requirements specification. The SRS even created a new nomenclature for the grouping of requirements that didn't match any previous document, which makes it difficult to assess the completeness of the requirements that are there. As can be seen from the Methodology Summary chart, there are so many components missing from this document that it is not possible to proceed to a Build phase.

In addition to the fact that the 2006 AERS II SRS does not follow standard IT methodology, it does not adequately address the long-standing needs of AERS users. In June of 2005, the Breckenridge Institute performed a User Satisfaction Survey of the AERS I system across all users of the system (see Appendix E). This report was presented to CDER managers upon completion in June 2005 and again to CDER managers and to the Quality Management Office in CDER's Business Process Planning (BPP) Office on May 13, 2006.⁶⁵ In addition to numeric rating questions, the survey contained written questions where users could provide specific comments regarding their level of satisfaction-dissatisfaction with AERS I. The comments received for two of the written questions regarding AERS Inefficiencies and AERS Weaknesses provided valuable input from the users with respect to missing, incomplete, and non-functioning areas of AERS I that were negatively impacting them on a day-to-day basis. The data from the survey indicated that AERS users were faced with day-to-day work-arounds, re-work, down-time, and inadequate functionality issues that cost FDA more than \$700,000 per year in squandered time and energy (see Appendix E for details).

Despite the number of meetings attended by AERS users during the AERS II requirements process, a comparison between the written comments in the survey and the contents of the SRS document shows that the long-time concerns of users about missing or inadequate functionality were not adequately addressed in the SRS document. The assessment team uploaded the comments from the 2005 AERS Users Survey and the requirements from the 2006 SRS document into the analysis database described in Appendix A, analyzed both sets of data, and then binned both sets of data into the Six Tiers. The results of this analysis process are shown in the chart

⁶⁵ See e-mail from Charlie Stone to Ralph Lillie, Paul Seligman, Anne Trontell, Kathleen Frost, Barbara McCary Lana Pauls, William Wyeth, and Rubynell Jordan.

below. The issues identified by the AERS 2005 Survey in the first column should have been given high priority by CDER's OIT and its contractors in the AERS II requirements process because they represented the "voice of the user" but they were not. In fact, the 2005 Users Survey is not even referenced in the 2006 AERS II SRS Document.

Tier	AERS 2005 Survey		AERS II SRS	
	#	%	#	%
Tier 1: CDER's Mission, Strategy, and Goals				
Tier 2: Post-Marketing Surveillance Business Processes				
Tier 3: AERS System-Wide Architecture	29	21%	80	8%
Tier 4: AERS Presentation/User Interface	44	32%	543	53%
Tier 5: AERS Application Logic	24	17%	273	27%
Tier 6: AERS Data Management	41	30%	119	12%

Tier Three represented 21% of the issues identified by users and only 8% of the requirements in the SRS covered this area. User concerns included items such as inadequate training for new and more experienced AERS users, help systems, and user documentation that is either non-existent or seriously out of date. For example, the only AERS User Manual that currently exists is from 1999 and contains none of the updates up through 2006. At the time the Users Survey was conducted, some OSE divisions like DMETS did not even have a single copy of the 1999 AERS User Manual to give new Safety Evaluators and training for new employees was conducted using the "oral tradition." The 2006 AERS II SRS only contains eight requirements on training, help systems, and documentation that are listed under the Supplemental Requirements section entitled "On-Line User Documentation and Help System Requirements." There is no further elaboration on these eight requirements. User problems with inadequate training, help systems, and documentation will become more and more problematic over time, especially if the turnover increases among AERS users.

The chart above also shows that 30% of the users' concerns with AERS I fell into the Data Management tier – an area that was largely ignored in the AERS II SRS. This included: a) Drug Dictionary (mostly data quality and lack of functionality with respect to the Drug Dictionary issues), and b) Data Quality and Data Integrity issues (lack of clean, consistent, timely, quality data). It is *not possible* to address these areas of concern without spending the time and effort to develop a quality data model and the associated application logic, neither of which were done as part of the AERS II requirements process. Even the 12% shown in the chart at Tier Six were simply lists of statements regarding types of data that needed to be included in the database, e.g., dictionaries. As mentioned previously, the documentation that should have been included was:

- Entity Relationship Model (ER Model). The ER Model starts out at a very high level during the High-Level Requirements phase, is refined to greater levels of detail during Detailed Requirements phase, and should be described in detail in the High-Level Requirements and Detailed Requirements Documents. Typically, this documentation would be comprised of:
 - The *things* that the organization must record information about (entities) – for example, the data contained in an adverse event report.
 - The connections or associations between one entity and another (relationships). For example, *one or more adverse events* about a specific drug.
 - The facts that describe an entity (attributes) – for example, drug ingredients, labeling information, etc.

- ER Model Dictionary Report – Contains definitions of entities and attributes as well as other detailed information about them.
- Entity usages – function/entity matrices and business unit/entity matrices.
- Data volumes – projected quantities of entities (e.g. there will be 10,000 customers).
- Data quality and data integrity logic.

The assessment team found Tier Six (Data Management) to be seriously deficient due to the complete lack of *all* of the components mentioned above – no ER model or dictionary, entity usages, detailed database design, or data quality and data integrity logic.

4.5 A Quantitative Analysis of the AERS Requirements Process

The assessment team found that the requirements activity from 2005 on was unnecessary, did not add any value to what had already been done, cost \$1,500,000, and did not follow proper IT methodology as defined by FDA and industry standards such as Oracle – the FDA standard for IT systems (OB 2-2006). More specifically, no new information on user requirements emerged from the HL Requirements Document that would have supported taking a different direction, yet this was used as the basis for a second “technical” alternatives analysis and a Detailed Requirement’s Document that took the AERS II project in an entirely different direction than the one established prior to July 2004. In addition, the AERS II requirements process violated procedures specific in the FDA’s Life Cycle Systems Document (LCSD) and standard industry methodologies like those developed by Oracle – the FDA standard for IT systems. In fact, the High-Level Requirements Document contains less information for purchasing a COTS than the information that was available in July 2004.

An analysis of the 2003 Requirements Traceability Matrix (RTM) that used the 1996 and 1998 Requirements Documents as a baseline revealed that almost 48% of the functionality of the AERS I system was removed from the original AERS system requirements, e.g. 381 out of 795 requirements (OB 12-2006).⁶⁶ Even after discussions with CDER’s OIT, it was unclear *why* these pieces of functionality were removed, *when* they had been removed, or *who* authorized their removal, yet many of the problems faced by users today in FY07 are *directly caused* by these missing pieces of functionality.⁶⁷ Further analysis has shown that at least 150 (40%) of the requirements that were removed from AERS I were *added back in* to the Detailed Requirements Document delivered by BAH in June of 2006, indicating that FDA will have to pay for this functionality a second time

The users did not get almost 50% of the functionality in AERS I that they were expecting from the 1996 Requirements Document, functionality that they paid for and needed. This is evidenced by the following:

- When the RTM was produced in 2003, 6 years after the initial delivery of AERS I, 48% (381 out of 795) of the requirements that were contained in the AERS I Requirements Document, and thus expected to be in the AERS I system, had a status of “Removed”.

⁶⁶ See the Booz Allen Hamilton, *FDA Center for Drug Evaluation and Research, AERS Requirements Traceability Matrix*, Task No. T06 – Contract No. 223-97-5513, September 8, 2003.

⁶⁷ See Booz Allen Hamilton, *AERS II System Requirements Specification*, Version 1.1, April 6, 2006, and Booz Allen Hamilton, *AERS II Safety Evaluator, FOI, & Compliance Requirements (with Changes Tracked Based on Input from Safety Evaluators Received on May 17, 2006)*, June 2006.

These 381 requirements span Tier 3 through Tier 6, with a large portion of them falling in Tier 4, Presentation/User Interface. The following chart demonstrates the distribution of AERS I "Removed" requirements by Tier:

Tier	Qty
3	17
4	293
5	61
6	10

This distribution is consistent with the 2005 AERS User Satisfaction Survey, as mentioned previously in this report. The users simply did not get what they wanted, or needed in AERS I.

- At least 148 or 15% of the requirements contained in the 2006 AERS II SRS are these same "Removed" requirements from the 1996 document. The users *still need* the functionality that they were supposed to get (but didn't) in AERS I.

There were inconsequential changes to the requirement wording, for example the wording of hundreds of requirements were changed from the "The system will" to "The system shall" with little or no other changes to the requirement.

- Time and effort was spent to adjust/readjust the wording of these requirements – in 1996 many of them were stated "The system must...", and by 2006 they were stated "The system shall". Even the requirements with more than one simple word change described the *exact same* functionality, implying that this functionality was analyzed, reanalyzed, and reworded, but *the needs of the users did not change*.
- Not only is FDA paying for the same functionality to be *implemented* in AERS II that they paid for but didn't get in AERS I, but the Agency has paid for this functionality to be *analyzed and reanalyzed* multiple times with no value-added.

The Breckenridge Institute has performed an analysis of several AERS requirements documents in order to identify the value that has been added by these documents. The documents that have been evaluated include:

1. AERS Requirements Document (AERS I RD) dated September 23, 1996
2. AERS Requirements Traceability Matrix (RTM) dated September 8, 2003
3. Basic Requirements for Conducting the AERS II Alternatives Analysis dated March 12, 2004
4. AERS II High Level Requirements (HLR) dated December 15, 2004
5. AERS II System Requirements Specification dated April 6, 2006 and amended May 17, 2006

The lists of requirements that were contained in tables in these documents were loaded into the assessment team's Microsoft Access database so that they could be compared and cross-referenced. This database provided powerful analysis abilities, and is described further in Appendix A. A summary of the mapping results is contained in the table below.

Document	Total Reqs	Mapped to RTM	% Mapped	Tier 3 Not Mapped	Tier 4 Not Mapped	Tier 5 Not Mapped	Tier 6 Not Mapped
1996 AERS I	795	704	89%	1	88	2	
2003 RTM	1550						
2004 AERS II Alternative Analysis	993	899	91%	1	90	2	1
2004 AERS II High Level Reqs & App	396						
2006 AERS II Detailed Requirements	1015	468	46%	57	294	108	88

AERS 2003 RTM

The AERS 2003 RTM was used as a “baseline” against which to compare the other requirements documents, since this document contained a “superset” of the original 1996 document. In addition to the requirements from 1996, the RTM also contained bug fixes and new requirements. Of the 1550 requirements listed in the 2003 RTM, 444 had a status of “Removed” (431) or “Not Implemented” (13). It is not known how or why these requirements attained this status.

AERS I Requirements Document

In order to establish a baseline of AERS I requirements, the AERS I Requirements Document and the AERS RTM were compared to each other, and the requirements from AERS I were mapped to the requirements in the RTM. As can be seen in the table above, 89% of the requirements from the AERS I document were found in the RTM. Of the 91 that could not be mapped, 80 were specific reports from the section labeled “Current and Desired Reports”. The remaining 11 requirements were from various other sections of the document.

In conclusion, it appears that almost half of the RTM was taken directly from the AERS I RD, with slight wording changes to the requirements that didn’t change the meaning. Other than not listing specific reporting requirements, the AERS I requirements that were missing from the RTM were a very small percentage and probably left out by error. They were mostly from the Presentation/User Interface Tier.

It also should be noted that, of the 795 requirements in the 1996 document, 381 or 48% of these requirements had a status of “Removed” in the 2003 RTM.

2004 Alternatives Analysis Document

This document was created by the OPaSS AERS Program Office for OIT’s Kathleen Keats in preparation for the Alternatives Analysis that was completed in 2004. Since it was derived to a great extent from user requirements in the 1996 AERS I design document, as well as the new requirements in the RTM, the requirements in this document also mapped well to the RTM. Of the 94 requirements that didn’t map to the RTM, 80 of them were the same specific reports in the AERS I document that weren’t listed in the RTM.

2004 High Level Requirements Document

The 2004 High Level Requirements document was completed at the end of 2004, after the Alternatives Analysis. Although the assessment team initially attempted to map these requirements to the 2003 RTM, a single requirement in the HLR was frequently a summarized statement of 20 or more requirements from the RTM, and thus this mapping was not of value to the process.

2006 Systems Requirements Specification

When compared to the RTM, almost 50% of the requirements contained in this document mapped, many of them with almost the exact same wording. Of the requirements that did map, 148 (15% of the requirements in this document) mapped to requirements that had a status of "Removed" in the RTM. These were all requirements from the 1996 AERS I Requirements Document.

In summary, the 2004 High Level Requirements document provided little or no value to the AERS II systems design life cycle. More specifically,

- From the perspective of prior documents, the 2004 HLR appears to have rolled detailed requirements from the 2003 RTM and/or the 2004 Alternatives Analysis document into summary level requirements. These requirements are grouped into the same "critical business processes" as previous documents, including the 1996 AERS I Requirements Document.
- Much of the additional functionality that was incorporated in this document, such as a new web-based technology and more sophisticated data searching and analysis capabilities, was standard capability in COTS packages at that time.
- From the perspective of the next step in the requirements process, the 2006 SRS, it is unclear how the information gained from performing the 2004 HLR analysis benefited or was used by the 2006 SRS analysis process. This is evidenced by the following:
 - Once again, numbering schemes were changed from the 2004 HLR to the 2006 SRS.
 - The seven domains of functionality described on Page 11 of the 2004 HLR (Manage Adverse Event Details, Manage Requests for Information and Services, Manage Dictionaries and Other Reference Information, Manage Drug Safety, Manage Risk Assessment, Perform Application Administration, Administer Web Site, and Utilize Public Web Site), which served as the primary groupings by business process in this and previous documents, were not used in the 2006 SRS document. Since the systems analysis process is supposed to be a "top-down" process where high level requirements (HLR) are broken down into more detailed requirements (SRS), a completely new taxonomy in the 2006 SRS document makes it difficult to understand the connection between the HLR and SRS.
 - There appears to be no relationship between the Use Cases and other Figures contained in the 2004 HLR and those contained in the 2006 SRS. As mentioned previously, Process Flow analysis (swimlane diagrams) should have been used to break processes down into increasing levels of detail, with Use Cases only at the most detailed level. This is a continuous process, whereby the high-level work done at the Strategy (HLR) phase feeds into the Analysis (SRS) phase. Instead, with the 2004 HLR and the 2006 SRS there appears to be a *complete disconnect*, to the extent that it appears that the SRS "started from scratch" and didn't follow the path started by the HLR.
 - The only connections documented between the 2004 HLR and the 2006 SRS are that the HLR is mentioned as a reference document in the SRS, and some of the requirements listed in the SRS are cross-referenced back to a requirement in the HLR.

In addition, the 2006 Systems Requirements Specification document was an unnecessary and inappropriate step to take when proceeding down the path of a COTS integration project.

- When describing what is necessary for a COTS integration process, Richard Barker states the following: “In some cases it is very sensible to implement one, or perhaps several parts of a system using proprietary software packages. Typically these would cover general topics such as financials, human or physical resource management; or in vertical industries specialized packages such as manufacturing. How are these integrated and where do they fit within the life-cycle? The optimum solution for an organization will be found by conducting a strategy study in the normal manner to ensure the enterprise requirement and business direction are fully understood. With this framework in place, alternative implementation vehicles may then be accurately assessed for their specific applicability and their ability to fit in with the wider picture. In particular, the entity relationship model and its back-up attribute definitions can be used to check whether a package addresses the appropriate data...”⁶⁸ Barker’s reference to a “strategy study” equates to the high level requirements phase, as previously discussed in the methodology section of this report. The detailed requirements listed in the SRS do not advance AERS II into a better position to select COTS package(s), and in fact, without a data model being completed for the 2004 HLR, the FDA is still unable to evaluate COTS packages for suitability.
- At least half of the requirements listed in the 2006 SRS existed in previous documents dating back to 1996. Of those requirements that did not map directly to the 2003 RTM, most belonged to functional areas that are either new (e.g. Public Web Site, Manufacturer Online, Data Mining with WebVDME) or areas that are described in significantly more detail (e.g. FOI, Medical Terms Dictionary, Product Dictionary, MedWatch Batch, Online, and Paper Receipt of ISRs, Inbox capabilities, Searching capabilities). Defining the business requirements properly during the Strategy/High Level Requirements phase would have addressed new requirements to an appropriate level.

⁶⁸ Richard Barker, *CASE*Method Tasks and Deliverables*, (Oracle – Addison-Wesley, 1991), p. 10-18

5.0 Impact of Not Having AERS II Operational in 2005

This section of the report evaluates the overall impact of not replacing the dysfunctional AERS I system with AERS II in 2005, and instead changing the project scope to building an FDA-wide adverse event reporting system which pushes a replacement for AERS I off until at least 2010. The key issue discussed below is the financial impact of not having replaced AERS I with AERS II in 2005. An equally important issue is the impact that it will have on CDER's ability to effectively conduct post-marketing surveillance and Drug Safety through safety evaluations, epidemiological studies, and the functions carried out by the Offices of Compliance and FOI. These are discussed in the 2005 Users Satisfaction Survey in Appendix E.

5.1 Financial Impact of Not Having AERS II Operational in 2005

The assessment team found that the unilateral decision by CDER's OIT Director to begin the AERS II requirements process all over again post-July 2004 had an enormous negative impact on AERS users by delaying the replacement of the dysfunctional AERS I system by at least five years (OB 10-2006). This decision was made despite the objections of: a) technical staff in CDER's OIT, b) CDER's OIT AERS II Project Manager, c) AERS users in multiple FDA Centers, d) the OPaSS AERS Program Manager, and e) numerous CDER managers and scientists.

But this decision also had an enormous financial impact that will ultimately cost FDA more than \$25,000,000 at a time when funding for computing is increasingly scarce. In other words, had FDA moved forward on the CDER OIT-OPaSS approved plan in July-2004 to replace AERS I rather than unilaterally changing direction, FDA would have: a) had a functioning AERS II system in 2005, and b) avoided spending more than \$25,000,000 in contracts and services - many of which were not value-added to FDA or its mission. The breakdown of these costs is shown in the chart below.

Item	FY 05	FY 06	FY 07	FY 08	FY 09	FY 10	Total
AERS Maintenance Contract	\$1,007,200	\$896,800	\$1,016,000	\$1,068,800	\$1,098,400		\$5,075,200
AERS Users Work-arounds	\$700,000	\$700,000	\$700,000	\$700,000	\$700,000		\$3,500,000
TOTAL for AERS	\$1,707,200	\$1,596,800	\$1,716,000	\$1,768,800	\$1,798,400	\$0	\$8,575,200
Data Entry, MedDRA Coding Contract	\$1,597,000	\$5,581,000	\$4,522,958	\$2,870,553	\$1,183,382		\$15,754,891
TOTAL Not Saved for DE, MedDRA	\$1,197,750	\$4,186,750	\$3,844,513	\$2,439,970	\$1,005,875	\$0	\$12,673,857
Oracle AERS Reverse Engineering	\$300,000	\$0	\$0	\$0	\$0		\$300,000
Escalation Cost of AERS II Product	\$4,500,000	\$225,000	\$461,250	\$945,563	\$1,938,403	\$0	\$3,570,216
TOTAL for NOT Doing AERS II in 2005	\$2,904,950	\$6,007,550	\$6,021,763	\$5,142,333	\$4,742,678	\$0	\$25,119,273
Post-July 2004 OMB Exhibit 300 Costs							
Alternatives Analysis	\$0						\$0
High Level Requirements Analysis	\$210,100						\$210,100
High Level Alternatives Analysis	\$169,900						\$169,900
Detailed Requirements Analysis	\$398,769						\$398,769
Acquisition (RFP & Phase One)	\$578,000		\$578,000				\$1,156,000
Project Support for OIT		\$140,000					\$140,000
Acquisition (RFP & Phase One)							\$0
TOTAL for AERS II	\$1,366,769	\$140,000	\$578,000	\$0	\$0	\$0	\$2,074,769
TOTAL for NOT Doing AERS II in 2005 plus AERS II non-value added costs (HL Repts, HL AA, and FEDSIM fee)							\$26,077,273

AERS Maintenance Contract: The figures in this line from FY05 to FY09 reflect what FDA agreed to pay SAIC/PSI under the AERS maintenance contract minus an estimated amount for somewhat similar maintenance that FDA would have been paying for AERS II maintenance had we implemented AERS II in FY 2005. In other words, because FDA did not implement AERS II in FY 2005, the Agency is spending about 80% of its AERS funds to maintain the system that FDA plans to replace.

AERS Users Workarounds: These figures are the estimated costs identified in the 2005 Users Satisfaction Survey (see Appendix E). A key factor is that this estimate does not include inflation-escalation costs. For example, using the most recent OIT example from their AERS II budget spreadsheet, the cost in FY 2005 would be \$700,000; followed by 5% in FY 2006 for \$735,000; followed by 10% in FY 2007 for \$808,500; followed by 10% in FY 2008 for \$889,350; and followed by 10% in FY 2009 for \$978,285. The total difference between the numbers in the spreadsheet versus the above inflation-adjusted numbers is \$3.5 million to \$4.1 million, e.g. \$600,000.

AERS Data Entry, MedDRA Coding Contract: These are the exact costs shown in the present contract with PSI International. See the next item for the impact of not having AERS II.

TOTAL Not Saved for AERS DE, MedDRA: The number shown represent the costs for not implementing AERS II in 2005 and thus, staying with CDER's present AE reporting environment. If FDA had AERS II operational in 2005, the PSI costs would be less. An estimate is that FDA would have saved at least 35% in efficiencies via eSub interface, coding MedDRA at LLT, and using a Thesaurus Mgmt Sys similar to CFSAN. Also FDA would have also had better dictionary management for data entry QA/QC and safety evaluator searching/reporting. In FY 2005 and FY 2006 FDA, would have been taking 75% of the present contract value. In FY 2007 through FY 2009, FDA would have been taking 80% of the present contract value as costs that could have been saved if the Agency had had AERS II operational in 2005.

TOTAL for Oracle AERS Reverse Engineering: The CDER OIT had a contract with Oracle to conduct AERS reverse engineering efforts to document the AERS system and make recommendations. This is the cost that OIT paid to Oracle Corporation for the reverse engineering effort that apparently OIT never used. Not only is the failure to use this data repository an obvious waste of money that could have gone to help in the AERS II process, it is also a root cause of why the requirements process had little or no value-added.

TOTAL Escalation Cost of AERS II Product: The cost for the AERS product assumes a COTS or COTS integration package requiring additional enhancements unique to FDA. The initial cost in 2004 was a discount price of \$4.5 million, which would have been less than the lowest value shown by OIT in the RFI analysis. The FY06-FY09 values show only a minimal 5% escalation on the original FY 2005 amount. If the recent OIT inflation percentages of 5% initial plus 10% for FY 2007 through FY 2009 are used, the total cost would be \$5,463,225. This is \$1,893,009 more than the value in the above spreadsheet.

TOTAL for NOT Doing AERS II in 2005: In FY 2005 this line is simply the total of AERS Maintenance Contract + AERS Users Work-arounds + TOTAL Not Saved for AERS DE, MedDRA. In FY 2006 through FY 2009 the totals are from FY 2005 (AERS Maintenance Contract + AERS Users Work-arounds + TOTAL Not Saved for AERS DE, MedDRA) + TOTAL Escalation Cost of AERS II Product. The spreadsheet shows a trend in which the total costs for not doing AERS II peaks in FY 2007, then tapers off. This is because of the reduced PSI International figures, which are the cost of *not* having AERS II operational in FY 2005.

AERS II Alternatives Analysis: The cost of the initial 2004 AERS II Alternatives Analysis is \$0 because OIT's Kathleen Keats conducted the analysis.

AERS II High Level Requirements Analysis and AERS II High Level Alternatives Analysis: The High Level Requirements and Technical Alternatives Analysis were performed by OIT's contractor, ISSA/HPTI.

AERS II Detailed Requirements Analysis: The funds for AERS II Detailed Requirements Analysis were given to FEDSIM to award the RFP/RFQ. OIT originally planned to use SETA, but the FEDSIM contracting process selected Booz*Allen & Hamilton.

AERS II Acquisition (RFP & Phase One): The funds for AERS II Acquisition (RFP & Phase One) were given to FEDSIM to award the RFP for AERS II design and initial build. Also, because of project delays, OIT needed to "obligate the funds or lose them. CDER OIT reported that FY06 funding delays caused FEDSIM to consider the \$578,000 as a fee; thus, FDA will need another \$578,000 for development.

AERS II Project Support for OIT: In addition to hiring George Jett full time, plus FEDSIM, plus BAH OIT hired a contractor to support Jett in FY 2006, even though CDER management had decided not to fund AERS II in FY 2006 and there was no money to conduct work in FY 2006.

6.0 The Path Forward

Based on the data and analysis presented in this report, the Breckenridge Institute proposes three recommendations that will begin the process of correcting the issues described in this report.

Recommendation 1: In an atmosphere in which IT management and contracting practices are coming under increased scrutiny, and in the wake of the recent report from the Institute of Medicine (IOM) that identifies organizational culture as a root cause of issues in FDA, the senior managers in CDER should conduct a thorough investigation into the leadership, management, and contracting practices of OIT.⁶⁹ In addition to characterizing the tacit, underlying patterns of organizational beliefs and behavior in CDER's organizational culture, they should investigate: a) how effectively CDER's portfolio of IT projects is being led and managed; b) the selection criteria by which contractors like the one mentioned above are screened and selected; c) and the way in which financial resources are being combined into larger and larger categories in CDER's OMB Exhibit 300. This *increases* the extent to which OIT can reprogram the IT funds of CDER's science-technical units like OSE, award those funds to contractors they select without the approval of science-technical managers, and *decreases* the level of traceability and overall accountability for doing so.⁷⁰

Recommendation 2: The senior managers in CDER should take immediate action to correct the problems in CDER's OIT as described in this report. In addition, under the auspices of the IT consolidation, organizations such as OSE that contain AERS users should have the opportunity to select a team of IT professionals from the consolidated FDA IT organization that have a proven track record of technical performance and providing outstanding service to end users like the Safety Evaluators who use AERS.

Recommendation 3: FDA should execute an updated version of the software acquisition plan that was developed by the CDER OIT AERS II Project Manager and AERS Program Manager in 2004 and begin the process of acquiring a replacement for AERS I immediately. The AERS II system has been absorbed into an FDA-wide IT system that includes multiple FDA Centers. This is a much more complex and daunting task than simply replacing the AERS system, and consequently making such a system functional is probably four-to-five years away – minimum. This forces Safety Evaluators in CDER and CBER and other FDA units such as the Offices of Compliance and FOI, to work with the dysfunction AERS I system for yet another extended period of time, thus further undermining their ability to effectively carry out FDA's mission of post-marking surveillance and drug safety. Based on the information contained in this report, a replacement for AERS could be operational in less than two years at a cost of about \$5 million dollars. More importantly, this fully functioning AERS II system could then be used as a solid foundation for an FDA-wide system. It is important to note, that in the wake of the IOM report, there seems to be a renewed interest on the part of OSE in replacing the dysfunctional AERS I system as a necessary first step in developing an Agency wide system, despite the fact that funding for AERS II has been zeroed out in FY 2007.

⁶⁹ See the Institute of Medicine's report entitled, *The Future of Drug Safety: Promoting and Protecting the Health of the Public*, published on Sept 26, 2006.

⁷⁰ For example, see the audit and investigation into the \$170 million IT system developed for the FBI that was unusable. See, "The FBI's Upgrade That Wasn't," by Dan Eggen and Griff Witte in, *The Washington Post*, August 18, 2006 (<http://www.washingtonpost.com/wp-dyn/content/article/2006/08/17/AR2006081701485.html>).

APPENDIX A

Requirements Analysis Database and Method

This section describes the process that the Breckenridge Institute used to analyze AERS requirements documents. The following documents were analyzed:

- AERS I Requirements Document, dated September 23, 1996
- AERS RTM dated September 2003
- AERS II Systems Requirements Specification, dated April 6, 2006 and revised May 17, 2006

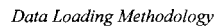
In order to perform the analysis, the Breckenridge Institute assessment team built a Microsoft Access 2003 database into which the requirements from the documents were uploaded. This provided the capability to perform text searches and other analysis of the requirements. It is important to note that this entire process would not have been necessary had CDER's OIT and its contractors utilized the back-engineered AERS I system in Oracle Designer, or some similar data repository system. The assessment team's database and methodology are further described below.

Database Design and Structure

The database structure that was used for the requirements analysis process consisted of 3 main tables, with 2 supporting tables for lookup purposes. The following ER Model below shows the tables and their relationships to each other.

Following are the descriptions of the 3 main tables:

- tblSources – contains basic information about the source documents
- tblRequirements – contains the text and additional information about each requirement; it connects the requirement back to the source document that it originated from through the SourceID field. This table also contains many other fields which are used to categorize the requirements. For example, the field Requirement6Tier describes which of the 6 Tiers that particular requirement fits into.
- tblRequirementMappings – this is the table that shows mappings between requirements from one document to another. For example, most of the requirements in the AERS I Requirement could be found in the AERS RTM with almost the exact same text. This table is where the AERS I requirement would be tied to the AERS RTM requirement.



Data Analysis Methodology

1. Comparing requirements from one document to another and mapping the same/similar requirements to each other.
2. Binning the requirements into the 6 Tiers described earlier in this document.
3. Analyzing the results of the mapping and binning processes in order to make observations.

59

document, and mapped it to the AERS RTM from September, 2003. The RTM was chosen as a baseline to map to because it represented a snapshot of the users' requirements in 2003. For each requirement in the AERS I document, text searches were done on all the requirements in the RTM to find a match using Access queries. A "complete" match was defined as two requirements that were *functionally* the same, with either the same wording or slightly different wording. A "partial" match was defined as two requirements that appeared to cover *some or most* of the functionality of each other. For "no match" requirements we could not find a requirement that appeared to cover the functionality. This process was repeated, mapping the 2006 AERS II requirements to the RTM.

In order to bin the requirements into the Six Tiers described in Section 4.1, the assessment team took a first cut at assigning tiers to requirements by looking at the headings and subheadings that the requirements were categorized by in their source document. We then ran a report in Access by assigned tier, and looked for "outliers" – individual requirements that didn't really fit in the first assigned tier. We subsequently re-assigned them to their better-fit tier.

Having this wealth of information in an Access database provided countless ways for the assessment team to "slice and dice" the requirements and their mappings. We created reports to view AERS I and AERS II requirements alongside the RTM requirements that they were mapped to, as well reports to analyze the requirements that we couldn't map. This enabled us to make observations on the progressive requirements documents from 1996 through 2006, and most of the observations regarding the contents these documents found in this report resulted from having this Access database capability.

APPENDIX B

Mapping the 1996 BAH Document To the 2003 RTM

Functional Area: Ad Hoc Reporting Tool

1996 BA Document

Sub Area: Cost

- 2301 Provide site (CPU) license
- 2302 Provide workstation license
- 2303 Provide royalty-free report distribution

Sub Area: Customer Support

- 2296 Sales force responsive to inquiries
- 2297 Provide telephone support during local business hours
- 2298 Provide one-hour response time
- 2299 Provide one-day response time
- 2300 Provide on-line support (e.g., CompuServe, BBS, WWW)

Sub Area: Database Access

- 2270 Support direct access to centralized Oracle7 database
- 2271 Support access to distributed Oracle7 tables
- 2272 Provide capability to download data from database server for querying/reporting
- 2273 Support concurrent table usage
- 2274 Support multiple table usage
- 2275 Provide capability for metadata definition
- 2276 Provide capability for custom views for selected tables
- 2277 Provide capability for custom views for predefined joins
- 2278 Provide capability for custom views for renamed tables
- 2279 Provide capability for custom subset views for specified users
- 2280 Provide capability to use stored procedures as data

Sub Area: Ease of Use

- 2232 Support interactive result formatting
- 2233 Support interactive query/report format definition, providing ability to pick field, type of operation, etc.
- 2234 Provide WYSIWYG
- 2235 Provide capability to document/query report
- 2236 Provide horizontal and vertical scrolling
- 2237 Support capability to build a query/report definition without knowledge of SQL
- 2238 Support English-based queries

2003 RTM

- 3928 Customer support shall include providing site (CPU) license
- 3930 Customer support shall include providing workstation license
- 3931 Customer support shall include providing royalty-free report distribution
- 3925 Customer support shall include sales force responsive to inquiries
- 3932 Customer support shall include providing telephone support during local business
- 3926 Customer support shall include providing one-hour response time
- 3927 Customer support shall include providing one-day response time
- 3929 Customer support shall include providing on-line support (e.g., CompuServe, BBS,
- 2406 The system shall support direct access to centralized Oracle7 database
- 2407 The system shall support access to distributed Oracle7 tables
- 2525 The system shall provide capability to download data from database server for querying/reporting
- 2606 The system shall support concurrent table usage
- 2607 The system shall support multiple table usage
- 2608 The system shall provide capability for metadata definition
- 2609 The system shall provide capability for custom views for selected tables
- 2610 The system shall provide capability for custom views for predefined joins
- 2611 The system shall provide capability for custom views for renamed tables
- 2612 The system shall provide capability for custom subset views for specified users
- 2613 The system shall provide capability to use stored procedures as data sources
- 3409 The system shall support interactive result formatting
- 3438 The system shall support interactive query/report format definition, providing ability to pick field, type of operation, etc
- 3439 The system shall provide WYSIWYG
- 3410 The system shall provide capability to document/query report
- 3411 The system shall provide horizontal and vertical scrolling
- 3412 The system shall support capability to build a query/report definition without knowledge of SQL
- 3440 The system shall support English-based queries

2239 Provide graphical query builder	3413 The system shall provide graphical query builder
2240 Support non-procedural query/report definition	3414 The system shall support non-procedural query/report definition
2241 Provide drop and drag feature for selection of data	3415 The system shall provide drop and drag feature for selection of data
2242 Support free form entry for report/query definition	3416 The system shall support free form entry for report/query definition
2243 Provide capability to pick (rather than enter) fields, type of operation, etc.	2517 The system shall provide capability to pick (rather than enter) fields, type of operation,
2244 Provide capability to preview output	3679 The system shall provide capability to preview output
2245 Provide capability to determine universe statistics prior to query/report formatting to permit user to narrow or increase universe	3417 The system shall provide capability to determine universe statistics prior to query/report formatting to permit user to narrow or increase universe
2246 Support result being larger than client's memory/disk space	2518 The system shall support result being larger than client's memory/disk space
2247 Provide capability to limit query time and size of return	3418 The system shall provide capability to limit query time and size of return output
2248 Provide capability to cancel long-running queries	3419 The system shall provide capability to cancel long-running queries
2249 Capability to view/edit generated SQL statements	3420 The system shall capability to view/edit generated SQL statements
2250 Support capability to save query/report definitions	2519 The system shall support capability to save query/report definitions
2251 Provide capability to retrieve last query/report definition	2520 The system shall provide capability to retrieve last query/report definition
2252 Provide capability to redisplay previous query result	2521 The system shall provide capability to redisplay previous query result
2253 Provide capability to copy/edit query/report definitions for similar queries/reports	3421 The system shall provide capability to copy/edit query/report definitions for similar queries/reports
2254 Provide command-driven execution	3422 The system shall provide command-driven execution
2255 Provide command-driven query/report definition	3423 The system shall provide command-driven query/report definition
2256 Provide menu-driven execution	3424 The system shall provide menu-driven execution
2257 Provide menu-driven query/report definition	3425 The system shall provide menu-driven query/report definition
2258 Provide descriptive on-line help	2522 The system shall provide descriptive on-line help
2258 Provide descriptive on-line help	2485 The system shall provide on-line help
2259 Provide descriptive, well-indexed user manual	3426 The system shall provide descriptive, well-indexed user manual
2260 Provide descriptive error messages	2523 The system shall provide descriptive error messages
2261 Provide on-line tutorial	3427 The system shall provide on-line tutorial
2262 Require minimal user training	2409 The system shall require minimal user training
2263 Provide capability to modify reports without reprocessing the database query, e.g., format, breaks, totals	3428 The system shall provide capability to modify reports without reprocessing the database query, e.g., format, breaks, totals
2264 Provide capability to drill down in summary reports	3429 The system shall provide capability to drill down in summary reports
2265 Provide undo and redo features	3430 The system shall provide undo and redo features
2266 Provide format hints, e.g., define columns in thousands to fit on specified output	2524 The system shall provide format hints, e.g., define columns in thousands to fit on specified output
2267 Provide wizards	3431 The system shall provide wizards
2268 Provide tool tips on menu	3441 The system shall provide tool tips on menu
2269 Provide built-in formulae for possible selection	3442 The system shall provide built-in formulae for possible selection
<i>Sub Area: Import/Export</i>	
2219 Support graphics import	3398 The system shall support graphics import

2220 Provide capability to export a text file	2515 The system shall provide capability to export a text file
2221 Provide capability to export a delimited file	3399 The system shall provide capability to export a delimited file
2222 Provide capability to export a Quattro or Lotus 1-2-3 file	3400 The system shall provide capability to export a Quattro or Lotus 1-2-3 file
2223 Provide capability to export a WordPerfect file	3401 The system shall provide capability to export a WordPerfect file
2224 Provide capability to import a text file	3402 The system shall provide capability to import a text file
2225 Provide capability to import a delimited file	3403 The system shall provide capability to import a delimited file
2226 Provide capability to import a Quattro or Lotus 1-2-3 file	3404 The system shall provide capability to import a Quattro or Lotus 1-2-3 file
2227 Provide capability to import WordPerfect file	3405 The system shall provide capability to import WordPerfect file
2228 Support DDE	2516 The system shall support DDE
2229 Support OLE for client/server	3406 The system shall support OLE for
2230 Support mail integration	3407 The system shall support mail integration
2231 Provide macro language recorder	3408 The system shall provide macro language recorder
Sub Area: Performance	
2281 Demonstrate response time for simple queries *(5 min., M+, M++)	3670 The system shall demonstrate response time for simple queries *(5 min., M+, M++)
2282 Demonstrate response time for moderately complex queries	3671 The system shall demonstrate response time for moderately complex queries *(30 min., M+, M++)
2283 Demonstrate response time for complex queries *(3 hr, M+, M++)	3672 The system shall demonstrate response time for complex queries *(3 hr, M+, M++)
Sub Area: Query/Report Format	
2177 Support custom format query/report definition	2503 The system shall support custom format query/report definition
2178 Support tabular query/report definition	2504 The system shall support tabular query/report definition
2179 Support crosstab query/report definition	2505 The system shall support crosstab query/report definition
2180 Support master/detail query/report definition	2506 The system shall support master/detail query/report definition
2181 Support pivot table query/report definition	3385 The system shall support pivot table query/report definition
2182 Support two-pass definition	3386 The system shall support two-pass definition
2183 Support multiple query query/report definition	2507 The system shall support multiple query query/report definition
2184 Support form letter definition	2508 The system shall support form letter definition
2185 Support mailing label definition	3387 The system shall support mailing label definition
2186 Support barcoding	2509 The system shall support barcoding
2187 Support generation of charts and graphs	2605 The system shall support generation of charts and graphs
2188 Support conditional text formatting	3388 The system shall support conditional text formatting
2189 Provide report template capabilities	3389 The system shall provide report template capabilities
2190 Support user input of live data during report design	2510 The system shall support user input of live data during report design
2191 Support multiple views of the same data	3390 The system shall support multiple views of the same data
2192 Provide capability to insert date and time	3676 The system shall provide capability to insert date and time
2193 Support page numbering	3677 The system shall support page numbering
2194 Provide capability to define data format (e.g., display numbers in thousands, define date format, request data truncation, etc.)	3798 The system shall provide capability to define data format (e.g., display numbers in thousands, define date format, request data truncation, etc.)

2195 Provide specification of a variety of font types and font	3799 The system shall provide specification of a variety of font types and font sizes
2196 Provide capability to underscore, shadow or box fields	3800 The system shall provide capability to underscore, shadow or box fields
2197 Provide capability to define report title	3801 The system shall provide capability to define report title
2198 Provide capability to define row and column headings	3808 The system shall provide capability to define row and column headings
2199 Support on-line or hardcopy output	3682 The system shall support on-line or hardcopy output
2200 Support batched hardcopy output	3802 The system shall support batched hardcopy output
2201 Support 8 1/2" x 11" hardcopy output	3803 The system shall support 8 1/2" x 11" hardcopy output
2202 Support 11" x 8 1/2" hardcopy output	3803 The system shall support 8 1/2" x 11" hardcopy output
2203 Support 11" x 17" hardcopy output	3804 The system shall support 11" x 17" hardcopy output
2204 Support report scheduling	3805 The system shall support report scheduling
2205 Provide capability to determine range of data to be included in query/report, (e.g., data range, field value)	2511 The system shall provide capability to determine range of data to be included in query/report, (e.g., data range, field value)
2206 Support use of Boolean logic	2512 The system shall support use of Boolean
2207 Provide ability to discard groups based on user criteria	2513 The system shall provide ability to discard groups based on user criteria
2208 Support generation of complex queries/reports (e.g., outer joins and nested queries)	3806 The system shall support generation of complex queries/reports (e.g., outer joins and nested queries)
2209 Provide capability to define simple calculated fields (e.g., query field 1 * query field 2 = query field 3)	3391 The system shall provide capability to define simple calculated fields (e.g., query field 1 * query field 2 = query field 3)
2210 Provide capability to define complex formulae for field definition	3392 The system shall provide capability to define complex formulae for field definition
2211 Provide capacity to specify totals independent of break specification	3393 The system shall provide capacity to specify totals independent of break
2212 Provide totaling/subtotaling capability	3444 The system shall provide totaling/subtotaling capability
2213 Provide crosstab capability	2505 The system shall support crosstab query/report definition
2214 Provide capability to display leading or trailing group (break) totals	3395 The system shall provide capability to display leading or trailing group (break) totals
2215 Provide ascending and descending sort capability	2514 The system shall provide ascending and descending sort capability
2216 Provide mixed ascending and descending sort capability	3396 The system shall provide mixed ascending and descending sort capability
2217 Provide multiple sort level capability	3397 The system shall provide multiple sort level capability
2218 Provide capability to sort groups based on group subtotal	3437 The system shall provide capability to sort groups based on group subtotal
Sub Area: Security	
2284 Provide capability to restrict access	3850 The system shall provide capability to restrict access
2285 Provide capability for data administrator to define access restrictions	3851 The system shall provide capability for data administrator to define access restrictions
2286 Provide backup/recovery capability for long queries	3895 The system shall provide backup/recovery capability for long queries
2287 Provide capability to define printer location	3852 The system shall provide capability to define printer location
Sub Area: System Architecture	
2288 Support capability to execute/define queries/reports from character mode workstation (DOS) and GUI workstation (Windows)	3907 The system shall support capability to execute/define queries/reports from character mode workstation (DOS) and GUI workstation (Windows)
2289 Support capability to execute/define queries/reports from a GUI workstation (Windows)	3908 The system shall support capability to execute/define queries/reports from a GUI

2290 Support capability to execute/define queries/reports from a character mode workstation (DOS)	workstation (Windows)
2291 Support data access to any Oracle-supported platform	3915 The system shall support capability to execute/define queries/reports from a character mode workstation (DOS)
2292 Provide capability to run tool off a server with multiple-user access	3906 The system shall support data access to any Oracle-supported platform
2293 Support execution of queries on client/server	3909 The system shall provide capability to run tool off a server with multiple-user access
2294 Provide capability to specify site of sorting (client or server)	3910 The system shall support execution of queries on client/server
2295 Support capability for computed columns to be on client/server	3911 The system shall provide capability to specify site of sorting (client or server)
	3912 The system shall support capability for computed columns to be on client/server

Functional Area: Current and Desired Reports

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2003 RTM

Sub Area: Canned SRS Reports: Epidemiology Reports Menu

- 2327 Single COSTART Term
- 2326 Individualized Group Of COSTART Terms
- 2325 Mid-Level Group Of COSTART Terms
- 2324 DPE Defined Disease Groups Of COSTART Terms
- 2323 Total 15 day, Periodic, And Direct Reports, By Year Of Receipt
- 2328 All Reports For Drug
- 2321 Number Of Cases Per Serious Outcome, By Body system
- 2320 Number Of Cases Per Serious Outcome, By Year Of Receipt
- 2319 Listing Of Case Numbers And Initial And Follow-up Microfilm/Image ID Numbers
- 2318 Comments For Cases
- 2322 Number Of Cases Per Serious Outcome, By COSTART Within Body System
- 2329 Drug Interactions (2 Drug List Codes)
- 2330 Labeled/Unlabeled COSTARTs For Specified Brand Name(s)
- 2307 Number Of De/Rechallenges Per Serious Outcome
- 2332 Mid-Level COSTART Terms From The COSTART Manual For A Specified Body System
- 2305 Number Of Cases Per Serious Outcome, By Sex And Age Category
- 2304 Number Of Cases Per Serious Outcome, By Age
- 2335 Create A Drug List Code
- 2334 File Utilities (Printing, Listing)
- 2333 COSTART Terms Grouped By Body system
- 2317 Line Listing Summary Of Cases
- 2306 Number Of Cases Per Serious Outcome, By Year/Quarter
- 2331 a) Total Cases In Database By Serious Outcome (All Domestic And Foreign)
- b) Total Cases Per Serious Outcome By Year Of Receipt
- c) Total Cases Per Report Type By Year Of Receipt For
- 2315 Number Of Cases By Serious Outcome, By Body System
- 2314 Number Of Cases By Serious Outcome, By Year Of
- 2313 Number Of Cases Per Serious Outcome, By Suspect And Other Drug
- 2312 Counts Of COSTARTs In Cases, With Most Frequent COSTART Terms Listed First
- 2311 Number Of Cases Per Serious Outcome, By Location Within A Geographic Region
- 2310 Number Of Cases Having 1, 2, 3 Or 4 Or More Drugs
- 2309 Number Of Cases Per Serious Outcome, By Report Type
- 2308 Number Of Foreign, Study, Consumer, And Literature Reports By General Source
- 2316 Number Of Cases Per Serious Outcome, By COSTART

Within Body System

Sub Area: *Current REB Reports*

- 2338 Reports With Positive Dechallenge (Abate) Indicated With Only One Drug Reported And An Unlabeled ADE For A Specific Time Frame, Indicating Labeled And Unlabeled
- 2345 To Health Care Provider Thank You For Inquiry On ADR Reporting
- 2344 To Correspondent After Phone Call/Mail: Request To Have Correspondent Contact Health Care Provider To Fill Out 3500 Or To Fill Out Themselves
- 2343 Thank You To Correspondent For Sending In ADR Report
- 2342 Thank you to Health professional for Sending in ADR
- 2337 Stratified By Body System, COSTART, And Outcome. Labeled Vs. Unlabeled Data For A Specified Time Frame
- 2346 To Manufacturer Sending Of Reporting Guidelines
- 2339 Reports That Have A Positive Rechallenge (Reoccur) A Suspect NME Associated With An Unlabeled ADE For A Specified Time frame, Indicating Labeled/Unlabeled
- 2340 Cover Page Summary And 2 Tables: Reports Evaluated By REB By Reviewer And Reports Evaluated By REB By Review Division
- 2341 MARS And Consults
- 2336 Count Of Current ADEs Stratified By Age And Outcome For A Specified Time Period

Sub Area: *Desired Future EPI Reports*

- 2376 Cooperative Agreement Log
- 2375 IMS Log
- 2374 Consult Log

Sub Area: *Desired Future REB Reports*

- 2352 Reporting Rate
- 2347 WHO Listing
- 2348 Drug Use Listing
- 2349 DORS Listing
- 2350 Pharm Class Comparative Listing
- 2351 Percent Listing

Sub Area: *MEDEX Reports*

- 2377 Cumulative MedWatch Report By Specialty, Method Of Reporting, And Number Serious For AE Reports Received Before A Specified Date
- 2382 Acknowledgment Of Receipt Of Voluntary Report
- 2383 Notification Of Receipt Of A Report Involved In The Expedited Transmission Program
- 2381 Summary of MedWatch Reports by Gender and Age
- 2380 Cumulative MedWatch Reporter Also Notified (E4) AE Reports Received Before A Specified Date
- 2379 Cumulative MedWatch Report By Outcome And Confidentiality For AE Reports Received Before A Specified Date
- 2378 Cumulative MedWatch Report By Specialty, Center, And Number Serious AE Reports Received Before A Specified Date
- 2384 Cover Letter For Instructions For Voluntary Reporting

Sub Area: *SDBP Reports*

- 2362 Graph: 2 Year Trend By Body System
- 2371 Data Output
- 2370 Adverse Event Reports Received
- 2369 Table: Distribution By Reporter Occupation In Cases

"Direct" From Health Professionals
 2368 Table: 20 Most Frequently First-Listed Suspect Drugs
 2367 Table: Distribution Of Cases By Therapeutic Class
 2353 Overview Of Cases
 2358 Graph: Comparison Of 15 day/Periodic/Direct Cases By Year
 2357 Table: Distribution Of Cases By Report Type: Year To Year Comparison
 2356 Graph: Distribution Of Cases By Report Type
 2355 Graph/Table: Number Of Cases Per Year (Over A x year Time Span)
 2373 Date, 15d, Periodic, Released
 2366 Table: Distribution Of Cases By Geographic Region
 2354 Table: Distribution Of Cases By Source: Year To Year Comparison
 2359 Graph: Distribution Of Cases By Selected Outcomes
 2363 Table: Distribution Of Cases By Age Group (All Ages)
 2360 Graph: Distribution Of Cases By Body System (Per Year)
 2364 Table: Distribution Of Cases By Age Group (Pediatric Only)
 2365 Graph: Distribution Of Cases By Gender
 2361 Table: Distribution Of Cases By Body System: Year To Year Comparison

Functional Area: Manage Adverse Event Information

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Sub Area: Manage Attachments

1755 The system must be able to link an Attachment to a report
 1756 The system must be able to assign the permanent AERS ID Number from the Adverse Event Report to the attachment with which it is associated
 1757 The system must be able to identify all attachments associated with a case
 1758 The system must be able to support imaging of
 1759 The system must be able to link an attached image to its associated report and its associated case
 1760 The system must be able to track the status of a report by: date sent, user requesting additional information, information requested, and date received
 1761 The system must have the ability to generate a standard letter to the sender of the report requesting an acceptable copy of the attachment
 1762 The user must have the ability to easily retrieve and view images associated with a particular ADR or case from the AERS System
 1763 The system must have the ability to request on-line printing of a single image or a batch printing of images and specify the printer output location
 1764 The system must have the ability to reference every report associated with a literature study when one literature study that refers to multiple patients is imaged
 1765 The system must have the ability to automatically identify reports that do not comply with new regulations and guidelines for required attachments and data
 1766 The system must be able to date stamp the receipt of the attachment and automatically record the date the AERS attachment data was created
 1767 The system must be able to create, open, close, and assign batches of attachments along with relevant dates to ensure document control
 1768 The system must be able to process individual attachments by:

2003 RTM

2451 The system shall link an attachment to an
 2584 The system shall assign the permanent ISR Number to the attachment to which it is associated.
 2585 The system shall identify all attachments associated with a case.
 2604 The system shall support attachment
 2452 The system shall link an attached image to its associated ISR and its associated case.
 2453 The system shall track the status of an ISR by date sent, user requesting additional information, information requested, and date received.
 3366 The system shall provide the ability to generate a standard letter to the sender of the ISR requesting an acceptable copy of the attachment.
 2454 The system shall provide the ability to easily retrieve and view images associated with a particular ISR or case.
 2876 The system shall provide the ability to request on-line printing of a single image or a batch printing of images and specify the printer output location.
 3367 The system shall provide the ability to reference every ISR associated with a literature study when one literature study that refers to multiple patients is imaged.
 3368 The system shall provide the ability to automatically identify ISRs that do not comply with new regulations and guidelines for required attachments and data.
 2455 The system shall date stamp the receipt of the attachment and automatically record the date the attachment data were created.
 3352 The system shall create, open, close, and assign batches of attachments and relevant dates for document control.
 2456 The system shall process individual attachments by: linking attachments to an

- Linking attachment to one or more adverse event report/s
 - Scanning
 - Indexing to the adverse event report or case series
 - Providing quality control of image and index
 - Recording image completion date
 - Generate performance report
- 1769 The system must be able to automatically capture, record, and report key processing event dates associated with reports and images, including:
- Receive date
 - Data entry date
 - Quality control date
 - Coded date
 - Imaging date
 - Review date
- 1770 The system must be capable of selecting and printing redacted direct reports and associated images based on drug product, manufacturer, and MedWatch Expedited Transmission Status
- 1771 The system must be able to track the date the attachment was received, the type of attachment, and the acceptability of the attachment by manufacturer.
- 1772 The system must be able to automatically generate letters requested attachments for given user criteria; letters should be able to be customized to report and case specific information
- Sub Area: Manage Electronic Receipts**
- 1680 Receive submissions through EDI or physical media
- 1681 Receive and maintain a database of manufacturers/sender with their electronic mail addresses and decryption keys to facilitate validation of transmission source, as well as electronic transmission of acknowledgments and problem reports from FDA Central
- 1682 Translate EDI transmissions from the ICH M2 standard
- 1683 Decrypt electronic submissions using commercially available encryption technology and authenticate the sender (ICH M2 standard)
- 1684 Send Receipt acknowledgment notice and send file problem notice via the FDA Central Receiving Site
- 1685 Messages sent back to the manufacturer should use the same authentication/encryption facilities as for transmissions received from the manufacturer.
- 1686 Maintain archive of all files submitted following FDA approved records retention schedules
- 1687 Upload ADR records from translated, decrypted files into the AERS data base
- 1688 Track date and time of file received, receipt acknowledgment, problem notice sent, file uploaded, and file archived, with individual ADRs
- 1689 Flag uploaded records for automated quality control
- 1690 Store archive file sequence number with each individual report received in a single transmission
- 1691 Process automated quality control check of electronically received ADRs prior to AERS database update
- ISR; enabling the scanning, and indexing of the ISR; providing Quality Control of image and index; recording image completion date; generating performance reports; and assigning and tracking security by user.
- 2457 The system shall automatically capture, record, and store ISRs key processing event dates associated with reports and images, including Data Entry date, Quality Control date, MedDRA Coding date, image date, and review date.
- 3435 The system shall select and print redacted direct ISRs and associated images based on drug product, manufacturer, and MedWatch expedited transmission status.
- 2458 The system shall track the date the attachment was received, the type of attachment, and the acceptability of the attachment by manufacturer.
- 3370 The system shall automatically generate letters requesting attachments for given user criteria; letters should be able to be customized to ISR and case specific information.
- 2824 The system shall receive submissions through Electronic Data Interchange or physical media
- 3445 The system shall receive and maintain a database of manufacturers/senders with their electronic mail addresses and decryption keys to facilitate validation of
- 3446 The system shall translate EDI transmissions from the ICH M2 standard.
- 3447 The system shall decrypt electronic submissions using commercially available encryption technology and authenticate the sender (ICH M2 standard).
- 3448 The system shall send receipt acknowledgment notices and send file problem notices via FDA Central Receiving Site.
- 3449 The system shall authenticate and encrypt all replies.
- 3450 The system shall maintain an archive of all electronic files submitted following FDA-approved records retention schedules.
- 2424 The system shall upload ISRs from translated, decrypted files into the system database.
- 2932 The system shall track date and time of file received, receipt acknowledgment, problem notice sent, file uploaded, and file archived with individual ISRs in the database
- 2933 The system shall flag uploaded electronic ISR records for automated quality control
- 3451 The system shall archive file sequence numbers with each individual electronic ISR received in a single transmission.
- 2615 The system shall process automated quality control checks of electronically received

1692 Generate and transmit electronically or manually AERS acknowledgment of total ADR reports accepted with corresponding AERS Report #s, manufacturer control #s and/or exception reports indicating reasons for non-acceptance back to the manufacturers

1693 All electronic submissions, whether EDI or physical media, should use encryption to facilitate authentication of the sender

Sub Area: Manage Manufacturer Compliance

1789 If a direct report indicates that information has been sent to the manufacturer, then set a tickler for receipt of similar report from the manufacturer

1790 The system must establish minimum data set or other conditions for determining compliance criteria by report type (e.g., 15-day, periodic, and E2B submissions)

1791 The system must flag mandatory fields that are missing on manufacturer reports, as well as identify instances where manufacturer coding varies from FDA risk assessor coding and/or where difference between receive date and event notification date are greater than

1792 Calculate and store a compliance score for each individual report received from manufacturers and compute a quarterly average manufacturer compliance

1793 The system must compare manufacturer compliance scores to one another, the industry average, and within each manufacturer over time (trends)

1794 The system must calculate industry average compliance scores and store these within AERS

1795 The system must determine whether 15-day and periodic reports are submitted on time and ability to count the number of serious reports that are late

1796 The system must view coding changes made by coders for a series of manufacturer reports

1797 Compliance Officer must be notified of late expedited reports within 15 days of receipt at FDA

1798 The system must maintain history of manufacturer compliance performance over time

- Store counts/dates of late/missing reports
- Store counts/dates of incomplete reports

1799 The system must check IMT coding for the following:

- Consistency
- Accuracy
- Completeness
- Down-coding (using a less serious IMT code in a serious event)

1800 The system must be able to identify serious and non-serious reports and distinguish foreign from domestic reports to support query and compliance score calculation requirements.

1801 The system must be able to query the database to identify potential compliance cases using compliance scores, counts of deficient reports, or other compliance related criteria

1802 The system must query the report database by manufacturer and view output on the screen and/or by

1803 Support modification of initial case series by allowing

ISRs prior to the system's database update.

2616 The system shall generate and transmit (electronically or manually) an acknowledgment of total ISRs implemented with corresponding ISR numbers, manufacturer control numbers, and/or exception reports indicating reasons for non-acceptance.

3452 The system shall provide encryption to facilitate sender authentication for electronic ISRs.

3328 The system shall enable automatic notification for receipt of any similar ISR from the manufacturer.

2425 The system shall establish a minimum data set to include: identifiable patient, suspect drug, identifiable reporter, and reaction per FDA business rules for determining compliance criteria by ISR type (e.g., expedited, periodic, and electronic submissions).

3329 The system shall flag mandatory fields that are missing on manufacturer reports, as well as identify instances where manufacturer coding varies from MedDRA

3330 The system shall calculate and store a compliance score for each ISR received from manufacturers and compute a quarterly average manufacturer compliance

3331 The system shall compare manufacturer compliance scores to one another, the industry average, and within each manufacturer over time (e.g., trends).

3332 The system shall calculate and store industry average compliance scores.

2426 The system shall determine whether expedited and periodic ISRs are submitted on time.

3333 The system shall view coding changes made by coders for a series of

2427 The system shall notify the Compliance Officer of late, expedited ISRs within 15 days of receipt at FDA.

3334 The system shall maintain a history of manufacturer compliance performance over time, store counts/dates of late/missing ISRs, and store counts/dates of incomplete

3335 The system shall check MedDRA coding for consistency, accuracy, completeness of code, as well as down-coding (e.g., using a less serious MedDRA code in a serious

3345 The system shall distinguish foreign from domestic reports to support query and compliance score calculation requirements.

3337 The system shall provide the ability to query the database to identify potential compliance cases using compliance scores, counts of deficient ISRs, or other compliance related-criteria.

3338 The system shall query the database by manufacturer and view output on the screen and/or by printed report.

3339 The system shall support modification of

- addition and deletion of reports
- 1804 Compliance Officers require notification of and access to risk assessor's case series and MARs
- 1805 Compliance Officers require notification of changes in status of risk assessor's case series and MARs
- 1806 The system must group a series of reports into a manufacturer compliance case series that can be accessed electronically
- 1807 The system must record and store an assessment of a compliance case series.
- 1808 The system must track compliance case series activities and status from initiation through to completion
- 1809 Maintain history of manufacturer compliance case series activities and status over time
- Store compliance officer comments
 - Store description of completed compliance actions
- 1810 FDA field investigators may require access to AERS when they are assigned to an ADR reporting compliance
- 1811 Access to all compliance case series, manufacturer compliance history, and individual safety report compliance scores should be limited to compliance officers and other authorized individuals
- 1812 The compliance officer needs to have access to case series and MAR information developed by the risk
- Sub Area: Manage Paper Receipts*
- 1729 The system must be able to identify the date the image was archived from the Excalibur Imaging System
- 1712 The system must be able to validate all data associated with a dictionary or reference table including:
- Drug
 - Biologic
 - Manufacturer
 - Patient Sex
 - Adverse Event Outcome
 - Reporter Information
 - Type of Report
 - Report Source
- 1694 The system must be able to capture a date stamp for date of receipt and permanent unique AERS ID Number for each report, as well as support displaying this information on the physical report for purposes of imaging and batch
- 1695 The system must be able to accept reports providing default values for certain fields based on report type
- 1696 The system must be able to automatically record the create date
- 1697 The system must be able to support current MEDEX data capture needs, including:
- Record the suspect medication(s) on the report
 - Record the suspect device(s) on the report
 - Record the specialty of the reporter
 - Record the method of reporting (mail, fax, phone, bulletin board)
 - Record and automatically determine whether the report is serious based on predefined business rules
 - Record the primary FDA Center for the report
 - Record the secondary FDA Center(s) for the report
 - Record the outcome of the adverse event on the report
 - Record the recipient category (distributor, manufacturer, user facility, not given) on the report
 - Record the publication associated with the report
- initial case series by allowing addition and deletion of ISRs.
- 3340 The system shall notify Compliance Officers of and provide access to Safety Evaluator case series and MARs.
- 3341 The system shall notify Compliance Officers of changes in status of Safety Evaluator case series and MARs.
- 3342 The system shall group a series of ISRs into a manufacturer compliance case series that can be accessed electronically.
- 3343 The system shall record and store an assessment of a compliance case series.
- 3347 The system shall track compliance case series activities and status from initiation through to completion.
- 3344 The system shall maintain a history of manufacturer compliance case series activities and status over time.
- 3891 The system shall provide the FDA field investigators access to the system when assigned to an ADR reporting compliance case.
- 3892 The system shall provide Compliance Officers with access to all compliance case series, manufacturer compliance history, and ISR compliance scores.
- 3893 The system shall provide the ability to access case series and MAR information developed by Safety Evaluators.
- 2582 The system shall capture a date stamp for date of receipt and a permanent, unique number for each ISR (i.e., ISR Number).
- 2583 The system shall provide default values for fields based on report type.
- 2429 The system shall automatically record the legacy ISR create date.
- 2430 The system shall support current MEDEX data capture needs.

- Record reporter information including:
 - Last Name, First Name, and Middle Initial
 - Degree and Profession
 - Address Heading, PO Box, Street Address, City, State, and Zip Code
 - Province and Country
 - Phone Number
- 1698 The system must be able to record, store, and report the number of pages printed by both the Excalibur Imaging System and the AERS System for MedWatch Expedited Transmission billing purposes
- 1699 The system must be able to automatically produce letters and mailing labels for the MedWatch Expedited Transmission Program
- 1700 The system must be able to record all data and text descriptions on the MedWatch 3500, MedWatch 3500 A, and 1639 Forms; verbatim data entry must be supported
- 1701 The system must be able to automatically produce MedWatch Expedited Transmission Letters, which are sent out with copies redacted reports
- 1702 The system must be able to enable faxing of MedWatch Expedited Report Letters and redacted reports to the manufacturers who are participating in the Expedited Transmission Program
- 1703 The system must be able to support electronic transmission of reports and images to fulfill the MedWatch Expedited Transmission requirements for participants and their registered drug products
- 1704 The system must be able to produce management reports for tracking/billing of the MedWatch Expedited Transmission Program
- 1705 The system's data entry screens must mirror the MedWatch Form(s) layout, specifically Form 3500 and
- 1706 The system must automatically derive and populate the patient's age when given birthdate and date of ADR event
- 1707 The system must record all dosage data including frequency by day, week, and month and calculate dosage by number of days
- 1708 The system must record an unlimited number of biologic products for each report entered
- 1709 The system must be able to accommodate lengthy names for biologic products
- 1710 The system must capture verbatim data, text, and image for all reports received on paper
- 1711 The system must support the capture and recording of all supplemental data currently requested from biologic manufacturers for ADR reports involving allergenic extracts.
- 1713 The system must support the following word processing capabilities to ensure ease and accuracy of data entry of narrative text description of the adverse event:
 - word wrap
 - spell checker (global)
 - medical/pharmaceutical spell checker
 - backspace, insert, and delete
 - cut and paste capabilities
- 1714 The system must create, open, close, and assign batches of attachments, and relevant dates, for document
- 1715 The system should be able to automatically generate word count statistics for the text narrative description for each report to assist managers in assessing the overall data entry performance
- 3468 The system shall provide the ability to record, store, and report the number of pages printed by both the Excalibur Imaging System and the system for MedWatch Expedited Transmission Program billing
- 3469 The system shall provide the ability to automatically produce letters and mailing labels for the MedWatch to Manufacturer Program
- 2431 The system shall support and record the verbatim Data Entry of all data and text descriptions on the MedWatch 3500, MedWatch 3500 A, and 1639 forms.
- 3470 The system shall provide the ability to automatically produce MedWatch Expedited Transmission letters, which are sent out with redacted ISR copies.
- 3471 The system shall enable faxing of MedWatch expedited ISR letters and redacted ISRs to the manufacturers who are participating in the MedWatch Expedited
- 3472 The system shall provide the ability to support electronic transmission of ISRs and images to fulfill the MedWatch Expedited Transmission Program requirements for participants and their registered drug
- 3473 The system shall provide the ability to produce management reports for tracking and billing of the MedWatch Expedited Transmission Program.
- 3351 The system shall mirror the layout of the MedWatch 3500 and 3500A forms.
- 2432 The system shall automatically derive and populate a patient's age when given birth date and event start date.
- 2433 The system shall record all dosage data including frequency by day, week, and
- 2434 The system shall record an unlimited number of biologic products for each ISR entered.
- 2435 The system shall accommodate lengthy names for biologic products.
- 2436 The system shall capture verbatim data, text, and images for all ISRs received on
- 3443 The system shall support the capture and recording of all supplemental data currently requested from biologic manufacturers for ISRs involving allergenic extracts.
- 2438 The system shall support word processing capabilities to ensure the ease and accuracy of the Data Entry of ISR narrative text, including a medical spellchecker.
- 3352 The system shall create, open, close, and assign batches of attachments and relevant dates for document control.
- 3353 The system shall automatically generate word count statistics for the ISR narrative text for each ISR to assist managers in assessing overall Data Entry performance.

- 1716 The system must be able to extract a subset or sample of reports from the production database data according to specified selection criteria for purpose of checking data quality
- 1717 The system must be able to queue a sample of reports completed by a specific data entry staff person to facilitate quality control studies
- 1718 The system must be able to track data entry errors by user, and type of error, and report the errors on management reports
- 1719 The system must be able to identify and track coding errors by the coder
- 1720 The system must be able to identify coding errors submitted by the manufacturer and report the errors for compliance purposes
- 1721 The system should be able to detach and reattach reports and attachments that were linked incorrectly
- 1722 The user must be able to easily access the Excalibur Imaging System without exiting AERS
- 1723 The system must be able to link the AERS data/ID Number to the Excalibur Imaging System
- 1724 The user must be able to retrieve, view, and print imaged reports from the Excalibur Imaging System from within AERS
- 1725 The system must be able to identify the date the report was scanned, indexed, QC'ed, and accepted into the Excalibur Imaging System
- 1726 The system must be able to track when a report or attachment was re-scanned or rejected from the imaging process
- 1727 The system must be able to identify the user who performed the imaging function
- 1728 The system must be able to calculate the number of images printed for MEDEX and FOI purposes
- 1730 The system must be able to support coding adverse event information including the Indication for Use and the Narrative Description of the Event in the IMT terminology
- 1731 The system must be able to interface with the FDA IMT database
- 1732 The system must be able to record the IMT code(s) in all data elements identified in the ICH E2B final document
- 1733 The system must be able to record unlimited suspect adverse reactions (in IMT codes) for each report
- 1734 The system must be able to identify the coder and the date the report was coded
- 1735 The system must be able to store codes that have been submitted electronically
- 1736 The system must provide the ability for the Risk Assessor to obtain label text by section from the Excalibur System, clean up coding errors if they exist, and feed this corrected text through the autoencoder, if it is available; the Risk Assessor must have the ability to view, edit (add, delete, modify) the autoencoder output before
- 1737 The system must provide security features that permits only the Risk Assessor who is assigned the drug to update the coding for a new or revised label
- 1738 The system must provide access to an on-line medical dictionary and Physician's Desk Reference (PDR)
- 1739 The system must provide access to a list that contains a standard range of laboratory values for use as a coding reference for assignment of the appropriate IMT term
- 2789 The system shall provide the ability to extract a subset or sample of ISRs from the production database data according to specified selection criteria for the purpose of checking data quality.
- 2790 The system shall provide the ability to queue a sample of ISRs completed by a specific Data Entry staff person to facilitate Quality Control studies.
- 3354 The system shall track Data Entry errors by user and type of error, and report the errors on management ISRs.
- 3355 The system shall identify and track MedDRA Coding errors by the coder.
- 3356 The system shall identify MedDRA coding errors submitted by the manufacturer and report the errors for compliance purposes.
- 3357 The system shall detach and reattach ISRs and attachments that were linked incorrectly.
- 2439 The system shall enable users to access the Excalibur Imaging System without exiting AERS.
- 2440 The system shall link the ISR Number to the Excalibur Imaging System.
- 2441 The system shall enable users to retrieve, view, and print imaged ISRs from the Excalibur Imaging System within the system.
- 3433 The system shall identify the date ISRs were scanned, indexed, Quality Controlled, and implemented into the Excalibur Imaging System
- 3434 The system shall track when an ISR or attachment was rescanned or rejected from the imaging process.
- 3358 The system shall identify the user who performed the imaging function for each ISR.
- 3359 The system shall calculate the number of images printed for MEDEX and FOI
- 2442 The system shall support MedDRA coding adverse event information including the indication for use and the narrative description of the event.
- 2443 The system shall interface with the FDA MedDRA database.
- 2444 The system shall record the MedDRA code(s) in all data elements identified in the ICH Electronic Submissions final document.
- 2445 The system shall record unlimited MedDRA codes related to suspect adverse reactions.
- 2446 The system shall identify the coder and the coding date for each ISR.
- 2447 The system shall store codes that have been submitted electronically.
- 3491 The system shall provide the ability for the Safety Evaluators to obtain label text by section from the Excalibur System, clean up coding errors, and feed this corrected text through the autoencoder.
- 3492 The system shall restrict the ability to update the coding for a new or revised drug label to the assigned Safety Evaluator.
- 3633 The system shall provide the ability to access the following external systems: Medline, PDR, DQRS, WHO, and VAERS (CBER Safety Evaluators only).
- 3362 The system shall provide access to a list that contains a standard range of laboratory values for use as a MedDRA coding reference for assignment of the appropriate

- 1740 The system must provide viewing capabilities to the IMT Dictionary with full access to:
- The descriptions of the IMT terms at all levels of the IMT Hierarchy
 - The IMT hierarchy and the multi-axial components as associated with a particular term(s) and Systems Organ Class(es)
 - The IMT coding procedures, principles, and on-line training manual, if available
- 1741 The system must provide a real time and batch interface to the FDA IMT encoding/autoencoding system
- 1742 The IMT autoencoder should have the following capabilities:
- Ability to learn from previous matches
- 1743 The IMT Coding Manual should contain the following:
- Definition of the IMT coding hierarchy and format
 - Definition of the categories, sub-categories, and terms
 - Description of coding principals, conventions, and rules including sequencing of codes, establishment of principle/primary reaction, use and establishment of NOS codes, coding of uncertain/undetermined indications or reactions, definitions of inclusion and exclusion terms,
- 1744 The system must have the ability to add, edit, and delete FDA Lower Level Terms (LLT) to the IMT Hierarchy that are specific to the agency
- 1745 The system must be able to validate the codes and report on quality and compliance related to coding
- 1746 The system must be able to correct and track coding errors when detected; management reports should indicate the incorrect and corrected codes and the
- 1747 The system must be able to identify reports that may have incomplete or erroneous data on the drug or manufacturer associated with the report
- 1748 The system must be able to allow for correction of any errors made to the drug and manufacturer data
- 1749 The system must be able to track the source (user or electronic report) of the drug and manufacturer data
- 1750 The system must be able to produce Thank You Letters to Direct Reporters
- 1751 The system must be able to process information on Direct Reporters, such as name and address, for Thank You Letters
- 1752 The system must be able to produce Manufacturer Acknowledgment Letters on a routine basis (weekly, bi-weekly, monthly)
- 1753 The system must be able to produce exception letters for those reports lacking the minimum data set
- 1754 The system must be able to indicate the permanent AERS ID Number as a reference for the manufacturer if follow-up is necessary
- Sub Area: Version Control and Case Assignment**
- 1773 The system must be able to identify reports from Direct Reporters, Manufacturers, and Risk Assessors as Follow-up Reports
- 1774 The system must be able to maintain report version and date of receipt history
- 1775 The system must be able to maintain an audit trail of relevant dates (e.g., date received by FDA, date entered by FDA, date attachments received and processed, date of review by Risk Assessors, date coded, date follow-up received) for all reports
- 1776 The system must be able to support automatic
- 2602 The system shall provide viewing capabilities to the MedDRA dictionary with full access to descriptions of all MedDRA terms at all levels, the MedDRA hierarchy, the multi-axial components associated with particular MedDRA term(s) and SOC(s), coding principles, and on-line Help Text.
- 3363 The system shall provide a real-time and batch interface to Autocode.
- 2403 The system shall support the MedDRA autoencoder ability to learn from previous matches and to maintain history tables.
- 2603 The system shall ensure that the MedDRA coding manual shall contain the following: a definition of the MedDRA coding hierarchy and format; the categories, sub-categories, terms and coding principles; the conventions and rules including codes; the establishment of principle/primary reaction; the use and establishment of not otherwise specified codes; the coding of uncertain/undetermined indications or reactions; and the inclusion definitions.
- 2791 The system shall provide the ability to add, edit, and delete FDA LLTs to the MedDRA Hierarchy that are specific to FDA.
- 3364 The system shall validate the MedDRA codes and report on quality and compliance related to MedDRA coding.
- 3365 The system shall correct and track MedDRA coding errors when detected.
- 2448 The system shall identify ISRs that may have incomplete or erroneous data on the associated drugs or manufacturers.
- 2449 The system shall allow for correction of any errors made to drug or manufacturer data.
- 2450 The system shall track the source (user or electronic report) of the drug and manufacturer data.
- 3474 The system shall provide the ability to produce thank you letters to direct reporters.
- 3475 The system shall provide the ability to process information on direct reporters for thank you letters (e.g., name, address).
- 3476 The system shall provide the ability to produce manufacturer acknowledgment letters on a routine basis (i.e., weekly, bi-weekly, monthly)
- 3477 The system shall provide the ability to produce exception letters for ISRs that lack the minimum data set.
- 3478 The system shall provide the ability to indicate a permanent ISR number on the generated letters as a reference for the manufacturer if follow-up is necessary.
- 2459 The system shall identify ISRs from direct reporters, manufacturers, and Safety Evaluators as follow-up ISRs.
- 3371 The system shall maintain ISR version and date of receipt history
- 2460 The system shall maintain an audit trail of relevant dates (e.g., date received by FDA, date entered by FDA, date attachments received and processed, date of review by Safety Evaluators.
- 2461 The system shall support automatic

- identification of multiple versions, duplicates, and follow-up Reports for a given case
- 1777 The system must record and report "invalid" follow-ups (follow-up Reports with no Initial report) and not permit the update of "follow-up flag field" in the database for these cases
- 1778 The system must be able to link the follow-up to the case
- 1779 The system must be able to link and validate the existence of a Follow-up to an Initial report
- 1780 The system must be able to link all reports associated with a case
- 1781 The system must be able to maintain for each report the Date of Receipt by the FDA and its corresponding Report Date (don't write over reports)
- 1782 The system should permit capture report data only as they appear on the received form or transmission received
- 1783 The system must be able to automatically identify duplicate reports and link them to the original
- 1784 The system must be able to "mask" a duplicate report from primary surveillance processing by recording its duplicate status
- 1785 The system must be able to assign an Adverse Event Case Number for each initial report for an adverse event
- 1786 The system must be able to link any subsequent duplicate or follow-up reports to the corresponding Case Number
- 1787 The system must allow the transfer or "re-linking" of a report assignment from one report to another as well as from one case to another
- 1788 The system must record and report all transactions that result in changes to an already processed report or case record
- identification of multiple versions, duplicates, and follow-up ISRs for a given case.
- 3372 The system shall record and report invalid follow-ups (e.g., follow-up ISRs with no initial ISR) and not permit the update of Follow-up flag field in the database for
- 2462 The system shall link a follow-up to the appropriate case.
- 2463 The system shall link and validate the existence of a follow-up to an initial ISR.
- 2464 The system shall link all ISRs associated with a case.
- 2465 The system shall maintain the date of receipt by the FDA and its corresponding date for each ISR. The system shall not enable over-writing ISRs.
- 2466 The system shall permit capture of ISR data only as they appear on the form or transmission received.
- 2467 The system shall automatically identify duplicate ISRs and link them to the original corresponding ISR.
- 3373 The system shall mask a duplicate ISR from primary surveillance processing by recording its duplicate status.
- 2468 The system shall assign a case number for each initial ISR for an adverse event.
- 2469 The system shall link any subsequent duplicate or follow-up ISRs to the corresponding case number.
- 2594 The system shall allow the transfer or re-linking of an ISR assignment from one ISR to another as well as from one case to
- 2595 The system shall record and report all transactions that result in changes to an already processed ISR or case record.

Functional Area: Manage Dictionaries

1996 BA Document

Sub Area: Document Applicant Transition

- 1672 The system must be able to access updated data pertaining to buyouts
- 1673 System must be able to access updated data pertaining to mergers
- 1674 System must be able to access updated data pertaining to all changes of responsibility within the pharmaceutical industry

Sub Area: Maintain AERS Lower Level Terms

- 1665 The system must be able to retain new AERS lower level IMT terms
- 1666 The system must be able to link AERS lower level IMT terms to preferred terms

Sub Area: Maintain AERS Special Category Terms

- 1667 The system must be able to retain new AERS special category IMT terms
- 1668 The system must be able to link preferred terms to AERS special category IMT terms

Sub Area: Maintain Drug Product Information

- 1638 The system must be able to add and retain drug product

2003 RTM

- 3348 The system shall provide the ability to access updated data pertaining to buyouts.
- 3349 The system shall provide the ability to access updated data pertaining to mergers.
- 3350 The system shall provide the ability to access updated data pertaining to all changes of responsibility within the pharmaceutical industry. The system shall provide the ability to access updated data pertaining to all changes of responsibility within the pharmaceutical industry
- 2600 The system shall retain new MedDRA LLTs.
- 2601 The system shall link MedDRA LLTs to MedDRA PTs.
- 2619 The system shall retain new special category MedDRA terms.
- 2614 The system shall link MedDRA PTs to special category MedDRA terms.

- 2886 The system shall provide the ability to add

data including information about drug product formulation.	
1639 The system must be able to modify drug product data including information about drug product formulation.	2887 The system shall provide the ability to modify drug product data including information about drug product formulation.
Sub Area: Maintain IMT Terms	
1663 The system must be able to load and retain new International IMT terms	2817 The system shall provide the ability to load and retain new international MedDRA terms.
1664 The system must be able to update International IMT terms	2818 The system shall provide the ability to update international MedDRA terms.
Sub Area: Maintain Ingredient	
1635 The system must be able to retain ingredient data for both biologic and drug products.	2884 The system shall provide the ability to retain ingredient data for both biologic and drug products.
1636 The system must be able to update ingredient data for both biologic and drug products.	2885 The system shall provide the ability to update ingredient data for both biologic and drug products.
1637 The system must be able to delete ingredient data, if justified for both biologic and drug products.	2823 The system shall provide the ability to delete ingredient data, if justified for both biologic and drug products.
Sub Area: Maintain Manufacturer Profile	
1669 The system must be able to add and retain a new product applicant profile.	2888 The system shall provide the ability to add and retain a new product applicant profile.
1670 The system must be able to update a product applicant profile.	2875 The system shall provide the ability to update a product applicant profile.
1671 The system must be able to access information pertaining to the licensing or authorization of a manufacturer/distributor or establishment for a product.	2428 The system shall provide the ability to access information pertaining to the licensing or authorization of a manufacturer/distributor or establishment
Sub Area: Maintain Therapeutic Biologic Product Information	
1640 The system must be able to add and retain biologic product data including information about biologic product	2813 The system shall provide the ability to add and retain biologic product data including information about biologic product
1641 The system must be able to modify biologic product data including information about biologic product formulation.	2814 The system shall provide the ability to modify biologic product data including information about biologic product
Sub Area: Manage Drug Label Information	
1651 Provide the ability to copy text from any portion of a label into an MS-Word or WordPerfect document.	
1644 Provide the ability to view the most current label for a new molecular entity or designated drugs of interest.	2825 The system shall provide the ability to view the most current label for an NME or designated drugs of interest.
1645 Provide the ability to access and view the appropriate drug label if user wants to view label for a generic drug	2826 The system shall provide the ability to access and view the appropriate drug label if a user wants to view a label for a generic drug product.
1646 Provide the ability to track label changes, including the ability to display information about when it was last updated, the section that changed, and the reason for the	3479 The system shall provide the ability to track label changes, including the ability to display information about when it was last updated, the section that changed, and the reason for the change.
1647 Provide the ability to create and view label history.	3480 The system shall provide the ability to create and view label history.
1648 Provide the ability to add data about a new drug label.	2827 The system shall provide the ability to add text for a new drug label.
1649 Provide the capability to perform full text search on the most current product label.	2773 The system shall provide the capability to perform a full text search on the most current product label.
1650 Provide the capability to directly view image of a label from inside the AERS system.	2828 The system shall provide the ability to directly view label images from inside the
1652 Provide the ability to copy image of a label into an MS-Word or WordPerfect document.	2775 The system shall provide the ability to copy the image of a label into a Microsoft Word or WordPerfect document.
1653 Provide the capability to compare a label with other relevant drug labels that have the same pharmacological class or the same therapeutic indication class.	3481 The system shall provide the capability to compare a label with other relevant drug labels that have the same pharmacological class or the same therapeutic indication

- 1654 Provide the ability to print a portion or a complete label.
- 1655 Provide the ability to compare a drug label with other relevant drug labels to promote identification of adverse reactions that are prevalent in a drug class, and use the results as screening criteria.
- 1656 Provide the ability to view on-line label information to obtain information needed for drugs that are not in the current Excalibur or AERS labeling system.
- 1657 Provide the ability to IMT code all reactions and record their corresponding label section names for biologics and drug products.
- 1658 Provide the ability to edit IMT terms for a drug or biologic label.
- 1659 Provide the ability to view IMT terms upon request.
- 1660 Provide the ability to IMT code, all indications for use listed on a drug or biologic label.
- 1661 Provide the ability to access the autoencoder.
- 1662 Provide the ability to handle search criteria which requires IMT coded labeled fields as input.
- Sub Area: Manage Expedited Transmission Status**
- 1677 The system must be able to add and retain new data pertaining to an applicant receiving MedWatch expedited transmissions
- 1678 The system must be able to add and retain new data pertaining to a new product as the subject of MedWatch expedited transmissions
- 1679 The system must be able to update data pertaining to the status of an applicant and its registered product(s)
- Sub Area: Manage Manufacturer/Applicant Contact**
- 1675 The system must be able to add and retain new data pertaining to a contact
- 1676 The system must be able to update data pertaining to a contact
- Sub Area: Manage Product Classifications**
- 1642 The system must be able to create, modify, and inactivate AHFS classification data.
- 1643 The system must be able to create, modify, and inactivate FDA standard drug and biologic class data.
- 2776 The system shall provide the ability to print a portion or a complete label.
- 3482 The system shall provide the ability to compare a drug label with other relevant drug labels to promote identification of adverse reactions that are prevalent in a drug class and use the results as screening
- 2777 The system shall provide the ability to view on-line label information to obtain information needed for drugs not in the current labeling systems.
- 2829 The system shall provide the ability to MedDRA code all reactions and record their corresponding label section names for biologics and drug products
- 2830 The system shall provide the ability to edit MedDRA terms for a drug or biologic label.
- 2831 The system shall provide the ability to view MedDRA terms upon request.
- 2832 The system shall provide the ability to MedDRA code all indications for use listed on a drug or biologic label.
- 2833 The system shall provide the ability to access the autoencoder.
- 3483 The system shall provide the ability to handle search criteria that require MedDRA-coded labeled fields as input.
- 2860 The system shall provide the ability to add and retain new data pertaining to an applicant receiving MedWatch expedited
- 2861 The system shall provide the ability to add and retain new data pertaining to a new product as the subject of MedWatch expedited transmissions.
- 2851 The system shall provide the ability to update data pertaining to the status of an applicant and its registered product(s).
- 2819 The system shall provide the ability to add and retain new data pertaining to a contact.
- 2820 The system shall provide the ability to update data pertaining to a contact.
- 2816 The system shall provide the ability to create, modify, and inactivate FDA standard drug and biologic class data.

Functional Area: Manage Requests for Information and Services

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Sub Area: Generate Reports

- 2087 The system must be able to identify report format by specifying header, footer, field, and data positions for
- 2083 The system must provide the ability to run user specified "canned" or standard reports
- 2084 A user must have the ability to adjust the content of reports and queries based on search criteria
- 2085 The system must allow for the selection by a user of the output device including view, print, e-mail, or save to an ASCII and other standard file formats
- 2086 The system must provide the ability to run reports based on user entered criteria
- 2088 The system must provide access to AERS by CDER FOI

2003 RTM

- 3711 The system shall provide the ability to run user-specified standard reports.
- 2628 The system shall provide the ability to adjust the content of reports and queries based on search criteria.
- 3593 The system shall allow selection by a user of the report output device including view, print, e-mail, or save to an ASCII and other standard file formats.
- 3712 The system shall provide the ability to run reports based on user-entered criteria.
- 3853 The system shall provide CDER FOI users

- technicians, with access to the FOI query screens only
- 2089 The system must capture management information, including number of queries in a time period
- 2090 The system must provide the ability to run canned FOI reports, as well as ad hoc queries
- 2091 The system must allow FOI technicians to run automatically redacted FOI queries, as well as retrieve
- 3466 The system shall capture management information including number of queries in a time period.
- 3713 The system shall provide the ability to run canned FOI reports as well as ad hoc
- 3467 The system shall allow FOI users to run automatically-redacted FOI queries and to retrieve images.

Sub Area: Manage Approvals

- 2043 Authorized users must have the ability to create an approval chain, indicating the individuals and the order necessary for approval of all request types
- 2044 The system must capture the date a chain is entered and by whom
- 2045 The system must be able to display the approval chain for the various request types
- 2046 The system must allow a user to process approvals as automatically as possible
- 2047 The system must capture the date a request is submitted, by whom, and to whom
- 2048 The system must be able to automatically send a request for approval to the appropriate user in the approval chain
- 2049 The system must automatically notify each level of approval of a request needing approval
- 2050 The system must be able to record the decision, the date of the decision, and the name of the person who made the decision
- 2051 The system must, after a decision is made, route notifications to the appropriate user, as well as route to the next level of the approval chain
- 2052 An approver must be able to choose on-line whether he/she is to be notified of a final approval decision
- 2053 The system must allow the user to view approval or action decision on-line and make the requested
- 2054 The system must capture the date a request is adjusted and by whom
- 2055 The system must capture date approved and by whom for each level of approval
- 3556 The system shall provide the ability to create an approval chain indicating the individuals and the order necessary for approval of all request types.
- 3557 The system shall capture the date a chain is entered and by whom.
- 3558 The system shall display the approval chain for the various request types.
- 3559 The system shall allow a user to process approvals as automatically as possible.
- 3560 The system shall capture the date a request is submitted, by whom, and to whom.
- 3561 The system shall automatically send a request for approval to the appropriate user in the approval chain.
- 3562 The system shall automatically notify each level of approval of a request needing
- 3563 The system shall record the decision, the date of the decision, and the name of the person who made the decision.
- 3564 The system shall, after a decision is made, route notifications to the appropriate user, as well as route to the next level of the approval chain.
- 3566 The system shall provide the ability to choose notification of a final approval
- 3565 The system shall allow the user to view approval or action decision on-line and make the requested adjustment.
- 3567 The system shall capture the date a consult request is adjusted and by whom.
- 3568 The system shall capture date approved and by whom for each level of approval.

Sub Area: Manage Assignments

- 2013 A user must have the ability to view his/her workload on-
- 2014 A supervisor must have the ability to view an individual's workload, as well as total workload for a specified group of users
- 2015 The system must provide the ability to view, print, or download workload summaries and reports
- 2016 The system must be able to automatically assign requests to users, based on system tables detailing user/task relationships
- 2017 A supervisor must have the ability to assign requests on-line to users
- 2018 A system administrator or supervisor must have the ability to create/update/edit/view assignment tables detailing individuals and their task assignments
- 2019 The system must automatically track all changes, the date a change was made, and by whom
- 2020 The system must be able to establish a relationship between a user and a request
- 2021 The system must capture the date a request is assigned
- 3527 The system shall provide the ability to view consult workload on-line.
- 3528 The system shall provide the ability to view an individual's consult workload, as well as total workload for a specified group of
- 3529 The system shall provide the ability to view, print, or download consult workload summaries and reports.
- 3530 The system shall automatically assign consult requests to users, based on system tables detailing user/task relationships.
- 3531 The system shall provide the ability to assign consult requests on-line to users.
- 3532 The system shall provide the ability to create, update, edit, and view consult assignment tables detailing individuals and their consult task assignments.
- 3533 The system shall automatically track all consult changes, the date a change was made, and by whom.
- 3534 The system shall establish a relationship between a user and a consult request.
- 3535 The system shall capture the date a consult

to a user and by whom (if manual)	request is assigned to a user and by whom (if manual).
2022 A supervisor must be able to change information about the assignment in a user's inbox, and automatically notify the user of the change	3536 The system shall provide the ability to change information about the consult assignment in a user's Inbox and automatically notify the user of the change.
2023 The system must capture the date an assignment is updated and by whom	3537 The system shall capture the date a consult assignment is updated and by whom.
2024 A supervisor must have the ability to change the request/user relationship on-line and route the reassigned assignment	3538 The system shall provide the ability to change the consult request/user relationship on-line and route the reassigned
2025 The system must capture the date an assignment is reassigned and by whom	3542 The system shall keep a history of all consult assignments, whom they are assigned and reassigned to, current status, and the dates assigned, reassigned, updated, or deleted, and by whom.
2026 A supervisor must have the ability to delete an	3539 The system shall provide the ability to delete a consult assignment.
2027 The system must capture the date an assignment is deleted and by whom	3540 The system shall capture the date a consult assignment is deleted and by whom.
2028 The system must capture tracking information about assignments, and provide management reporting on the information gathered	3541 The system shall capture tracking information about consult assignments and provide management reporting on the information gathered.
2029 The system will keep a history of all assignments; to whom they have been assigned/reassigned; current status; and the dates assignments were assigned, reassigned, updated, or deleted, and by whom	3542 The system shall keep a history of all consult assignments, whom they are assigned and reassigned to, current status, and the dates assigned, reassigned, updated, or deleted, and by whom.
2030 The system will track request status (closed, in progress) for each request	3543 The system shall track consult request status (i.e., closed, in progress) for each
2031 The system must capture the date any changes in status take place and who changes the status	3544 The system shall capture the date any changes in status take place and who changes the status.
Sub Area: Manage Notifications	
2056 The system must automatically create notifications of assignment, reassignment, disapproval, and performance standard problem	3569 The system shall automatically create notifications of consult assignment, reassignment, disapproval, and performance standard problem.
2057 The system must automatically send notification to appropriate user's inbox	3570 The system shall automatically send notification to appropriate user's inbox
2058 The system must automatically notify a user of an assignment	3571 The system shall automatically notify a user of a consult assignment.
2059 The system must automatically notify a user of a reassignment	3572 The system shall automatically notify a user of a reassignment.
2060 The system must automatically notify an approver of a request needing an approval decision	3573 The system shall automatically notify an approver of a request needing an approval decision.
2061 The system must automatically notify a user of a	3574 The system shall automatically notify a user of a disapproval.
2062 An approver must be able to choose on-line whether he/she is notified of a final approval decision	3566 The system shall provide the ability to choose notification of a final approval
2063 Automatically notify system administrator of a performance standard problem based on the	3575 The system shall automatically notify the System Administrator of a performance standard problem.
2064 The system must provide the ability to customize an inbox, according to user detailed criteria	3576 The system shall provide the ability to customize an Inbox according to user-detailed criteria.
2065 A user or supervisor must be able to assign a priority to incoming tasks, showing the order in which they should be processed	3577 The system shall provide the ability to assign a priority to incoming consult tasks showing the order in which they are
2066 Must be able to assign a priority to a task (high, normal,	3578 The system shall assign a priority to a consult task (i.e., high, normal, low).
2067 The system must be able to sort by date received, date due, type, priority, drug, and manufacturer	3579 The system shall sort by date received, date due, type, priority, drug, and manufacturer.
2068 The system must provide the ability to report on both individual and total workload	3529 The system shall provide the ability to view, print, or download consult workload summaries and reports.
2069 Allows the viewing of both individual and group	3580 The system shall allow the viewing of both

assignments, including date assigned, date due, who assigned to, type, drug, and reaction

individual and group consult assignments including date assigned, date due, whom assigned to, type, drug, and reaction.

Sub Area: Manage Receipt of Consult Request

- 2009 The system must have the ability to record date request received and by whom
- 2010 Must provide ability to assign a request type to a request (congressional, consult, etc.)
- 2011 Must be able to assign a priority to a request (high, normal, low)
- 2012 The system must capture the following about each request: Requester Name, Requester Organization, Date Received, Date Due, Supervisor Name

- 3897 The system shall record date consult requests received and by whom.
- 3525 The system shall provide the ability to assign a request type to a request (e.g., congressional, consult).
- 3526 The system shall assign a priority to a consult request (i.e., high, normal, low).
- 3898 The system shall capture the following fields about each consult request: Requester Name, Requester Organization, Date Received, Date Due, and Supervisor

Sub Area: Manage Workflow

- 2070 The system must allow the on-line management of workflow chains
- 2071 The system must allow for the on-line establishment of workflow chains, detailing the steps a request must be automatically routed through
- 2072 The system must capture date created and by whom
- 2073 The system must allow for the changing of workflow information on-line by a system administrator
- 2074 The system must capture date modified and by whom
- 2075 The system must provide the ability for a system administrator or supervisor to view an entire workflow chain on-line, printed, or downloaded
- 2076 The system must provide the ability for a system administrator or supervisor to delete an entire workflow chain or a portion of one
- 2077 The system must capture date deleted and by whom
- 2078 The system must allow for the generation of workflow reports
- 2079 The system must allow on-line management of performance standards
- 2080 The system must capture date created and by whom
- 2081 The system must capture date updated and by whom
- 2082 The system must be able to produce performance standard reports dealing with the entered standards

- 3581 The system shall allow the on-line management of consult workflow chains.
- 3582 The system shall allow on-line establishment of consult workflow chains, detailing the steps a request must be automatically routed through.
- 3583 The system shall capture date consult created and by whom.
- 3584 The system shall allow for the changing of consult workflow information on-line by a System Administrator
- 3585 The system shall capture date consult modified and by whom.
- 3586 The system shall provide the ability for a System Administrator or Supervisor to view an entire workflow chain on-line, printed, or downloaded.
- 3587 The system shall provide the System Administrator or Supervisor to delete a portion or an entire workflow chain.
- 3588 The system shall capture date deleted and by whom.
- 3589 The system shall allow generation of workflow reports.
- 3590 The system shall allow on-line management of performance standards.
- 3591 The system shall capture date created and by whom.
- 3592 The system shall capture date updated and by whom.
- 3843 The system shall produce performance standard reports dealing with the entered standards.

Sub Area: Process Consult Request

- 2032 Provide Canned and Ad Hoc searches for users to query the database
- 2033 Adjust the content of reports and queries based on search criteria
- 2034 The system must save user entered search criteria
- 2035 Users must have the ability to retrieve AERS data and incorporate it into COTS word processing or spreadsheet software
- 2036 The system must capture information indicating which user created each response, as well as the date created and modified
- 2037 The system must be able to save responses and link unique ones to the Drug Safety Profile of the appropriate
- 2038 The system must provide the ability to electronically route a response to requesters by e-mail

- 3545 The system shall provide canned and ad hoc searches for users to query the
- 3546 The system shall adjust the content of reports and queries based on search
- 3547 The system shall save user-entered search criteria.
- 3548 The system shall provide the ability to retrieve data and incorporate it into COTS word processing or spreadsheet software.
- 3549 The system shall capture information indicating which user created each response and the date created and
- 3550 The system shall save and link unique responses to the Drug Safety Profile of the appropriate drug.
- 3551 The system shall provide the ability to electronically route a response to requesters by e-mail.

- 2039 The system must capture the date the response is delivered, to whom, and by whom
- 2040 A user or supervisor must have the ability to close a request
- 2041 The system must capture the date the request is closed and by whom
- 2042 The system must flag a closed request as "Closed"
- 3552 The system shall capture the date the response is delivered, to whom, and by whom
- 3553 The system shall provide the ability to close a request
- 3554 The system shall capture the date the request is closed and by whom
- 3543 The system shall track consult request status (i.e., closed, in progress) for each

Functional Area: Manage Risk Assessment

1996 BA Document

Sub Area: Manage ADR Review

- 1846 An authorized user shall have the ability to establish, modify, and delete the rules for automatic generation of follow-up requests (i.e., missing data on a report).
- 1847 The system shall periodically screen ADR reports for purposes of flagging and generating automatic written follow-up request letters based on pre-defined follow-up
- 1848 The system shall provide for automated generation of a follow-up letter for those reports that are flagged as matching the pre-defined follow-up criteria (see Process Follow-Up Criteria).
- 1849 The user will have the ability to request a follow-up activity (oral follow-up, or written correspondence) to clarify an adverse event report/case. This request should include the target for the follow-up, the type of follow-up activity to be performed, the date the request was made, and the requester.
- 1850 The system should create an REB Follow-up or REB Initial Report when an oral follow-up request is received. This report should be populated with values from the last received direct report associated with the case or with the values from the last received report regardless of report source for the case. The risk assessor should be given complete edit capability for modifying or changing
- 1851 The system shall provide on-line questionnaire information to support risk assessor telephone case Follow-Up.
- 1852 The system must be able to link all risk assessor follow-up reports to associated reports and to an associated
- 1853 The system shall be able to link follow-up information received from a written request to the appropriate follow-up request activity to support follow-up performance measurement.
- 1854 The system will provide the ability to record comments for a risk assessor follow-up report.
- 1855 The system must be able to record the FDA receipt date, report date, and version for each follow-up report.
- 1856 The system shall record risk assessor follow-up reports with direct reporters as initial direct reports for cases that have no prior recorded direct report.
- 1857 The system shall provide the appropriate option to locate an initial report for a case, given information on the risk assessor follow-up report.
- 1858 The system must permit the risk assessor to manually assign or reassign a report to an initial report and/or to an existing case.
- 1859 The system shall generate a standard follow-up letter for written follow-up requests using information from the AERS database to customize the letter and the mailing

2003 RTM

- 3605 The system shall provide the ability to establish, modify, and delete the rules for automatic generation of follow-up requests (i.e., missing data on an ISR).
- 3606 The system shall periodically screen ISRs for purposes of flagging and generating automatic written follow-up request letters based on pre-defined follow-up criteria.
- 2648 The system shall provide automated generation of a follow-up letter for ISRs that are flagged as matching the pre-defined follow-up criteria.
- 2649 The system shall provide the ability to request follow-up activity (e.g., oral follow-up, written correspondence) to clarify an ISR. This request shall include the person contacted for the follow up and the type of
- 2650 The system shall provide the ability to create a Safety Evaluator follow up or Safety Evaluator initial ISR when an oral follow-up request is received. This ISR shall populate with values from the last received direct ISR associated with the case.
- 3607 The system shall provide on-line questionnaire information to support Safety Evaluator telephone case follow up.
- 2651 The system shall link all Safety Evaluator follow-up ISRs to associated ISRs and to an associated case.
- 2652 The system shall link follow-up information received from a written request to the appropriate follow-up request activity to support follow-up performance
- 2653 The system shall provide the ability to record comments for a Safety Evaluator follow-up ISR.
- 2654 The system shall record the FDA receipt date, report date, and version for each follow-up ISR.
- 2655 The system shall record Safety Evaluator follow-up ISRs with direct reporters as initial direct ISRs for cases that have no prior recorded direct ISR.
- 2656 The system shall provide the option to locate an initial ISR for a case, given the information on the Safety Evaluator follow-up
- 2657 The system shall permit Safety Evaluators to manually assign or reassign an ISR to an initial ISR and/or an existing case.
- 2658 The system shall generate a standard follow-up letter for written follow-up requests using information from the system database to customize the letter and the

- 1860 The system shall record all oral and written follow-up activities, including follow-up status, dates, contacts, reviewer, and comments associated with a case.
- 1861 The system shall provide the ability to establish a reminder flag for follow-up activities.
- 1862 The user shall have the capability to change follow-up status from open to closed. The system will record all changes to follow-up activity status.
- 1863 The user will have the ability to record comments associated with an ADR report or merged case.
- 1864 The system shall populate merged case comment fields with data from all comments of all reports related to a merged case and provide the user with full edit rights on the comment data.
- 1865 The risk assessor shall have full edit rights to modify or add to the comment data of a report or merged case over
- 1866 The risk assessor shall have the capability to access and view a pull down list of normal value ranges for common lab tests to assist in diagnosis of the severity of the reported patient reaction and lab test results.
- 1867 The system shall provide the ability to record the risk assessor's clinical assessment for a case including evaluation of confounding factors, rechallenge/dechallenge, biological plausibility, temporal plausibility, and text comments.
- 1868 Provide the ability to record the strength of an initial case and its potential for case series development
- 1869 The system shall keep a history of changes to the report/merged case assessment.
- 1870 The system shall provide the user with a view of the latest case assessment and merged case report data or "best report" data when a case is included in a case
- 1871 The risk assessor will have the ability to record and store the coding of the diagnosis and relevant IMT terms for a report or a merged case report. This information will be kept in addition to the reporter and manufacturer provided IMT terms. The risk assessor's coding or FDA coding for the merged case report or best case report will be used for searches through the AERS database (i.e., creating a case series).
- 1872 The system should provide the ability to create a merged case report that summarizes the results of all the adverse reports (direct, manufacturer, follow-up, etc.) regarding a single event.
- 1873 Upon receipt of a valid risk assessor request to create a merged case report, the system will automatically populate the appropriate fields of the merged case report with the default values of the latest recorded direct report. If no direct report exists for a case, then the last recorded manufacturer report values will be used instead. The system should identify for the risk assessor differences in field values between the last received direct and manufacturer reports. Risk assessors should be able to either select one of these default values or provide their own.
- 1874 The system should record the date and risk assessor identification associated with the initial creation or subsequent update of a merged case report.
- 1875 The system should provide the ability for a risk assessor to link multiple manufacturer or direct reports to a single
- 2659 The system shall record all oral and written follow-up activities, including follow-up status, dates, contacts, reviewer, and comments associated with a case.
- 2660 The system shall provide the ability to establish automatic notification for follow-up activities.
- 3608 The system shall provide the ability to change follow-up status from Open to Closed. The system shall record all changes to follow-up activity status.
- 2620 The system shall provide the ability to record comments about a case.
- 2662 The system shall populate merged Case Comment fields with data from all comments of all reports related to a merged case and provide the user with full edit rights on the comment data.
- 2663 The system shall provide Safety Evaluators with full edit rights to modify or add to the comment data of a report or merged case over time.
- 3609 The system shall provide the ability to access and view a pull-down list of normal value ranges for common lab tests.
- 3610 The system shall provide the ability to record the Safety Evaluator's clinical assessment for a case including evaluation of confounding factors, rechallenge or dechallenge, biological plausibility, and
- 3611 The system shall provide the ability to record the strength of an initial case and its potential for case series development.
- 3612 The system shall archive changes to ISRs and merged case assessments.
- 2664 The system shall provide a view of the latest case assessment, merged case ISR data, or best representative ISR data when a case is included in a case series.
- 2665 The system shall provide the ability to record and store the coding of the diagnosis, relevant MedDRA terms, and the reporter for an ISR or a merged case ISR.
- 3613 The system shall provide the ability to create a merged case report that summarizes the results of all the adverse reports (e.g., direct, manufacturer, follow-up) regarding a single event.
- 3614 The system shall automatically populate the appropriate fields of a merged case report with default values from the latest recorded direct ISR upon a Safety Evaluator's request.
- 2666 The system shall record the date and Safety Evaluator identification associated with the initial creation or subsequent update of a merged case ISR.
- 2667 The system shall provide the ability to link multiple manufacturers or direct ISRs to a

- 1876 The user will have the ability to modify the merged case report based upon the receipt of new information or follow-up reports.
- 1877 The user shall have the ability to view all reports and attachments associated with a case and select any of the following options - view the data (drill down capability) for a specific report or the image of a selected report or the image of an attachment that is linked to a single case.
- 2668 The system shall provide the ability to modify the merged case report based upon the receipt of new information or follow-up
- 2670 The system shall provide the ability to view all ISRs and attachments associated with a case view specific ISR data (drill down capability) or specific ISR images.

Sub Area: Manage Case Series

- 1890 The user will have the ability to view or print search summary statistics based on the performed case series search. An example statistic is the total number of occurrences (reports/cases, drugs, manufacturers, etc.) for a given search or a given search criteria (outcome,
- 1878 The user will have the ability to select which type of new search (report, drug, reaction, label) he/she would like to construct. The system shall then provide an interactive utility, based on the search type, to help establish the search criteria.
- 1879 The user will have the ability to view and select ADR event criteria for performing a search against the report/case database for the purpose of generating a case series. This criteria will include the selection of a reported drug or biologic (i.e., biologic product lot, biologic product, drug product or drug generic base or other special drug group) and a reported IMT term (i.e., preferred term, HLG, HLT, SOC or standard or personal search category) and selected ADR event related criteria (i.e., date of event, sex or age of the patient, part of the country, report type, report source, report "seriousness"
- 1880 The user shall have the ability to view and select search criteria for performing a drug search against the drug dictionary.
- 1881 The user shall have the ability to view and select search criteria for performing a manufacturer search against the manufacturer dictionary.
- 1882 The user shall have the ability to view and select search criteria for performing a drug label search against the AERS drug label database.
- 1883 The system shall provide the ability to browse the IMT database to easily and graphically view related entities associated with a particular IMT entity (HLT, HLG, PT, LLT, search category).
- 1884 The system shall provide users the ability to create a special IMT search category, by offering a save and name option and edit option for IMT search results. Special search category data will include a creation date, user ID, search category name, search category comment, and selected IMT codes).
- 1885 The system shall provide users with the capability to view all personal search categories, regardless of creator, and to update or inactivate those IMT special search categories that were created by them.
- 1886 The system shall provide the user the ability to create a user defined drug criteria group by offering a save and name option and edit option for drug database search results. User defined drug criteria group data will include a creation date, user ID, drug group name, drug group comment, and selected drug names and IDs.
- 1887 The system shall provide users with the capability to view all user defined drug criteria groups, regardless of creator, and to update or inactivate those special drug groups that were created by them.
- 1888 The system shall provide the user the ability to create a special manufacturer group by offering a save and name
- 2669 The system shall provide the ability to select search types (e.g., ISR, drug, reaction, label) and the system shall then provide an interactive utility based on those new search types.
- 2672 The system shall provide the ability to view and select ISR event criteria for searches against the ISR/case database.
- 2671 The system shall provide the ability to view and select search criteria drug searches against the drug dictionary.
- 2673 The system shall provide the ability to view and select search criteria for manufacturer searches from the manufacturer dictionary.
- 2675 The system shall provide the ability to view and select search criteria for drug label searches against the drug label database.
- 2674 The system shall provide a MedDRA database browser to graphically view related entities associated with a particular MedDRA entity (HLT, HLG, PT, LLT, search
- 2678 The system shall provide the ability to create a MedDRA search category through save, name, and edit options for MedDRA search results.
- 2677 The system shall provide users with the capability to view all personal search categories, regardless of creator, and to update or inactivate those MedDRA search categories that were created by them.
- 2679 The system shall provide the ability to create drug criteria groups though
- 2678 The system shall provide users with the capability to view all personal drug groups, regardless of creator, and to update or inactivate those drug groups that were created by them.
- 2845 The system shall provide users with the capability to view all personal manufacturer

- option and edit option for manufacturer database search results. Special manufacturer group data will include a creation date, user ID, manufacturer group name, comment, and selected manufacturer names and IDs.
- 1889 The system shall provide users with the capability to view all user defined manufacturer groups, regardless of creator, and to modify or inactivate those user defined manufacturer groups that were created by them.
- 1891 Case series work assignments generated from secondary surveillance criteria are to have the same capabilities as case series created from an initial search against the case/report database.
- 1892 The risk assessor will have the capability to record the trigger event (consult request, primary surveillance work assignment, secondary surveillance, literature reference), and a specific reference entity (report number, literature ID, etc.) for each case series.
- 1893 The user will have the ability to create, view, edit, save, print, and inactivate a case series.
- 1894 The user will have the ability to perform a search of existing case series and view or print these case series. The user will have an option to update an existing case series (i.e., to use the specified case series information to populate a new case series and the case series' associated search criteria to update the contents of the original). Both the original case series and the update will be maintained as separate data entities.
- 1895 The risk assessor will have the ability to view a line listing of all cases within the case series. Each case line listing should include key data to assist the assessor in quickly determining whether a case warrants further investigation. These data may include key attributes of the case assessment, such as confounding factors, rechallenge/dechallenge, biological plausibility, seriousness of outcome, and temporal plausibility.
- 1896 The user will have the ability to record a case series query and all subsequent edits (addition and removal of individual cases, dates, reasons), plus assessment and comments associated with the final case-series result.
- 1897 System default for create a case series should include all reports/cases, regardless of labeledness, with the ability to easily view and separate labeled from unlabeled reports/cases. System should permit ability to request just labeled or unlabeled reports without requiring the user to create a user defined search criteria group.
- 1898 The user will have the ability to request a search of reported drug interactions containing specified IMT terms and/or containing one or more drugs.
- 1899 The user will have the ability to request all ADR reports/cases (search of report/case database) associated with a drug whether or not the drug is listed as suspect or concomitant in conjunction with one or
- 1900 The user will have the ability to request a search of reported drug interactions with selected IMT terms and with one or more drugs.
- 1901 The user will have the ability to request a search of all ADR reports/cases for a particular standard drug or biologic group such as by AHFS code or FDA
- 1902 The system default for a drug should be the generic name without requiring the user to create a special drug group prior to requesting a case series creation (a search of the report/case database). The system should
- groups, regardless of creator, and to update or inactivate those manufacturer groups that were created by them.
- 2845 The system shall provide users with the capability to view all personal manufacturer groups, regardless of creator, and to update or inactivate those manufacturer groups that were created by them.
- 3615 The system shall provide the same capabilities (i.e., send to reports, refresh, and edit case series) as a case series created from an initial search against the case/ISR database to case series work assignments generated from secondary
- 3616 The system shall provide the ability to record trigger events (e.g., consult requests, primary surveillance work assignments, secondary surveillance, literature references) and specific reference entities (e.g., report number).
- 2681 The system shall provide the ability to create, view, edit, save, print, and inactivate a case series.
- 2682 The system shall provide search, view, print, and update options for existing case
- 2683 The system shall provide Safety Evaluators with the ability to view a line listing of all cases within the case series. Each case line listing shall include key data for quick determination of further investigation.
- 2684 The system shall provide the ability to record a case series query, all subsequent edits (addition and removal of individual cases, dates, reasons), assessments, and comments associated with final case series results.
- 3617 The system shall provide a default to include all cases, regardless of labeledness, when creating a case series and shall provide the ability to easily view and separate labeled from unlabeled cases.
- 2685 The system shall provide the ability to search reported drug interactions containing specified MedDRA terms and/or one or
- 2686 The system shall provide the ability to search all ISRs and cases associated with a drug regardless of whether the drug is listed as the primary suspect drug or a
- 2687 The system shall provide the ability to search reported drug interactions with selected MedDRA terms and one or more
- 3618 The system shall provide the ability to search all ISRs and cases for a particular standard drug or biologic group such as AHFS code or FDA pharmacological
- 2688 The system default for a drug name shall be the drug's generic name and shall not require a user to create a special drug group prior to requesting a case series

- automatically search for all formulations containing a generic drug unless otherwise specified by the user.
- 1903 The user will have the ability to create a case series (search of the report/case database) with more than one drug and more than one IMT term.
- 1904 The system will have the ability to give parameters for time period, age, weight, and other relevant ADR event related criteria (e.g., greater than, less than, etc.).
- 1905 The system shall permit the user to change the status of a case series or MAR from Active to Inactive. For example, if a regulatory action or decision has already been made concerning a specific drug/reaction, then an active case series should be changed to inactive based upon this decision.
- 1906 The system shall allow the user to manually add or delete cases from a case series that has an "active" update
- 1907 The user will have the ability to view case series changes, including addition or deletion dates.
- 1908 The user will have the ability to deactivate the automatic update of a case series.
- 1909 The system shall permit the user to request an update to a case series when new cases/reports are entered into the system that meet the stored query criteria associated with the case series.
- 1910 The appropriate risk assessor will be permitted to add a new case to a case series.
- 1911 The system shall allow the risk assessor to flag certain cases in the case series as being pivotal to the overall strength of the case series. Subsequent modifications, additions, and deletions of these flags should be allowed if the case series status is active.
- 1912 The system will provide the ability to use statistical and graphical tools, such as SAS and CrossGraph, to perform analysis of a case series.
- 1913 The system will provide the ability to view both case series data and drug usage data in graphical or tabular
- 1914 The system will provide the ability to access external clinical morbidity data if they are available for use in providing signal context information.
- 1915 The system will provide the ability to manipulate or view, using statistical and graphical tools, all data fields which are part of any case that is a member of an active case
- 1916 The system will provide the ability to perform biologic lot analysis to compare frequency and percentage of ADR reported reactions across biologic lots for a particular biologic product.
- 1917 The system will provide the ability to access, capture, and manipulate denominator data from external data sources, such as IMS, to provide signal context data.
- 1918 The system will provide the ability to access and manipulate denominator data without requiring in-depth knowledge of how IMS works.
- 1919 The system will provide the ability to transform or manipulate denominator data with statistical and graphical
- 1920 The system will provide the appropriate denominator data to support calculation of estimated magnitude of exposure and other risk assessor defined calculations.
- 1921 The risk assessor will have the ability to record his/her evaluation of the case series, based upon assessment of causality criteria, such as confounding factors, biological
- 2689 The system shall provide the ability to create a case series with one or more drugs and MedDRA terms.
- 2690 The system shall provide parameters for time period, age, weight, and other relevant ISR event related criteria (e.g., greater than, less than)
- 2691 The system shall provide the ability to change the status of a case series or MAR from active to inactive.
- 2693 The system shall provide the ability to manually add or delete active cases from a case series.
- 2692 The system shall provide the ability to view case series changes, including addition or deletion dates.
- 2694 The system shall provide the ability to deactivate the automatic update of a case series.
- 2695 The system shall provide the ability to update a case series.
- 2696 The system shall provide the ability to add a new case to a case series.
- 2697 The system shall provide the ability to flag certain cases in the case series as pivotal.
- 3619 The system shall provide the ability to use statistical and graphical tools such as SAS and CrossGraph to perform analysis of a case series.
- 3620 The system shall provide the ability to view case series data in graphical or tabular form.
- 3621 The system shall provide the ability to access external clinical morbidity data for use in signal context information.
- 3622 The system shall provide the ability to manipulate or view all data fields in an active case series using statistical and graphical tools.
- 3623 The system shall provide the ability to perform biologic lot analysis to compare frequency and percentage of reported reactions across biologic lots for a
- 3624 The system shall provide signal context data through the access, capture, and manipulation of denominator data from external data sources such as IMS.
- 3625 The system shall provide the ability to access and manipulate denominator data without in-depth knowledge of IMS' data and service offerings.
- 3626 The system shall provide the ability to transform or manipulate denominator data with statistical and graphical analysis tools.
- 3627 The system shall provide the appropriate denominator data to support calculation of estimated magnitude of exposure and other Safety Evaluator-defined calculations.
- 3628 The system shall provide the ability to record case series evaluations based on causality criteria assessment such as

- plausibility, temporal relationships, rechallenge/dechallenge data, etc.
- 1922 The system shall provide an automatic notification to the appropriate reviewer to notify him/her that a case series assessment may need to be updated due to a change in a case assessment that is part of the case series.
- 1923 The system shall provide the ability to record case series comments and case series assessment with a default population of the appropriate fields from all pivotal cases within a case series and with full risk assessor edit
- 1924 The system shall provide the ability to save a case series assessment as a word processing file.
- 1925 The system shall track what information (cases, case assessments, etc.) was available at the time of the case series assessment to permit case series reconstruction.
- 1926 The system shall provide the ability to access the following external systems from within AERS: Medline, PDR, DQRS, ISS, and WHO. In addition, CBER risk assessors will also require access to VAERS and the CBER Lot Management System.
- 1927 The system shall allow the user to link summarized raw data files from an external system (Medline, PDR, IMS America, and WHO) to the case series confirmation
- 1928 The system shall provide the ability to link query results from the IMS system (NDTI, NPA, etc.) to the case series assessment.
- 1929 The authorized user will have the ability to view the current status and history of statuses, dates, comments, and activities associated with a case series.
- Sub Area: Manage Surveillance Methods**
- 1825 The system will permit all risk assessors to view the current standard DME criteria list.
- 1823 The system shall provide the appropriate users with the ability to create, edit, and delete a standard DME (Designated Medical Event) criteria list to be used for primary surveillance.
- 1824 The system will maintain an audit trail of all changes to the standard DME criteria list and permit viewing of these changes by appropriate parties.
- 1826 Each user will have the option to suppress the designation as "active" assignment of reports that meet the standard DME criteria for specified drugs for which he/she has responsibility.
- 1827 The system will display total count or number of ADR reports for a suppressed drug and reaction pair as part of the user's assigned workload.
- 1828 Each user and his/her manager should have the capability to view his/her individual criteria, including suppressed standard DME criteria and drug, and the activation date for each of the criteria.
- 1829 Each user will have the ability to create, modify, view, and delete individual criteria that will be drug and reaction based for flagging reports for primary surveillance work assignments.
- 1830 The system shall screen incoming ADE reports upon their entry into the AERS system and flag adverse event reports that meet the standard DME criteria, serious and unlabeled criteria, or individual primary surveillance
- 1831 The system shall assign and deliver the reports flagged by primary surveillance to the risk assessor with suspect drug review responsibility.
- 1832 The system must support automatic identification and
- confounding factors, biological plausibility, and temporal relationships.
- 3629 The system shall provide an automatic notification to Safety Evaluators when a case series assessment may require updating due to a change in a case
- 3630 The system shall provide the ability to record case series comments and assessments with appropriate field default population from all pivotal cases within a
- 3631 The system shall provide the ability to save a case series assessment as a word processing file.
- 3632 The system shall provide tracking capabilities of what information (e.g., cases, case assessments) was available at the time of the case series assessment to permit case series reconstruction.
- 3633 The system shall provide the ability to access the following external systems: Medline, PDR, DQRS, WHO, and VAERS (CBER Safety Evaluators only).
- 3634 The system shall provide access to summarized raw data files from external systems (e.g., Medline, PDR, IMS, WHO) to a case series confirmation analysis.
- 3635 The system shall provide the ability to access query results from the IMS system (e.g., NDTI, NPA) to the case series
- 2698 The system shall provide the ability to view the current status, status history, dates, comments, and activities associated with a case series.
- 2726 The system shall provide users the ability to add personal DMEs.
- 3854 The system shall maintain audit trails for all functional data changes within the
- 2638 The system shall provide the option to suppress the designation as active assignment of ISRs that meet the standard DME criteria for specified drugs for which the user has responsibility.
- 3595 The system shall display total number of ISRs for a suppressed drug and reaction pair as part of the user's assigned workload.
- 2639 The system shall provide the ability to view individual criteria including suppressed standard DME criteria and drug and the activation date for each of the criteria.
- 2640 The system shall provide the ability to create, modify, view, and delete individual drug and reaction-based criteria for flagging ISRs for primary surveillance work
- 2641 The system shall screen incoming ISRs upon their entry into the system and flag ISRs that meet the standard DME criteria, serious and unlabeled criteria, or individual
- 2642 The system shall assign and deliver the ISRs flagged by primary surveillance to the Safety Evaluator with suspect drug review responsibility.
- 2643 The system shall support automatic

- recording of "seriousness" and "labeledness" for each ADR report subject to primary surveillance processing.
- 1833 The system will use IMT coded drug label information if it is available, to determine the "labeledness" of a reported reaction for purposes of primary and secondary surveillance processing.
- 1834 If the IMT coded label for a suspect drug isn't available, then AERS will use the manufacturer's designation of a report as "expedited" as the criteria for determining the "labeledness" of the reported reaction.
- 1835 The system must support automatic identification and recording of the "seriousness" of each ADR report, as determined by the seriousness of the event outcome or the presence of a reported reaction that matches the standard DME criteria list.
- 1836 The system must support the automatic identification of an ADR report that meets individual primary surveillance criteria, including the individual criteria to suppress a standard DME term for a particular assigned drug.
- 1837 The system should permit the user to activate or deactivate the automatic flagging of daily ADR reports that match the drug and reaction criteria for their active case series, MARs, and consults.
- 1838 The system must support the identification of an ADR report that matches the drug and reaction criteria for an individual's active case series, MARs, and consults if the automatic flagging for this criteria is activated.
- 1839 The system shall provide the ability to establish drug safety index levels and assign appropriate thresholds to each drug safety index level. These thresholds will be used to determine the ADR database polling frequency and reporting thresholds for generating secondary
- 1840 The system shall provide an authorized risk assessor with the ability to assign and reassign a drug to an appropriate drug safety index level.
- 1841 The system will provide the ability to view history of a specified drug's safety index assignments over time with dates, responsible individual, and reason for each assignment or reassignment.
- 1842 The system will provide the capability to change or modify polling frequency or threshold numbers or types associated with a drug safety index level to authorized
- 1843 The system shall periodically screen the AERS database and count and flag relevant cases that meet or exceed the threshold criteria associated with a reported suspect drug's assigned drug safety index level. When total counts or other measurable secondary surveillance criteria meet or exceed one or more of the designated thresholds, the system will create a secondary surveillance work assignment for the responsible risk
- 1844 The system shall deliver a secondary surveillance work assignment or case series to the appropriate risk assessor. The work assignment should include a total count of flagged cases, the threshold number, the drug name, the drug's safety index level, the reaction, and the "labeledness" of the reaction for that particular drug.
- 1845 The system will provide the reviewer with an option to request a line listing of all the ADR cases associated with a secondary surveillance work assignment.
- identification and recording of seriousness and labeledness for each ISR subject to primary surveillance processing.
- 2644 The system shall use MedDRA-coded drug label information, if available, to determine the labeledness of a reported reaction for purposes of primary and secondary surveillance processing.
- 2645 The system shall provide the ability to use the manufacturer designation of an ISR as expedited as the criterion for determining the labeledness if the MedDRA-coded label for a suspect drug is not available.
- 2646 The system shall support automatic identification and recording of the seriousness of each ISR as determined by the seriousness of the event outcome or the presence of a reported reaction.
- 2647 The system shall support the automatic identification of an ISR that meets individual primary surveillance criteria including the individual criteria to suppress a standard DME term for a particular drug.
- 3596 The system shall enable the activating or deactivating of the automatic flagging of daily ISRs that match the drug and reaction criteria for their active case series, MARs, and consults.
- 3597 The system shall support the identification of an ISR that matches the drug and reaction criteria for an individual's active case series, MARs, and consults.
- 3598 The system shall establish drug safety index levels and assign appropriate thresholds to each drug safety index level. These thresholds shall determine the ISR
- 3599 The system shall provide an authorized Safety Evaluator with the ability to assign and reassign a drug to an appropriate drug safety index level.
- 3600 The system shall display the history of a specified drug's safety index assignments over time with dates, responsible individual, and reason for each assignment or reassignment.
- 3601 The system shall provide the ability to change or modify polling frequency or threshold numbers or types associated with a drug safety index level.
- 3602 The system shall periodically screen the system database and count and flag relevant cases that meet or exceed the threshold criteria associated with a reported suspect drug's assigned drug safety
- 3603 The system shall deliver a secondary surveillance work assignment or case series to the appropriate Safety Evaluator. The work assignment shall include a total count of flagged cases and threshold
- 3604 The system shall provide an option to request a line listing of all the cases associated with a secondary surveillance

Sub Area: Manage Workload

- 1813 The system shall provide the ability to create and update drug and biologic responsibilities for individual risk assessors and epidemiologists.
- 1814 The system shall select and assign ADR reports to the responsible risk assessor based on assigned drug or biologic responsibilities and on primary surveillance standard DME and individual criteria.
- 1815 The system should maintain a history of assignment dates and transfer dates for each drug and risk assessor.
- 1816 The system shall provide the capability to assign and reassign valid risk assessors to valid supervisors for purposes of accessing and reviewing employee work assignments and workload.
- 1817 The system should provide the user with the ability to view his/her assigned active list of triaged reports/work assignments with the following data displayed: line listing for each assigned ADR Report including report type, date, reaction, suspect drug and cumulative counts of associated reports in the AERS database that represent the same reaction and drug.
- 1818 The system should provide the user with the ability to view his/her active assignment list of ADR reports with the following options: option to select a line listing and display the image of the report, the data for the report, or create a case series using as the default the suspect drug and reported reaction that resulted in selection of the report for primary surveillance triage or create a case series with the user inputting new criteria.
- 1819 The system should provide the user with the capability to further classify, sort, and prioritize work assignments.
- 1820 The system shall allow an authorized user the ability to reassign a work assignment to another individual for whom he/she has supervisory responsibility.
- 1821 The system shall provide the user with a history of activity related to risk assessment activities associated with a work assignment.
- 1822 The system shall provide the user with the ability to assign a current status to each work assignment such as assigned (default), reviewed, pending, closed, and
- 3594 The system shall provide the ability to create and update drug and biologic responsibilities for individual Safety Evaluators and Epidemiologists.
- 2629 The system shall select and assign ISRs to the responsible Safety Evaluator based on assigned drug or biologic responsibilities and on primary surveillance standard DME and individual criteria.
- 2630 The system shall maintain a history of consult assignment dates and transfer dates for each drug and Safety Evaluator.
- 2631 The system shall provide the capability to assign and reassign valid Safety Evaluators to valid Supervisors for purposes of accessing and reviewing employee work assignments and workload.
- 2632 The system shall provide the ability to view an assigned active list of triaged ISRs and work assignments with the line listing displayed for each assigned ISR.
- 2633 The system shall provide the ability to view active assignment lists of ISRs with the ability to select a line listing and display the image of the ISR.
- 2634 The system shall provide the ability to further classify, sort, and prioritize work
- 2635 The system shall allow an authorized user to reassign a work assignment to another individual.
- 2636 The system shall provide a history of activity related to safety evaluation activities associated with a work assignment.
- 2637 The system shall provide the ability to assign a status to each work assignment such as assigned (the default), reviewed, pending, closed, and suppressed.
- Sub Area: MAR Management (Alert)**
- 1943 The user shall have the ability to record post-review related information concerning a particular MAR.
- 1930 The authorized user shall have the ability to create, edit, update, and delete the criteria for determining whether a case series can be classified as a potential MAR.
- 1931 All risk assessors shall have the ability to view MAR
- 1932 The system shall, at risk assessor request, screen edited case series against MAR criteria to determine potential MARs.
- 1933 The risk assessor shall have the capability to request potential MAR status for any of his/her active case series. The system will record the date of the change in
- 1934 The risk assessor will have the capability to record the minutes of the MAR meetings and link these with the potential MAR.
- 1935 The system shall support the generation of a MAR Summary Document from data stored within the AERS database including data on the drug, drug label, drug dosage and administration; individual cases and their case assessments; pivotal cases; signal context data; signal confirmation data; and case series assessment.
- 1936 The system shall allow the authorized user to fully edit the MAR Summary Document
- 3636 The system shall provide the ability to create, edit, update, and delete any case series criteria with potential MAR status.
- 3637 The system shall provide Safety Evaluators the ability to view MAR criteria.
- 3638 The system shall provide screen-edited case series against MAR criteria to determine potential MARs.
- 2699 The system shall provide the ability to request potential MAR status for any active case series and record the change date in
- 3639 The system shall provide the ability to record MAR meeting minutes and link them to the potential MAR.
- 3640 The system shall provide MAR Summary Document generation support from data stored within the database including drug data, drug label, drug dosage and administration, individual cases, and individual case assessments.
- 3641 The system shall provide edit privileges to the MAR Summary Document.

- 1937 The system shall allow the capture of all recommendations and subsequent activities related to the approval of the MAR, including final regulatory actions.
- 1938 The appropriate user will have the ability to construct or select a pre-defined workflow approval chain for a MAR.
- 1939 The appropriate user will have the ability to modify the approval chain for a MAR.
- 1940 The user will have the ability to record an approval/disapproval and associated comments for a MAR. The system shall automatically record the reviewer's name and approval/disapproval date.
- 1941 The user will have the ability to record regulatory recommendations based upon the MAR review process.
- 1942 The system will enable the user to update the MAR status (signal, annual, or ended), based upon post-MAR decisions and regulatory actions.
- 3642 The system shall provide the capture of all recommendations and subsequent activities related to the approval of
- 3643 The system shall provide the ability to construct or select a pre-defined workflow approval chain for a MAR.
- 3644 The system shall provide the ability to modify the approval chain for a MAR.
- 3645 The system shall provide the ability to record an approval, disapproval, and associated comments for a MAR
- 3646 The system shall provide the ability to record regulatory recommendations based upon the MAR review process.
- 3647 The system shall provide the ability to update the MAR status (e.g., signal, annual, or ended), based upon post-MAR decisions and regulatory actions.

Functional Area: Manage System Administration

1996 BA Document

Sub Area: Manage Archiving, Extract and Backup

- 1628 The system must be able to archive data
- 1629 The system must be able to extract data
- 1630 The system must be able to back up data periodically

Sub Area: Manage Data Warehouse

- 1633 The system must be able to extract data from the production database periodically and load it in the
- 1634 The system must be able to load extract ADR data received periodically from the WHO.

Sub Area: Manage Drug Exposure Data

- 1625 The system must be able to obtain NPA data, such as total sales of the drug, etc., from National Prescription Audit Plus (NPA), an external database
- 1626 The system must be able to obtain prescription-specific data, such as number of prescriptions written for a drug from National Prescription Audit Plus (NPA), an external database
- 1627 The system must be able to obtain demographic drug usage data such as age, gender, region for a generic or trade name product from National Disease and Therapeutic Index (NDTI), an external database

Sub Area: Manage MedWatch Partner Registration

- 1631 The system must be able to register a health care organization to participate in the MedWatch Program
- 1632 The system must be able to modify health care organization information due to address or contact

Sub Area: Manage Reference Tables

- 1623 The system must be able to add new codes to the respective reference code tables
- 1624 The system must be able to change verbose description of a code due to changes in the standard or misspelling

2003 RTM

- 2810 The system shall provide the ability to archive data.
- 2811 The system shall provide the ability to extract data.
- 3882 The system shall provide the ability to back up data periodically.
- 3657 The system shall provide the ability to extract data from the production database periodically and load it into the warehouse
- 3658 The system shall provide the ability to load extracted ISR data received periodically from the WHO.
- 3654 The system shall provide the ability to obtain prescription data, such as total sales of the drug, from NPA Plus, an external database.
- 3655 The system shall provide the ability to obtain prescription-specific data, such as number of prescriptions written for a drug from NPA Plus, an external database.
- 3656 The system shall provide the ability to obtain demographic drug usage data such as age, gender, region for a generic or trade name product from ISS' NDTI, an external
- 2859 The system shall provide the ability to register a health care organization to participate in the MedWatch to Manufacturer
- 2812 The system shall provide the ability to modify health care organization information due to address or contact change in support of the MedWatch Partner program.
- 3880 The system shall provide the ability to add new reference codes to the respective reference code tables.
- 3881 The system shall provide the ability to modify verbose code descriptions due to

or other clerical error

Sub Area: Manage Security

- | | |
|---|--|
| 1606 Incorporate security awareness and training as it pertains to AERS in training initiatives. | |
| 1588 Ensure passwords to the AERS system meet HHS AISS Program Handbook May 94 requirements (e.g., no fewer than six characters, changed at least every 90 days) and ISA Perimeter Security Guideline | 3883 The system shall ensure that passwords to the system meet DHHS AISS Program Handbook May 1994 requirements (e.g., no fewer than six characters, changed at least every 90 days) and ISA Perimeter Security Guideline. |
| 1589 Ensure that AERS application user names meet DHHS/FDA naming standards and are similar to user names for e-mail, LAN etc. | 3884 The system shall ensure that application user names meet DHHS FDA naming standards and are similar to user names for e-mail, LAN, and other accounts. |
| 1590 Maintain audit trails for all functional data changes within the application. | 3854 The system shall maintain audit trails for all functional data changes within the |
| 1591 Implement capability of a single system log-on for access to all AERS functions and data | 3855 The system shall implement the capability of a single system log on for access to all system functions and data. |
| 1592 Prevent unauthorized access to the system | 3856 The system shall minimize the possibility of unauthorized access to the system. |
| 1593 Implement data access controls that limit authorized access to the least amount of information needed to accomplish each particular job function | 3857 The system shall enable users to limit data views and access based on defined user roles and user identification. |
| 1594 Protect sensitive information when transmitted by open or unprotected means (may include encryption) | 3899 The system shall protect sensitive information when transmitted by open or unprotected means (may include |
| 1595 Control printer destinations for sensitive output | 3885 The system shall control printer destinations for sensitive output. |
| 1596 Protect the data by systematic and regular backup routines | 2502 The system shall perform nightly incremental backup of the data files and weekly image backups of the data and system files during the night batch window |
| 1597 Develop all contingency/risk management plans before initial roll-out of each AERS module | 3887 The system shall require the development of all contingency/risk management plans before initial roll out of each system module. |
| 1598 Limit data views and access based on defined user roles and user identification | 3857 The system shall enable users to limit data views and access based on defined user roles and user identification. |
| 1599 Ensure that on-line updates of personal data that affect a user's access/approval authority in the system are performed by authorized individuals | 3862 The system shall ensure that on-line updates of personal data that affect a user's access/approval authority in the system are performed by authorized |
| 1600 Keep user access permissions separate from query satisfactions | 3863 The system shall keep user access permissions separate from query |
| 1601 Identify and authenticate all users; authenticate users by location | 3864 The system shall identify and authenticate all users and authenticate users by location. |
| 1602 Ensure that discretionary access control mechanisms are in-place on the platform | 3865 The system shall ensure that discretionary access control mechanisms are in place on the platform. |
| 1603 Write security policies that clearly define AERS user/administrator responsibilities | 3866 The system shall require that security policies that clearly define user/administrator responsibilities are |
| 1604 Establish policies for personnel with access to AERS (roles, clearances, backups, responsibilities, etc.) | 3867 The system shall require that policies for personnel with access to AERS (e.g., roles, clearances, back ups, responsibilities |
| 1605 Provide controls to prevent unauthorized access to executive or control software system (separate user and master modes of operation). | 3868 The system shall provide controls to prevent unauthorized access to executive or control software system (e.g., separate user and master modes of operation). |
| 1607 Print a confidential notice on sensitive documents | 3900 The system shall print a confidential notice on sensitive documents. |
| 1608 Define procedures for marking and handling special categories of information (include in data dictionary) | 3870 The system shall require that procedures for marking and handling special categories of information (included in the data dictionary) are defined. |
| 1609 Identify sensitive data in the database | 3901 The system shall identify sensitive data in the database. |
| 1610 Provide an additional password/ID reconfirmation where | 3902 The system shall provide an additional |

changes in standards, misspellings, or other

	there is a specific reason or need		password and ID reconfirmation where there is a specific reason or need.
1611	Implement policies to discourage the sharing of user identifiers and/or user authenticators	3903	The system shall require that policies are implemented to discourage the sharing of user identifiers and/or user authenticators.
1612	Add and deactivate users from the system in a timely	3871	The system shall add and deactivate users from the system in a timely manner.
1613	Establish policy and procedure to deactivate user accounts when persons transfer positions, change jobs, resign, or are terminated for other reasons	3872	The system shall establish policies and procedures to deactivate user accounts when persons transfer positions, change jobs, resign, or are terminated for other
1614	Establish policies and procedures for identifying and responding to security incidents	3873	The system shall require that policies and procedures for identifying and responding to security incidents are established.
1615	Review system audit logs on a periodic basis	3874	The system shall require that system audit logs are reviewed on a periodic basis.
1616	Establish a standard policy for the determination of appropriate user access permissions	3875	The system shall require that a standard policy for the determination of appropriate user access permissions is established.
1617	Track AERS function usage	3904	The system shall track function usage.
1618	Ensure each user has documented, official approval before being granted authorization to access the system remotely and maintain current list of users with such	3876	The system shall require each user to have documented, official approval before being granted authorization to access the system remotely and maintain current list of users with such authorization.
1619	Establish emergency shutdown and restart procedures	3877	The system shall require emergency shutdown and restart procedures to be established.
1620	Establish a backup library, including version control measures (off-site storage)	3878	The system shall require a back-up library, including version control measures (off-site storage), be established.
1621	Limit the level of access to data by record and data element for each user	3905	The system shall limit the level of access to data by record and data element for each
1622	Limit the level of access to data by assigning functional groupings or roles for each user	3879	The system shall provide the ability to limit the level of access to data by assigning functional groupings or roles for each user.

Functional Area: Monitor Drug Safety Concerns

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Sub Area: Manage Drug Safety Concerns

- 1944 The system must be capable of recording residual safety concerns at the time a new product is approved.
- 1945 The system must be capable of determining the role and identity of the individual who is recording his/her
- 1946 The system must be capable of capturing safety concerns throughout the product's marketed life cycle.
- 1947 The system must be capable of allowing modifications or updates for any recorded safety concern to permit the capture of related yet new information.
- 1948 The system will record the date, the time, and the requester for the initial record creation and any subsequent updates of a product safety concern record.
- 1949 The system must permit authorized viewers the capability to view recorded drug or biologic safety concern data and/or print or save it to a file.
- 1950 The system must permit redaction of product safety concern data for purposes of FOI reporting, should it be determined that this information cannot be obtained under
- 1951 Recorded safety concerns may be inactivated when it is determined by the creator or another authorized user that the safety concern has been resolved.

2003 RTM

- 3493 The system shall record residual safety concerns at the time a new product is approved.
- 3494 The system shall determine the role and identity of the individual recording their concerns.
- 3495 The system shall capture safety concerns throughout the marketed life cycle of the product.
- 3496 The system shall allow modifications or updates to any recorded safety concern.
- 3497 The system shall record the date, time, and requester for the initial record creation and any subsequent updates
- 3498 The system shall permit authorized viewers the capability to view recorded drug or biologic safety concern data and/or print or save them to a file.
- 3499 The system shall permit redaction of product safety concern data for purposes of FOI reporting if this information cannot be obtained under the FOI Act.
- 3500 TThe system shall enable the creator or another authorized user to inactivate recorded safety concerns when it is determined the safety concern has been

- 1952 Recorded safety concerns that are inactivated are not deleted from the database. They will be kept for historical purposes. Users can specify whether they wish to view only active safety concerns or all (active and inactive) safety concerns.
- 1953 Authorized users must be able to query a history of product safety concerns for a particular drug product or generic drug base.
- 1954 Product safety concern queries should display concerns in chronological order (e.g., date concern was initially recorded).
- 1955 There should be no defined limit to the number of safety concerns that may be recorded for a given drug or biologic product, at any given point in time, for any given authorized user.
- 3501 The system shall not delete inactivated safety concerns from the database. Users shall view only active safety concerns or all safety concerns (active and inactive).
- 3502 The system shall provide a history of product safety concerns to authorized users for a particular drug product or
- 3503 The system shall display product safety concern queries in chronological order (e.g., date concern was initially recorded).
- 3504 The system shall define no limit to the number of safety concerns that may be recorded for a given drug or biologic product, at any given point in time, for any

Sub Area: Manage Drug Safety Profile Standard Reports

- 1989 The system must provide pre-determined parameterized report templates for generating and viewing summarized drug manufacturer compliance history, including relevant Agency compliance actions, by type and date, that have been recorded over a specified time period.
- 1977 The system must provide pre-determined parameterized report templates for generating and viewing drug ADR summary activity with capability to drill down to increasingly granular levels of detail to answer "why" questions, easily perform comparisons, and easily transform data into graphical or statistical presentations.
- 1966 The system must present a user friendly interface(s) for requesting, viewing, printing, and/or saving standard parameterized drug or biologic safety profile reports.
- 1967 The system must use a query tool that is able to perform comparisons flexibly and immediately. For example, a single row of an answer set should be simultaneously able to show comparisons over multiple time periods of different grain (month, quarter, year-to-date, year) and comparisons over other dimensions (for example, share of a reported adverse reaction for a drug to all same reported reactions for the drug's pharmacological class). These query tool comparison alternatives should be available in a pull-down menu or its equivalent where the user doesn't need to know or see how the comparison is
- 1968 Page-formatted report documents with row headers, column headers, and break rows.
- 1969 Transformation of numerical values into tertiles (high, medium, low), rankings, moving averages, moving sums, and cumulative totals.
- 1970 Presentation of reports to the screen with some method to display exceptions (e.g., blinking, asterisked, or colored entries).
- 1971 Presentation of reports to the screen that allows drilling down to the next logical level of detail for a given report/data cell entry.
- 1972 Presentation of reports to the screen, printer, or data file that permits transforming data into graphical charts of many types, including bar, pie, and scatter charts.
- 1973 Presentation tools should allow answer sets to be transferred easily by the user (push of a button) into multiple presentation environments for different purposes.
- 1974 Query tool must permit easy drilling up and down within a single dimension (for example, drug product, drug generic base, drug pharmacological class) to facilitate the users analysis of the fact being displayed (i.e., asking why).
- 1975 The query tool must be simple and intuitive from the user
- 3814 The system shall present an interface(s) for requesting, viewing, printing, and/or saving standard parameterized drug or biologic safety profile reports.
- 3815 The system shall use a query tool with the ability to perform comparisons flexibly and immediately.
- 3816 The system shall provide formatted reports with row headers, column headers, and break rows.
- 3817 The system shall provide transformation of numerical values into rankings (i.e., high, medium, low), moving averages, moving sums, and cumulative totals.
- 3818 The system shall display reports on the screen with some method to display exceptions (e.g., blinking, asterisks, color).
- 3819 The system shall display reports on the screen, enabling the user to drill down to the next logical level
- 3820 The system shall display reports on the screen, printer, or data file that permit transforming data into graphical charts of many
- 3821 The system shall provide presentation tools to support the transfer of result sets into multiple presentation environments.
- 3822 The system shall provide a query tool that supports drilling up and down within a single dimension (e.g., drug product, drug generic base, drug pharmacological class) to facilitate analysis.
- 3823 The system shall provide a button to create

- interface. The user should be able to achieve his/her desired report result within "one button click."
- 1976 The query tool should allow the user to create his/her own unique reports to further support the Monitor Drug Safety Risk function.
- 1978 The system must provide the capability to easily split and compare data on total reported reactions for a specific drug product, or for all drug products with the same generic base by patient demographic factors including age, sex, and weight.
- 1979 The system must provide the capability to easily compare the number of reports received for a particular reported reaction for a specified drug product against another drug product with the same generic base and/or against another an average of all drug product within the same pharmacological class.
- 1980 The system must provide the capability to easily identify the top ten reported reactions for a specific drug product with corresponding counts and percentages.
- 1981 The system must provide exception reports that identify, for a specific drug product or all drug products with the same generic drug base, conditions where received ADR reports for non-approved indications (per coded drug label) represent over a certain percentage of total ADR reports received for the respective drug product or drug.
- 1982 The system must provide exception reports that identify, for a specific drug product, reported lack of effectiveness rates that are significantly higher (by DPE defined criteria) than the average lack of effectiveness rates for other drugs containing the same generic base.
- 1983 The system must provide exception reports that identify, for a specific drug product, reported adverse drug interactions where the total count of these reports is over a certain DPE specified threshold.
- 1984 The system must provide exception reports that identify for a specific drug product reported overdose rates that are significantly higher (by DPE defined criteria) than the average expected overdose rate for similar drug products (as defined by DPE).
- 1985 The system must provide pre-determined parameterized report templates for generating and viewing a summary of Agency initiated regulatory actions for a specific drug. Regulatory Actions include all drug label changes, post-marketing safety or effectiveness studies, and any other regulatory actions initiated by the Agency, including letters, drug withdrawal, etc. The capability to drill down to increasingly granular levels of detail in the drug label dictionary or the MAR database to answer "why" questions is required.
- 1986 The system must provide pre-determined parameterized report templates for generating and viewing summarized drug information, specifically all other drugs that contain the same generic base as the drug of interest, all other drugs within the same pharmacological class as the drug of interest, and all drugs that are approved for the same indication as the drug of interest.
- 1987 The system must provide pre-determined parameterized report templates for generating and viewing summarized drug manufacturer compliance scores for various compliance criteria compared to industry averages for those same criteria over for a specified time period.
- 1988 The system must be able to compute and display the corresponding quartile in which the compliance scores can be viewed against average drug product reporting
- the desired report result.
- 3824 The system shall provide a query tool to create unique reports to further support the Monitor Drug Safety Risk function.
- 3708 The system shall provide the ability to compare data on the total reported reactions for a specific drug product or for all drug products with the same generic base, by patient demographic factors.
- 3709 The system shall provide the ability to compare the number of ISRs received for a particular reported reaction for a specified drug product against another drug product with the same generic base.
- 3710 The system shall provide the ability to easily identify the top ten reported reactions for a specific drug product with corresponding counts and percentages.
- 3825 The system shall provide exception reports that identify (for a specific drug product or all drug products with the same generic drug base) conditions where received ISRs for non-approved indications
- 3826 The system shall provide exception reports that identify (for a specific drug product) reported lack of effectiveness rates that are significantly higher (by DPE-defined criteria) than the average lack of effectiveness.
- 3827 The system shall provide exception reports that identify (for a specific drug product) reported adverse drug interactions where the total count of these ISRs is over a certain DPE-specified threshold.
- 3828 The system shall provide exception reports that identify overdose rates significantly higher (by DPE-defined criteria) than the average expected overdose rate for a
- 3829 The system shall provide pre-determined parameterized report templates for generating and viewing a summary of FDA-initiated regulatory actions for a specific
- 3830 The system shall provide pre-determined parameterized report templates for generating and viewing summarized drug information, specifically all other drugs that contain the same generic base.
- 3831 The system shall provide pre-determined parameterized report templates for generating and viewing summarized drug manufacturer compliance scores for various compliance criteria compared to
- 3832 The system shall compute and display the corresponding quartile in which the compliance scores can be viewed against average drug product reporting scores.
- 3834 The system shall provide the ability for authorized viewers to drill down from any specific compliance action to its

be provided.

- 1991 The system must provide pre-determined parameterized report templates for viewing a summary of Agency efforts that have resulted in documented workproduct, such as related drug consults, Monitored Adverse Reactions (MARs), and Post-Marketing Safety Studies.
- 1992 The ability to drill down from any specific line listing on the Summary of Consults and Studies to more granular data or the document itself should be provided.
- 1993 The system must provide pre-determined parameterized report templates for viewing drug usage patterns over time for a specific drug product or a drug group where all drugs contain the same generic base.
- 1994 The system must provide the ability to view Drug Usage Summary Reports for a drug product or for a drug group by various demographic patient factors such as sex, age, as well as information on indication for use, and other patient concomitant medications.
- 1995 Comparisons of usage between drug products within the same drug group and between a given drug product and its respective drug group should be easily computed and displayed by the system.
- 1996 The system should provide comparisons of total reported adverse events for a specific drug product or drug group against total estimated drug usage for the same category. Where differences among estimated adverse reaction reporting rates between drug products in the same drug group exceed a certain pre-defined DPE limit, the system should display this fact to the user as an
- 1997 Drug Usage Summary Reports must be viewable and easily transformable to the graphic or statistical format of the user's choice.

corresponding detail activity log, narrative description, or case series.

- 3835 The system shall provide pre-determined parameterized report templates for viewing a summary of FDA efforts that resulted in a documented work product.
- 3836 The system shall provide the ability to drill down from any specific line listing on the Summary of Consults and Studies to more granular data or the document itself.
- 3837 The system shall provide pre-determined parameterized report templates for viewing drug usage patterns over time for a specific drug product or a drug group where all drugs contain the same generic base.
- 3838 The system shall provide the ability to view Drug Usage Summary Reports for a drug product or for a drug group by various demographic patient factors such as gender, age, and information on indication
- 3839 The system shall provide comparisons of usage between drug products within the same drug group and between a given drug product and its respective drug group.
- 3840 The system shall provide comparisons of total reported adverse events for a specific drug product or drug group against total estimated drug usage for the same category.
- 3841 The system shall provide Drug Usage Summary Reports viewable and easily transformable to the graphic

Sub Area: Manage Post-Marketing Safety Assessment (PMSA)

- 1998 The system must provide the authorized user with the capability to schedule a PMSA.
- 1999 The system must provide the capability to generate ticklers or reminders about a scheduled PMSA.
- 2000 The system must capture information on all PMSAs performed over a drug's marketed life.
- 2001 The system must be able to identify who the assigned compliance, risk assessor, and epidemiologist are for a given PMSA.
- 2002 The system must provide automated support for generating PMSA Documents from data within the AERS
- 2003 The system must provide the capability to link and view one to many versions of a PMSA document to PMSA data within AERS.
- 2004 The system must provide the capability to create, modify, and inactivate PMSA Document Templates that define data content, style and format, and map appropriate AERS data to its corresponding template location.
- 2005 The system must permit recording of agency review, approval, comments, and dates for each PMSA for a standard pre-defined PMSA approval chain.
- 2006 The system must permit authorized users to create and modify risk assessment and recommendation data for various types of drug safety assessment by multiple authorized user roles.
- 3515 The system shall provide the authorized user with the capability to schedule a PMSA.
- 3516 The system shall provide the capability to generate automatic notification or reminders about a scheduled PMSA.
- 3517 The system shall capture information on all PMSAs performed over a drug's marketed life cycle.
- 3518 The system shall identify the assigned Compliance Officer, Safety Evaluator, and Epidemiologist for a given PMSA.
- 3519 The system shall provide automated support for generating PMSA documents from data within the database.
- 3520 The system shall provide the capability to link and view one to many versions of a PMSA document to PMSA data within the
- 3521 The system shall provide the capability to create, modify, and inactivate PMSA document templates that define data content, style, format, and map appropriate system data to its corresponding template
- 3522 The system shall record agency review, approval, comments, and dates for each PMSA for a standard pre-defined PMSA approval chain.
- 3896 The system shall permit authorized users to create and modify safety evaluation and recommendation data for various types of drug safety assessments by multiple authorized user roles.

- 2007 The system must capture information about PMSA triggered regulatory actions.
- 2008 The system must capture information about all Agency activity associated with a specific PMSA.

Sub Area: Manage Post-Marketing Studies

- 1956 An authorized user must be able to enter information about approved study protocols for a product into the
- 1957 AERS should provide authorized users with access to Integrated Safety Summary information (when it is available in electronic format for a new molecular entity) without requiring the user to leave the AERS system. This will permit AERS users to review pre-marketing clinical study summary and assessment data.
- 1958 Electronic data files created as a result of a post-marketing study should be archived and linked to the post-marketing study information to permit AERS user retrieval and usage with other analytical, statistical, and
- 1959 Documents created as a result of a post-marketing study should be linked and cross-referenced to the post-marketing study information to permit AERS user retrieval and viewing. This may be via imaging, Binary Large Object (BLOB) or other technology that supports linking word processing files to study data within AERS.
- 1960 Each post-marketing safety study shall be abstracted and recorded into the AERS database and linked to its appropriate post-marketing study information.
- 1961 Post-marketing safety study data must be searchable by drug, manufacturer, safety issue, reaction(s), demographic, and cooperative agreement/contract
- 1962 The AERS system must record information related to feasibility studies that are performed with negative
- 1963 The system must be able to record information about safety conclusions and recommendations associated with a post-marketing safety study.
- 1964 The system must permit zero to many conclusions and recommendations for a given study. The system must capture the date, source, and nature for each conclusion and recommendation. These may come from non-AERS users or authorized AERS epidemiologists or drug or biologic reviewers.
- 1965 The system must be able to permit users to detect and track post-marketing study status (in progress or completed) for a given study and cumulatively for a given Epidemiologist or for the entire Epidemiology Branch.
- 3523 The system shall capture information about PMSA-triggered regulatory actions.
- 3524 The system shall capture information about all FDA activity associated with a specific
- 3505 The system shall enable an authorized user to enter information about approved study protocols for a product into the system.
- 3506 The system shall provide authorized users with access to Integrated Safety Summary information (when it is available in electronic format for an NME) without requiring the user to leave the system.
- 3507 The system shall archive and link electronic data files created as a result of a post-marketing study to the post-marketing study information.
- 3508 The system shall link and cross-reference documents created as a result of a post-marketing study to the post-marketing study information to permit system user retrieval and viewing.
- 3509 The system shall ensure each post-marketing safety study is abstracted and recorded into the database and linked to its appropriate post-marketing study
- 3510 The system shall retrieve post-marketing safety study data by drug, manufacturer, safety issue, reaction(s), demographic, and cooperative agreement/contract database name.
- 3511 The system shall record information related to feasibility studies that are performed with negative results.
- 3512 The system shall record information about safety conclusions and recommendations associated with a post-marketing safety
- 3513 The system shall permit zero to many conclusions and recommendations for a given study. The system shall capture the date, source, and nature for each conclusion and recommendation.
- 3514 The system shall permit users to detect and track post-marketing study status (in progress or completed) for a given study and cumulatively for a given Epidemiologist or the entire Epidemiology Branch.

Functional Area: Other Requirements

1996 BA Document

Sub Area: General System Interface

- 2147 Allow the updating of files and table information by importing/exporting of data through electronic interfaces with a variety of systems external to AERS
Note: Specific interfaces with systems will be specified in the functional module sections.
- 2148 Autoload data to AERS database after transactions are run successfully and provide a time/date stamp report
- 2149 Populate data tables automatically from external systems
- 2150 Perform automatic stream initiation of jobs to export data to other external systems and provide a time/date stamp

2003 RTM

- 2499 The system shall allow the updating of files and table information by importing/exporting of data through electronic interfaces with a variety of systems external to AERS
- 2500 The system shall autoload data to the AERS database after transactions are run successfully and provide a time/date stamp report
- 2399 The system shall populate data tables automatically from external systems
- 2417 The system shall perform automatic stream initiation of jobs to export data to other

- 2151 Export data to other software packages through ASCII or other file formats
- 2152 Export user generated reports to other platforms (e.g., IBM, VAX, PC, Mac, or server)
- 2153 Create links between AERS modules and all of the FDA E-Mail systems
- 2154 Create a note/message in any AERS module and send this message through the stipulated FDA E-Mail system
- 2155 Use automatic notification mechanism for pending approvals through E-Mail
- 2156 Trigger processing in one AERS module when certain processing occurs in another AERS module (i.e., upload of electronic submissions triggers quality control)
- Sub Area: Human Factor/Ergonomic*
- 2092 On-line access to relevant AERS policy and procedures manual
- 2093 Graphical User Interface (GUI) with mouse capabilities
- 2094 Scroll forward and backward within a list
- 2095 Search both forward and backward for specific values when reading textual information (where applicable)
- 2096 Scroll through a list of entry options by typing the first few letters of the desired entry to move the cursor to the correct entry
- 2097 Implement a table-driven system to provide flexibility for changes in data values and allow on-line update of these data tables
- 2098 Pop-up menus (where feasible) to allow the user to view and select acceptable data values
- 2099 Edit input data on a field-by-field basis, rather than a screen basis
- 2100 Translate codes to make them understandable to the user
- 2101 Input appropriate fields with default values automatically; allow the user to override the automatic fill, within the parameters of any associated edit
- 2102 Implement screens with clear instructions so that a user can examine a screen independent of the system and system flow and know what to do
- 2103 Assign screen identifiers for all screens
- 2104 Allow a user to go directly to a selected function
- 2105 Identify screens associated with a given function
- 2106 Implement screens that are standardized as to screen purpose and function
- 2107 Design user friendly screens, including constant information appearing in the same place on every screen (i.e., screen identification, screen header, date)
- 2108 Design aesthetically appealing screens, including
- external systems and provide a time/date
- 2418 The system shall export data to other software packages through ASCII or other
- 2419 The system shall export user generated reports to other platforms (e.g., IBM, VAX, PC, Mac, or server)
- 2420 The system shall create links between AERS modules and all of the FDA E-Mail
- 2421 The system shall create a note/message in any AERS module and send this message through the stipulated FDA E-Mail system
- 3382 The system shall use automatic notification mechanism for pending approvals through E-Mail
- 2501 The system shall trigger processing in one AERS module when certain processing occurs in another AERS module (i.e., upload of electronic submissions triggers quality control)
- 3374 The system shall enable users to access relevant AERS policy and procedures manual on-line
- 3663 The system shall have a Graphical User Interface (GUI) with mouse capabilities
- 2470 The system shall enable the user to scroll forward and backward within a list
- 3375 The system shall enable the user to search both forward and backward for specific values when reading textual information (where applicable)
- 2471 The system shall enable the user to scroll through a list of entry options by typing the first few letters of the desired entry to move the cursor to the correct entry
- 2472 The system shall implement a table-driven system to provide flexibility for changes in data values and allow on-line update of these data tables
- 2596 The system shall utilize pop-up menus (where feasible) to allow the user to view and select acceptable data values
- 2586 The system shall edit input data on a field-by-field basis, rather than a screen basis
- 2587 The system shall translate codes to make them understandable to the user
- 2588 The system shall input appropriate fields with default values automatically; allow the user to override the automatic fill, within the parameters of any associated edit
- 2597 The system shall implement screens with clear instructions so that a user can examine a screen independent of the system and system flow
- 3659 The system shall assign screen identifiers for all screens
- 2473 The system shall enable a user to go directly to a selected function
- 2474 The system shall identify screens associated with a given function
- 2475 The system shall implement screens that are standardized as to screen purpose and function
- 2476 The system shall be designed with user friendly screens, including constant information appearing in the same place on every screen (i.e., screen identification, screen header, date)
- 3660 The system shall designed with

appealing colors, logical layout, and readable fonts	aesthetically appealing screens, including appealing colors, logical layout, and
2109 Screen printing capabilities	2477 The system shall support screen printing capabilities
2110 Implement pop-up screens that are distinguishable from the underlying screen(s)	2617 The system shall implement pop-up screens that are distinguishable from the underlying screen(s)
2111 Use standard numbers, codes, and keystrokes for universal system functions	2478 The system shall use standard numbers, codes, and keystrokes for universal system functions
2112 Implement function key standards that are compatible with CARS toolkit design, whenever possible and desirable	3376 The system shall implement function key standards that are compatible with CARS toolkit design, whenever possible and
2113 Allow function keys and alternative navigation to function keys	2479 The system shall allow function keys and alternative navigation to function keys
2114 Explain key mapping using on-line help for the function	2480 The system shall explain key mapping using on-line help for the function keys
2115 Implement standard navigational conventions that are available on all menus and screens	3661 The system shall implement standard navigational conventions that are available on all menus and screens
2116 Return the user to the previous menu of the function	3662 The system shall return the user to the previous menu of the function
2117 Have "cancel" (or "return" where appropriate) capability for each screen as appropriate; cancel will return the user to the previous screen without executing any	2481 The system shall have "cancel" (or 'return' where appropriate) capability for each screen as appropriate; cancel will return the user to the previous screen without executing any commands
2118 Exit to the main systems menu via a standard means	2482 The system shall exit to the main systems menu via a standard means
2119 Quit the system via a standard means	2483 The system shall quit the system via a standard means
2120 Go directly to selected function via a standard means	2484 The system shall enable a user to go directly to selected function via a standard
2121 On-line help	2485 The system shall provide on-line help
2122 Index help topics to facilitate users' locating a specific topic	2486 The system shall index help topics to facilitate users' locating a specific topic
2123 Have "hot links" in a help screen to other help topics so the user can go to them directly	2487 The system shall have "hot links" in a help screen to other help topics so the user can go to them directly
2124 Implement screen-level help	2488 The system shall implement screen-level help
2125 Implement field-level help	2489 The system shall implement field-level help
2127 Allow authorized users to perform on-line updates to help screens	3377 The system shall enable authorized users to perform on-line updates to help screens
2128 Implement user friendly error handling capabilities that include understandable error messages, as well as error handling routines that react to software errors and send the user back to either the main menu or relevant sub-menu to correct the problem	2492 The system shall implement user friendly error handling capabilities that include understandable error messages, as well as error handling routines that react to software errors and send the user back to either the main menu or relevant sub-menu to correct the problems
2129 Alert the user with error/warning messages when data checks or inter-field data consistency checks detect	2493 The system shall alert the user with error/warning messages when data checks or inter-field data consistency checks detect errors
2130 Implement system/user messages that are understandable and that direct the user to the proper	2490 The system shall implement system user messages that are understandable and that direct the user to a proper course of action
2131 Download reports to another platform, server, or E Mail	3378 The system shall download reports to another platform, server, or E Mail
2132 Generate ad hoc queries using a menu-driven interface and variable parameters	3436 The system shall generate ad hoc queries using a menu-driven interface and variable parameters
2133 Allow the user to specify the output device, such as printer, PC screen, disk file, or other output destination	3844 The system shall allow selection by a user of the report output device including view, print, e-mail, or save to an ASCII and other standard file formats.
2134 Save ad hoc queries and reports for retrieval and subsequent modification	2494 The system shall save ad hoc queries and reports for retrieval and subsequent

2135	Submit a job request of stored queries to run as a single job stream	3379	The system shall submit a job request of stored queries to run as a single job stream
2136	Generate reports during off-hours and save the reports for user access	3807	The system shall generate reports during off-hours and save the reports for user
2137	Retrieve a previously saved ad hoc query or report	3380	The system shall retrieve a previously saved ad hoc query or report format
2138	Allow other users to use previously saved queries	3381	The system shall enable users to use previously saved queries
2139	Access AERS via a uniform access method for users and a single point of entry into the system (i.e., only one log-on and password, when consistent with functional security requirements, should be necessary to access all components of AERS available to a specific user)	2495	The system shall allow users to access AERS via a uniform access method for users and a single point of entry into the system (i.e., only one log-on and password, when consistent with functional security requirements, should be necessary to access all components of AERS)
2140	Access AERS through a GUI icon	2618	The system shall be accessed through a GUI icon.
2141	Allow a user to log-in to AERS remotely	3894	The system shall allow a user to log-in to AERS remotely
2142	Access other systems without leaving the AERS	3848	The system shall allow users to access other systems without leaving the AERS
2143	Access data entered into the AERS application from a variety of AERS functional modules	2496	The system shall allow users to access data entered into the AERS application from a variety of AERS functional modules
2144	Ensure data has a single point of entry and is maintained by the designated "owner" (originator of the data)	2497	The system shall ensure data has a single point of entry and is maintained by the designated "owner" (originator of the data)
2145	Access generic processes through a single point (i.e., provide a single point for managers to approve different functions)	3849	The system shall access generic processes through a single point (i.e., provide a single point for managers to approve different functions)
2146	Allow generic processes to be called and accept or pass parameters from other AERS functions	2498	The system shall allow generic processes to be called and accept or pass parameters from other AERS functions
<i>Sub Area: Performance</i>			
2157	Perform nightly incremental backup of the data files and weekly image backups of the data and system files during the night batch window	2502	The system shall perform nightly incremental backup of the data files and weekly image backups of the data and system files during the night batch window
2158	Run system software to capture data for measuring system performance	3383	The system shall capture data for measuring system performance
2159	Capture usage data from within the AERS application	3384	The system shall capture usage data
2160	Automate a means to checkpoint/restart the host/server portion application from sudden failures	2404	The system shall automate a means to checkpoint/restart the host/server portion application from sudden failures

- 2161 Automate a means to checkpoint/restart the client application from sudden failures
- 2162 Design a user-interface that supports the Windows 95 platform currently in use at CDER
- Sub Area: Special*
- 2163 Develop user-friendly user and operations guides and training manuals
- 2164 Conform to FDA's life-cycle methodology and configuration management requirements, including problem reporting and change requests
- 2165 Develop a system that is as intuitive as possible, thereby minimizing user training
- 2166 Develop and implement a training plan
- 2167 Provide user support through the CDER Help Desk
- 2168 Develop an AERS Users Group building on the PAG grass-roots structure
- 2169 Facilitate and cooperate with requirements for disabled employees
- 2170 Develop "trouble-shooting plan" to address problem resolution during integration and acceptance testing
- 2171 Develop an AERS feature column for the CDER
- 2172 Develop reference guides and standard operating procedure manuals for systems developers; system
- 2173 Develop and implement a strategy and implementation plan and program to convert ADR data from the SRS system and MAR data from the MART system to the new AERS
- 2174 Develop and implement guidelines, strategy, and an implementation plan for coding all drug labels for new molecular entities and other drugs of interest prior to AERS
- 2175 Develop coding principles, guidelines, manuals, and training program for IMT prior to AERS implementation
- 2176 Develop policies and procedures for receipt of manufacturer electronic transmission of Individual Safety Reports by the FDA Central Receiving Site
- 2405 The system shall automate a means to checkpoint/restart the client application from sudden failures
- 2400 The system shall have a user-interface that supports the Windows 95 platform currently in use at CDER
- 3933 The system shall be supported by user-friendly user and operations guides and training manuals
- 2408 The system design shall conform to FDA's life-cycle methodology and configuration management requirements, including problem reporting and change requests
- 2409 The system shall require minimal user training
- 3917 Develop and implement a training plan
- 3918 Provide user support through the CDER Help Desk
- 3919 Develop an AERS Users Group building on the PAG grass-roots structure
- 3669 Facilitate and cooperate with requirements for disabled employees
- 3920 Develop "trouble-shooting plan" to address problem resolution during integration and acceptance testing
- 3921 Develop an AERS feature column for the CDER newsletter
- 3922 Develop reference guides and standard operating procedure manuals for systems developers; system documentation
- 3916 Develop and implement a strategy and implementation plan and program to convert ISR data from the SRS system and MAR data from the MART system to the new AERS system
- 3934 Develop and implement guidelines, strategy, and an implementation plan for coding all drug labels for new molecular entities and other drugs of interest prior to AERS
- 3923 Develop coding principles, guidelines, manuals, and training program for MedDRA prior to AERS implementation
- 3924 Develop policies and procedures for receipt of manufacturer electronic transmission of Individual Safety Reports by the FDA Central Receiving Site

APPENDIX C

Mapping the 2006 BAH Document To the 2003 RTM

Functional Area: Applicable Standards

2006 SRS Document

2003 RTM

Sub Area:

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| <p>5980 AERS II will comply with the following emerging International Conference on Harmonization (ICH) standard: M1 The medDRA terminology.</p> <p>5981 AERS II will comply with the following emerging ICH standard: M2 Electronic transmission standards.</p> <p>5982 AERS II will comply with the following emerging ICH standard: E2B Electronic data exchange format.</p> <p>5983 AERS II will comply with the following emerging ICH standard: E2C Periodic safety update reporting.</p> <p>5984 AERS II will support Health Level Seven (HL7) (http://www.hl7.org) data standards for message formats and message exchanges.</p> <p>5985 The system shall utilize the GUI standards outlined in the AERS GUI Requirements Document.</p> <p>5986 AERS II will comply with the Consolidated Health Informatics (CHI) (http://www.whitehouse.gov/omb/egov/glob/health_informatics.htm) standard.</p> <p>5987 AERS II will comply with the Clinical Data Interchange Standard Consortium (CDISC): (http://www.cdisc.org).</p> <p>5988 The proposed system shall be consistent with current and emerging FDA Enterprise Architecture standards. Any deviation from these FDA technology standards should be explicitly listed, accompanied by a discussion of any possible impact to the FDA.</p> | <p>3446 The system shall translate EDI transmissions from the ICH M2 standard.</p> <p>146 The system must be able to record the IMT code(s) in all data elements identified in the ICH E2B final document</p> <p>2996 The system shall incorporate GUI standards outlined in the AERS GUI Requirements Document approved by the CCB on November 9, 1999.</p> |
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Functional Area: Core Functionality

2006 SRS Document

2003 RTM

Sub Area:

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| <p>4964 The system shall support the capability to conduct activities related to the surveillance of post market</p> <p><i>Sub Area: Assign Inbox Status</i></p> <p>5040 The system shall provide the ability to assign a status of closed or assigned to each ISR.</p> <p>5041 The system shall support the ability to close an ISR.</p> <p>5042 The system shall define an ISR with a status of closed as no longer being visible in the user inbox.</p> <p>5043 The system shall maintain the visibility of closed ISRs referenced in inbox sub-folders until manually removed by the user.</p> <p>5044 The system shall automatically retain a closed ISR in an inbox folder for a designated period of time prior to</p> | <p>2637 The system shall provide the ability to assign a status to each work assignment such as assigned (the default), reviewed, pending, closed, and suppressed.</p> <p>2637 The system shall provide the ability to assign a status to each work assignment such as assigned (the default), reviewed, pending, closed, and suppressed.</p> <p>2703 The system shall provide access to an incoming folder, an Active ISRs/Case Series folder, a Monitored Case Series folder, and a Close ISRs/Case Series folder.</p> <p>2627 The system shall clear items from the closed ISRs/case series folder based on the</p> |
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- permanent removal from the inbox.
- 5045 The system shall provide the ability to close multiple ISRs without accessing the details for each ISR individually.
- 5046 The system shall support the capability to return a closed ISR to the User's Inbox folders and subfolders.
- 5047 The system shall set the default status of an ISR to assigned upon its receipt in the inbox.
- 6551 The system shall track all locations and movements of an ISR (e.g. to different locations in the Inbox, in and out of the Inbox).
- 6552 The system shall display the audit trail of the ISR to any user in the system when viewing the ISR or its case.
- Sub Area: Case Management*
- 5048 The system shall provide users access to a summary screen of all ISRs in a given case.
- 5049 The system shall support a case summary display utilizing the same default sort and display properties as the user's inbox.
- 5050 The system shall allow users to modify and save case summary display settings.
- 5051 The system shall allow users to access details for any ISR in a case from the case summary.
- 5052 The system shall support the accessibility of ISR attachments at the case level.
- 5053 The system shall support a method to request a case merge.
- 5054 The system shall enable users to access a manual merge case tool from all folders in the Inbox and all search (including search outputs) screens.
- 5055 The system shall require the permission of all users with primary surveillance responsibility before performing a
- 5056 The system shall allow multiple cases to be merged at one time in the Merge Cases tool.
- 5057 The system shall provide users with a mechanism for creating and registering requests to modify ISR data.
- 5058 The system shall support the ability to view controlled vocabulary comments entered when a case is changed.
- 5059 The system shall allow an ISR to be re-coded (i.e. the addition or modification of adverse event coded terms to the ISR) without creating a new ISR.
- 5060 AERS II shall enable users to run a pre-defined "case linking" algorithm to search for duplicate reports or cases anywhere the reports or cases are displayed in the system (e.g., in an Inbox, within a saved case search outputs or case series, from a search outputs screen). After this algorithm is run, the system shall display potential matches in order from most closely matching to
- 5060 AERS II shall enable users to run a pre-defined "case linking" algorithm to search for duplicate reports or cases anywhere the reports or cases are displayed in the system (e.g., in an Inbox, within a saved case search outputs or case series, from a search outputs screen). After this algorithm is run, the system shall display
- selected retention period.
- 2637 The system shall provide the ability to assign a status to each work assignment such as assigned (the default), reviewed, pending, closed, and suppressed.
- 3854 The system shall maintain audit trails for all functional data changes within the
- 2670 The system shall provide the ability to view all ISRs and attachments associated with a case view specific ISR data (drill down capability) or specific ISR images.
- 3576 The system shall provide the ability to customize an Inbox according to user-detailed criteria.
- 2670 The system shall provide the ability to view all ISRs and attachments associated with a case view specific ISR data (drill down capability) or specific ISR images.
- 2755 The system shall provide the ability to merge cases based on the determination that two or more cases represent a single adverse
- 3046 The system shall enable users to access the ad hoc merge case tool from all folders in the Risk Assessment Inbox and all ISR, Case, and Case Series Search (including search outputs) screens.
- 2755 The system shall provide the ability to merge cases based on the determination that two or more cases represent a single adverse
- 2967 The system shall enable users to view the comments entered when an ISR is updated (e.g., pulled back) in the View ISR screen.
- 2736 The system shall provide the ability to view images, view case information, view ISR history, and re-code in the View ISR screen.
- 2461 The system shall support automatic identification of multiple versions, duplicates, and follow-up ISRs for a given case.
- 2467 The system shall automatically identify duplicate ISRs and link them to the original corresponding ISR.

- potential matches in order from most closely matching to
- 6553 The system shall capture ISR pullbacks in an audit trail viewable throughout the system.
 - 6554 The system shall allow a user to re-code a routed ISR only if the user is an owner of the ISR (i.e., is assigned one or more of the suspect products reported on the ISR).
 - 6555 The system shall support the concept of an "associated case", whereby separate cases that ultimately refer to the same patient/event may be linked in the system.
 - 6555 The system shall support the concept of an "associated case", whereby separate cases that ultimately refer to the same patient/event may be linked in the system.
 - 6556 The system shall ensure that all "associated cases" are counted only once in searches, search outputs, and reports (e.g., to avoid double counting).
 - 6557 The system shall allow a user to link multiple cases together through a wizard.
 - 6558 The system shall support the concept of a system-generated "master report", which contains all of the data from all of the associated cases, to support searching.
 - 6559 The system shall provide a wizard whereby a user is shown all the reported values for a given data element on all cases in the associated case and is allowed to select which data elements will be captured on the "master"
 - 6560 The system shall notify the creator of the "master report" or, if this user is not active, then the user with primary surveillance responsibility for the product that a new report has come in for one of the "associated cases" and prompt the user to review the master report wizard, to allow the user to update it as appropriate.
 - 6561 The system shall provide a default "master report" which contains the data from the latest best representative manufacturer ISR in the "associated case".
 - 6562 The system shall overwrite the default "master report" if a user creates their own "master report" using the master report wizard.
 - 3854 The system shall maintain audit trails for all functional data changes within the
 - 3492 The system shall restrict the ability to update the coding for a new or revised drug label to the assigned Safety Evaluator.
 - 2464 The system shall link all ISRs associated with a case.
 - 2758 The system shall provide the ability to link two ISRs together to eliminate redundancy within a case.
 - 3431 The system shall provide wizards
 - 3613 The system shall provide the ability to create a merged case report that summarizes the results of all the adverse reports (e.g., direct, manufacturer, follow-up) regarding a single event.
 - 3614 The system shall automatically populate the appropriate fields of a merged case report with default values from the latest recorded direct ISR upon a Safety Evaluator's request.

Sub Area: *Case Series Evaluation*

- 5308 The system shall provide robust functionality to allow the manipulation, analysis, and tracking of case series.
- 5309 The system shall provide the ability to record the strength of an initial case and its potential for case series
- 5310 The system will enable users to execute a search to display "similar" cases to those in a saved case search
- 5311 The system shall notify any case series owner for whom the modified ISR is a best representative ISR in a case that is marked as pivotal that an ISR has been modified.
- 5312 The system shall provide the ability to record case series comments and case series assessment with a default population of the appropriate fields from all pivotal cases within a case series and with full risk assessor edit
- 5313 The system shall provide an automatic notification to the appropriate reviewer to notify him/her that a case series assessment may need to be updated due to a change in a case assessment that is part of the case series.
- 5314 The system will provide the ability to view both case series data and drug usage data in graphical or tabular
- 5314 The system will provide the ability to view both case series data and drug usage data in graphical or tabular
- 3611 The system shall provide the ability to record the strength of an initial case and its potential for case series development.
- 3597 The system shall support the identification of an ISR that matches the drug and reaction criteria for an individual's active case series, MARs, and consults.
- 2963 The system shall notify any case series owner for whom the modified ISR is a best representative ISR in a case that is marked as pivotal that an ISR has been modified.
- 3630 The system shall provide the ability to record case series comments and assessments with appropriate field default population from all pivotal cases within a case series.
- 3629 The system shall provide an automatic notification to Safety Evaluators when a case series assessment may require updating due to a change in a case
- 3620 The system shall provide the ability to view case series data in graphical or tabular form.
- 3489 The system shall provide the ability to view drug usage data in graphical or tabular form.

- 5315 The system will provide the ability to access external clinical morbidity data if they are available for use in providing signal context information.
- 5316 The system will provide the ability to manipulate or view, using statistical and graphical tools, all data fields which are part of any case that is a member of an active case
- 5317 The system will provide the ability to perform biologic lot analysis to compare frequency and percentage of ADR reported reactions across biologic lots for a particular biologic product.
- 5318 The system shall track what information (cases, case assessments, etc.) was available at the time of the case series assessment to permit case series reconstruction.
- 5319 The system shall support the data capture and computer aided generation of MAR documentation from the AERS II database; this includes the MAR processes of documentation, recommendations, and follow-up.
- 5320 The system shall provide the ability to request potential MAR status for any active case series and record the change date in status.
- 5321 The authorized user shall have the ability to create, edit, update, and delete the criteria for determining whether a case series can be classified as a potential MAR.
- 5322 All risk assessors shall have the ability to view MAR
- 5323 The system shall, at risk assessor request, screen edited case series against MAR criteria to determine potential MARs.
- 5324 The risk assessor shall have the capability to request potential MAR status for any of his/her active case series. The system will record the date of the change in status.
- 5325 The risk assessor will have the capability to record the minutes of the MAR meetings and link these with the potential MAR.
- 5326 The system shall support the generation of a MAR Summary Document from data stored within the AERS database including data on the drug, drug label, drug dosage and administration; individual cases and their case assessments; pivotal cases; signal context data; signal confirmation data; and case series assessment.
- 5327 The system shall allow the authorized user to fully edit the MAR Summary Document
- 5328 The system shall allow the capture of all recommendations and subsequent activities related to the approval of the MAR, including final regulatory actions.
- 5329 The appropriate user will have the ability to construct or select a pre-defined workflow approval chain for a MAR.
- 5330 The appropriate user will have the ability to modify the approval chain for a MAR.
- 5331 The user will have the ability to record an approval/disapproval and associated comments for a MAR. The system shall automatically record the reviewer's name and approval/disapproval date.
- 5332 The user will have the ability to record regulatory recommendations based upon the MAR review process.
- 5333 The system will enable the user to update the MAR status (signal, annual, or ended), based upon post-MAR decisions and regulatory actions.
- 5334 The user shall have the ability to record post-review related information concerning a particular MAR.
- 3621 The system shall provide the ability to access external clinical morbidity data for use in signal context information.
- 3622 The system shall provide the ability to manipulate or view all data fields in an active case series using statistical and graphical
- 3623 The system shall provide the ability to perform biologic lot analysis to compare frequency and percentage of reported reactions across biologic lots for a particular
- 3632 The system shall provide tracking capabilities of what information (e.g., cases, case assessments) was available at the time of the case series assessment to permit case series reconstruction.
- 3640 The system shall provide MAR Summary Document generation support from data stored within the database including drug data, drug label, drug dosage and administration, individual cases, and individual case assessments.
- 2699 The system shall provide the ability to request potential MAR status for any active case series and record the change date in
- 3636 The system shall provide the ability to create, edit, update, and delete any case series criteria with potential MAR status.
- 3637 The system shall provide Safety Evaluators the ability to view MAR criteria.
- 3638 The system shall provide screen-edited case series against MAR criteria to determine potential MARs.
- 2699 The system shall provide the ability to request potential MAR status for any active case series and record the change date in
- 3639 The system shall provide the ability to record MAR meeting minutes and link them to the potential MAR.
- 3640 The system shall provide MAR Summary Document generation support from data stored within the database including drug data, drug label, drug dosage and administration, individual cases, and individual case assessments.
- 3641 The system shall provide edit privileges to the MAR Summary Document.
- 3642 The system shall provide the capture of all recommendations and subsequent activities related to the approval of
- 3643 The system shall provide the ability to construct or select a pre-defined workflow approval chain for a MAR.
- 3644 The system shall provide the ability to modify the approval chain for a MAR.
- 3645 The system shall provide the ability to record an approval, disapproval, and associated comments for a MAR
- 3646 The system shall provide the ability to record regulatory recommendations based upon the MAR review process.
- 3647 The system shall provide the ability to update the MAR status (e.g., signal, annual, or ended), based upon post-MAR decisions and regulatory actions.

- 5335 Compliance Officers require notification of and access to risk assessor's case series and MARs
- 5336 Compliance Officers require notification of changes in status of risk assessor's case series and MARs
- 5337 The system must group a series of reports into a manufacturer compliance case series that can be accessed electronically.
- 5338 The system must record and store an assessment of a compliance case series.
- 5339 The system must track compliance case series activities and status from initiation through to completion
- 5340 Maintain history of manufacturer compliance case series activities and status over time:
- Store compliance officer comments
 - Store description of completed compliance actions.
- 5340 Maintain history of manufacturer compliance case series activities and status over time:
- Store compliance officer comments
 - Store description of completed compliance actions.
- 5341 The system shall deliver a secondary surveillance work assignment or case series to the appropriate risk assessor. The work assignment should include a total count of flagged cases, the threshold number, the drug name, the drug's safety index level, the reaction, and the "labeledness" of the reaction for that particular drug.
- 3340 The system shall notify Compliance Officers of and provide access to Safety Evaluator case series and MARs.
- 3341 The system shall notify Compliance Officers of changes in status of Safety Evaluator case series and MARs.
- 3342 The system shall group a series of ISRs into a manufacturer compliance case series that can be accessed electronically.
- 3343 The system shall record and store an assessment of a compliance case series.
- 3347 The system shall track compliance case series activities and status from initiation through to completion.
- 3346 The system shall store Compliance Officer comments and store descriptions of completed compliance actions.
- 3344 The system shall maintain a history of manufacturer compliance case series activities and status over time.
- 3603 The system shall deliver a secondary surveillance work assignment or case series to the appropriate Safety Evaluator. The work assignment shall include a total count of flagged cases and threshold numbers.
- Sub Area: Compliance**
- 5401 The system shall include specialized searches and reports to support evaluation and tracking of manufacturers and ISRs by Compliance users.
- 5402 The system shall include a modified Direct ISRs Without Matching Manufacturer ISRs Compliance report which provides case-level information for cases with serious, processed, Direct ISRs that were sent to a manufacturer and do not match any processed manufacturer ISRs in the system based on the combination of: compressed Primary Suspect Trade Name if available (otherwise, compressed Primary Suspect Verbatim Substance Name will be used), Calculated Patient Age, and Patient Gender. This report shall handle null values such that a Direct ISR with null Patient Gender and a manufacturer ISR with null Patient Gender will 'match' for this field.
- 3892 The system shall provide Compliance Officers with access to all compliance case series, manufacturer compliance history, and ISR compliance scores.
- 3772 The system shall include a modified Direct ISRs Without Matching Manufacturer ISRs Compliance report which provides case-level information for cases with serious, processed, Direct ISRs that were sent to a manufacturer and do not match any processed manufacturer ISRs in the system based on the combination of: compressed Primary Suspect Trade Name if available (otherwise, compressed Primary Suspect Verbatim Substance Name will be used), Calculated Patient Age, and Patient Gender. This report shall handle null values such that a Direct ISR with null Patient Gender and a manufacturer ISR with null Patient Gender will 'match' for this field.
- 5403 The system shall provide the ability to execute canned reports that include pre-defined criteria for Compliance
- 5404 The system shall establish a minimum data set to include: identifiable patient, suspect drug, identifiable reporter, and reaction per FDA business rules for determining compliance criteria by ISR type (e.g., expedited, periodic, and electronic submissions).
- 2425 The system shall establish a minimum data set to include: identifiable patient, suspect drug, identifiable reporter, and reaction per FDA business rules for determining compliance criteria by ISR type (e.g., expedited, periodic, and electronic).
- 5405 The system must flag mandatory fields that are missing on manufacturer reports, as well as identify instances where manufacturer coding varies from FDA risk assessor coding and/or where difference between receive date and event notification date are greater than
- 3329 The system shall flag mandatory fields that are missing on manufacturer reports, as well as identify instances where manufacturer coding varies from MedDRA coders.
- 5406 The system shall determine whether expedited and periodic ISRs are submitted on time.
- 2426 The system shall determine whether expedited and periodic ISRs are submitted on
- 5407 The system shall notify the Compliance Officer of late, expedited ISRs within 15 days of receipt at FDA.
- 2427 The system shall notify the Compliance Officer of late, expedited ISRs within 15 days

5408 The system shall provide the ability to access information pertaining to the licensing or authorization of a manufacturer/distributor or establishment for a product.	2428 The system shall provide the ability to access information pertaining to the licensing or authorization of a manufacturer/distributor or establishment for a product.
5409 The system shall provide the ability to create manufacturer criteria groups through save, name and edit options.	2838 The system shall provide the ability to create manufacturer criteria groups through save, name and edit options.
5410 The system shall provide the ability to update a product applicant profile.	2875 The system shall provide the ability to update a product applicant profile.
5411 The system shall provide the ability to count the number of serious ISRs that are late.	3675 The system shall provide the ability to count the number of serious ISRs that are late.
5412 The system shall provide compliance reports that include a line listing of incomplete ISRs. The report shall include ISRs with no reaction specified, ISRs with no suspect product specified, ISRs with no reporter specified, ISRs with no patient specified, and ISRs with no outcome	3741 The system shall provide compliance reports that include a line listing of incomplete ISRs. The report shall include ISRs with no reaction specified, ISRs with no suspect product specified, ISRs with no reporter specified, ISRs with no patient specified, and ISRs with no outcome specified.
5413 The system shall provide compliance reports including a line listing of late expedited ISRs.	3742 The system shall provide compliance reports including a line listing of late expedited ISRs.
5414 The system shall provide compliance reports including ISRs received per manufacturer and provide a line listing of verbatim manufacturer sender, the reported valid trade name, and the reported seriousness, as well as provide a detailed line listing of ISRs per manufacturer.	3743 The system shall provide compliance reports including ISRs received per manufacturer and provide a line listing of verbatim manufacturer sender, the reported valid trade name, and the reported seriousness, as well as provide a detailed line listing of
5415 The system shall provide compliance reports including a detailed line listing of expedited reports that are late based on user input timeliness limits.	3744 The system shall provide compliance reports including a detailed line listing of expedited reports that are late based on user input timeliness limits.
5416 The system shall provide compliance reports including ISR counts based on ISR types, activity, and timeliness, as well as provide a line listing of inactivated ISRs.	3745 The system shall provide compliance reports including ISR counts based on ISR types, activity, and timeliness, as well as provide a line listing of inactivated ISRs.
5417 The system shall provide compliance reports including a detailed line listing of cases and the associated ISRs that consist of mixed seriousness.	3746 The system shall provide compliance reports including a detailed line listing of cases and the associated ISRs that consist of mixed seriousness.
5418 The system shall provide compliance reports including a line listing of manufacturer information.	3747 The system shall provide compliance reports including a line listing of manufacturer information.
5419 The system shall provide compliance reports including an ISR line listing per NME.	3749 The system shall provide compliance reports including an ISR line listing per NME.
5420 The system shall provide compliance reports including a line listing of ISRs in which the Manufacturer field was indicated in the direct ISR, but no matching manufacturer ISR was found.	3750 The system shall provide compliance reports including a line listing of ISRs in which the Manufacturer field was indicated in the direct ISR, but no matching manufacturer ISR was found.
5421 The system must be able to track the date the attachment was received, the type of attachment, and the acceptability of the attachment by manufacturer.	2458 The system shall track the date the attachment was received, the type of attachment, and the acceptability of the
5422 The system must establish minimum data set or other conditions for determining compliance criteria by report type (e.g., 15-day, periodic, and E2B submissions).	2425 The system shall establish a minimum data set to include: identifiable patient, suspect drug, identifiable reporter, and reaction per FDA business rules for determining compliance criteria by ISR type (e.g., expedited, periodic, and electronic)
5423 Calculate and store a compliance score for each individual report received from manufacturers and compute a quarterly average manufacturer compliance	3330 The system shall calculate and store a compliance score for each ISR received from manufacturers and compute a quarterly average manufacturer compliance score.
5424 The system must compare manufacturer compliance scores to one another, the industry average, and within each manufacturer over time (trends).	3331 The system shall compare manufacturer compliance scores to one another, the industry average, and within each manufacturer over time (e.g., trends).
5425 The system must calculate industry average compliance	3332 The system shall calculate and store industry

- scores and store these within AERS.
- 5426 The system must maintain history of manufacturer compliance performance over time:
- Store counts/dates of late/missing reports
 - Store counts/dates of incomplete reports
- 5427 The system must check medical coding for the following:
- Consistency
 - Accuracy
 - Completeness
 - Down-coding (using a less serious medical code in a serious event)
- 5428 The system shall notify a Compliance officer every time a verbatim manufacturer name is entered but not linked to a valid manufacturer name.
- 5429 The system must be able to identify serious and non-serious reports and distinguish foreign from domestic reports to support query and compliance score calculation requirements.
- 5429 The system must be able to identify serious and non-serious reports and distinguish foreign from domestic reports to support query and compliance score calculation requirements.
- 5430 The system must be able to query the database to identify potential compliance cases using compliance scores, counts of deficient reports, or other compliance related
- 5431 The system shall provide Safety Evaluators, Medical Officers, and Compliance users with access to site inspection data (from FACTS).
- average compliance scores.
- 3334 The system shall maintain a history of manufacturer compliance performance over time, store counts/dates of late/missing ISRs, and store counts/dates of incomplete ISRs.
- 3335 The system shall check MedDRA coding for consistency, accuracy, completeness of code, as well as down-coding (e.g., using a less serious MedDRA code in a serious
- 3345 The system shall distinguish foreign from domestic reports to support query and compliance score calculation requirements.
- 3336 The system shall provide the ability to identify serious and non-serious ISRs.
- 3337 The system shall provide the ability to query the database to identify potential compliance cases using compliance scores, counts of deficient ISRs, or other compliance related-

Sub Area: Data Mining

- 5290 The system shall interface with WebVDME, to provide all data mining needs.
- 5291 The AERS II data warehouse shall be used by WebVDME for data mining.
- 5292 The system shall conduct a preprocessing step (TBD) to ensure the AERS data in the AERS II data warehouse are normalized and cleaned prior to use in WebVDME.
- 5293 The system shall allow WebVDME users to conduct controlled cleanup of data (TBD) to ensure clean data use in WebVDME.
- 5294 The system shall perform a regularly-scheduled, automated cleanup of data (TBD) to conduct case linking based on a "smart" algorithm, to ensure cases counts are valid in WebVDME.
- 5295 The system shall perform a regularly-scheduled, automated cleanup of product and manufacturer data (TBD), to ensure all verbatim product and manufacturer names are linked wherever possible, to support data
- 5296 The system shall include "smart" algorithms in Data Entry to ensure that all reports are appropriately linked to a case and to ensure all verbatim product and manufacturer names are linked wherever possible.

Sub Area: Data Warehouse

- 5152 The system shall support a data warehouse, updated daily, which supports most searching and analysis functions; there shall be a seamless interface between AERS II and the AERS II data warehouse from a user
- 5153 The AERS II data warehouse shall be refreshed at least every 24 hours.
- 5154 The AERS II data warehouse shall be used for all safety evaluator, compliance, and FOI searches and reporting.
- 5155 AERS II shall allow users to directly access the AERS II
- 3657 The system shall provide the ability to extract data from the production database periodically and load it into the warehouse
- 3657 The system shall provide the ability to extract data from the production database periodically and load it into the warehouse

data warehouse from within the application.

5156 AERS II shall support single sign-on with the AERS II data warehouse.

5157 The system shall retain real-time searching against the transaction database only for use by data entry staff (e.g., to search for duplicates, to provide a count of number of certain cases in data entry or coding).

Sub Area: Drug and Supervisor Assignments

4974 The system shall provide the ability to create and update drug and biologic responsibilities for individual users by supervisors or individuals with a supervisory role.

3594 The system shall provide the ability to create and update drug and biologic responsibilities for individual Safety Evaluators and Epidemiologists.

4975 The system shall allow supervisors or individuals with a supervisory role to change temporary reassignment criteria for each user subsequent to system routing.

4976 The system shall provide users with notification when a change in their routing and reassignment criteria has occurred.

4977 The system shall maintain a history of assignment and transfer dates for each set of routing and reassignment criteria as well as each AERS II user.

2630 The system shall maintain a history of consult assignment dates and transfer dates for each drug and Safety Evaluator.

4978 The system shall provide drug assignment read-only access for users. All users shall be able to view but not change routing and reassignment criteria. This functionality shall include the ability to view unassigned

2724 The system shall provide read-only access to view drug assignments for Safety Evaluators and update rights to Safety Evaluator Supervisors.

4979 The system shall allow a supervisor or designee the ability to reassign an ISR or group of ISRs to another individual.

2635 The system shall allow an authorized user to reassign a work assignment to another individual.

4980 The system shall allow supervisors or designees to select from an available list of users when temporarily re-assigning an ISR.

4981 The system shall provide the capability to assign and reassign active users to active supervisors or individuals with a supervisory role.

2631 The system shall provide the capability to assign and reassign valid Safety Evaluators to valid Supervisors for purposes of accessing and reviewing employee work assignments and workload.

4982 The system shall allow supervisors or individuals with a supervisory role to assign/inactivate names to the list of active users from a valid list of employees.

6526 The system shall allow supervisors or individuals with a supervisory role to designate another active safety evaluator to perform his/her assignment responsibilities.

2635 The system shall allow an authorized user to reassign a work assignment to another individual.

6527 The system shall enable supervisors or individuals with a supervisory role to input a time period (start and end dates) for which supervisor designations will be valid.

6528 The system shall ensure that after the user-defined time is up, the system will automatically revert back to the original user (supervisor or individual with a supervisory role) for assignment privileges.

6529 The system shall ensure that the designating supervisor or individual with a supervisory role may update his/her designee or associated timeframes for performing assignments at any time.

Sub Area: FOI

5383 The system shall support FOI users in responding to FOI requests using the AERS II data warehouse.

502 The system must provide access to AERS by CDER FOI technicians, with access to the FOI query screens only

5384 The system must permit redaction of product safety concern data for purposes of FOI reporting, should it be determined that this information cannot be obtained under

3499 The system shall permit redaction of product safety concern data for purposes of FOI reporting if this information cannot be obtained under the FOI Act.

5385 The system shall provide FOI users access to FOI query screens only.

3853 The system shall provide CDER FOI users with access to the FOI query screens only.

- 5386 The system shall support various types of requests (FDA-internal and external triggers) for accessing information stored in the AERS II database including post marketing surveillance data, adverse event reports, and case series reports.
- 5387 The system shall allow for the archival and extraction of data from AERS for public or regulatory use, such as FOI extracts.
- 5388 The system will have an "auto-redact" capability; the ability to select "FOI" and print a report with selected fields
- 5390 The system shall provide the ability to define the workflow rules to support the means for creating, updating, and maintaining approval hierarchies for requests for information and/or consultations.
- 5390 The system shall provide the ability to define the workflow rules to support the means for creating, updating, and maintaining approval hierarchies for requests for information and/or consultations.
- 5391 The system shall provide a facility to manage the assignment of workloads (for information/consultations) including automated notification of assignments, classification of requests, assignment of request, progress monitoring, distribution of consults for reviews,
- 5391 The system shall provide a facility to manage the assignment of workloads (for information/consultations) including automated notification of assignments, classification of requests, assignment of request, progress monitoring, distribution of consults for reviews,
- 5391 The system shall provide a facility to manage the assignment of workloads (for information/consultations) including automated notification of assignments, classification of requests, assignment of request, progress monitoring, distribution of consults for reviews,
- 5392 The system shall support various types of requests (FDA-internal and external triggers) for accessing information stored in the AERS II database including post marketing surveillance data, adverse event reports, and case series reports.
- 5394 The system shall provide the ability to run pre-defined FOI searches with pre-determined output formats (reports).
- 5395 The system shall provide an FOI report line listing of completed ISRs as well as the total number of ISRs based on user input criteria.
- 5396 The system shall enable a user to save an FOI search output or report as a 508-compliant, importable, electronic file format of their choice: ASCII, PDF, or comma delimited.
- 5397 The system shall display the search parameters on the last page of the FOI report.
- 5399 The system shall provide the ability to execute canned reports that include pre-defined criteria for FOI users.
- 5400 The system shall print a "AERS Background" page with every FOI report, describing the AERS system at a high level, the data the file was generated, and providing a glossary for key fields (e.g., ISR Number, Case Number, Valid Trade Name).
- 6571 The system shall allow all safety evaluators to access all FOI screens.
- 6572 The system shall maintain a list accessible/maintainable by FOI supervisors of all data elements and whether they are to be redacted on FOI reports or not.
- 505 The system must allow FOI technicians to run automatically redacted FOI queries, as well as retrieve images
- 485 The system must allow for the on-line establishment of workflow chains, detailing the steps a request must be automatically routed through
- 484 The system must allow the on-line management of workflow chains
- 428 A supervisor must have the ability to view an individual's workload, as well as total workload for a specified group of users
- 230 The system shall provide the capability to assign and reassign valid risk assessors to valid supervisors for purposes of accessing and reviewing employee work assignments and workload.
- 429 The system must provide the ability to view, print, or download workload summaries and reports
- 504 The system must provide the ability to run canned FOI reports, as well as ad hoc queries
- 3768 The system shall provide an FOI report line listing of completed ISRs as well as the total number of ISRs based on user input criteria.
- 3593 The system shall allow selection by a user of the report output device including view, print, e-mail, or save to an ASCII and other standard file formats.
- 3770 The system shall display the search parameters on the last page of the FOI report.
- 3713 The system shall provide the ability to run canned FOI reports as well as ad hoc
- 1023 The system shall enable users to access the following reports when AERS Reports (formerly Standard Reports) are accessed from the Tools menu, provided the user has the appropriate role(s) assigned to them in System Administration: FOI, Compliance, and Other (e.g., workload management).

- 6573 The system shall support auto-redaction of verbatim or text fields.
- 6574 The system shall provide a wizard which allows the user to review the auto-redaction performed and modify the redaction (e.g., select additional fields to redact) prior to saving or printing.
- 6575 The system shall ensure that all redaction that occurs on electronic files (e.g., PDF) is impervious to hacking or otherwise accessing the original underlying data elements.
- 6576 The system shall support re-imaging and indexing manually and/or auto-redacted files.
- 6577 The system shall enable FOI users to create sub-folders of redacted ISR images (e.g., used in a common FOI request) which are releasable to the public.
- 6578 The system shall support tracking which ISRs have been released to the public.
- 6579 The system shall provide FOI users with the ability to run ad hoc queries.
- 3713 The system shall provide the ability to run canned FOI reports as well as ad hoc
- Sub Area: Follow-up**
- 5353 The system shall allow provide robust follow-up capabilities, to support the initiation, creation, and tracking of requests for follow-up information by safety evaluators.
- 5354 The system shall provide the ability to request follow-up activity (e.g., oral follow-up, written correspondence) to clarify an ISR. This request shall include the person contacted for the follow up and the type of follow up.
- 5355 The system shall provide automated support for requesting, recording, and tracking follow-up information that is necessary in the initial review of adverse event
- 2649 The system shall provide the ability to request follow-up activity (e.g., oral follow-up, written correspondence) to clarify an ISR. This request shall include the person contacted for the follow up and the type of
- 263 The user will have the ability to request a follow-up activity (oral follow-up, or written correspondence) to clarify an adverse event report/case. This request should include the target for the follow-up, the type of follow-up activity to be performed, the date the request was made, and the requester.
- 5356 The system shall generate a standard follow-up letter for written follow-up requests using information from the system database to customize the letter and the mailing
- 2658 The system shall generate a standard follow-up letter for written follow-up requests using information from the system database to customize the letter and the mailing label.
- 5357 The system shall record all oral and written follow-up activities, including follow-up status, dates, contacts, reviewer, and comments associated with a case.
- 2659 The system shall record all oral and written follow-up activities, including follow-up status, dates, contacts, reviewer, and comments associated with a case.
- 5358 The system shall provide the ability to establish automatic notification for follow-up activities.
- 2660 The system shall provide the ability to establish automatic notification for follow-up
- 5359 The system shall provide the ability to access Microsoft Word templates to create standard follow-up letters and routing slips.
- 2412 The system shall provide the ability to access Microsoft Word templates to create standard follow-up letters and routing slips.
- 5360 The system shall provide the ability to edit follow-up
- 2413 The system shall provide the ability to edit follow-up letters.
- 5361 The system shall provide the ability to merge appropriate data from the system into a user-defined template in Microsoft Word that executes a mail merge function to create a follow-up letter.
- 2414 The system shall provide the ability to merge appropriate data from the system into a user-defined template using an OLE call to Microsoft Word that executes a mail merge function to create a follow-up letter.
- 5362 The system shall provide the ability to save the letters to a shared or local drive, as decided by the Safety Evaluator.
- 2415 The system shall provide the ability to save the letters to a shared or local drive, as decided by the Safety Evaluator.
- 5363 The system shall provide automated generation of a follow-up letter for ISRs that are flagged as matching the pre-defined follow-up criteria.
- 2648 The system shall provide automated generation of a follow-up letter for ISRs that are flagged as matching the pre-defined
- 5364 The system shall enable a Safety Evaluator user to create a letter that is modifiable using an external word processing application.
- 3133 The system shall enable a Safety Evaluator user to create a letter that is modifiable using an external word processing application in the Risk Assessment Follow-up screen.
- 6570 The system shall interface with desktop software for
- 3471 The system shall enable faxing of MedWatch

faxing (e.g., to support faxing follow-up requests).

expedited ISR letters and redacted ISRs to the manufacturers who are participating in the MedWatch Expedited Transmission

Sub Area: Forwarding ISRs

- 5019 The system shall allow users with primary surveillance responsibility for an ISR to forward a copy of the ISR to multiple user inboxes.
- 5020 The system shall support the ability to automatically forward ISRs based on user-defined criteria.
- 5021 The system shall support the ability to manually forward ISRs on an ad hoc basis.
- 5023 The system shall maintain an audit record of forwarded and re-routed ISR copies.
- 5024 There shall be a standard disclaimer attached to each ISR provided to a non-user stating that the ISR details are not to be released to other parties without review by FOI.
- 5025 The system shall support an email/interface to communicate information regarding ISRs/adverse events between users and other centers and agencies.
- 5026 The system shall support the capability to forward multiple ISRs to one or more users.
- 6541 The system shall make accessible to any user the ISR audit record.
- 6542 The system shall support the use of a user-modifiable distribution list of active users, for use in forwarding or re-routing ISRs.

Sub Area: Inbox Display/Reports

- 4988 The system shall provide users with an inbox module for the organization and prioritization of individual workload.
- 4989 The system shall support a default inbox display format for users prior to individual customization.
- 4990 The system shall display a default summary view of assigned ISRs by drug name. Users shall be able to drill down on the summary listing in order to view greater
- 4991 The system shall provide the user with the ability to create a customized view of assigned ISRs according to user defined filter criteria.
- 4992 The system shall support the capability to customize the inbox ISR display based on any available ISR data fields.
- 4993 The system shall support a summary display field that will identify ISRs with attachments and allow viewing of such attachments.
- 4994 The system shall support the display of all inbox filter criteria employed by the user.
- 4995 The system shall provide the ability to restore the inbox display to default settings.
- 4996 The system shall ensure that each adverse event coded term's status (labeled/unlabeled) is displayed in the inbox in a visual and 508 compliant manner (by color, symbol, italics, etc).
- 4998 The system shall support the ability to set ISR-based surveillance criteria that will trigger the display of a flag and a customizable pop-up message.
- 5001 The system shall support the ability to generate and print a
- 2700 The system shall provide a Safety Evaluator Inbox populated with ISRs that meet primary surveillance criteria or those re-routed from another user.
- 3576 The system shall provide the ability to customize an Inbox according to user-detailed criteria.
- 3576 The system shall provide the ability to customize an Inbox according to user-detailed criteria.
- 3576 The system shall provide the ability to customize an Inbox according to user-detailed criteria.
- 291 The user shall have the ability to view all reports and attachments associated with a case and select any of the following options - view the data (drill down capability) for a specific report or the image of a selected report or the image of an attachment that is linked to a case.
- 938 The system shall enable the filter or sort being performed to be displayed in the title bar of the active screen.
- 939 The system shall provide the ability to return the line listing to the default sort order in the front-end inbox.

- customizable summary report of ISRs displayed in the
- 5002 The system shall allow users to select fields for display when printing an ISR summary report from the ISR Inbox.
- 5003 The system shall be capable of printing an individual ISR report without accessing ISR details.
- 5004 The system shall allow users to view and print part or all of a label from the Inbox.
- 5005 The system shall support the ability to track inbox counts for any assigned drug over a user-defined time period.
- 6530 The system shall allow a user to customize the criteria for viewing a pop-up message (e.g., only certain DMEs, or certain DMEs with certain outcomes but not other outcomes) using any of the available data elements for an
- 6531 The system shall allow the pop-up message feature for Inbox notification to be turned-off completely by an
- 6532 The system shall support a default setting (TBD) for all new safety evaluators given AERS accounts, which governs Inbox pop-up notification and flagging.
- 6533 The system shall provide a visual flag that an ISR that meets user-defined surveillance criteria, which remains as long as the ISR is in the user's Inbox.
- 6534 The system shall display on the pop-up message the reason the ISR is flagged (i.e., why it meets the user-defined criteria).
- 6535 The system shall support the generation of a Medwatch-like form to display the corresponding fields from the ISR, or, if a case, from the best representative ISR for that
- 6536 The system shall allow a Medwatch-like form to be generated from anywhere in the system where ISRs or cases are displayed (either individually or in line-listing)
- 6537 The system shall allow a user to "Save As" the system-generated MedWatch-like form in PDF format (e.g., to save to their local drive).
- 6538 The system shall support printing the Medwatch-like form either individually (e.g., when viewing one ISR) or in a batch (e.g., by multi-selecting a number of ISRs or cases from a line listing).
- 6539 The system shall ensure that a large, clearly identifiable watermark is generated on the MedWatch-like form, so as to distinguish it as being different that the form actually submitted by the manufacturer or direct reporter. (For example, the watermark could read "FDA INTERNAL USE ONLY. This report may or may not represent data as originally submitted.")
- 6540 The system shall support the ability to track inbox counts for any assigned safety evaluator over a user-defined time period.
- 2771 The system shall provide a pop-up message in a Safety Evaluator's Inbox triggered by the expiration of the automatic notification functionality.
- Sub Area: Inbox Filter Management*
- 4983 The system shall enable the user to receive any ISRs that meet the drug/biologic/medical term code (reaction) combination regardless of the seriousness and/or labeledness of the ISR based on the adverse event coded terms in the personal DME list.
- 4984 The system shall support the capability to filter ISRs coming into the Inbox based on standard DME lists (by choosing which center DMEs to apply to their Inbox).
- 4985 The standard DME list shall serve as the default (prior to modification by user) DME list for the users of the system.
- 4986 AERS II shall allow users to multi-select products and DMEs when managing their individual surveillance criteria, and suppress all values at once (instead of having to do one at a time). (Note: This is a GUI standard).
- 4987 The system shall maintain an audit trail of filters in place for each inbox. The user instituting the filter shall be able
- 2727 The system shall enable the Safety Evaluator to receive any ISRs that meet the drug/MedDRA code (reaction) combination regardless of the seriousness and/or labeledness of the ISR based on the PTs in the personal DME list.
- 2730 The system shall not suppress Center DMEs until indicated as such by the Safety

to record a comment about the filter. The filters shall be viewable by appropriate parties.

Sub Area: Inbox Organization

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| <p>5006 The system shall support the ability for individual users to customize the organization of the AERS II inbox.</p> <p>5007 The system shall allow users to apply dynamic sorting criteria to ISRs in their inbox, utilizing all available data</p> <p>5008 The system shall provide ascending and descending sort capability for each data field visible in the inbox.</p> <p>5009 The system shall provide mixed ascending and descending sort capability for multiple data fields</p> <p>5010 The system shall allow users to group ISRs in nameable folders and subfolders.</p> <p>5011 The system shall support the ability for ISRs to be viewed in more than one folder and/or subfolder.</p> <p>5012 The system shall maintain ISRs in folders and/or subfolders until manually removed by the user with primary surveillance responsibility.</p> <p>5013 The system shall automatically update ISRs that are located in a folder with the best representative cases as they are entered into the system.</p> <p>5014 The system shall automatically notify users with primary surveillance responsibility when an ISR located in a folder has been updated with a best representative case.</p> <p>5015 The system shall enable users to utilize Inbox filtering and sorting capability in any folder or subfolder of the Inbox.</p> <p>5016 The system shall support the capability to save and name filter and sort criteria.</p> <p>5017 The system shall retain filtering and sorting criteria while working in a specific functional area. If a user filters data in the front-end inbox and navigates to another functional area the original filter will not be lost in the front-end inbox unless the user rescinds criteria.</p> <p>5018 The system shall support the use of automatic notification functionality (tickler) reminders based on individualized user criteria. When an ISR is marked by a tickler, the ISR shall be automatically placed in a "tickler folder".</p> | <p>3576 The system shall provide the ability to customize an Inbox according to user-detailed criteria.</p> <p>2869 The system shall provide an ISR search that sorts the results in ascending or descending order.</p> <p>3396 The system shall provide mixed ascending and descending sort capability</p> <p>2660 The system shall provide the ability to establish automatic notification for follow-up</p> |
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Sub Area: Inbox Signal Detection

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| <p>5027 The AERS II system shall provide automated signal generation capabilities, the details and path of which is captured in an audit trail.</p> <p>5028 The system shall allow a user to create and modify automated signal generation criteria.</p> <p>5029 The system shall support the availability of dictionary-coded drug/biologic labels for comparison to the adverse event coded terms in each ISR.</p> <p>5030 The system shall ensure that each adverse event coded term within an ISR shall have a status (labeled/unlabeled/unavailable) which will be automatically noted by the system.</p> <p>5031 The system shall use medical dictionary coded drug/biologic label information, if available, to determine the labeledness (using SPL) of a reported reaction.</p> <p>5032 The system shall support the ability to sort AE coded terms based on whether coded adverse events are</p> <p>5033 The system shall support the capability to manually assign a status to the adverse event coded term if the coded term's status is not available. The status shall be retained for each subsequent AE coded term/NDA/STN</p> | <p>2644 The system shall use MedDRA-coded drug label information, if available, to determine the labeledness of a reported reaction for purposes of primary and secondary surveillance processing.</p> |
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- 5034 The system shall support the availability from the inbox of product labeling for all US approved drug/biologics in multiple formats (PDF, SPL, MSWord).
- 5035 The system shall support the availability of medical coding shall be accessible from the inbox. Coding shall be available in an expandable form so that coding hierarchy can be viewed.
- 5036 The system shall support the ability of each user to identify, for each drug/biologic assigned, other persons responsible for reviewing the drug within the center (PM, MO, chemist, etc).
- 5037 The system shall support the availability of secondary surveillance analysis functionality (Quick Counts) from the Inbox.
- 5038 The system shall periodically screen the AERS data base in order to count and flag relevant cases that meet or exceed the threshold criteria associated with a reported suspect drug's assigned drug safety index level as determined by the user.
- 5039 The system shall notify the user if one or more of the user-defined thresholds for case counts has been
- 6543 The system shall support combining labeled data with Outcome data when setting signal generation criteria (e.g., Fatal Rash not Rash alone).
- 6544 The system shall support the ability to sort AE coded terms based on data mining score
- 6545 The system shall support the ability to sort AE coded terms based on quick counts score.
- 6546 The system shall support the availability of data mining scores from the Inbox.
- 6547 The system shall support the availability of labeled (or labeled+Outcome) determination from the Inbox.
- 6548 The system shall allow the user to customize the automated notification criteria using any of the available data elements on an ISR.
- 6549 The system shall maintain an audit trail of all notifications and the reasons why ISR(s) exceeded the thresholds.
- 6550 The system shall allow a user to create different sub-folders in the Inbox to contain ISRs or cases which meet different user-defined thresholds.
- 3603 The system shall deliver a secondary surveillance work assignment or case series to the appropriate Safety Evaluator. The work assignment shall include a total count of flagged cases and threshold numbers.
- 3602 The system shall periodically screen the system database and count and flag relevant cases that meet or exceed the threshold criteria associated with a reported suspect drug's assigned drug safety identifier.

Sub Area: Individual ISR Display

- 5122 The system shall support a display of all available data relevant to an individual ISR in the form of a detailed view.
- 5123 The system shall display ISR details in the format similar to the MedWatch form.
- 5124 The system shall display all information in the ISR detailed view as read-only.
- 5125 The system shall allow users the ability to view all data related to the ISR if the data is received in the proper
- 5126 The system shall allow users to navigate to specific sections of the ISR record.
- 5127 The system shall support the ability to view an individual ISR audit trail.
- 5128 The system shall support the ability to access updated data pertaining to all changes of regulatory responsibility within the pharmaceutical industry from the detailed ISR
- 5129 The system shall support access to all approved product labeling.
- 5130 The system shall support access to all carton labeling and color images.
- 5131 The system shall allow users to view the FDA active ingredient for combination products table/system from the

- ISR detail screen.
- 5132 The system shall support access to data mining scores from the detailed ISR view.
- 5133 The system shall provide the user with a history of activity related to risk assessment activities associated with an
- 5134 The history of activity comments shall be associated with the ISR and is not releasable to the public.
- 5135 The system shall support the ability to re-code an ISR from the ISR detail screen.
- 5136 The system shall allow users to view the audit trail of an ISR from the ISR detail screen.
- 5137 The system shall display the calculated and the reported age on the ISR detail screen.
- 2636 The system shall provide a history of activity related to safety evaluation activities associated with a work assignment.
- 2736 The system shall provide the ability to view images, view case information, view ISR history, and re-code in the View ISR screen.
- 2736 The system shall provide the ability to view images, view case information, view ISR history, and re-code in the View ISR screen.
- Sub Area: ISR Routing**
- 4965 The system shall ensure that users receive the appropriate 15-day, Direct Reports, and DME tagged
- 4966 The system shall assign ISR reports to the responsible user(s) based on assigned drug/biologic or biologic responsibilities and surveillance standard DME.
- 2629 The system shall select and assign ISRs to the responsible Safety Evaluator based on assigned drug or biologic responsibilities and on primary surveillance standard DME and individual criteria.
- 4967 The system shall provide the capability for automatic routing of ISRs to one or more users (DDRE and DMETS users and Medical Officers) based on flexible assignment combinations. When a report has been automatically routed, the receiver shall be notified.
- 4968 The system routing assignment criteria shall be determined by dynamic filter criteria based on any fields contained within the ISR (e.g., NDA number, STN, BLA, trade name, date of approval, adverse event, indication, etc).
- 4969 The system shall provide users with the capability to view the active routing criteria for their inbox.
- 3576 The system shall provide the ability to customize an Inbox according to user-detailed criteria.
- 4970 The system shall include the functionality to manage standard DME lists including viewing, adding, and suppressing entries.
- 4971 The system shall support the capability to manage DME lists by AI and/or Trade Name.
- 4973 The system shall automatically route ISRs with the HLGT Medication Error to the corresponding Medication Errors Inbox.
- Sub Area: ISR Screen Printing**
- 5138 The system shall support printing the information displayed on the ISR detail screen.
- 2477 The system shall support screen printing capabilities
- 5139 The system shall support the capability to view and print multi-page ISR images and eSub reports from the ISR detail screen.
- 5140 The system shall allow users to generate a PDF file of the MedWatch form.
- 5141 The system shall support re-sizing ISR images and eSub reports.
- Sub Area: Label Search**
- 5227 The system shall support the capability to search product labels and use product label data in AERS.
- 2773 The system shall provide the capability to perform a full text search on the most current product label.
- 5228 The system shall provide the ability to view and select search criteria for product label searches against the drug label database.
- 2675 The system shall provide the ability to view and select search criteria for drug label searches against the drug label database.

- 5229 The system shall support the ability to view and select search criteria for performing a product label search against the AERS drug label database.
- 5230 The system shall use a coded label or a suspect product reported in an ADR to determine the "labeledness" of the adverse reaction if a coded label is available.
- 5231 The system shall provide the ability to view the most current label for a new molecular entity or designated product of interest.
- 5232 The system shall provide the ability to access and view the appropriate product label if user wants to view label for a generic product.
- 5233 The system shall provide the capability to perform full text search on the most current product label.
- 5234 The system shall provide the capability to directly view image of a label from inside the AERS system.
- 5235 The system shall provide the capability to compare a label with other relevant product labels that have the same pharmacological class or the same therapeutic indication class.
- 5236 The system shall provide the ability to compare a product label with other relevant product labels to promote identification of adverse reactions that are prevalent in a product class, and use the results as screening criteria.
- 5237 The system shall provide the ability to code all reactions and record their corresponding label section names for biologics and drug products.
- 5238 The system shall provide the ability to edit medical code terms for a drug or biologic label.
- 5239 The system shall provide the ability to view medical code terms upon request.
- 5240 The system shall provide the ability to medical code, all indications for use listed on a drug or biologic label.
- 5241 The system shall provide the ability to handle search criteria which requires medically coded labeled fields as
- 5242 The system shall provide the ability to compare a drug label with other relevant drug labels to promote identification of adverse reactions that are prevalent in a drug class, and use the results as screening criteria.
- 5243 The system shall provide the capability to compare a label with other relevant drug labels that have the same pharmacological class or the same therapeutic indication class
- 2675 The system shall provide the ability to view and select search criteria for drug label searches against the drug label database.
- 2644 The system shall use MedDRA-coded drug label information, if available, to determine the labeledness of a reported reaction for purposes of primary and secondary surveillance processing.
- 2825 The system shall provide the ability to view the most current label for an NME or designated drugs of interest.
- 2826 The system shall provide the ability to access and view the appropriate drug label if a user wants to view a label for a generic drug
- 2773 The system shall provide the capability to perform a full text search on the most current product label.
- 2828 The system shall provide the ability to directly view label images from inside the system.
- 3481 The system shall provide the capability to compare a label with other relevant drug labels that have the same pharmacological class or the same therapeutic indication
- 3482 The system shall provide the ability to compare a drug label with other relevant drug labels to promote identification of adverse reactions that are prevalent in a drug class and use the results as screening
- 2829 The system shall provide the ability to MedDRA code all reactions and record their corresponding label section names for biologics and drug products
- 2830 The system shall provide the ability to edit MedDRA terms for a drug or biologic label.
- 2831 The system shall provide the ability to view MedDRA terms upon request.
- 2832 The system shall provide the ability to MedDRA code all indications for use listed on a drug or biologic label.
- 3483 The system shall provide the ability to handle search criteria that require MedDRA-coded labeled fields as input.
- 3482 The system shall provide the ability to compare a drug label with other relevant drug labels to promote identification of adverse reactions that are prevalent in a drug class and use the results as screening
- 3481 The system shall provide the capability to compare a label with other relevant drug labels that have the same pharmacological class or the same therapeutic indication

Sub Area: Miscellaneous Expanded Search Criteria

- 5180 The system shall support a new data element, pharm
- 5181 The system shall allow users to have the ability to search the database by pharm class.
- 5182 The system shall have the ability to identify adverse events due to generic products.
- 5183 The ISR details display shall present NCI CTCAE events that are reported with a grade in the narrative.
- 5184 The system shall support fuzzy searches on lot numbers.
- 5185 The system shall support the ability to search by the date a report was first received.
- 5186 The system shall support the ability to search by the date of receipt of the most recent information on reports.

- 5187 The system shall ensure that post-marketing safety study data are searchable by drug, manufacturer, safety issue, reaction(s), demographic, and cooperative agreement/contract database name.
- 5188 The system shall support the ability to request a search of reported drug interactions with selected medical terms and with one or more drugs.
- 5189 The system shall support the ability to request a search of all ADR reports/cases for a particular standard drug or biologic group such as by AHFS code or FDA pharmacologic category.
- 5190 AERS II shall support query-building wizards that allow certain types of searches (e.g., interaction searches) to be programmed into the wizard such that the wizard will walk a user through the process of building a query of that type, to help the user establish the search criteria, relationship between data elements, logic statements, etc.
- 5191 The system shall allow users to build a query definition without having any knowledge of SQL.
- 5192 The system shall provide drop and drag feature for selection of search criteria.
- 5193 The system shall support the generation of ad hoc queries using a menu-driven interface and variable parameters
- 5194 The system shall support free form entry for query definition, which will enable users to choose to enter search criteria without a standard format.
- 5195 The system shall support canned (e.g., in the form of the search Wizard) and ad Hoc searches for users to query the database.
- 5196 The system shall have links to each FDA active ingredient for combination products table/system.
- 5197 The system shall have the ability to search all dictionaries.
- 5198 The system shall have the ability to allow users to customize database and dictionary searches.
- 5199 The system shall support the ability to view and select search criteria for performing a manufacturer search against the manufacturer dictionary.
- 5200 The system shall have the ability to retain saved FDA searches after application software upgrades.
- 5201 The system shall provide the ability retrieve information about drug safety studies, including study type, requirements, protocols, findings, and recommendations
- 5202 The system shall provide Medical Officers with access to pre-market safety data (TBD). (Note: Medical Officers interviewed determined that this requires validation with FDA management and may be a longer-term goal rather than an immediate need for AERS II.)
- 5203 AERS II shall use the term "Safety Evaluator" throughout the system instead of "Risk Assessor."
- 6569 The system shall support additional miscellaneous search criteria (note: this is a catch-all requirement and includes numerous, often unrelated sub-requirements).
- 3510 The system shall retrieve post-marketing safety study data by drug, manufacturer, safety issue, reaction(s), demographic, and cooperative agreement/contract database
- 2685 The system shall provide the ability to search reported drug interactions containing specified MedDRA terms and/or one or more
- 3618 The system shall provide the ability to search all ISRs and cases for a particular standard drug or biologic group such as AHFS code or FDA pharmacological category.
- 3431 The system shall provide wizards
- 3412 The system shall support capability to build a query/report definition without knowledge of SQL
- 3415 The system shall provide drop and drag feature for selection of data
- 3436 The system shall generate ad hoc queries using a menu-driven interface and variable parameters
- 3416 The system shall support free form entry for report/query definition
- 3545 The system shall provide canned and ad hoc searches for users to query the database.
- 2673 The system shall provide the ability to view and select search criteria for manufacturer searches from the manufacturer dictionary.

Sub Area: Public Online Access

- 6581 The Public Web Site shall support a "Most Populated FOI Requests" feature which provides online access to FOI reports and/or redacted images for common public

Sub Area: Quick Counts & At-A-Glance Functionality

- 5365 The system shall provide Quick Counts (high-level information about a case and summary statistics) and other at-a-glance functionality in AERS.

- 5366 The system shall provide Quick Counts based on the ISR data (active ingredient/reaction combination).
- 5367 The first ingredient displayed in Quick Counts should always be the ingredient that was searched on, or, if not accessed from a search, the first primary suspect product ingredient displayed for a case.
- 5368 The system shall include Quick Counts, which provides counts of cases meeting any valid active ingredient and reaction combination.
- 5369 The system shall enable users to conduct Quick Counts from the ISR or case detail screen.
- 5370 The system shall provide the ability to obtain Quick Counts for any ingredient and reaction combination.
- 5371 The system shall enable users to use existing product and reaction group lists in Quick Counts.
- 5372 The system shall provide Quick Counts based solely on the ingredient and reaction combination contained in the ISR and count all the cases that meet the display ingredient in the database.
- 5373 The system shall provide Quick Counts at the PT level of MedDRA by default.
- 5374 The system shall provide the ability to reset and return to the original criteria used to conduct Quick Counts.
- 5375 The system shall provide medical terms displayed in Quick Counts screen in descending frequency.
- 5376 The system shall provide the ability to include active ingredients and the appropriate salts when conducting Quick Counts.
- 5377 The system shall enable the safety evaluator to conduct Quick Counts at all levels of the medical coding thesaurus.
- 5378 The system shall enable users to drill up or down the medical coding hierarchy in Quick Counts.
- 5379 The system shall provide a print out of the Quick Counts screen including the selected active ingredients case counts, selected medical terms, case, death, and serious
- 5380 AERS II shall include other "at-a-glance" screens (TBD), which provide a quick view of user-defined parameters. Examples include: "Quick Compliance" (to display key dates and calculations of interest, for example, the difference between the manufacturer received date and the initial FDA received date for the case) and "Quick Labeledness" (to display the reported reactions on the case being viewed against the labeled reactions for the primary suspect product).
- 5381 All "at-a-glance" screens (including Quick Counts) shall allow users to access the search screens directly.
- 5382 The system shall enable fuzzy searching on active ingredient names in Quick Counts.
- 3043 The system shall include a functional Secondary Surveillance Counts screen, renamed to 'Quick Counts', which provides counts of cases meeting any valid active ingredient and reaction combination.
- 3043 The system shall include a functional Secondary Surveillance Counts screen, renamed to 'Quick Counts', which provides counts of cases meeting any valid active ingredient and reaction combination.
- 3052 The system shall enable users to conduct Secondary Surveillance Counts from the modified More Information screen.
- 2737 The system shall provide the ability to obtain secondary surveillance counts for any ingredient and reaction combination.
- 2738 The system shall provide secondary surveillance counts based solely on the ingredient and reaction combination contained in the ISR and count all the cases that meet the display ingredient in the
- 2739 The system shall provide secondary surveillance counts at the PT level of MedDRA by default.
- 2741 The system shall provide the ability to reset and return to the original criteria used to conduct secondary surveillance counts.
- 2872 The system shall provide PTs displayed in the Secondary Surveillance Counts screen in descending frequency.
- 2881 The system shall provide the ability to include active ingredients and the appropriate salts when conducting secondary surveillance counts.
- 3673 The system shall enable the Safety Evaluator to conduct secondary surveillance counts at the HLT or HLGT level of MedDRA.
- 3721 The system shall provide a print out of the Secondary Surveillance Counts screen including the selected active ingredients case counts, selected PTs case, death, and serious counts.

Sub Area: Risk Assessor Summary Reports

- 5342 The system shall allow support the creation of Risk

Assessor Summary Reports by safety evaluators.

- 5343 The system shall provide the ability to create a Risk Assessor Summary Report (initial or follow-up) when an oral follow-up request is received. This ISR shall populate with values from the last received direct ISR associated with the case.
- 5344 The system shall link all Risk Assessor Summary Reports to associated ISRs and to an associated case.
- 5345 The system shall link follow-up information received from a written request to the appropriate follow-up request activity to support follow-up performance measurement.
- 5346 The system shall provide the ability to record comments for a Risk Assessor Summary Report.
- 5347 The system shall record the FDA receipt date, report date, and version for each Risk Assessor Summary Report.
- 5348 The system shall record Risk Assessor Summary Reports with direct reporters as initial direct ISRs for cases that have no prior recorded direct ISR.
- 5349 The system shall provide the option to locate an initial ISR for a case, given the information on the Risk Assessor Summary Report.
- 5350 AERS II will allow the appropriate user (the owner of the primary suspect product) to choose to be alerted that a follow-up report has come in for a case in which there is a Risk Assessor Summary Report. Users will have the ability to turn off this notification.
- 5351 AERS II shall include a flag on the screen that displays case line listings, which will signify whether any of the cases displayed has a Risk Assessor Summary Reports associated with it.
- 5352 AERS II shall print Risk Assessor Summary Report reports (i.e., as though they were an image) whenever Batch Print is selected for that case.
- 2650 The system shall provide the ability to create a Safety Evaluator follow up or Safety Evaluator initial ISR when an oral follow-up request is received. This ISR shall populate with values from the last received direct ISR associated with the case.
- 2651 The system shall link all Safety Evaluator follow-up ISRs to associated ISRs and to an associated case.
- 2652 The system shall link follow-up information received from a written request to the appropriate follow-up request activity to support follow-up performance measurement.
- 2653 The system shall provide the ability to record comments for a Safety Evaluator follow-up.
- 2654 The system shall record the FDA receipt date, report date, and version for each.
- 2655 The system shall record Safety Evaluator follow-up ISRs with direct reporters as initial direct ISRs for cases that have no prior recorded direct ISR.
- 2656 The system shall provide the option to locate an initial ISR for a case, given the information on the Safety Evaluator follow-up ISR.
- 2683 The system shall provide Safety Evaluators with the ability to view a line listing of all cases within the case series. Each case line listing shall include key data for quick determination of further investigation.

Sub Area: Saving/Exporting Search Results

- 5265 The system shall support the retention and export of searches to systems external to AERS II.
- 5266 The system shall have the ability to retain saved FDA searches after application software upgrades.
- 5267 The system shall provide users with the capability to redisplay a previous query result.
- 5268 The system shall have the ability to save or export results of database searches into text, delimited, Microsoft Excel, Microsoft Access, SAS, WordPerfect, Quattro or Lotus 1-2-3 file.
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- 5268 The system shall have the ability to save or export results of database searches into text, delimited, Microsoft Excel, Microsoft Access, SAS, WordPerfect, Quattro or Lotus 1-2-3 file.
- 2519 The system shall support capability to save query/report definitions
- 2521 The system shall provide capability to redisplay previous query result
- 2515 The system shall provide capability to export a text file
- 3399 The system shall provide capability to export a delimited file
- 3400 The system shall provide capability to export a Quattro or Lotus 1-2-3 file
- 2418 The system shall export data to other software packages through ASCII or other
- 3401 The system shall provide capability to export a WordPerfect file

- 5269 The system shall support the capability to select result set fields for export while excluding others.
- 5270 The system shall provide the ability to save a case series assessment as a word processing file attached to a saved case search (case series).
- 5271 The system shall have the capability to copy and paste outputs and searches to other applications.
- 5272 The system shall support the retrieval of a previously saved ad hoc query or report format.
- 5273 The system shall support the ability for users other than the report author to use previously saved queries.
- 5274 The system shall provide a history for each saved search to indicate when the search was last executed.
- 5275 The system shall support the ability to save ad hoc queries and reports for retrieval and subsequent modification.
- 5276 AERS II shall provide a collaboration area (TBD) where certain users are allowed to view saved searches/outputs placed in this shared area. For example, this area shall support threaded discussions, folders/sub-folders, the ability to post other documents to the shared area, and the ability to control access to each.
- 5277 AERS II shall enable users to save their searches in such a manner that they are private (viewable only to that user) or can be published to a shared area designated by the user (e.g., a team or group area).
- 5278 AERS II shall allow search results/outputs to be published to a shared area with comments entered by the search.
- 5279 AERS II shall support the concept of a search "owner", and allow only that individual to modify the search criteria or change the output display format, when a search is published to a shared area if desired. The user may choose at the time of publishing whether to allow others to update the search.
- 5280 AERS II shall allow users to have a "Save As" function, which enables them to modify an existing saved search and save it with a different name.
- 5281 AERS II shall prompt a user whether or not they want to save changes to saved search criteria once modified.
- 5282 AERS II shall support the concept of flagging cases within a set of search results in order to determine which cases have been reviewed by the search requester.
- 5283 AERS II shall allow users to send search outputs to another AERS user with text comments.
- 5284 AERS II shall allow users to send search outputs sent via FDA email as an attachment.
- 5285 AERS II shall allow users sending search outputs to designate before sending whether the outputs will be Read Only or Updatable when viewed by the recipients.
- 5286 AERS II shall enable users to add comments regarding a saved or published search output or case series.
- 5287 The system shall provide the ability to view, edit, save, print, lock, and delete a published saved search outputs or case series.
- 5288 The system shall support the capability to record the trigger event (consult request, primary surveillance work assignment, secondary surveillance, literature reference), and a specific reference entity (report number, literature ID, etc.) for each saved case search (case series).
- 5289 The system shall provide the ability to save a case series assessment as a word processing file attached to a saved case search (case series).
- 3631 The system shall provide the ability to save a case series assessment as a word processing file.
- 3380 The system shall retrieve a previously saved ad hoc query or report format.
- 3381 The system shall enable users to use previously saved queries.
- 2494 The system shall save ad hoc queries and reports for retrieval and subsequent modification.
- 3616 The system shall provide the ability to record trigger events (e.g., consult requests, primary surveillance work assignments, secondary surveillance, literature references) and specific reference entities.
- 3631 The system shall provide the ability to save a case series assessment as a word processing file.

Sub Area: Search Output

- 5244 The system shall support user-customizable formats for

- the display of search results.
- 5245 The system shall support tabular query definition.
- 5246 The system shall support cross-tab query definition.
- 5247 The system shall support master/detail query.
- 5248 The system shall support pivot table query definition.
- 5249 The system shall enable the filter or sort being performed by a user to be displayed in the title bar of the active
- 5250 The system shall provide the ability to temporarily "hide" portions of the result set.
- 5251 The system shall provide the ability to easily merge search results.
- 5252 The system shall ensure that users may define the format in which the search results will be displayed at the time a search is being created (e.g., pie charts, radial diagrams, tables, cross-tabs, bar charts).
- 5253 The system shall provide a "Print Preview" function for search outputs and reports to assist users in ensuring that their outputs may be printed in a user-friendly way.
- 5254 The system shall enable the user to designate which ISRs or cases in a saved ISR or case list to display in a search output format (e.g., table, crosstab).
- 5255 The system shall ensure that graphical search outputs (e.g., pie charts, bar charts) shall be customizable by users with regard to colors, chart titles, labels, and
- 5256 AERS II shall allow users to drill down/up (e.g., within medical coding hierarchy, or drill down to see individual case information) within their search results.
- 5257 AERS II shall allow users sort or filter their search results using any of the available data elements in the system.
- 5258 AERS II users must be able to refine the search results displayed using any of the available data elements in the system without requiring a new search to be executed (for example, instructing the system to remove all Non-Serious cases from the search results display without having to go back and re-run a search).
- 5259 The system shall provide certain predefined or "canned" reports (TBD) which will enable a user to create a designated output format for a group of cases, and print
- 5260 The system shall allow users to convert unit measurements where practical when executing
- 5261 The system shall assist users when creating the search output / report format.
- 5262 AERS II shall support the capability to save the filter or sort conducted on the saved search outputs so that the next time that saved search is opened, the user-defined view is displayed (and the cases that are hidden are still attached to the search output).
- 5263 AERS II shall enable users to hide or exclude cases in a saved case search output (case series).
- 5264 AERS II shall allow users to create their own grouping of cases (case series) which are not necessarily tied to similar underlying search criteria / query parameters. (For example, a user could run a case search, and then key in case numbers of the cases they wanted to add to the search and/or exclude other cases, and then save the group of cases and still have full access to all available
- 2504 The system shall support tabular query/report definition
- 2505 The system shall support crosstab query/report definition
- 2506 The system shall support master/detail query/report definition
- 3385 The system shall support pivot table query/report definition
- 2975 The system shall enable the filter or sort being performed to be displayed in the title bar of the active screen.
- 3413 The system shall provide graphical query builder
- 3429 The system shall provide capability to drill down in summary reports
- 3068 The system shall enable users to filter using Active Ingredient, Trade Name, Review Division, or NDA/PLA Number in the Assign Product Responsibility Unassigned and Re-assign screens.
- 2750 The system shall provide the ability to evaluate each individual case marked as pivotal, exclude cases from the case series, add reason information in the Results screen, and save everything into a case series.
- 2684 The system shall provide the ability to record a case series query, all subsequent edits (addition and removal of individual cases, dates, reasons), assessments, and comments associated with final case series

search output formats.]

Sub Area: Search Performance and Batch Searching

- 5142 The AERS II system will support fast performance for "simple" and "complex" searches. There should be no differentiation in terms of performance.
- 5143 The system shall ensure that results are returned within 5 seconds.
- 5144 The AERS II system must retain the batch search capability, where a search is run "in the background" and sent to a batch search area/screen for display when complete, thus allowing a user to edit (the previous search criteria) and send multiple searches without waiting for the previous search to complete.
- 5145 The AERS II system must allow users to save a batched search.
- 5146 The AERS II system must allow users to create a batch print job from a newly created or saved search.
- 5147 The AERS II system must allow for the identification of batch searches by a user-defined name.
- 5148 The system shall display the search criteria name and/or high level information about the search to allow easy identification of searches in the Batch Search monitoring
- 3129 The system shall display a message after clicking Execute in the ISR and Case Search screen providing users with the option of choosing to display search outputs on the screen (On Line Search) or send the search to a batch job (Batch Search). If users select On Line Search, the system will not enable users to execute the search while concurrently using other AERS application functions. If users select Batch Search, the system will enable users to execute the search while concurrently using other AERS application functions and allowing users to use non-AERS applications..
- 3009 The system shall enable users to send ISR or case searches to a Batch Search job (an option for regular searches, and a requirement for interaction or combination searches), and shall enable users to track search jobs and retrieve ISRs or cases returned from search jobs using a new
- 5149 The AERS II system must clearly display the criteria used for the search as part of the batch search list.
- 5150 The AERS II system shall support the display of the remaining time for search completion.
- 5151 The AERS II system shall allow users who executed a search to terminate a search that is still in progress.

Sub Area: Search Result Consistency

- 5158 The AERS II system will provide users with reproducible and consistent search results.
- 5159 AERS II must allow the user to save the search criteria and results of a search, and allow the user to choose to automatically refresh the results or to refresh only when requested.
- 5159 AERS II must allow the user to save the search criteria and results of a search, and allow the user to choose to automatically refresh the results or to refresh only when requested.
- 5160 The AERS II "System Create Date" – a.k.a. the date when a report has completed data entry and is routed to safety evaluators – must be available for searching and reporting. (Note: this field will allow users to re-create the results of a search conducted some time ago, assuming the report data remained consistent with search criteria.)
- 5161 The system shall ensure that when a saved search is re-run in AERS II, the search results list must clearly indicate which new cases have been added and also identify which cases have been removed from the search results.
- 5162 The system shall support the display of a flag related to a saved search to indicate that the best representative ISR for the saved search has changed since the user last
- 3010 The system shall enable users to save up to 20 search criteria in the Search ISR/Case
- 2994 The system shall enable users to refresh the line listing of data without removing any sort or filter by pressing a button called 'Refresh Query' when conducting a front-end Inbox
- 2429 The system shall automatically record the legacy ISR create date.
- 2913 The electronic submission software shall record whether the periodic submission file has completed the M2 validation process.

- viewed the saved search.
- 5163 The system shall support the inclusion of an audit trail for saved searches, which will enumerate any changes made to any of the cases in the case series since it was last run, and will identify what the last case count was vs. what the current case count is.
- 5164 The system shall ensure that an ISR must not be flagged as "Best Representative" until it completes data entry, even if it is a follow-up report.
- 5165 AERS II must have a new field for Initial Received Date – this will be a dynamic field and will always be the earliest FDA received date in a case (i.e., the date at which a case was first reported to FDA) – that is associated with every ISR in the system.
- 5166 The system shall ensure that Follow-Up ISR dates must be added to the Case report.
- 5167 AERS II must include combination products in all valid result sets unless they are specifically excluded in the search parameters.
- 5168 The system should permit the inclusion of one or more custom algorithms to identify possible redundant reports regarding the same event, patient, and product and report these to a SE for further investigation.
- 5169 The system must record and report "invalid" follow-ups (follow-up Reports with no initial report) and not permit the update of "follow-up flag field" in the database for these
- 2654 The system shall record the FDA receipt date, report date, and version for each
- 2461 The system shall support automatic identification of multiple versions, duplicates, and follow-up ISRs for a given case.
- 3372 The system shall record and report invalid follow-ups (e.g., follow-up ISRs with no initial ISR) and not permit the update of Follow-up flag field in the database for these cases.
- Sub Area: Searching Attachments and Narrative Fields**
- 5221 The system shall support the capability to conduct searches outside of individually defined fields.
- 5222 The system shall support the ability to search attachments (images) for text that appears on that attachment.
- 5223 The system shall support the ability to search the narrative text for free form characters.
- 5224 The system shall support the ability to print the narrative in a pre-defined output format (TBD), for example, to include the ISR and case number, and basic information about the report, in addition to the narrative itself.
- 5225 The system shall enable users to search the verbatim field.
- 5226 The system shall support fuzzy searching of all verbatim fields.
- Sub Area: Statistics & Denominator Data**
- 5297 The system shall interface seamlessly with various statistical packages and tools (TBD).
- 5298 The system shall interface with various statistical packages and tools (TBD), and allow only certain users to access the statistical tools.
- 5299 The system shall provide the ability to conduct what-if scenarios and predictive analysis.
- 5300 The user will have the ability to view or print search summary statistics for the group of cases being displayed. An example statistic is the total number of occurrences (reports/cases, drugs, manufacturers, etc.) for a given search or a given search criteria (outcome).
- 5301 The system will have the ability to perform case counts and trending over time; sort by onset date or by receipt date; and record initial report as receipt date, follow-up report date or manufacture date.
- 5302 The system will provide statistical information (TBD) on a generic or trade name drug product.
- 5303 The system will provide the ability to use statistical and
- 3619 The system shall provide the ability to use statistical and graphical tools such as SAS and CrossGraph to perform analysis of a case series.
- 3619 The system shall provide the ability to use statistical and graphical tools such as SAS and CrossGraph to perform analysis of a case series.
- 3619 The system shall provide the ability to use

- graphical tools, such as SAS and CrossGraph, to perform analysis of a case series.
- 5304 The system will provide the ability to access, capture, and manipulate denominator data from external data sources to provide signal context data.
- 5305 The system will provide the appropriate denominator data to support calculation of estimated magnitude of exposure and other risk assessor defined calculations.
- 5306 The system shall allow the user to link summarized raw data files from an external system (e.g., Medline, PDR, WHO) to the case series confirmation analysis.
- 5307 The system shall provide the ability to link query results from the denominator data to the case series assessment.
- Sub Area: User Control of Parameters*
- 5170 The system shall ensure that every database field in AERS II is available for searching, and allow users fine control over how the query is built.
- 5171 The system must have every variable (field) in the database to be searchable, sortable, and retrievable by users with appropriate roles.
- 5172 The system shall support user definition of search parameters.
- 5173 The system shall support the generation of complex queries (e.g., outer joins and nested queries).
- 5174 The system shall enable certain users to view/edit the code used to generate the search query.
- 5175 The system shall support the use of Boolean logic for search queries.
- 5176 The system shall enable the user to select numerous database search terms at one time.
- 5177 The system must enable users to use more than one search term when searching for medication errors.
- 5178 AERS II must contain custom criteria for establishing relationships between and among data elements used to build a query in "plain English". These values include:
 Equals
 Is Greater Than
 Is Less Than
 Is Greater Than or Equal To
 Is Less Than or Equal To
 Does not Equal
 Like
 Sounds Like (e.g., to support Medication Error searching)
 Contains
 Does Not Contain
 Starts With
 Does Not Start With
 Ends With
 Does Not End With
 Include Unknown Values
 Include Null Values
- 5179 The system must allow FOI users to run automatically redacted FOI queries, as well as retrieve images.
- 6567 The system shall allow users to return all ISRs or cases that meet their search criteria, regardless of whether they have primary surveillance responsibility.
- 6568 The system shall default to searching only active data elements (e.g., reaction terms, product terms), however, will allow the user to select inactive fields if desired for an
- statistical and graphical tools such as SAS and CrossGraph to perform analysis of a case series.
- 3624 The system shall provide signal context data through the access, capture, and manipulation of denominator data from external data sources such as IMS.
- 3627 The system shall provide the appropriate denominator data to support calculation of estimated magnitude of exposure and other Safety Evaluator-defined calculations.
- 3634 The system shall provide access to summarized raw data files from external systems (e.g., Medline, PDR, IMS, WHO) to a case series confirmation analysis.
- 3806 The system shall support generation of complex queries/reports (e.g., outer joins and nested queries)
- 3420 The system shall capability to view/edit generated SQL statements
- 2512 The system shall support use of Boolean
- 3467 The system shall allow FOI users to run automatically-redacted FOI queries and to retrieve images.

individual search.

Sub Area: *User Lists Requirements*

- 5204 The system shall support the ability to save and reuse search criteria and calculated fields.
- 5205 The system shall repopulate the screen when a user selects a saved search criteria list and enable users to edit the screen, and enable only the user who created the list to save any modifications made to the list or delete the list.
- 5206 The system shall provide the capability to define simple calculated fields (e.g., query field 1 * query field 2 = query field 3).
- 5207 The system shall provide the capability to define complex formulae for field definition.
- 5208 The system shall support the ability to create a special medical term search category, by offering a save and name option as well as an edit option for medical term search results. Special search category data will include a creation date, user ID, search category name, search category comment, and selected medical term codes).
- 5209 The system shall support the capability to view all personal search categories, regardless of creator, and to update or inactivate those medical term special search categories that were created by them.
- 5210 The system shall support the ability to create a user defined drug criteria group by offering a save and name option and edit option for drug database search results. User defined drug criteria group data will include a creation date, user ID, drug group name, drug group comment, and selected drug names and IDs.
- 5211 The system shall support the ability to create a special manufacturer group by offering a save and name option and edit option for manufacturer database search results. Special manufacturer group data will include a creation date, user ID, manufacturer group name, comment, and selected manufacturer names and IDs.
- 5212 The system shall enable users to create and save the criteria of a search for later reuse.
- 5213 The system shall provide users with the capability to retrieve last query definition.
- 5214 The system shall provide users with the capability to copy/edit query definitions for similar queries.
- 5215 AERS II users must be able to create, save, and use lot number lists, whereby all of the lot numbers in the list re-populate in lot number field.
- 5216 AERS II users must be able to create, save, and use search lists, whereby all of the criteria used to build a search query re-populate in the search screen and are
- 5217 All lists (i.e., manufacturer, lot number, entire search criteria, reaction, and product lists) must include any of the logic statements allowed for querying:
 Equals
 Is Greater Than
 Is Less Than
 Is Greater Than or Equal To
 Is Less Than or Equal To
 Does not Equal
 Like
 Sounds Like (e.g., to support Medication Error searching)
- 3124 The system shall repopulate the screen when a user selects a saved search criteria list and enable users to edit the screen, and enable only the user who created the list to save any modifications made to the list or
- 3124 The system shall repopulate the screen when a user selects a saved search criteria list and enable users to edit the screen, and enable only the user who created the list to save any modifications made to the list or
- 3391 The system shall provide capability to define simple calculated fields (e.g., query field 1 * query field 2 = query field 3)
- 3392 The system shall provide capability to define complex formulae for field definition
- 2676 The system shall provide the ability to create a MedDRA search category through save, name, and edit options for MedDRA search
- 2677 The system shall provide users with the capability to view all personal search categories, regardless of creator, and to update or inactivate those MedDRA search categories that were created by them.
- 2679 The system shall provide the ability to create drug criteria groups through
- 2747 The system shall provide the ability to create and save lists (e.g., drug lists, manufacturer lists, reaction lists) frequently used in defining search criteria.
- 2520 The system shall provide capability to retrieve last query/report definition
- 3421 The system shall provide capability to copy/edit query/report definitions for similar queries/reports

Contains
Does Not Contain
Starts With
Does Not Start With
Ends With
Does Not End With
Include Unknown Values

- 5218 The system shall ensure that all types of lists in AERS II (i.e., manufacturer, lot number, entire search criteria, reaction, and product lists) may be multi-selected such that the criteria and logic from one list are added to those from another list when building the search criteria.
- 5219 The system shall enable multi-select and delete of multiple user lists at one time.
- 5220 The system shall retain excluded product names or manufacturer names when saving user lists.

Sub Area: User Notepad

- 5113 The system shall support a user "notepad" to record free form comments at either the ISR level or the case level.
- 5113 The system shall support a user "notepad" to record free form comments at either the ISR level or the case level.
- 5113 The system shall support a user "notepad" to record free form comments at either the ISR level or the case level.
- 5114 The system shall support the accessibility of notepad comments from any ISR or case.
- 5114 The system shall support the accessibility of notepad comments from any ISR or case.
- 5115 The system shall restrict the modification of the user notepad to users with primary surveillance responsibility.
- 5116 The user notepad shall be viewable by users with read only access or primary surveillance responsibility for the associated case.
- 5117 The system shall support comment functionality that allows users to create free form text notes up to 10,000 characters regarding an ISR or case.
- 5119 The system shall support ability to designate a free form comment as public or private.
- 5120 The system shall define a private comment as viewable only by the user that entered the comment.
- 5121 The system shall define a public comment as viewable by any user with access to the case.
- 6563 The system shall display a prominent warning at the top of the User Notepad that all user comments entered are releasable to the public.
- 6564 The system shall display all comments entered for all ISRs in a case, separated by ISR number, when displaying comments at the case level.
- 6565 The system shall number each User Notepad entry uniquely (e.g., concatenation of ISR number and a uniquely-increasing sequence number).
- 6566 The system shall capture in the ISR's audit trail: the user name, the date of entry or modification, the unique User Notepad comment ID, and the affected ISR and case numbers.
- 2661 The system shall provide the ability to record comments associated with an ISR or merged case.
- 2732 The system shall display ISRs information as read only with the exception of adding comments.
- 2620 The system shall provide the ability to record comments about a case.
- 2698 The system shall provide the ability to view the current status, status history, dates, comments, and activities associated with a case series.
- 2718 The system shall provide the ability to view case data including reporter information, case comments, sender information and all ISRs that make up the case.

Functional Area: Data Input

2006 SRS Document**Sub Area:**

4096 The system shall support reception of adverse reports in paper format, digital physical media, as well as electronic submissions using a secure and authenticated approach and provide the Data Entry, Data Entry Quality Control, MedDRA Coding, and MedDRA Coding Quality Control for the entry of adverse event report.

Sub Area: Case Linking

- 4888 The system shall enable users to manually create a new case.
- 4889 The system shall allow the transfer or re-linking of an ISR assignment from one ISR to another as well as from one case to another.
- 5101 The system shall support case linking of adverse event reports.
- 5102 The system shall support automatic identification of multiple versions, duplicates, and follow-up ISRs for a
- 5103 The system shall link a follow-up to the appropriate case.
- 5104 The system shall link and validate the existence of a follow-up to an initial ISR.
- 5105 The system shall link all ISRs associated with a case.
- 5106 The system shall automatically identify duplicate ISRs and link them to the original corresponding ISR.
- 5107 The system shall assign a case number for each initial ISR for an adverse event.
- 5108 The system shall link any subsequent duplicate or follow-up ISRs to the corresponding case number.
- 5109 The system shall display potential links in the Data Entry Quality Control and Case Linking screens.
- 5110 The system shall check for the manufacturer name and control number to search for potential links. If no link is found, the patient gender, age, reporter state, and drug are checked.
- 5111 The system shall display the Case Linking screen and not populate the case sequence number when no potential links are found.
- 5112 The system shall enable users to manually link an ISR to a case.

Sub Area: Data Entry QC

- 5096 The system shall support QC of the adverse event report data entry process.
- 5097 The system shall not enable double Data Entry if the system preference is not 'DDE ON', if the ISR form type equals E2B, and/or the checked code in the double Data Entry table is flagged.
- 5098 The system shall display the Double Data Entry screen when discrepancies are found between the Report Receipt Log (Key 1) and the Data Entry (Key 2), and shall ensure that the screen displays in large, black, bold italic
- 5099 The system shall enable the Data Entry Quality Control Divisional Inbox to display all ISRs or to filter ISRs by paper ISRs only or electronic E2B ISRs.

2003 RTM

- 2565 The system shall enable users to manually create a new case.
- 2594 The system shall allow the transfer or re-linking of an ISR assignment from one ISR to another as well as from one case to another.
- 2461 The system shall support automatic identification of multiple versions, duplicates, and follow-up ISRs for a given case.
- 2462 The system shall link a follow-up to the appropriate case.
- 2463 The system shall link and validate the existence of a follow-up to an initial ISR.
- 2464 The system shall link all ISRs associated with a case.
- 2467 The system shall automatically identify duplicate ISRs and link them to the original corresponding ISR.
- 2468 The system shall assign a case number for each initial ISR for an adverse event.
- 2469 The system shall link any subsequent duplicate or follow-up ISRs to the corresponding case number.
- 2559 The system shall display potential links in the Data Entry Quality Control and Case Linking screens.
- 2560 The system shall check for the manufacturer name and control number to search for potential links. If no link is found, the patient gender, age, reporter state, and drug are checked.
- 2562 The system shall display the Case Linking screen and not populate the case sequence number when no potential links are found.
- 2564 The system shall enable users to manually link an ISR to a case.

- 2552 The system shall not enable double Data Entry if the system preference is not 'DDE ON', if the ISR form type equals E2B, and/or the checked code in the double Data Entry table is flagged.
- 2553 The system shall display the Double Data Entry screen when discrepancies are found between the Report Receipt Log (Key 1) and the Data Entry (Key 2), and shall ensure that the screen displays in large, black, bold italic
- 2865 The system shall enable the Data Entry Quality Control Divisional Inbox to display all ISRs or to filter ISRs by paper ISRs only or

electronic E2B ISRs.

5100 The system shall fuzzy searching on manufacturer control number to identify duplicate ISRs.

Sub Area: Detail Data Entry

5072 The system shall support detail data entry of adverse event reports.

5073 The system shall support and record the verbatim Data Entry of all data and text descriptions on the MedWatch 3500 and MedWatch 3500A forms.

5074 The system shall automatically derive and populate a patient's age when given birth date and event start date.

5075 The system shall record all dosage data including frequency by day, week, and month.

5076 The system shall record an unlimited number of biologic products for each ISR entered.

5077 The system shall accommodate lengthy names for biologic products.

5078 The system shall capture verbatim data, text, and images for all ISRs received on paper.

5079 The system shall support word processing capabilities to ensure the ease and accuracy of the Data Entry of ISR narrative text, including a medical spellchecker.

5080 The system shall sort the Data Entry Inbox by ISR type (e.g., Expedited, Direct, then Periodic), FDA received date, and ISR sequence number.

5081 The system shall provide the ability to sort the Data Entry Inbox by any column by pressing the appropriate column header.

5082 The system shall display the Data Entry Personal Inbox to contain ISRs that are currently being processed.

5083 The system shall enable users with supervisory roles to access a drop-down list on the Data Entry Personal Inbox canvas that shall allow them to change their view of the Inbox from their Personal Inbox to that of another user.

5084 The system shall support the verbatim Data Entry ISR, including all of the narrative text.

5085 The system shall activate a medical spellchecker from the indicated button to make corrections and return to AERS for the completion of Data Entry.

5086 The system shall capture one primary suspect medication per ISR and any number of secondary or concomitant medications per ISR.

5087 The system shall display the Drug, Manufacturer, and Patient Age Resolution screen if the primary and/or secondary suspect medications cannot be validated, if the manufacturer name cannot be validated, or if there is greater than one age unit discrepancy between the verbatim age and the calculated age (calculated age is the difference between the data of birth and the event start date or the FDA received date if the event start date is

5088 The system shall calculate dosage by number of days.

5089 The system shall enable users to modify the patient age data and to re-calculate age if necessary.

5090 Lab, past medical history and patient history shall be

2431 The system shall support and record the verbatim Data Entry of all data and text descriptions on the MedWatch 3500, MedWatch 3500 A, and 1639 forms.

2432 The system shall automatically derive and populate a patient's age when given birth date and event start date.

2433 The system shall record all dosage data including frequency by day, week, and

2434 The system shall record an unlimited number of biologic products for each ISR entered.

2435 The system shall accommodate lengthy names for biologic products.

2436 The system shall capture verbatim data, text, and images for all ISRs received on paper.

2438 The system shall support word processing capabilities to ensure the ease and accuracy of the Data Entry of ISR narrative text, including a medical spellchecker.

2531 The system shall sort the Data Entry Inbox by ISR type (e.g., Expedited, Direct, then Periodic), FDA received date, and ISR sequence number.

2532 The system shall provide the ability to sort the Data Entry Inbox by any column pressing the appropriate column header.

2534 The system shall display the Data Entry Personal Inbox to contain ISRs that are currently being processed.

2535 The system shall enable users with supervisory roles to access a drop-down list on the Data Entry Personal Inbox canvas that shall allow them to change their view of the Inbox from their Personal Inbox to that of

2548 The system shall support the verbatim Data Entry ISR, including all of the narrative text.

2549 The system shall activate a medical spellchecker from the indicated button to make corrections and return to AERS for the completion of Data Entry.

2550 The system shall capture one primary suspect medication per ISR and any number of secondary or concomitant medications per

2554 The system shall display the Drug, Manufacturer, and Patient Age Resolution screen if the primary and/or secondary suspect medications cannot be validated, if the manufacturer name cannot be validated, or if there is greater than one age unit discrepancy between the verbatim age and the calculated age (calculated age is the difference between the data of birth and the

2580 The system shall calculate dosage by number of days.

2582 The system shall enable users to modify the patient age data and to re-calculate age if necessary.

captured in a tabular format supporting the structure defined with E2B

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|---|---|
| <p>5091 The system shall not route an ISR from Data Entry unless Initial or Follow-up is selected.</p> <p>5092 The system shall enable users to turn off the population of the Data Entry Inbox line listing.</p> <p>5093 The system shall provide the ability to sort the Data Entry Inbox by any column pressing the appropriate column</p> <p>5094 The system shall allow users to search for an ISR using any of the available data elements within the database related to a report.</p> <p>5095 The system shall prohibit a user from entering an event start date that is greater than the present date.</p> | <p>2837 The system shall not route an ISR from Data Entry unless Initial or Follow-up is selected.</p> <p>2849 The system shall enable users to turn off the population of the Data Entry Inbox line listing.</p> <p>2864 The system shall provide the ability to sort the Data Entry Inbox by any column pressing the appropriate column header.</p> |
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Sub Area: Digital Media Receipt

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| <p>4101 The system shall support digital media receipt of adverse event reports.</p> <p>4102 The electronic submission manual procedures shall allow an operator to copy all files contained on the physical media onto a working directory for later electronic submission processing.</p> <p>4103 The electronic submission manual procedures shall allow the operator to archive each periodic file submission to the</p> <p>4104 The manual procedures shall allow for the processing of data submitted via physical media (CD-ROM or 3.5 inch floppy diskette).</p> <p>4105 To uniquely identify each submission the procedures shall allow for the manual assignment of a sequence number for each submission received within the FDA.</p> | <p>2824 The system shall receive submissions through Electronic Data Interchange or</p> <p>2895 The electronic submission manual procedures shall allow an operator to copy all files contained on the physical media onto a working directory for later electronic submission processing.</p> <p>2896 The electronic submission manual procedures shall allow the operator to archive each periodic file submission to the</p> <p>2897 The manual procedures shall allow for the processing of data submitted via physical media (CD-ROM or 3.5 inch floppy diskette).</p> <p>2898 To uniquely identify each submission the procedures shall allow for the manual assignment of a sequence number for each submission received within the FDA.</p> |
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Sub Area: Electronic Load

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| <p>3999 The system shall support the loading of electronically received adverse event reports.</p> <p>4000 The system shall upload ISRs from translated, decrypted files into the system database.</p> <p>4001 The system shall store codes that have been submitted electronically.</p> <p>4002 The system shall generate and transmit (electronically or manually) an acknowledgment of total ISRs submitted with corresponding ISR numbers, manufacturer control numbers, and/or exception reports indicating reasons for non-acceptance.</p> <p>4003 The electronic submission software shall validate that the submission complies with specifications for ICH ICSR DTD version 1.0.</p> <p>4004 The electronic submission software shall process ICSRs in an SGML or XML format (following E2B standard) and package as a mandatory submission. This means one or more ICSRs related to a single submission will be packaged together in a single SGML file.</p> <p>4005 The electronic submission software shall validate the ICSR data to be compliant with ICH ICSR specifications.</p> <p>4006 The electronic submission software shall provide the ability to execute the following core processes independently and sequentially: validating SGML syntax, validating the ICSR data for compliance with M2 specifications, loading data into AERS tables, identifying and tracking errors and status of loading ICSRs, and</p> | <p>2424 The system shall upload ISRs from translated, decrypted files into the system</p> <p>2447 The system shall store codes that have been submitted electronically.</p> <p>2616 The system shall generate and transmit (electronically or manually) an acknowledgment of total ISRs implemented with corresponding ISR numbers, manufacturer control numbers, and/or exception reports indicating reasons for non-</p> <p>2899 The electronic submission software shall validate that the submission complies with specifications for ICH ICSR DTD version 1.0.</p> <p>2900 The electronic submission software shall process ICSRs in SGML format and packaged as a periodic submission. This means one or more ICSRs related to a single submission will be packaged together in a</p> <p>2901 The electronic submission software shall validate the ICSR data to be compliant with ICH ICSR specifications.</p> <p>2902 The electronic submission software shall provide the ability to execute the following core processes independently and sequentially: validating SGML syntax, validating the ICSR data for compliance with M2 specifications, loading data into AERS tables, identifying and tracking errors and</p> |
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- 4007 The electronic submission software shall process electronic files submitted in SGML format.
- 4008 The electronic submission software shall use the James Clark parser to check for correct SGML syntax.
- 4009 The electronic submission software shall create an error file for those SGML files that fail the syntax check. The error file will be a text file that lists the location of the SGML file, line number, and a brief description of the error
- 4010 The electronic submission software shall record whether the periodic submission file has completed the SGML validation process.
- 4011 The electronic submission software shall continue with subsequent processing only after successfully parsing the entire periodic submission file.
- 4012 The electronic submission software shall not continue processing the periodic submission file if SGML syntax errors are encountered for any ICSR contained within the periodic submission file.
- 4013 The electronic submission software shall validate the data to meet the M2 length, type, and value specifications outlined by the ICH.
- 4014 The electronic submission software shall create an error file identifying all invalid data, an explanation of the errors found, and the ICSR in the SGML file to which the error
- 4015 The electronic submission software shall continue with subsequent processing only after successfully parsing the entire periodic submission file.
- 4016 The electronic submission software shall not continue processing the periodic submission file if errors are encountered for any ICSR contained within the periodic submission file.
- 4017 The electronic submission software shall record whether the periodic submission file has completed the M2 validation process.
- 4018 The electronic submission software shall load ICSR data from the SGML file into the AERS database.
- 4019 The electronic submission software shall allow for the loading of only a perfect submission for ICH ICSR version 1.0. A perfect submission for version 1.0 is defined as:
 An SGML file that has been validated by the James Clark parser and version 1.0 ICH ICSR DTD specification for proper syntax, an SGML file that has all the ICSR data validated by the M2 validation tool to ensure that the data complies with the proper data type, length and value specifications. This validation is also necessary for continuation of the electronic submission process.
 The ICSR data fields that contain medically coded fields must use valid MedDRA codes; data from these fields will be captured and processed for loading into AERS if the submitter is registered as a MedDRA enabled manufacturer.
 An ICSR that contains valid data for those AERS terms that have been identified as not null fields, data contained within the ICSR must comply with any data restrictions imposed by the AERS database.
- status of loading ICSRs, and generating
- 2903 The electronic submission software shall process electronic files submitted in SGML format.
- 2904 The electronic submission software shall use the James Clark parser to check for correct SGML syntax.
- 2905 The electronic submission software shall create an error file for those SGML files that fail the syntax check. The error file will be a text file that lists the location of the SGML file, line number, and a brief description of the error encountered.
- 2906 The electronic submission software shall record whether the periodic submission file has completed the SGML validation process.
- 2907 The electronic submission software shall continue with subsequent processing only after successfully parsing the entire periodic submission file.
- 2908 The electronic submission software shall not continue processing the periodic submission file if SGML syntax errors are encountered for any ICSR contained within the periodic submission file.
- 2909 The electronic submission software shall validate the data to meet the M2 length, type, and value specifications outlined by the ICH.
- 2910 The electronic submission software shall create an error file identifying all invalid data, an explanation of the errors found, and the ICSR in the SGML file to which the error
- 2911 The electronic submission software shall continue with subsequent processing only after successfully parsing the entire periodic submission file.
- 2912 The electronic submission software shall not continue processing the periodic submission file if errors are encountered for any ICSR contained within the periodic submission file.
- 2913 The electronic submission software shall record whether the periodic submission file has completed the M2 validation process.
- 2914 The electronic submission software shall load ICSR data from the SGML file into the AERS database.
- 2915 The electronic submission software shall allow for the loading of only a perfect submission for ICH ICSR version 1.0. A perfect submission for version 1.0 is defined as: 1) An SGML file that has been validated by the James Clark parser and version 1.0 ICH ICSR DTD specification for proper syntax, an SGML file that has all the ICSR data validated by the M2 validation tool to ensure that the data complies with the proper data type, length and value specifications. This validation is also necessary for continuation of the electronic submission process. 2) The ICSR data fields that contain medically coded fields must use valid MedDRA codes; data from these fields will be captured and processed for loading into AERS if the submitter is registered as a MedDRA enabled manufacturer. 3) An ICSR that contains valid data for those AERS terms that have been identified as not null fields,

- data contained within the ICSR must comply with any data restrictions imposed by the AERS database.
- 4020 To load ICSR data into AERS the electronic submission software shall pre-populate the Sender Type field (A.3.1.1) with a value of 1 (for Pharmaceutical Company) for those ICSRs where this data is omitted.
- 4021 The electronic submission software shall provide the capability to resume the loading of data in the event that the loading process is interrupted by a system failure. However, an operator will have to manually re-start the loading process.
- 4022 The electronic submission software shall record whether the periodic submission file has completed the AERS table load process.
- 4023 The electronic submission software shall record the status of an entire submission.
- 4024 The electronic submission software shall record the SGML syntax errors encountered within a submission.
- 4025 The electronic submission software shall record the electronic submission file and the ICSRs that have been successfully loaded into AERS.
- 4026 The electronic submission software shall record the ICSRs that failed to load into AERS and the errors encountered such as an invalid minimum data set fields.
- 4027 The electronic submission software shall record the error field names, original data value, and an error message.
- 4028 For version 1.0, the electronic submission software shall generate an error message with all the SGML errors that were found for each electronic submission file.
- 4029 For version 1.0, the electronic submission software shall generate an error message that documents certain ICSR identification fields, name of the descriptor that has an error, the actual data, error type, and a brief error description. The following is the format of the error message: `ICHICRSASFETYREPORTSAFETYREPORTIDSAFETYREPORTSQDUPPLICATENUMB = ||Duplicate number 00001 duplicate number||ERROR: Invalid Data LengthCount of Significant Characters is 39. Max Allowable Length is EPORTIDSAFETYREPORTSQDUPPLICATENUM 35`
- 4030 The electronic submission software shall record whether the periodic submission file has completed the acknowledgement process.
- 4031 The data of an electronically submitted ICSR shall be processed like the data of a paper individual safety report (ISR) that has been manually entered.
- 4032 If the ISR meets any of the above criteria then it shall stop in DEQC for review. However, the electronically submitted ISRs are not subject to data entry sampling rates.
- 4033 Once the manufacturer name is validated AERS shall check if the sender is MedDRA enabled. If the manufacturer is not MedDRA enabled then, the electronically submitted ISR will stop in MedDRA Coding to be coded. If the manufacturer is MedDRA enabled then, the text supplied in the appropriate field is validated and
- 2916 To load ICSR data into AERS the electronic submission software shall pre-populate the Sender Type field (A.3.1.1) with a value of 1 (for Pharmaceutical Company) for those ICSRs where this data is omitted.
- 2917 The electronic submission software shall provide the capability to resume the loading of data in the event that the loading process is interrupted by a system failure. However, an operator will have to manually re-start the loading process.
- 2918 The electronic submission software shall record whether the periodic submission file has completed the AERS table load process.
- 2919 The electronic submission software shall record the status of an entire submission.
- 2920 The electronic submission software shall record the SGML syntax errors encountered within a submission.
- 2921 The electronic submission software shall record the electronic submission file and the ICSRs that have been successfully loaded into AERS.
- 2922 The electronic submission software shall record the ICSRs that failed to load into AERS and the errors encountered such as an invalid minimum data set fields.
- 2923 The electronic submission software shall record the error field names, original data value, and an error message.
- 2924 For version 1.0, the electronic submission software shall generate an error message with all the SGML errors that were found for each electronic submission file.
- 2925 For version 1.0, the electronic submission software shall generate an error message that documents certain ICSR identification fields, name of the descriptor that has an error, the actual data, error type, and a brief error description. The following is the format of the error message: `ICHICRSASFETYREPORTSAFETYR B = ||Duplicate number 00001 duplicate number||ERROR: Invalid Data LengthCount of Significant Characters is 39. Max Allowable Length is 35`
- 2926 The electronic submission software shall record whether the periodic submission file has completed the acknowledgement process.
- 2927 The data of an electronically submitted ICSRs shall be processed like the data of a paper individual safety report (ISR) that has been manually entered.
- 2928 If the ISR meets any of the above criteria then it shall stop in DEQC for review. However, the electronically submitted ISRs are not subject to data entry sampling rates.
- 2929 Once the manufacturer name is validated AERS shall check if the sender is MedDRA enabled. If the manufacturer is not MedDRA enabled then, the electronically submitted ISR will stop in MedDRA Coding to be coded. If the manufacturer is MedDRA enabled then,

	the electronically submitted ISR will not stop in MedDRA		the text supplied in the appropriate field is validated and the electronically submitted ISR will not stop in MedDRA Coding.
4034	An electronically submitted ISR shall stop in MedDRA Coding Quality Control (MCQC) based on sampling rates or if none of the supplied text could be validated. Sampling rates are established for all MedDRA enabled manufacturers and it is used to determine the percentage of ISRs that stop at the MCQC step for coding review.	2930	An electronically submitted ISR shall stop in MedDRA Coding Quality Control (MCQC) based on sampling rates or if none of the supplied text could be validated. Sampling rates are established for all MedDRA enabled manufacturers and it is used to determine the percentage of ISRs that stop at the MCQC step for coding review.
4035	To load ICSR data into AERS the electronic submission software shall pre-populate the Receiver Type field (A.3.2.1) with a value of 2 (for Regulatory Authority) for those ISRs where this data is omitted.	2931	To load ICSR data into AERS the electronic submission software shall pre-populate the Receiver Type field (A.3.2.1) with a value of 2 (for Regulatory Authority) for those ISRs where this data is omitted.
4036	Decrypt electronic submissions using commercially available encryption technology and authenticate the sender (ICH M2 standard)	3447	The system shall decrypt electronic submissions using commercially available encryption technology and authenticate the sender (ICH M2 standard).
4037	Send Receipt acknowledgment notice back to	3448	The system shall send receipt acknowledgment notices and send file problem notices via FDA Central Receiving
4038	Send file problem notice back to manufacturers	3448	The system shall send receipt acknowledgment notices and send file problem notices via FDA Central Receiving
4039	Messages sent back to the manufacturer should use the same authentication/encryption facilities as for transmissions received from the manufacturer	3449	The system shall authenticate and encrypt all replies.
4040	Maintain archive of all files submitted following FDA approved records retention schedules	3450	The system shall maintain an archive of all electronic files submitted following FDA-approved records retention schedules.
4041	Upload ADR records from translated, decrypted files into the AERS database	2424	The system shall upload ISRs from translated, decrypted files into the system
4042	Track date and time of file received, receipt acknowledgment, problem notice sent, file uploaded, and file archived, with individual ADRs	2932	The system shall track date and time of file received, receipt acknowledgment, problem notice sent, file uploaded, and file archived with individual ISRs in the database
4043	Flag uploaded records for automated quality control check	2933	The system shall flag uploaded electronic ISR records for automated quality control check
4044	Store archive file sequence number with each individual report received in a single transmission	3451	The system shall archive file sequence numbers with each individual electronic ISR received in a single transmission.
4045	Process automated quality control check of electronically received ADRs prior to AERS database update	2615	The system shall process automated quality control checks of electronically received ISRs prior to the system's database update.
4046	Generate and transmit electronically or manually AERS acknowledgment of total ADR reports accepted with corresponding AERS Report #s, manufacturer control #s and/or exception reports indicating reasons for non-acceptance back to the manufacturers	2616	The system shall generate and transmit (electronically or manually) an acknowledgment of total ISRs Implemented with corresponding ISR numbers, manufacturer control numbers, and/or exception reports indicating reasons for non-
4047	All electronic submissions, whether EDI or physical media, should use encryption to facilitate authentication of the	3447	The system shall decrypt electronic submissions using commercially available encryption technology and authenticate the sender (ICH M2 standard).
4048	The system must be able to capture a date stamp for date of receipt and permanent unique AERS ID Number for each report, as well as support displaying this information on the physical report for purposes of imaging and batch	2582	The system shall capture a date stamp for date of receipt and a permanent, unique number for each ISR (i.e., ISR Number).
4049	The system must be able to accept reports providing default values for certain fields based on report type	2583	The system shall provide default values for fields based on report type.
4050	The system must be able to automatically record the create date	2429	The system shall automatically record the legacy ISR create date.
4051	The system must be able to record all data and text descriptions on the MedWatch 3500 and MedWatch 3500A Forms; verbatim data entry must be supported	2431	The system shall support and record the verbatim Data Entry of all data and text descriptions on the MedWatch 3500.

MedWatch 3500 A, and 1639 forms.

- 4052 The system shall process electronically received submissions based on an established priority ranking (note: need to identify the ranking criteria)
- 4053 The system shall provide a method for deleting a series of ICSRs received electronically from a manufacturer that they wish to retract as a batch
- 4054 The electronic submissions software shall require the E2B field A.1.1 (<primarysourcecountry>) data element in the minimum data set validation. If the submission, does not contain a (<primarysourcecountry>) it should be rejected and a negative acknowledgement generated.
- 4055 The electronic submission software shall generate acknowledgement files in XML for incoming E2B XML submissions
- 4056 The electronic submission software shall convert a lower case manufacturer control number (MCN) to upper case.
- 4057 The electronic submission software shall calculate age when the verbatim age field is null and the eventstartdate and dateofbirth are not null.
- 4058 The electronic submissions minimum data set shall include either A.1.10.2 <companynumb> or A.1.10.1 <authoritynumb>.

Sub Area: Imaging/Imaging QC

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| <ul style="list-style-type: none"> 5061 The system shall support imaging and imaging QC of adverse event reports. 5062 The system shall link the ISR Number to the Imaging 5063 The system shall enable users to retrieve, view, and print imaged ISRs from the Imaging System within the system. 5064 The system shall provide the ability to easily retrieve and view images associated with a particular ISR or case. 5065 The system shall link an attachment to an ISR. 5066 The system shall link an attached image to its associated ISR and its associated case. 5067 The system shall date stamp the receipt of the attachment and automatically record the date the attachment data were created. 5068 The system shall process individual attachments by: linking attachments to an ISR; enabling the scanning, and indexing of the ISR; providing Quality Control of image and index; recording image completion date; generating performance reports; and assigning and tracking security 5069 The system shall track the date the attachment was received, the type of attachment, and the acceptability of the attachment by manufacturer. 5070 The system shall assign the permanent ISR Number to the attachment to which it is associated. 5071 The system shall identify all attachments associated with a case. | <ul style="list-style-type: none"> 3143 The system shall interface with CDER's new imaging system (RetrievalWare) while providing users with existing functionality for View image and Batch Print. RetrievalWare is a 32-bit application developed by Excalibur. It is a third-party tool that is replacing the former EFS application used within versions of AERS (prior to v2.1) for image retrieval functionality. This also includes updating the AERS Image Update script to reflect the RetrievalWare changes. 2440 The system shall link the ISR Number to the Excalibur Imaging System. 2441 The system shall enable users to retrieve, view, and print imaged ISRs from the Excalibur Imaging System within the system. 2454 The system shall provide the ability to easily retrieve and view images associated with a particular ISR or case. 2451 The system shall link an attachment to an ISR. 2452 The system shall link an attached image to its associated ISR and its associated case. 2455 The system shall date stamp the receipt of the attachment and automatically record the date the attachment data were created. 2456 The system shall process individual attachments by: linking attachments to an ISR; enabling the scanning, and indexing of the ISR; providing Quality Control of image and index; recording image completion date; generating performance reports; and assigning and tracking security by user. 2458 The system shall track the date the attachment was received, the type of attachment, and the acceptability of the 2584 The system shall assign the permanent ISR Number to the attachment to which it is associated. 2585 The system shall identify all attachments associated with a case. |
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Sub Area: Manufacturer Online

- 3935 Manufacturer Online must provide an introductory/calling page with general instructions for the application, registration process, browser issues, and the comments
- 3936 Manufacturer Online must allow for the collection of all form elements on the mandatory Form 3500A.
- 3937 Manufacturer Online must provide online help and general instructions to guide the user through their submission
- 3938 Manufacturer Online must provide pull-down lists, check boxes, and radio buttons, where appropriate, for standard responses
- 3939 Manufacturer Online must enter "unspecified" if no value entered into Section A1
- 3940 Manufacturer Online must validate all dates to the proper MMDDYYYY format, and ensure that the correct century is used in all dates.
- 3941 Manufacturer Online must provide functionality to convert weights (i.e., lbs. to kgs).
- 3942 Manufacturer Online must enter the current date when no date of the report (B4) is specified.
- 3943 Manufacturer Online must provide field limitations to ensure that data does not exceed database standards and is consistent with E2B standards.
- 3944 Manufacturer Online must provide functionality for the submitter to print a copy of their submission, and have the printout be in the format of the mandatory 3500A form.
- 3945 Manufacturer Online must provide validation to ensure a minimum set of data elements contain values before processing the submission.
- 3946 Manufacturer Online must automatically identify the manufacturer for the report based on the login and registration information provided and the manufacturer dictionary.
- 3947 Manufacturer Online shall provide a capability for the user to specify the product from the product and manufacturer dictionaries.
- 3948 Manufacturer Online shall provide a capability for the user to specify medical terminology from the medical dictionary.
- 3949 Manufacturer Online shall allow the submitter to receive an electronic version (PDF) of their submission via email.
- 3950 Upon submission, Manufacturer Online must provide the submitter an acknowledgement of receipt and processing using a dynamically generated HTML page.
- 3951 If the submitter provides an email address, Manufacturer Online must provide acknowledgement of receipt and processing, via email, to the submitter once the submission is loaded into the system.
- 3952 Manufacturer Online shall allow the submitter to store their "common" information for retrieval and use in subsequent submissions
- 3953 Manufacturer Online shall compile several submissions in a single session, and reuse information as appropriate
- 3954 Manufacturer Online must force responses based on specific answers (i.e. Death-must report date, receipt of PDF must provide an email address)
- 3955 If the submitter provides an email address, Manufacturer Online must provide functionality for a PDF version of a submission to be emailed to the submitter.
- 3956 Manufacturer Online must insert online submissions into an appropriate format for further processing once they have been pulled through the FDA firewall and decrypted.
- 3957 Manufacturer Online shall allow the submitter to save partially completed submissions and retrieve the information within 30 days.

- 3958 Manufacturer Online must allow the manufacturer to delete reports never submitted and unwanted reports from the system
- 4106 The system shall support the receipt of mandatory adverse event reports through an online data entry.
- 4107 Manufacturer Online shall receive and maintain a database of manufacturers/senders with their electronic mail addresses and decryption keys to facilitate validation of transmission source, as well as electronic transmission of acknowledgments and problem reports
- 4108 Manufacturer Online shall support file uploads in Adobe PDF format.
- 4109 Manufacturer Online must provide a user-friendly mechanism for the mandatory reporting of adverse drug and medical device events by manufacturers from the FDA Internet site
- 4110 Manufacturer Online must support multiple Web browsers (Microsoft Internet Explorer, Netscape Navigator, FoxFire, and Mozilla) and platforms (Intel and Macintosh).
- 4111 Manufacturer Online must provide a secure environment for the electronic submission and transmission of
- Sub Area: MEDEX Report Entry**
- 4952 The system shall support the entry of direct reports into MEDEX.
- 2430 The system shall support current MEDEX data capture needs.
- 4953 The system shall support the entry of the following information for both paper and electronic reports: receipt method, one or more rejected categories, applicable
- 4954 The system shall support the entry of the following information for paper only reports: outcomes, primary suspect medication, suspect medical device, all information regarding the reporter, generate report acknowledgement, report confidentiality, and the also
- 4955 The system shall generate the received date
- 4956 The system shall generate the Serious/Non-Serious identifier by analyzing the outcome responses.
- 4957 The system shall determine if the suspect drug referenced is one of the current drugs on the expedited list.
- 4958 The system shall prompt the user to verify the confidentiality indicator if the drug is found to be on the
- 4959 If the drug is identified as on the expedited list and the user verifies that the report is not confidential then the system will send an email to FOI to have a redacted report sent to the registered manufacturer.
- Sub Area: MEDEX Report Query**
- 4948 The system shall support querying reports captured in the MEDEX program.
- 4949 The system shall present the user with the following search criteria options: receipt date range, event date range, suspect medication name, suspect medical device name, and reporter name
- 4950 The system shall show a list of the results of a query with the following information: reporter name, submitted date, suspect medication name, suspect medical device name, adverse event, and product problem.
- 4951 The user shall have the option to view, print or save the selected report to a PDF file.
- Sub Area: MEDEX Support Functions**
- 4960 The system shall provide support options for managing the MedWatch Expedited program.
- 4961 The system shall support a MEDEX Manage Registered

Firms and Drugs option that allows MEDEX Users and Supervisors to register firms and their drugs to participate in the Expedited Reporting Program. Firms may register their NME's for participation in six-month intervals called phases. This option also allows MEDEX Supervisors to delete (remove from participation) firms and/or selected drugs. Registered firms and drugs may be deleted for the current phase and/or the future phase.

- 4962 The system shall support a MEDEX Report Deletion option that allows MEDEX Users or Supervisors to delete the MEDEX data for the selected direct AE report. However, the option is only available to MEDEX Users if the report has not been expedited to a manufacturer. Only MEDEX Supervisors can delete a report or individual drugs that have been expedited to a manufacturer.
- 4963 The system shall support a MEDEX Reference Data Entry option that allows a MEDEX User or Supervisor to manage the list of professions used within the MEDEX data by allowing professions to be added, edited, and deleted. Only professions not used within the data will be allowed to be deleted.

Sub Area: Medical Coding

- 4901 The system shall support medical coding of adverse event reports.
- 4902 The system shall support the medical terminology search algorithm the ability to learn from previous matches and to maintain history tables.
- 4903 The system shall support the medical coding of adverse event information including the indication for use and the narrative description of the event.
- 4904 The system shall interface with the FDA Medical
- 4905 The system shall record the medical code(s) in all data elements identified in the ICH Electronic Submissions final document.
- 4906 The system shall record unlimited medical codes related to suspect adverse reactions.
- 4907 The system shall identify the coder and the coding date for each ISR.
- 4908 The system shall provide medical coding tools to code reaction and indication data.
- 4909 The system shall display identifying information from the ISR in the medical coding screens.
- 4910 The system shall display the event problem narrative information entered during Data Entry for medical coding purposes.
- 4911 The system shall enable medical coding through an interface that allows the user to browse the medical dictionary, select appropriate terms, and use the Search functionality that scans the narrative and provides
- 4912 The system shall support the 'heads up' medical coding process since the narrative needs to be read and appropriate terms need to be selected.
- 4913 The system shall display the medical coding principles in the AERS Help Text.
- 4914 The system shall provide viewing capabilities to the medical dictionary with full access to descriptions of all medical terms at all levels, the medical hierarchy, the multiaxial components associated with particular medical term(s) and SOC(s), coding principles, and on-line Help
- 2403 The system shall support the MedDRA autoencoder ability to learn from previous matches and to maintain history tables.
- 2442 The system shall support MedDRA coding adverse event information including the indication for use and the narrative description of the event.
- 2443 The system shall interface with the FDA MedDRA database.
- 2444 The system shall record the MedDRA code(s) in all data elements identified in the ICH Electronic Submissions final document.
- 2445 The system shall record unlimited MedDRA codes related to suspect adverse reactions.
- 2446 The system shall identify the coder and the coding date for each ISR.
- 2540 The system shall provide MedDRA Coding a set of tools to code reaction and indication data using the Autocode software.
- 2541 The system shall display identifying information from the ISR in the MedDRA
- 2542 The system shall display the event problem narrative information entered during Data Entry for MedDRA Coding purposes.
- 2543 The system shall enable MedDRA Coding to interface with the Autocode software that allows the user to browse the MedDRA dictionary, select appropriate terms, and use the Search functionality that scans the narrative and provides suggested terms.
- 2544 The system shall support the 'heads up' MedDRA Coding process since the narrative needs to be read and appropriate terms need to be selected.
- 2545 The system shall display the MedDRA coding principles in the AERS Help Text.
- 2602 The system shall provide viewing capabilities to the MedDRA dictionary with full access to descriptions of all MedDRA terms at all levels, the MedDRA hierarchy, the multiaxial components associated with particular

MedDRA term(s) and SOC(s), coding principles, and on-line Help Text.

- 4915 The system shall provide interactive encoding support for coding products and manufacturers using the appropriate dictionaries.
- 4916 The system shall use a medical dictionary that supports an appropriate level of granularity
- 4917 The system shall support a required granularity required of LLT when using MedDRA.
- 4918 The system shall enable medical coding users to add valid indications without an existing verbatim term.
- 4919 The system shall enable medical coding users to modify the narrative text in the event an error is found.
- 4920 The system shall enable codes medical terms to be saved in a user-defined order.
- 4921 The system shall display product role (e.g., primary, secondary) in addition to product name when coding indications.
- 4922 The system shall display the verbatim reaction terms on the medical coding screen during medical coding.
- 4923 The system shall enable medical coders to designate a reaction or multiple reactions that are most important to the case.
- 2866 The system shall enable MedDRA Coding users to add valid indications without an existing verbatim term.
- 2868 The system shall enable MedDRA Coding users to modify the narrative text in the event an error is found.

Sub Area: Medical Coding QC

- 4924 The system shall support medical coding QC of adverse event reports.
- 4925 Provide more data within coding and coding QC to allow a more efficient analysis without having to view the entire report. (define a toggle to view the ISR screen to gain access to all the report data)
- 4926 Coding and QC capabilities need to be integrated into AERS to provide a more efficient transition between locating terms and performing analysis (coding utility is separate application that causes issues when transitioning between tool and AERS application)
- 4927 Terms should be displayed in a natural order (how supplied) but also allow alphabet sorting. Paper reports are generally coded in order found but eSub reports have
- 4928 Provide a method for restructuring large blobs of narrative text into smaller more manageable structures (sentences) to support analysis.
- 4929 Coding shall support no limit on narrative text for coding.
- 4930 Coder QC shall have edit access to narrative and
- 4931 User shall be able to cancel/terminate medical terminology searches during processing.
- 4932 The system shall display the name of the user who coded the ISR in the Medical Coding Quality Control screen.
- 2867 The system shall display the name of the user who coded the ISR in the MedDRA Coding Quality Control screen.

Sub Area: MedWatch Batch

- 3990 The system shall support the receipt of direct adverse event reports through an online batch interface.
- 3991 MedWatch Batch shall provide a user-friendly mechanism for the voluntary reporting of adverse drug and medical device events as a batch from the FDA Internet site
- 3992 MedWatch Batch must support multiple Web browsers (Microsoft Internet Explorer, Netscape Navigator, FoxFire, and Mozilla) and platforms (Intel and Macintosh).
- 3993 MedWatch Batch must provide a secure environment for the electronic submission and transmission of information
- 3994 MedWatch Batch must provide an introductory/calling page with general instructions for the application.
- 2824 The system shall receive submissions through Electronic Data Interchange or

browser issues, and the comments form.

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| <p>3995 MedWatch Batch must allow for the collection of all form elements on the mandatory Form 3500A.</p> <p>3996 MedWatch Batch must provide online help and general instructions to guide the user through their submission</p> <p>3997 MedWatch Batch shall only accept submission structured according to the FDA HL7 specification.</p> <p>3998 MedWatch Batch must stage the submission file for further processing once pulled through the FDA firewall and decrypted.</p> | <p>2431 The system shall support and record the verbatim Data Entry of all data and text descriptions on the MedWatch 3500, MedWatch 3500 A, and 1639 forms.</p> <p>2522 The system shall provide descriptive on-line help</p> |
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Sub Area: MedWatch Online

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| <p>3959 The system shall support the receipt of direct adverse event reports through an online data entry.</p> <p>3960 MedWatch Online shall include the facility for the public to submit an adverse event report via a publicly available web site.</p> <p>3961 The system shall denote reports received by phone and entered by a MedWatch Operator.</p> <p>3962 MedWatch Online shall support file uploads in Adobe PDF format.</p> <p>3963 MedWatch Online shall generate a unique identifier for each report submitted.</p> <p>3964 MedWatch Online must provide a user-friendly mechanism for the voluntary reporting of adverse drug and medical device events by consumers and health care professionals (i.e., Reporters) from the FDA Internet site</p> <p>3965 MedWatch Online must support multiple Web browsers (Microsoft Internet Explorer, Netscape Navigator, FoxFire, and Mozilla) and platforms (Intel and Macintosh).</p> <p>3966 MedWatch Online must provide a secure environment for the electronic submission and transmission of information</p> <p>3967 MedWatch Online must provide an introductory/calling page linked from the MedWatch home page, with general instructions for the application, browser issues, and links to the online form, MedWatch home page, and comments</p> <p>3968 MedWatch Online must allow for the collection of all form elements on the MedWatch Voluntary Form 3500.</p> <p>3969 MedWatch Online must provide online help and general instructions to guide the user through their submission</p> <p>3970 MedWatch Online must provide pull-down lists, check boxes, and radio buttons, where appropriate, for standard responses</p> <p>3971 MedWatch Online must enter "unspecified" if no value entered into Section A1</p> <p>3972 MedWatch Online must validate all dates to the proper MMDDYYYY format, and ensure that the correct century is used in all dates.</p> <p>3973 MedWatch Online must provide functionality to convert weights (i.e., lbs. to kgs).</p> <p>3974 MedWatch Online must enter the current date when no date of the report (B4) is specified.</p> <p>3975 MedWatch Online must provide field limitations to ensure that data does not exceed database standards and is consistent with E2B standards.</p> <p>3976 MedWatch Online must provide functionality for the submitter to print a copy of their submission at any time, and have the printout be in the format of the MedWatch</p> <p>3977 MedWatch Online must provide validation to ensure a minimum set of data elements contain values before processing the submission.</p> | <p>2431 The system shall support and record the verbatim Data Entry of all data and text descriptions on the MedWatch 3500, MedWatch 3500 A, and 1639 forms.</p> <p>2522 The system shall provide descriptive on-line help</p> <p>3351 The system shall mirror the layout of the MedWatch 3500 and 3500A forms.</p> <p>3258 The electronic submissions software shall validate that each report contains the minimum data set, which is defined as one</p> |
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primary suspect product, an event narrative, and, for MedDRA-enabled manufacturers, at least one reaction (valid MedDRA preferred term). Note: This is subject to change based on clarification from FDA. Note: Per CCB request on 10/17/2000, the software will also include the fullfilexpedited tag in the minimum data set check.

- 3978 MedWatch Online shall allow the submitter to receive an electronic version (PDF) of their submission via email.
- 3979 Upon submission, MedWatch Online must provide the submitter an acknowledgement of receipt and processing using a dynamically generated HTML page.
- 3980 If the submitter provides an email address, MedWatch Online must provide acknowledgement of receipt and processing, via email, to the submitter once the submission is loaded into the MedWatch database.
- 3981 MedWatch Online shall allow the submitter to store their "common" information for retrieval and use in subsequent submissions
- 3982 MedWatch Online shall compile several submissions in a single session, and reuse information as appropriate
- 3983 MedWatch Online must force responses based on specific answers (i.e. Death-must report date, receipt of PDF must provide an email address)
- 3984 If the submitter provides an email address, MedWatch Online must provide functionality for a PDF version of a submission to be emailed to the submitter.
- 3985 MedWatch Online must insert online submissions into an appropriate format for further processing once they have been pulled through the FDA firewall and decrypted.
- 3986 MedWatch Online must allow the MedWatch Office to query, view, and print new submissions as they are
- 3987 MedWatch Online must allow the MedWatch Office to query, view, and print previously stored and routed
- 3988 MedWatch Online shall allow the submitter to save partially completed submissions and retrieve the information within 30 days.
- 3989 MedWatch Online must allow the MedWatch Office to delete MedWatch submissions from the system

Sub Area: Paper Media Receipt

- 4097 The system shall support paper media receipt of adverse event reports.
- 4098 The system shall track the number of reports received by report type (i.e., Direct, Expedited, Periodic).
- 4099 The system shall track the number of reports processed by report type (i.e., Direct, Expedited, Periodic).
- 4100 The process for receiving and preparing paper reports received for data entry shall not inhibit the timeliness of getting the reports into AERS
- 2436 The system shall capture verbatim data, text, and images for all ISRs received on paper.

Sub Area: Product/Manufacturer Validation

- 4890 The system shall support the validation of products and manufacturers regarding adverse event reports.
- 4891 The system shall identify ISRs that may have incomplete or erroneous data on the associated drugs or
- 4892 The system shall allow for correction of any errors made to drug or manufacturer data.
- 4893 The system shall track the source (user or electronic report) of the drug and manufacturer data.
- 4894 The system shall update the appropriate synonym table
- 2448 The system shall identify ISRs that may have incomplete or erroneous data on the associated drugs or manufacturers.
- 2449 The system shall allow for correction of any errors made to drug or manufacturer data.
- 2450 The system shall track the source (user or electronic report) of the drug and manufacturer data.
- 2556 The system shall update the appropriate

when a valid term is selected from the drug dictionary or manufacturer dictionary. The next time the same verbatim is entered, the system shall validate it. If an error is made, the system shall enable the user to clear the selection, including the update to the synonym table.

synonym table when a valid term is selected from the drug dictionary or manufacturer dictionary. The next time the same verbatim is entered, the system shall validate it. If an error is made, the system shall enable the user to clear the selection, including the update to the synonym table.

4895 The system shall populate active ingredient data based on a selected valid trade name.

2557 The system shall populate active ingredient data based on a selected valid trade name.

4896 The system shall enable users to select one or more active ingredients for a verbatim drug if there is not an appropriate match in the drug dictionary.

2558 The system shall enable users to select one or more active ingredients for a verbatim drug if there is not an appropriate match in the drug dictionary.

4897 Safety evaluator shall have the ability to perform manufacturer and product validation.

4898 The system shall provide a quality check on synonym creation by generating a report on new synonyms for manufacturers and trade names within a user specified period of time.

4899 The system shall automatically generate a report for ISRs where a trade name and active ingredient is blank.

4900 Every trade name in the product dictionary shall have at least one active ingredient.

Sub Area: Report Receipt Log

4088 The system shall support the logging in of the receipt of a paper report for data entry.

4089 The system shall support barcoding

2509 The system shall support barcoding

4090 The system shall capture and completely process data for CDER, CBER, and CFSAN ISRs.

2574 The system shall capture and completely process data for CDER, CBER, and CFSAN ISRs.

4091 The system shall assign a unique system ISR number and check digit when committing data.

2575 The system shall assign a unique system ISR number and check digit when committing

4092 The system shall print labels for specific pages or range of pages, including the page numbers on the label from the Barcode Label Printing screen

2576 The system shall print labels for specific pages or range of pages, including the page numbers on the label from the Barcode Label Printing screen

4093 The system shall double data enter the following fields: Manufacturer Control Number, ISR Type, ISR Date, Initial or Follow-up Information, Manufacturer Received Date, Drug Name, and Outcome.

4094 The system shall capture a date stamp for date of receipt and a permanent, unique number for each ISR (i.e., ISR Number).

2582 The system shall capture a date stamp for date of receipt and a permanent, unique number for each ISR (i.e., ISR Number).

4095 The system shall display a message when a record is committed to the database in Report Receipt Log prompting the user if they wish to continue.

2846 The system shall display a message when a record is committed to the database in Report Receipt Log prompting the user if they wish to continue.

Sub Area: Report Routing

4059 The system shall support the routing of reports through the data input process.

4060 The system shall route ISRs to the appropriate Inbox based on the validations performed by the routing

2533 The system shall route ISRs to the appropriate Inbox based on the validations performed by the routing algorithm.

4061 The system shall route ISRs that are not pre-coded to the MedDRA Coding Divisional Inbox.

2536 The system shall route ISRs that are not pre-coded to the MedDRA Coding Divisional

4062 The system shall route MedDRA-enabled manufacturers ISRs submitted electronically to MedDRA Coding Quality Control if they meet sampling rates or do not have any valid MedDRA LLTs.

2537 The system shall route MedDRA-enabled manufacturers ISRs submitted electronically to MedDRA Coding Quality Control if they meet sampling rates or do not have any valid MedDRA PTs.

4063 The system shall route paper ISRs from MedDRA Coding that meet sampling rates or do not have LLT(s) assigned

2538 The system shall route paper ISRs from MedDRA Coding that meet sampling rates or

to MedDRA Coding Quality Control.

- 4064 The system shall route ISRs to MedDRA Coding Quality Control for the following reasons: no MedDRA codes are saved for an ISR during MedDRA Coding; MedDRA Coding staff manually route the ISR to MedDRA Coding Quality Control when assistance is needed; electronic ISRs are submitted by MedDRA-enabled submitters who do not have any LLTs available; electronic and paper ISRs that meet system sampling rates.
- 4065 The system shall display the reason an ISR was routed to the Quality Control area.
- 4066 The system shall create a new case sequence number and not display the Case Linking screen when no potential links are found.
- 4067 The system shall process automated quality control checks of electronically received ISRs prior to the system's database update.
- 4068 The system shall route ISRs that do not meet the Data Entry Quality Control checks to the Data Entry Quality Control Divisional Inbox.
- 4069 The system shall maintain an activity log when ISRs are moved backwards within the Data Input process.
- 4070 Manufacturer sampling rates shall override AERS user sampling rates.
- 2546 The system shall route ISRs to MedDRA Coding Quality Control for the following reasons: no MedDRA codes are saved for an ISR during MedDRA Coding; MedDRA Coding staff manually route the ISR to MedDRA Coding Quality Control when assistance is needed; electronic ISRs are submitted by MedDRA-enabled submitters who do not have any PTs assigned to MedDRA Coding Quality Control; electronic and paper ISRs that meet system sampling rates.
- 2547 The system shall display the reason an ISR was routed to the Quality Control area.
- 2561 The system shall create a new case sequence number and not display the Case Linking screen when no potential links are found.
- 2615 The system shall process automated quality control checks of electronically received ISRs prior to the system's database update.
- 2591 The system shall route ISRs that do not meet the Data Entry Quality Control checks to the Data Entry Quality Control Divisional Inbox.
- 2850 The system shall insert an activity log when ISRs are moved backwards within Data Entry.

Sub Area: Report Tracking and Monitoring

- 4942 The system shall allow the tracking and monitoring of paper and electronic reports through the Data Input process.
- 3763 The system shall provide a total number of ISRs completed through the Data Entry process and then broken down by ISR type with the average time (e.g., the time in days between the log date and when processing is complete) per ISR type in a Data Entry management report.
- 4943 The system shall allow users to view all reports currently being processed.
- 2534 The system shall display the Data Entry Personal Inbox to contain ISRs that are currently being processed.
- 4944 The system shall allow users to view reports currently being processed based on a specified date range.
- 3766 The system shall provide a count of electronic ISRs received in a specified month in a Data Entry management report.
- 4945 The system shall allow users to view reports currently being processed based on a specified CTU number range.
- 4946 The system shall display an audit trail of processes completed, when, and by who for any report selected to be processed.
- 4947 The system shall allow the use to track the status of file being loaded through the electronic load process.

Sub Area: Routing Override

- 4936 The system shall support the re-routing of AE reports within the data input process.
- 4937 The system shall present the Data Input Supervisor with available process steps prior to the current process step that are acceptable for re-routing.
- 4938 The system shall allow the Data Input Supervisor to select the prior process step for re-routing the reports.
- 4939 The system shall present the Data Input Supervisor with available process steps after the chosen step and no further along than the last step completed for the selected report.
- 4940 The system shall allow the Data Input Supervisor to select

the next process step for where the report should restart in the process after the re-routed step is completed.

- 4941 The system shall only allow a Data Input Supervisor to re-route a report.

Sub Area: Safety Evaluator Routing

- 4933 The system shall support the routing of adverse event reports to safety evaluators when data entry is complete.
- 4934 The system shall assign adverse event reports to the appropriate evaluator based on assigned drug responsibility. Specifications of these responsibilities are also managed by the system.
- 4935 NDA's dealing with Med-Errors need to be routed appropriately to DMETS

Sub Area: Triage

- 4071 The system shall support paper and electronic triaging of Direct reports.

- 4072 The system must be able to support current MEDEX data capture needs, including:
- Record the suspect medication(s) on the report
 - Record the suspect device(s) on the report
 - Record the specialty of the reporter
 - Record the method of reporting (mail, fax, phone, bulletin board)
 - Record and automatically determine whether the report is serious based on predefined business rules
 - Record the primary FDA Center for the report
 - Record the secondary FDA Center(s) for the report

- 2430 The system shall support current MEDEX data capture needs.

- Record the outcome of the adverse event on the report
- Record the recipient category (distributor, manufacturer, user facility, not given) on the report
- Record the publication associated with the report
- Record reporter information including:
 - Last Name, First Name, and Middle Initial
 - Degree and Profession
 - Address Heading, PO Box, Street Address, City, State, and Zip Code
 - Province and Country
 - Phone Number

- 4073 The system must be able to automatically produce letters and mailing labels for the MedWatch Expedited Transmission Program

- 3469 The system shall provide the ability to automatically produce letters and mailing labels for the MedWatch to Manufacturer

- 4074 The system must be able to automatically produce MedWatch Expedited Transmission Letters, which are sent out with copies redacted reports

- 3470 The system shall provide the ability to automatically produce MedWatch Expedited Transmission letters, which are sent out with redacted ISR copies.

- 4075 The system must be able to enable faxing of MedWatch Expedited Report Letters and redacted reports to the manufacturers who are participating in the Expedited Transmission Program

- 3471 The system shall enable faxing of MedWatch expedited ISR letters and redacted ISRs to the manufacturers who are participating in the MedWatch Expedited Transmission

- 4076 The system must be able to support electronic transmission of reports and images to fulfill the MedWatch Expedited Transmission requirements for participants and their registered drug products

- 3472 The system shall provide the ability to support electronic transmission of ISRs and images to fulfill the MedWatch Expedited Transmission Program requirements for participants and their registered drug

- 4077 The system must be able to produce management reports for tracking/billing of the MedWatch Expedited Transmission Program

- 3473 The system shall provide the ability to produce management reports for tracking and billing of the MedWatch Expedited Transmission Program.

- 4078 The system must be able to register a health care organization to participate in the MedWatch Program

- 2859 The system shall provide the ability to register a health care organization to participate in the MedWatch to Manufacturer

- 4079 The system must be able to modify health care organization information due to address or contact change

- 2812 The system shall provide the ability to modify health care organization information due to

- 4080 The system must be able to add and retain new data pertaining to an applicant receiving MedWatch expedited transmissions
- 4081 The system must be able to add and retain new data pertaining to a new product as the subject of MedWatch expedited transmissions
- 4082 The system must be able to update data pertaining to the status of an applicant and its registered product(s)
- 4083 The system must be capable of selecting and printing redacted direct reports and associated images based on drug product, manufacturer, and MedWatch Expedited Transmission Status
- 4084 The system must be able to record, store, and report the number of pages printed by both the Imaging System and the AERS System for MedWatch Expedited Transmission billing purposes
- 4085 To support accurate and timely capture of registration information to support MedWatch's Expedited Transmission Program for manufacturers and their
- 4086 To provide timely redacted Direct Reports to manufacturer's participating in the MedWatch Expedited Transmission Program
- 4087 The system shall allow records to be appropriately identified as duplicate entries based on feedback from AERS users (e.g., Safety Evaluator)
- 2860 The system shall provide the ability to add and retain new data pertaining to an applicant receiving MedWatch expedited
- 2861 The system shall provide the ability to add and retain new data pertaining to a new product as the subject of MedWatch expedited transmissions.
- 2851 The system shall provide the ability to update data pertaining to the status of an applicant and its registered product(s).
- 3435 The system shall select and print redacted direct ISRs and associated images based on drug product, manufacturer, and MedWatch expedited transmission status.
- 3468 The system shall provide the ability to record, store, and report the number of pages printed by both the Excalibur Imaging System and the system for MedWatch Expedited Transmission Program billing purposes.
- 3471 The system shall enable faxing of MedWatch expedited ISR letters and redacted ISRs to the manufacturers who are participating in the MedWatch Expedited Transmission

Functional Area: Design Constraints

2006 SRS Document

Sub Area:

- 5907 The system shall support secured read and write access to distributed and centralized Oracle 9i tables.
- 5908 The system shall provide support for seamless interaction with data analysis tools such as SAS, CrossGraph, and other third party COTS analysis tools.
- 5909 The system shall support the printing and reading of barcode devices from any manufacturer that supports standard PC based wireless and wired solutions (e.g., serial RS-232, PS/2 style, USB)
- 5910 The system shall integrate with the FDA RetrievalWare enterprise search tool.
- 5911 The system shall interact seamlessly with COTS ad-hoc querying and data reporting tools such as Business
- 5912 The system shall permit the creation and displaying of paper forms, using the current and planned capabilities of the CDER imaging system.
- 5913 The system shall include the ability to receive and provide select information to secure, wireless hand-held devices, such as cellular telephones, Blackberry devices and
- 5914 The system shall integrate with WebVDME.

2003 RTM

- 2407 The system shall support access to distributed Oracle7 tables
- 3619 The system shall provide the ability to use statistical and graphical tools such as SAS and CrossGraph to perform analysis of a case series.
- 2576 The system shall print labels for specific pages or range of pages, including the page numbers on the label from the Barcode Label Printing screen
- 3143 The system shall interface with CDER's new imaging system (RetrievalWare) while providing users with existing functionality for View Image and Batch Print. RetrievalWare is a 32-bit application developed by Excalibur; it is a third-party tool that is replacing the former EFS application used within versions of AERS (prior to v2.1) for image retrieval functionality. This also includes updating the AERS Image Update script to reflect the RetrievalWare changes.

- 5915 The system shall have enhanced autocoder functionality which extends the functionality of the MedDRA browser.
- 5916 The system shall be web enabled.
- 5917 The system shall emulate all of the required functionality of AERS I in AERS II before AERS can be turned off. The required core functionality of AERS includes electronic submission, data entry, dictionary management, quality control, primary surveillance, cases and case series management, data warehousing, and reporting.
- 5918 The system shall include all of the relevant AERS data in order for AERS I to be turned off.
- 5919 The system shall be compatible with, and leverage (where applicable), FDA's technology, applications, and data dictionaries.

Functional Area: Dictionary Management
2006 SRS Document

2003 RTM

Sub Area:

- 5432 The system shall support the management of product, ingredient, label, manufacturer, and medical term dictionaries to promote data integrity and consistency.

Sub Area: Ingredient Dictionary

- 5472 The system shall support an ingredient dictionary.
- 5473 The system shall have "real-time" lookups into the ingredient dictionary for validation of data entry and
- 5474 The system shall be able to retain ingredient data for both biologic and drug products.
- 5475 The system shall be able to update ingredient data for both biologic and drug products.
- 5476 The system shall be able to delete ingredient data, if justified for both biologic and drug products.
- 5477 The system shall allow an active ingredient to be linked to one or more products.
- 5478 The system shall allow users to search for products, including combination products, by ingredient (active and inactive).
- 5479 The system shall allow a user to save a list or grouping of certain ingredients to apply to future queries and reports.
- 5480 The system shall allow a user to view (read-only) another user's saved list or grouping of ingredients to apply to future queries and reports.
- 5481 The ingredient dictionary shall be available at data capture to verify product data on an ISR.
- 2884 The system shall provide the ability to retain ingredient data for both biologic and drug products.
- 2885 The system shall provide the ability to update ingredient data for both biologic and drug products.
- 2823 The system shall provide the ability to delete ingredient data, if justified for both biologic and drug products.

Sub Area: Label Dictionary

- 5482 The system shall support a label dictionary.
- 5483 The system shall have "real-time" lookups into the label dictionary for validation of data entry and reporting.
- 5484 The system shall provide the ability to view the most current label for all drug or biologic products.
- 5485 The system shall have the ability to pull in approved label and other information, as well as carton information.
- 5486 The system reporting module shall provide the ability to view the most current label for all drug or biologic
- 5487 The system shall provide the ability to view versions of
- 2825 The system shall provide the ability to view the most current label for an NME or designated drugs of interest.
- 2825 The system shall provide the ability to view the most current label for an NME or designated drugs of interest.
- 3479 The system shall provide the ability to track label changes, including the ability to display information about when it was last updated, the section that changed, and the reason for

- the change.
- 5488 The system shall provide the ability to track and view label history (what changed from version to version).
- 5489 The system shall provide the capability to perform full text search on the current or previous versions of a product
- 5490 The system shall provide the ability to copy text from any portion of a label into an MS-Office product.
- 5491 The system shall provide the ability to copy image of a label into an MS-Office product.
- 5492 The system shall provide the ability to print a portion or a complete label.
- 5493 The system shall provide the ability to compare the current product label, (package insert, vial labels, carton labels, etc.) with other relevant labels to promote identification of adverse reactions that are prevalent in a drug class, and use the results as screening criteria.
- 5494 The system shall provide the ability to medically code all reactions and record their corresponding label section names for biologics and drug products.
- 5495 The system shall provide the ability to edit medical terms for a drug or biologic label.
- 5496 The Label dictionary and the Medical Terms dictionary shall be in synch to match terms from the label to the verbatim terms on an ISR.
- 5497 The system shall provide the ability to medically code all indications for use listed on a drug or biologic label.
- 5498 The system shall provide the ability to search coded labeled fields.
- 3480 The system shall provide the ability to create and view label history.
- 2773 The system shall provide the capability to perform a full text search on the most current product label.
- 2774 The system shall provide the capability to perform a full text search on the most current product label.
- 2775 The system shall provide the ability to copy the image of a label into a Microsoft Word or WordPerfect document.
- 2776 The system shall provide the ability to print a portion or a complete label.
- 3482 The system shall provide the ability to compare a drug label with other relevant drug labels to promote identification of adverse reactions that are prevalent in a drug class and use the results as screening
- 2829 The system shall provide the ability to MedDRA code all reactions and record their corresponding label section names for biologics and drug products
- 2830 The system shall provide the ability to edit MedDRA terms for a drug or biologic label.
- 2832 The system shall provide the ability to MedDRA code all indications for use listed on a drug or biologic label.
- 3483 The system shall provide the ability to handle search criteria that require MedDRA-coded labeled fields as input.
- Sub Area: Manufacturer Dictionary**
- 5499 The system shall support a manufacturer dictionary.
- 5500 The manufacturer dictionary shall include address type (i.e., main contact, inspection plant, joint venture).
- 5501 The manufacturer dictionary shall allow a single address to relate to one or more manufacturers.
- 5502 The manufacturer dictionary shall allow an authorized user to edit data for the manufacturer
- 5503 The manufacturer dictionary shall allow users to search for the Manufacturer of a product, including the use "Fuzzy" search using wildcards.
- 5504 The manufacturer dictionary shall record the complete product ownership history, including name changes, mergers, and buyouts.
- 5504 The manufacturer dictionary shall record the complete product ownership history, including name changes, mergers, and buyouts.
- 5505 The manufacturer dictionary shall allow for the return of the manufacturer history for a product, or searching for the history of a manufacturer by date.
- 5506 The manufacturer dictionary shall be able to add and retain a new product applicant profile.
- 5507 The manufacturer dictionary shall be able to update a product applicant profile.
- 5508 The manufacturer dictionary shall be able to access information pertaining to the licensing or authorization of a manufacturer/distributor or establishment for a product.
- 5509 The manufacturer dictionary shall be able to access updated data pertaining to mergers.
- 2673 The system shall provide the ability to view and select search criteria for manufacturer searches from the manufacturer dictionary.
- 3348 The system shall provide the ability to access updated data pertaining to buyouts.
- 3349 The system shall provide the ability to access updated data pertaining to mergers.
- 2888 The system shall provide the ability to add and retain a new product applicant profile.
- 2875 The system shall provide the ability to update a product applicant profile.
- 2428 The system shall provide the ability to access information pertaining to the licensing or authorization of a manufacturer/distributor or establishment for a product.
- 3349 The system shall provide the ability to access updated data pertaining to mergers.

- 5510 The manufacturer dictionary shall be able to access updated data pertaining to buyouts.
- 5511 The manufacturer dictionary shall be able to access updated data pertaining to all changes of the person of regulatory responsibility for a manufacturer.
- 5512 The manufacturer dictionary must be able to add and retain new data pertaining to a contact.
- 5513 The manufacturer dictionary shall be able to update data pertaining to a contact.
- 5514 The manufacturer dictionary shall be able to add and retain new data pertaining to an applicant receiving MedWatch expedited transmissions (MedWatch to Manufacturer Program).
- 5515 The manufacturer dictionary shall be able to add and retain new data pertaining to a new product as the subject of MedWatch expedited transmissions (MedWatch to Manufacturer Program).
- 5516 The manufacturer dictionary shall be able to update the MedWatch to Manufacturer Program status of the applicant and its registered product(s).
- 3348 The system shall provide the ability to access updated data pertaining to buyouts.
- 3350 The system shall provide the ability to access updated data pertaining to all changes of responsibility within the pharmaceutical industry. The system shall provide the ability to access updated data pertaining to all changes of responsibility within the pharmaceutical industry.
- 2819 The system shall provide the ability to add and retain new data pertaining to a contact.
- 2820 The system shall provide the ability to update data pertaining to a contact.
- 2860 The system shall provide the ability to add and retain new data pertaining to an applicant receiving MedWatch expedited transmissions.
- 2861 The system shall provide the ability to add and retain new data pertaining to a new product as the subject of MedWatch expedited transmissions.

Sub Area: *Medical Terms Dictionary*

- 5843 The system shall be able to incorporate new versions of the medical dictionary without system downtime.
- 5844 The system shall have the ability to review dictionary updates and mappings and apply changes automatically after QC is complete.
- 5845 The system shall be able to retain new lower level medical terms when using the MedDRA as a medical terms dictionary.
- 5846 The system shall be able to link lower level medical terms to preferred terms when using the MedDRA as a medical terms dictionary.
- 5847 The system shall be able to retain new special category (i.e., Standardized MedDRA Queries - SMQ) medical terms when using the MedDRA as a medical terms dictionary.
- 5848 The system's medical terms dictionary upgrades shall not lose data or reports that use dictionary terms.
- 5849 The medical terms dictionary shall be able to support multiple dictionaries from sources outside of the FDA.
- 5850 The system shall be able to track and display the relationship between previous versions of a term with the most recent dictionary update for that term.
- 5851 The medical terms dictionary shall be able to relate terms across multiple dictionaries (e.g., MedDRA and SNOMED).
- 5852 The medical terms dictionary shall allow for the conversion of terms from one dictionary to another.
- 5853 The system shall allow for the coding of fields designated for coding to multiple dictionary terms.
- 5854 The system shall allow for the selection of a section or word within the narrative for coding.
- 5855 The system must allow the coder to select the entire narrative for coding.
- 5856 Coders shall be able to manually type in a medical term verbatim to match to a verbatim and have it validated by the dictionary.
- 5857 Coder QC shall be able to manually type in a medical term verbatim to match to a verbatim and have it validated by the dictionary.
- 5858 Safety evaluators shall be able to manually type in a medical term verbatim to match to a verbatim and have it
- 2600 The system shall retain new MedDRA LLTs.
- 2601 The system shall link MedDRA LLTs to MedDRA PTs.
- 2619 The system shall retain new special category MedDRA terms.

validated by the dictionary.

- 5859 The system shall allow for the viewing of the hierarchy of medical terms when searching or reporting.
- 5860 The medical terms dictionary shall maintain and display a history of changes to individual dictionaries.
- 5861 The system shall have the capability to include an update of medical terms on ISR's when initiated by a user with specific authorization to make the change.
- 5862 All terms in the medical dictionary shall be available for report queries.
- 5863 The system shall maintain a history of changes to a coded verbatim term.
- 5864 The system shall permit the flexible creation, use, and maintenance of Special Search Groups of medical terms.
- 5865 The system shall provide the capability to integrate medical dictionary online training.
- 5989 The system shall support a medical terms dictionary.
- 5990 The medical terms dictionary shall allow for the coding of adverse events and indications within the Patient Drug Reaction.
- 5991 The medical terms dictionary shall allow for the coding of adverse events and indications within the Patient Death Report.
- 5992 The medical terms dictionary shall allow for the coding of adverse events and indications within the Patient Determine Autopsy.
- 5993 The medical terms dictionary shall allow for the coding of adverse events and indications within the Parent Medical Episode Name.
- 5994 The medical terms dictionary shall allow for the coding of adverse events and indications within the Parent Drug Indication.
- 5995 The medical terms dictionary shall allow for the coding of adverse events and indications within the Parent Drug Reaction.
- 5996 The medical terms dictionary shall allow for the coding of adverse events and indications within the Primary Source Reaction.
- 5997 The medical terms dictionary shall allow for the coding of adverse events and indications within the Reaction MedDRA PT.
- 5998 The medical terms dictionary shall allow for the coding of adverse events and indications within the Reaction Term.
- 5999 The medical terms dictionary shall allow for the coding of adverse events and indications within the Drug Indication.
- 6000 The medical terms dictionary shall allow for the coding of adverse events and indications within the Drug
- 6001 The medical terms dictionary shall allow for the coding of adverse events and indications within the Drug Reaction Asses.
- 6002 The medical terms dictionary shall allow for the coding of adverse events and indications within the Sender
- 6003 The system shall provide the ability to view the complete list of medical terms.
- 6004 The system shall provide the ability to access the medical terms dictionary as part of the coding process for an ISR.
- 6005 The system shall be able to load and retain new medical terms, including individual terms and new dictionaries.

Sub Area: *Product Dictionary*

- 5433 The system shall support a product dictionary.
- 5434 The system shall be able to add and retain drug product data including information about drug product formulation.
- 2886 The system shall provide the ability to add and retain drug product data including

- 5435 The system shall be able to modify drug product data including information about drug product formulation.
- 5436 The system shall be able to add and retain biologic product data including information about biologic product
- 5437 The product dictionary shall support post-marketing surveillance on blood derivative biological products.
- 5438 The product dictionary shall support post-marketing surveillance on biological blood component products.
- 5439 The product dictionary shall support post-marketing surveillance on biological cellular and tissue products.
- 5440 The product dictionary shall support post-marketing surveillance on biological therapeutic products.
- 5441 The product dictionary shall support post-marketing surveillance on biological diagnostic products.
- 5442 The product dictionary shall support post-marketing surveillance on biological vaccine products.
- 5443 The product dictionary shall support post-marketing surveillance on other biological products that have NDA assignments.
- 5444 The system shall be able to modify biologic product data including information about biologic product formulation.
- 5445 The product dictionary shall have the capability to include additional pharmacological classification (from outside sources) and relate them to the products within the dictionary (such as AHFS data).
- 5446 The pharmacological classification and product relationships shall be available for querying and reporting.
- 5447 The product dictionary shall contain a relationship between the product and its active ingredients.
- 5448 The product dictionary shall indicate if a product is a combination product by indicating the product line (e.g., food, drug, biologic, device).
- 5449 The indicator for a combination product shall be available for reporting (to allow the ability to include or exclude from a search).
- 5450 The system shall allow dictionary management to include the ability to add terms to the dictionary, fix dictionary errors; develop a drug dictionary specific to AERS.
- 5451 The system shall have the ability to search the product dictionary.
- 5452 The product dictionary shall maintain a history of all changes to a product, including Trade Name changes, ingredient changes.
- 5453 The system shall have the ability to support multiple product dictionaries and multiple versions of each
- 5454 The system shall have the ability to allow users to customize product dictionary searches.
- 5455 The system shall have a dictionary that will translate verbatim names into Trade names.
- 5456 The dictionary shall indicate if a trade name is a foreign or domestic name.
- 5457 The system shall relate a foreign trade name to a "domestic" trade name.
- 5458 The Product Dictionary must interface with the Manufacturer Dictionary to link products with specific
- 5459 The system shall allow the user to search the history of a Manufacturer for a product.
- 5460 The system shall allow for the capture of a Re-Packager (corporation) for a Product.
- 5461 The system shall allow the user to associate a "[Product] NOS" for a reported product that cannot be linked based
- information about drug product formulation.
- 2887 The system shall provide the ability to modify drug product data including information about drug product formulation.
- 2813 The system shall provide the ability to add and retain biologic product data including information about biologic product formulation.
- 2814 The system shall provide the ability to modify biologic product data including information about biologic product formulation.

on NDA# or STN#.

- 5462 The first two portions of the NDC – Labeler code and product code shall be the unique identifier for a drug product and shall link to NDA #.
- 5463 The system shall provide the capability to link products by Trade Name, Active Ingredient, and Manufacturer.
- 5464 The system shall allow for trade name specification from the 6-digit STN #, which presently links only to the level of the manufacturer.
- 5465 The system shall have "real-time" lookups into the product dictionary for validation of data entry and reporting.
- 5466 A product shall allow one or more active ingredients.
- 2558 The system shall enable users to select one or more active ingredients for a verbatim drug if there is not an appropriate match in the drug dictionary.
- 5467 The system shall allow a user to save a list or grouping of certain drug names to apply to future queries and reports.
- 5468 The system shall allow a user to view (read-only) another user's saved list or grouping of drug names to apply to future queries and reports.
- 5469 The system shall have the ability to determine the "date due" for periodic reports for a given product.
- 5470 The product dictionary shall contain the international "birth date" for a product.
- 5471 The system shall have the ability to identify and differentiate OTC products.

Functional Area: Interfaces

2006 SRS Document

Sub Area: Communications Interfaces

- 5979 The system shall support e-mail integration at the end-user application and the server-side application.
- 2420 The system shall create links between AERS modules and all of the FDA E-Mail systems

2003 RTM

Sub Area: Hardware Interfaces

- 5956 The system shall interface with barcode readers and barcode printers in a fashion which is device or manufacturer independent.
- 2576 The system shall print labels for specific pages or range of pages, including the page numbers on the label from the Barcode Label Printing screen
- 5956 The system shall interface with barcode readers and barcode printers in a fashion which is device or manufacturer independent.
- 3164 The system shall support the Eltron Programming Language 1 for the Eltron LP 2042 Barcode Printers.
- 5956 The system shall interface with barcode readers and barcode printers in a fashion which is device or manufacturer independent.
- 3185 The system shall support the Eltron Programming Language 2 for the Eltron LP 2642 Barcode Printers.

Sub Area: Software Interfaces

- 5957 The system shall support across system databases searches and queries.
- 2406 The system shall support direct access to centralized Oracle7 database
- 5958 The system shall support across system databases reports generation.
- 5959 The system shall interface with DAARTS.
- 5960 The system shall interface with ADIMS.
- 5961 The system shall interface with CBER's CBAER.
- 5962 The system shall interface with the FDA Product Labeling System (SPL).
- 5963 The system shall interface with FDA CFSAN CAERS.
- 5964 The system shall interface with the FDA FACTS system to coordinate enforcement activities in the field.
- 5965 The system shall interface with the FDA Drug Quality Reporting System (DQRS).
- 5966 The system shall be able to interact with other FDA Safety Evaluator databases, i.e., signals database.
- 5967 The system shall be able to integrate with existing FDA

- dictionaries for drug, biologic, manufacturer and label information.
- 5968 The system shall interface with the existing EDOC system.
- 5969 The system shall interface with the existing EDR system.
- 5970 The system shall provide for periodic extraction of data to effectively support Agency management reporting requirements and other requirements related to decision support for assessing and monitoring drug safety risk.
- 5971 The system shall support data integrity and data consistency by having access to existing dictionaries. When no relevant dictionary is available the system will maintain a centralized location for storing related, ISR-specific drug, biologic, label, MedDRA and manufacturer
- 5972 The system shall interface with the interagency AHRQ Safety Net and the National Patient Safety Task Force.
- 5973 The system shall interface with the Veterans Affairs (VA) Administration.
- 5974 The system shall be able to obtain prescription-specific data, such as number of prescriptions written for a drug from National Prescription Audit Plus (NPA), an external
- 5975 The system shall be able to obtain demographic drug usage data such as age, gender, region for a generic or trade name product from National Disease and Therapeutic Index (NDTI), an external database.
- 5976 The system shall be able to receive and integrate ADR data received periodically from the World Health Organization (WHO).
- 5977 The system shall interface with the Viral AERS (VAERS) system at the Center for Disease Control (CDC).
- 5978 The system shall interface with various systems and databases at the National Library of Medicine (NLM).
- 2811 The system shall provide the ability to extract data.
- 3655 The system shall provide the ability to obtain prescription-specific data, such as number of prescriptions written for a drug from NPA Plus, an external database.
- 3656 The system shall provide the ability to obtain demographic drug usage data such as age, gender, region for a generic or trade name product from ISS' NDTI, an external database.
- 3658 The system shall provide the ability to load extracted ISR data received periodically from the WHO.
- 3633 The system shall provide the ability to access the following external systems: Medline, PDR, DQRS, WHO, and VAERS (CBER Safety Evaluators only).

Functional Area: On-Line User Documentation and Help System Requirements

2006 SRS Document

Sub Area:

- 5920 The system shall provide an on-line training manual and help function with interactive screens.
- 5921 The system shall provide the capability to integrate MedDRA online training or other training subjects as
- 5922 The system should provide online training information that is suitable for specialized groups, such as medication
- 5923 Online training and help activities should indicate caveats.
- 5924 Online training information must meet the needs of new employees and be easily updateable.
- 5925 The system should have Help balloons that pop-up when sliding the cursor over the menu selection.
- 5926 The system's training module should have a searchable message board having current issues and input from other users that may show workarounds to current
- 5927 The system should incorporate security awareness and training as it pertains to AERS in training initiatives.
- 3933 The system shall be supported by user-friendly user and operations guides and training manuals
- 2522 The system shall provide descriptive on-line help

2003 RTM

Functional Area: Other Requirements

2006 SRS Document

Sub Area:

- 5943 The system shall include a migration plan for all relevant data currently in AERS I.
- 3916 Develop and implement a strategy and implementation plan and program to convert ISR data from the SRS system and MAR data from the MART system to the new AERS

Functional Area: Security and Privacy Requirements**2006 SRS Document****Sub Area:**

- 5928 Access to the AERS II application will be limited to previously approved FDA employees. Employees will be required to provide a username and password in accordance with FDA guidelines. There are standards for the values that are valid for username and password.
- 5929 Access to the public AERS II web site will be open to anonymous, unrestricted access.
- 5930 The system shall include data access controls that limit authorized access to the least amount of information needed to accomplish each particular job function.
- 5931 The system shall allow the administrator to limit data views (by record and data element) and access based on defined user roles and user identification.
- 5932 The system shall ensure that on-line updates of personal data that affect a user's access/approval authority in the system are performed by authorized individuals.
- 5933 The system shall ensure that discretionary access control mechanisms are in-place on the platform.
- 5934 The system shall ensure that each user has documented, official approval before being granted authorization to access the system remotely and maintain current list of users with such authorization.
- 5935 The system administrator shall be able to assign users with appropriate roles.
- 5936 The system shall provide an additional password/ID reconfirmation where there is a specific reason or need.
- 5937 The system shall be compliant with OMB Circular A-130, Appendix III, and Security of Federal Automated Information Systems.
- 5938 The system shall be compliant with the HHS Automated information Systems Security Program, ISSP Handbook
- 5939 The system shall be compliant with Federal Information Security Management Act (FISMA) of 2002.
- 5940 The system shall be compliant with NIST SP 800-53.
- 5941 The solution must be compliant with the Information Security (Privacy Act), the Privacy Provisions of the e-Government Act of 2002 and technology security
- 5942 The system must include a tamper-proof (self-auditing) facility to record any change to AERS II.

2003 RTM

- 3884 The system shall ensure that application user names meet DHHS FDA naming standards and are similar to user names for e-mail, LAN, and other accounts.
- 3851 The system shall provide capability for data administrator to define access restrictions
- 3862 The system shall ensure that on-line updates of personal data that affect a user's access/approval authority in the system are performed by authorized individuals.
- 3865 The system shall ensure that discretionary access control mechanisms are in place on the platform.
- 3876 The system shall require each user to have documented, official approval before being granted authorization to access the system remotely and maintain current list of users with such authorization.
- 2805 The system shall provide the ability for the System Administrator to maintain user accounts that include adding new users and assigning roles to added users.
- 3902 The system shall provide an additional password and ID reconfirmation where there is a specific reason or need.
- 3883 The system shall ensure that passwords to the system meet DHHS AISS Program Handbook May 1994 requirements (e.g., no fewer than six characters, changed at least every 90 days) and ISA Perimeter Security

Functional Area: Supportability**2006 SRS Document****Sub Area:**

- 5891 The system shall support the ability to add new application functionality
- 5892 The system shall support the ability to change business
- 5893 The system shall support the ability to add new elements/fields to the data repository
- 5894 The system shall support the ability to establish new relationships between the elements
- 5895 The system shall support the ability to introduce data analysis modules

2003 RTM

- 5896 The system shall support the ability to introduce data querying modules
- 5897 The system shall support the ability to introduce data reporting and formatting modules
- 5898 The system shall support the ability to introduce new printing capabilities
- 5899 The system shall support the ability to introduce new searching engines, algorithms
- 5900 The system shall support the ability to export data in new formats
- 5901 The system shall support the ability to import and merge
- 5902 The system shall support the ability to change workflow
- 5903 The system shall support the ability to add new roles
- 2809 The system shall provide the ability to add, modify, or soft delete the list of AERS roles and the specific functions associated with those roles.
- 5904 The system shall support the ability to quickly change data and software accesses
- 5905 The system shall support the ability to utilize/integrate multiple data dictionaries (versions)
- 5906 The system shall support the ability to change data exchange standards (new versions and different

Functional Area: System Performance

2006 SRS Document

Sub Area:

- 5880 The system running within the FDA intranet shall meet all of the specified response time requirements.
- 5881 The system shall be able to save data changes in less than 5 seconds when used within the FDA intranet.
- 5882 The system shall be able to retrieve simple data in less than 2 seconds when used within the FDA intranet.
- 5883 The system shall be able to perform searches, queries, and reporting in less than 3 minutes when used within the FDA intranet.
- 5884 The system shall be able to perform a user login or logout in less than 5 seconds when used within the FDA
- 5885 The latency between system-to-system connections shall be less than 3 seconds when used within the FDA
- 5886 The public web site shall meet the specified response time requirements when connected through using broadband technologies.
- 5887 The system shall be able to retrieve static data for the public web site in less than 10 seconds when connected through using broadband technologies.
- 5888 The system shall be able to retrieve semi-static data for the public web site in less than 10 seconds when connected through using broadband technologies.
- 5889 The system shall be sized to accommodate a lifespan of 10 years of growth, maintaining the required performance metrics.
- 5890 The system shall be able to process one thousand (1000) new adverse event report transactions per day (six days per week).

2003 RTM

- 3670 The system shall demonstrate response time for simple queries *(5 min., M+, M++)
- 3671 The system shall demonstrate response time for moderately complex queries *(30 min., M+, M++)

Functional Area: System Reliability

2006 SRS Document

Sub Area:

- 5874 All end-user functionality for all roles shall be accessible via a standard web browser.
- 5875 The system must be compliant with Section 508 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794d) –

2003 RTM

commonly known as "Section 508 Compliance".

- 5876 The system should have a role-specific interface or front-
- 5877 The system shall use consistent terminology in field labeling by ensuring that all field labels (e.g., screens, reports) correspond to the equivalent field label from the mandatory and voluntary MedWatch forms.
- 5878 The system shall use button and menu names that match the screen, dialog, or screen area that becomes activate when selected.
- 5879 Except for a scheduled downtime of 4 hours per week, all AERS II functionality must be available (in a non-degraded mode) to all users, 98% of the time. The AERS II system can operate in a downgraded mode defined as less than 1% of the time.
- 3857 The system shall enable users to limit data views and access based on defined user roles and user identification.
- 2979 The system shall have established GUI standards for the naming conventions of buttons and screen names within AERS (e.g., ISRs vs. reports, drugs vs. products). These standards are outlined in the AERS GUI Requirements Document approved by the CCB on November 9, 1999.

Functional Area: System Usability

2006 SRS Document

Sub Area:

- 5873 The system shall be web based (i.e., have a browser centric user interface that is available over an Internet, and Extranet or an Intranet).

2003 RTM

APPENDIX D
Report of Findings on OIT
By Linda Rule

Because of its scope and complexity, the content of the Report of Findings on OIT that was published in October 2003 was transmitted to FDA separately.

APPENDIX E
AERS Users Satisfaction Survey

**Adverse Event Reporting
System (AERS) Program**

User's Satisfaction Survey

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TABLE OF CONTENTS

INTRODUCTION.....	3
BRIEF OVERVIEW OF THE ODP PROCESS	5
AERS USER'S SURVEY OVERVIEW	8
OBSERVATIONS	10
SUMMARY OF INTERVIEW DATA.....	15
SUMMARY OF VERBATIM COMMENTS.....	17
QUANTITATIVE SURVEY DATA	19
APPENDIX A: AERS USER'S SATISFACTION SURVEY QUESTIONS.....	27
APPENDIX B: INTERVIEWS CONDUCTED	30
APPENDIX C: UNEDITED VERBATIM COMMENTS	31
APPENDIX D: INITIAL OBSERVATIONS FOR IMPROVEMENT	38

Introduction

The FDA is responsible for pre-market and post-market safety and efficacy assessments of human drugs and certain biologics through its Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER), respectively. Clinical trials, which represent the pre-market process that leads to formal marketing approval, only begin to quantify the safety and efficacy of a given pharmaceutical compound or biological product. The post-market assessment of safety and efficacy is conducted largely by means of reviewing and monitoring of adverse event reports.

An adverse event is any undesirable event associated with the use of a drug or biologic in humans. Given the approach of spontaneous or "passive" surveillance, the collection and analysis of adverse event data must be reported to FDA in order for the agency to carry out its mission of performing post-marketing safety surveillance (PMSS) throughout the entire life cycle of the product. The Adverse Event Reporting System (AERS) is a computing system that FDA staff uses to carry out the PMSS function. The Office of Pharmacoeconomics and Statistical Science (OPaSS) AERS Program Office is the organizational unit in FDA that *orchestrates* the needs of users in all FDA Centers who perform the PMSS function and the technical support of CDER's Office of Information Technology (OIT) and Office of Information Management (OIM).

The genesis of the FDA spontaneous reporting system for drugs dates to the 1962 Kefauver-Harris Amendment to the Food, Drug, and Cosmetic Act that required drug manufacturers to report all adverse reactions for any product marketed under an approved New Drug Application (NDA). FDA began computerizing adverse drug reaction reports in the mid-1960s. The automated Spontaneous Reporting System (SRS) was initially designed in 1969 to serve as a means for FDA to detect rare, unexpected adverse drug and biologics reactions, where biologics included blood, allergenics, cellular tissue and gene products and therapies. In 1986, prescription drugs on the market without an approved application (i.e., those drugs and biologics marketed before 1938) became subject to adverse event reporting requirements. In 1993, the FDA initiated the MedWatch program to increase public awareness about the importance of reporting adverse reactions, to educate health professionals on reporting requirements, to standardize reporting formats, and to provide an agency-wide single point of entry for adverse reaction reports submitted by the public and health professionals.

The SRS worked well when CDER and CBER were receiving a total of 10,000 reports a year. But by the mid-1990s, the increasing scope of FDA's requirements for spontaneous reporting of adverse events combined with the agency's desire to increase public awareness about reporting adverse events increased the number of reports to over 150,000 per year. The enormous volume of reports pushed the SRS to its operational and technical limits. It also hampered the agency's ability to effectively perform PMSS. The Adverse Events Reporting System (AERS I) replaced the SRS in 1997 and became the primary post-marketing spontaneous reporting system for human drugs and biologic therapeutics. It was designed to utilize state-of-the-art technology to facilitate the collection, analysis, and dissemination of post-marketing spontaneous reporting information.

Since that time the number of adverse event reports has grown to over 400,000 per year, and the FDA's commitment to gathering larger data samples, communicating risks to the public and encouraging reporting of adverse events will drive this number even higher. While FDA's efforts were successful in increasing the amount of data that the agency could use to protect public health and safety, this success has created an enormous IT challenge that the current AERS I computer system can no longer handle. The OPaSS AERS Program Office will *orchestrate* the needs of users in all FDA Centers and the technical support of CDER's OIT and OIM to ensure that a new AERS computer system (AERS II) will serve the needs of the users who carry out FDA's PMSS mission.

This document summarizes a three-year process called the Organizational Design and Planning Process (ODP) that was designed to understand the issues problems and needs that users were having with the AERS I system. Together with the AERS Program Strategic Plan, the ODP process was designed to map out the foundation of the new AERS II system. As described in the next section, the ODP process began by identifying and creating a baseline of the needs of AERS I users. This document contains the data, analysis and conclusions from a User's Survey that was conducted in June 2005. It has two main purposes. First, the User's Survey and this report are a way to measure progress on the eleven Initial Observations for Improvement identified in 2003 and progress toward the goals defined as part of the ODP process. Second, this report presents additional Observations for Improvement and suggests a path forward for the AERS II system.

Brief Overview Of the ODP Process

The purpose of this section of the report is to provide background and an overall context for the ODP process and the User's Satisfaction Survey.

1. In February 2003, the Director of OPaSS, Paul Seligman, told staff of the Breckenridge Consulting Group (BCG) that many AERS users were very unhappy with the ineffective performance of the AERS I system. Seligman identified three primary issues that BCG used to focus the initial set of exploratory interviews of users and other FDA personnel during the first visit in March 2003.

- Making better public health use of data
- Improving the database and its performance
- Better management of the AERS program

2. March 11-12, 2003 was the initial site visit where BCG interviewed about 25 people from ODS, DSRCS, DMETS, CBER, DDRE, OB, CDER OIT, and CDER OIM. We used the then current version of the CDER OIT/OIM Strategic Plan (February 2003), as a guide for what the FDA needed from the AERS system. The interviews resulted in eleven Initial Observations for Improvement that helped focus the ODP process. The complete list of these eleven Initial Observations for Improvement can be found in Appendix D below.

3. Prior to the first ODP meeting held on June 24-25, 2003, Charlie Stone joined OPaSS on a detail and subsequently became the AERS Program Manager. The first ODP session was attended by 21 people from OPaSS, OIT, OIM, ODS, DSRCS, DMETS, DDRE, OND, OC, CBER, and CFSAN. This meeting was facilitated by BCG. BCG presented an overview of: a) the ODP process, b) Human Factors issues associated with this kind of project, and c) the eleven Initial Observations for Improvement that emerged from the initial visit. Attendees did an exercise with all AERS users where people wrote what they thought other organizations did and how they used AERS and then each organization debriefed their actual roles, responsibilities and how they used AERS. The group exercise helped attendees understand the function of other organizations and the overall scope of AERS as a system that is vital to FDA's post-marketing surveillance responsibilities. Participants reviewed the outline of the Charter for the ODP Process, developed five working groups and gave attendees the opportunity to sign up for the one they were most interested in or in which they had expertise.

- Data Input
- Data Structure
- Data Queries and Retrieval
- Contract Management
- Training

The strengths, areas for improvement, and user needs that were identified in this meeting are summarized in the CDER OPaSS Adverse Event Reporting Program Strategic Plan, dated June 26, 2004. The attendees decided that the scope of AERS users was still wider and needed to be expanded to CDRH, CVM, FOI, DRLS, FURLS, and OTC. We developed action items for a path forward and these are also summarized in the latest version of the CDER OPaSS Adverse Event Reporting Program Strategic Plan.

4. The second ODP meeting was held on July 15-16, 2003. This meeting was attended by 23 people from OPaSS, OIT, ODS, DSRCS, DMETS, and DDRE. This meeting was facilitated by BCG. Because many of the attendees were not at the first meeting, BCG presented an overview of what happened at the previous meeting, as well as an overview of: a) the ODP process, b) Human Factors issues associated with this kind of projects, c) the Initial Observations for Improvement, and d) the scope and purpose of the five working groups that had been developed in the first meeting. Sandra Valencia who was the AERS project manager in CDER OIT gave an overview presentation on the AERS Configuration Management Process and the associated structure and functioning of the Change Control Reports process (CCR) and the three Change Control Boards (CCBs) that existed at that time. Using the topics of the five working groups as a kind of

matrix, attendees used flip charts to document the current AERS system's areas for improvement, functionality that was promised but never received, and strengths that should be capitalized on. Each issue was identified as to its scope of impact on users and organizations (Safety Evaluators, Epidemiologists, Medical Errors, FOI, OIT, etc.). These items were identified and summarized in the latest version of the CDER OPaSS Adverse Event Reporting Program Strategic Plan. At that time there were 209 outstanding CCRs. We divided them up among the attendees then broke them into small groups, with each group being assigned about 50 CCRs. The goal was to evaluate the CCRs as to their importance to the work of the organizations present. Each CCR was also assigned to one of the five working groups. We developed action items for a path forward that are summarized in the latest version of the CDER OPaSS Adverse Event Reporting Program Strategic Plan.

5. The third ODP meeting was held on August 5-6, 2003. This ODP session was attended by 21 people from OPaSS, OIT, ODS, DSRCS, DMETS, DDRE, PSI and BAH. This meeting was facilitated by BCG. Because many of the attendees were not at the other meetings, BCG presented an overview of what happened at the previous meetings, as well as an overview of: a) the ODP process, b) Human Factors issues associated with this kind of projects, c) the Initial Observations for Improvement from the initial visit, and d) the scope and purpose of the five working groups established at the initial meeting. Sandra Valencia the AERS project manager gave an overview presentation on the AERS Configuration Management Process and the associated structure and functioning of the CCR process and the three CCBs that existed at that time. Using flip charts, we gathered user needs, strengths, areas for improvement, functionality that was promised in the current AERS system but was not delivered, and our end-user feedback. The strengths, areas for improvement, and user needs that were identified in this meeting are summarized in the latest version of the CDER OPaSS Adverse Event Reporting Program Strategic Plan. Charlie gave an overview talk of how he planned to handle the AERS program management based on his previous experience with the FACTS system he managed in ORA, and then entertained questions and feedback from those present. The PSI and BAH attendees presented the issues from their perspective and entertained comments and feedback from the end users who were present. Surprisingly, BAH claimed that this was the first time that they had heard how unhappy users in OPaSS were, which only reinforced questions about the effectiveness of the interface between CDER OIT and users in OPaSS and CBER. We developed action items for a path forward that are summarized in the latest version of the CDER OPaSS Adverse Event Reporting Program Strategic Plan.

6. The fourth meeting was held on September 15, 2003. This ODP session was attended by about 10 people from CVM, CBER, CFSAN, CDRH, FOI, PSI, BAH as a way of gathering the input of all AERS users. Many of the attendees were not at the first meeting, so BCG presented an overview of what happened at the previous meeting, as well as an overview of: a) the ODP process, b) Human Factors issues associated with this kind of projects, c) the Initial Observations for Improvement from the initial visit, and d) the scope and purpose of the five working groups. Using flip charts, we gathered user needs, strengths, areas for improvement, functionality that was promised in the current AERS system but was not delivered, and our end-user feedback. The strengths, areas for improvement, and user needs that were identified in this meeting are and action items for a path forward are summarized in the latest version of the CDER OPaSS Adverse Event Reporting Program Strategic Plan.

7. The fifth meeting was held on September 16-17, 2003 and was attended by about fourteen safety evaluators from CDER and CBER. The purpose was to analyze the safety evaluators' work processes and areas that required AERS functionality. These were binned out into the areas of the five working groups, including labeled versus unlabeled, the drug dictionary, text word searching, printing standard and customized reports, and many other issues. The entire group did a page-by-page review of the significant screens of the AERS system and identified which buttons, items, and features did not function or did not function completely or correctly. The results of this meeting were summarized in the latest version of the CDER OPaSS Adverse Event Reporting Program Strategic Plan.

8. The final meeting was held on October 30, 2003 to bring closure to the ODP Process. The five working groups identified in the initial meeting were never chartered because the method of gathering user needs from all AERS user constituencies at ODP meetings was successful and the extra time and effort needed to initiate and run the five working groups was not viewed as being value added. The first draft of the CDER OPaSS Adverse Event Reporting Program Strategic Plan was completed on October 30, 2004. Since that

time it has undergone seven revisions, incorporating FDA comments and suggestions for improvement. As of the publication of this report, the latest revision is dated June 26, 2004.

AERS User's Survey Overview

The questionnaire for the AERS User's Satisfaction Survey was designed to collect information about the operation of the AERS Program from the perspective of AERS users. Participants were asked to give their most accurate and honest response that they could, based on their *personal knowledge* of:

1. The functionality of AERS system.
2. The performance of the AERS Program Office, e.g. Charles Stone, and
3. The performance of the AERS Help Desk, e.g. SAIC/PSI.

There were 27 radio button questions and five open-ended questions. The quantitative data from the radio buttons has been analyzed and is shown below in the section called Quantitative Survey Data. The data from the five open-ended questions have been summarized into themes and are presented below in the section entitled Summary of Verbatim Comments. The raw unedited data from the verbatim comments is shown in Appendix C below. Participants were instructed that answering "Don't Know/No Opinion" was as valid an answer as any of the other choices. Since the questionnaire asked for their *personal knowledge* about the three bullets listed above, if they had *second hand knowledge* or no knowledge at all, then they were instructed to answer "Don't Know/No Opinion." Questions where participants answered "Don't Know/No Opinion" were not counted in the data analysis to increase the validity of the assessment results. Significant instances of the answer "Don't Know/No Opinion" (50% or greater) included the following:

1. Questions 1.1, 2.9, and 3.7 ask about the comparison between the current operation of the AERS Program and the way things were 18 months ago. These answers probably indicate that these respondents honestly didn't have first hand knowledge about these questions or just didn't know how to answer them.
2. Questions 1.3 and 1.4 ask about whether these participants' concerns are being brought to the CCB meetings through their representative. Data from one-on-one interviews indicate that respondents have a lack of knowledge about the role and function of their CCB representative. Some people who were interviewed did not even know that they had a CCB representative.
3. The question, "How would the proposed AERS II system positively impact your ability to do your job?" had a significant number of "Don't Know/No Opinion" responses. This may indicate a lack of knowledge about the capabilities of the new AERS II system and the degree to which it will positively impact the professional life of AERS users.

Non-Response Error

Every effort was made by BCG to remind participants to complete the survey, including numerous reminder e-mails, phone calls, and notification of the OPaSS management team of the non-participation. Unfortunately, the low-level of completion in some organizations has caused a large Non-Response Error in four out of five the organizations. These numbers are indicated on the data graphs presented below.

Confidentiality

The responses of individual participants were confidential. In accordance with Public Law 93-579 (Privacy Act of 1974) providing personal information is completely voluntary. Collection of this information has been authorized by Sections 1302, 3301, and 3304 of Title 5 US Code. Completed surveys were sent directly to the Breckenridge Consulting Group Inc. for analysis. No one in FDA will ever have access to the individual responses. Individual responses were compiled and summarized with the responses of other participants into the overall summary report contained in this document so individual answers cannot be identified.

Observations

An initial set of interviews was conducted by BCG on March 11 and 12, 2003, with about 25 people being interviewed from ODS, DSRCS, DMETS, CBER, DDRE, OB, CDER OIT, CDER OIM. We used the then current version of the CDER OIT/OIM Strategic Plan (February 2003), as a guide for what the FDA needed from the AERS system. The interviews resulted in eleven Initial Observations for Improvement that helped focus the ODP process. The complete list of these observations can be found in Appendix D.

This section begins with an analysis of the observations from the 2003 assessment used as a baseline against which current performance of the program can be measured. As the data from the AERS User's Satisfaction Survey shows, the following four Initial Observations for Improvement from 2003 have been addressed over the last 18 months and show substantial improvement.

Observation 2-2003 (Project Management) concerned better oversight of the former contractor (BAH), and the reengineering of the CCB and CCR processes to make them more effective and efficient. BAH is no longer the contractor and interviews and other data show that the current contractor (SAIC/PSI) is doing a great job. In addition, the AERS Program Manager is doing an excellent job providing oversight for all contractors working on the AERS Program by holding them to task and closely monitoring the number of tasks being completed and the contractor's performance on those tasks. The AERS Program Manager has made the following progress in this area. The three CCBs have been combined into a single, more effective entity, the number of outstanding CCRs has been substantially reduced, CCRs for organizations such as DMETS and CBER that were outstanding for years have been completed, and the number of CCRs addressed per new release of AERS I has increased dramatically.

Observation 3-2003 (Communication) concerned better communication between the IT people and AERS I users through the equivalent of a business systems analyst that mediated between users and IT professionals. Interviews and other data indicate that the AERS Program Manager has effectively filled the role of liaison between CDER's OIT/OIM organizations and the spectrum of users in OPaSS, CBER and throughout the Agency. With few exceptions, the level, kind, frequency, and quality of communication that the Program Manager provides to AERS I users about the system has improved substantially over the last 18 months.

Observation 7-2003 (AERS Ownership) concerned the ownership of the AERS I system. Prior to beginning the ODP Process, organizational responsibility for the AERS I system was unclear, which led to the comment, "If everyone is responsible for AERS, then no one is responsible." The Program Manager within OPaSS has demonstrated commitment and dedication to assuming responsibility for the AERS Program. Interviews and other data in this report confirm that OPaSS (through the AERS Program Manager) owns and is responsible for the effective operation of the AERS Program. But as described in more detail below, the IT Consolidation process within FDA mandates that funding for AERS I is controlled by CDER's OIT organization. This has complicated the issue of AERS ownership and at times made it difficult for the AERS Program Manager in OPaSS to succeed because he has the *responsibility* for effectively running the program, without the funding *authority* needed to make this happen.

Observation 8-2003 (Identify All AERS Users) concerned understanding the needs and requirements of all AERS Users including other safety evaluators in OPaSS (DMETS), CBER, epidemiologists, Office of Compliance, FOI, and the Review Divisions in the Office of New Drugs (OND). Interviews and other data in this report indicate that the AERS Program Manager in OPaSS has gone to great lengths to identify and seek out all users of the system and this area has improved dramatically over the last 18 months.

As the data from the AERS User's Satisfaction Survey also show, the following Initial Observations for Improvement from the beginning of the ODP process in 2003 remain problematic. As of the writing of this report, these areas still need to be addressed with corrective action.

Observation 4-2003 (Poor System Design) was about the poor design of the AERS I system that resulted in lost functionality from the previous SRS, the proliferation of work-arounds for individual users, decreased analytical capabilities over the SRS's capabilities, and the emergence of costly tangential systems designed to increase analytical capabilities on a user-group, by user-group basis (for example, Data Mart and CBEAR). *Observation 8-2003 (AERS Activity)* concerned estimates of the "usability" of the AERS system, what this User's Survey called "functionality." Data gathered for the Initial Observations for Improvement in 2003 indicated that the usability of AERS I ranged from 60-90% depending on who was asked. The data from interviews and other data from this present survey indicate that there has been some limited increase in functionality, for example regular MedDRA upgrades and some limited data cleanup. But in other critical areas (data dictionary, data integrity, labeling issues, data retrieval, heuristic search capabilities, and the ability to do batch printing), the functionality of AERS I is about the same as it was 18 months ago. This is probably the result of a conscious decision by OPaSS management and the AERS Program Manager to not invest resources in fixing problems in AERS I, and instead focus on obtaining this increased level of functionality in the AERS II system. Interviews and other data from this survey indicate, that if the AERS II system is substantially delayed, or does not receive the funding needed to go forward, resources *must* be dedicated to increasing the functionality of the AERS I system. As described below, AERS I users indicated that "on-average" they spend about 3/4 of an hour per day on AERS I-related inefficiencies. Some users spend as much as four hours per day on such inefficiencies. For the 75 users who participated in this survey, spending 3/4 of an hour per day amounts to about \$700,000 per year in lost salary and is the equivalent of about 6 FTEs. Based on interviews and other data gathered in this survey, BCG estimates that about half of this time is probably due to functionality issues, and half is due to a lack of training for Safety Evaluators and a lack of up-to-date AERS system documentation for these same users. However, some Safety Evaluators commented in interviews that they have been doing the work-arounds for the AERS I system for so long, that they have come to seem these tasks as a part of doing the job. This means that the *actual* time wasted on AERS I inefficiencies is probably much larger than 3/4 of an hour per day. The issue of increased functionality is more than adequately addressed in the AERS Program Strategic Plan, but is slated for completion as part of the AERS II process.

Observation 5-2003 (Lack of Documentation and Training) concerned the difficulties of back-engineering the AERS system because of a lack of documentation and the inability of BAH or CDER OIT Project Management personnel to reconstruct the history of what the original specifications and system functionality were, compared to the level of functionality that was actually delivered when the AERS I became operational. This 2003 observation also concerned the lack of up-to-date user documentation and training. The documentation and User's Manual for the AERS I system that did exist in 2003 was badly out of date back then. It was originally written in 1999 and none of the system upgrades or enhancements were included in this 1999 version. In addition, there was no regularly offered formal training on how to use the AERS system provided to existing or even new users at the time the ODP process began in 2003. Increased change in AERS I and employee turnover among Safety Evaluators has made the training and documentation problems worse than they were 18 months ago. This is reflected in the extremely low score on questions 3.8 and 3.9 of the User's Satisfaction Survey. As mentioned, about half of the \$700,000 in lost salary and 6 FTEs is probably due to this lack of training and up-to-date system documentation. The AERS Program Strategic Plan states that the AERS Program Office is responsible for documentation and training, but no resources have been made available to the AERS Program Office in OPaSS to correct this problem. An immediate way to address the lack of user documentation and not divert substantial resources away from moving toward the ultimate AERS II solution might be to identify which AERS users need a copy of the AERS I User's Manual, then create a PDF from a machine readable copy of the 1999 version and distribute it to these users.

Observation 6-2003 (Electronic Submissions) concerned the problem of electronic submissions, especially the data input problems associated with FDA's ability to receive attachments from submitting organizations. This Observation is more than adequately addressed in the AERS Program Strategic Plan, is slated for completion as part of the AERS II process, but was beyond the scope of this User's Survey.

Observation 9-2003 (IT Consolidation) concerned the potential problems created by the centralization of CDER's IT and IM resources and funds for the AERS Program under a CDER-wide CIO. As mentioned above, interviews and other data confirm that the AERS Program Manager in OPaSS is responsible for

the effective operation of AERS, but funding for the AERS Program is controlled by CDER's OIT organization. This has complicated the issue of AERS ownership and at times made it difficult for the AERS Program Manager in OPaSS to succeed because he has the *responsibility* for effectively running the AERS program, without the funding *authority* needed to make this happen. Here's one example of the problem of separating responsibility for AERS Program performance from the funding authority needed to effectively run the program. In May 2005 CDER's OIT informed the AERS Program Manager that AERS I would have to take a 25% cut in funding. What is most problematic was that the OIT knew about this reduction in funding since January 2005, but failed to inform the AERS Program Manager until five months later. If current trends continue, IT Consolidation may have a major negative impact on OPaSS's ability to obtain AERS II. With the number of AERS reports increasing to over 400,000 per year and \$700,000 per year in lost productivity with the existing system (6 FTEs), this matrix-management approach to IT could eventually impact OPaSS's and CBER's ability to protect the American public from drug and biologic-related incidents and hamper FDA's ability to conduct effective post-marketing safety surveillance (PMSS).

Observation 10-2003 (System Interfaces) concerned the need for interfacing with other systems inside the FDA (Drug Quality Reporting System, Clinical Trials system), and outside the FDA (AHRQ safety net, etc). This was beyond the scope of this User's Survey, but is more than adequately addressed in the AERS Program Strategic Plan and is slated for completion as part of the AERS II process.

The following are additional Observations for Improvement that emerged from the interviews and data gathering activities associated with this User's Survey.

Observation 1-2005: Given the importance of protecting the American public from drug and biologic-related incidents and its potential ability to hamper FDA's ability to conduct effective post-marketing safety surveillance, the highest levels of management in FDA and CDER should move aggressively toward obtaining of the funds needed to obtain the AERS II system as soon as possible. As mentioned, if the AERS II system does not receive the funding needed to go forward or is substantially delayed, resources *must* be dedicated to increasing the functionality of the AERS I system along the lines defined in this report and the AERS Program Strategic Plan. The cost-benefit of doing so is obvious, because over a four-year period, the \$700,000 per year wasted due to AERS I inefficiencies totals \$2.8 million. This is much more than the cost of obtaining any of the scenarios for a new AERS II system.

Observation 2-2005: As a follow-on to the comments in *Observation 1-2005*, the AERS Program Office's staffing level (or resources) should be increased to provide the training and documentation support needed to service the multi-functional and cross-organizational needs of the AERS user community (especially training and documentation). These staffing levels have been well-defined in the AERS Program Strategic Plan for the last 18 month, but have not been acted on by CDER management or the CDER OIT organization.

Observation 3-2005: Interviews and other data collected during this User's Survey indicate that the AERS Program Manager needs to take more control in running the CCB meetings and develop a more systematic approach to defining levels of priority for corrective action on CCRs. The Program Manager should not allow a few "vocal" people to dominate the meeting and to derail the orderly agenda that he has developed and handed out prior to people arriving at the meeting. The Program Manager should seriously consider using a facilitator (non-CCB member) who can keep the meeting on track and allow the Program Manager to freely participate in the meeting. In terms of defining the levels of priority for CCRs, the Program Manager and CCB members might develop a prioritizing matrix with criteria such as: a) the number of users affected, b) the number of hours of down time, c) the number of times the problem occurs, d) the degree to which the problem hampers FDA's ability to conduct effective post-marketing safety surveillance, and e) the cost benefit of fixing the problem now versus later with the AERS II system. When the question of priority level for a CCR emerges or is in conflict between CCB members, these predefined criteria can be used to adjudicate between legitimate but conflicting demands on AERS I resources.

Observation 4-2005: The high incidence of “Don’t Know/No Opinion for questions 1.3 and 1.4 probably indicates that AERS users do not know who their representative is on the CCB and don’t know who to report problems to. The AERS Program Manager should address this issue as soon as possible.

Summary of the Interview Data

The Breckenridge Consulting Group conducted fourteen interviews to gather more detailed information on the Program Management, Functionality, and User Support dimensions of the AERS Program. These interviews were conducted on-site at FDA's Parklawn Building on May 24-25, 2005 and by phone on June 1-2, 2005. A list of people were interviewed can be found in APPENDIX B. This section of the report contains a very brief summary of the data gathered during the interviews.

Program Management

The overall consensus of people interviewed was that the AERS Program Manager is doing an excellent job providing oversight for all contractors working on the AERS Program, closely monitoring the number of tasks being completed and their performance on those tasks. These comments made during interviews are also reflected in the quantitative data and the verbatim comments in this report. The Program Manager is working very hard to keep communication open between his Office, numerous user communities, and CDER's OIT and OIM organizations and does a good job *orchestrating* all activities in the best interest of the entire user community. He is also effectively functioning as the communication bridge between all parties and organizations that formerly felt ignored (DMETS and CBER) are receiving much more service and support in the last 18 months.

The Program Manager has also made significant progress over the last 18 months in the following areas. The three CCBs have been combined into a single, more effective entity, the number of outstanding CCRs has been substantially reduced, CCRs for organizations such as DMETS and CBER that were outstanding for years have been completed, and the number of CCRs addressed per new release of AERS I has increased dramatically. The Program Manager is very responsive to the needs of all users, and even tries to anticipate problems they might have and address them before they even become problems.

The AERS Program Manager is also extremely committed to getting the new AERS II approved and operational, but as described elsewhere in this report, the IT Consolidation process within FDA has made it difficult for the AERS Program Manager in OPaSS to move forward on AERS II because he has the *responsibility* for effectively running the AERS Program, but does not have the *funding authority* needed to move forward on AERS II.

Functionality

The data from interviews and other data from this User's Survey indicate that there has been some limited increase in functionality over the last 18 months, for example regular MedDRA upgrades and some limited data cleanup. But in other critical areas (data dictionary, data integrity, labeling issues, data retrieval, heuristic search capabilities, and the ability to do batch printing), the functionality of the AERS I system is about the same as it was 18 months ago. In fact, some people commented that they have been doing the work-arounds for the AERS I system for so long, that they have come to seem these tasks as a part of doing the job. This means that the *actual* time wasted on AERS I inefficiencies is probably much larger than the 3/4 of an hour per day identified by users in this User's Survey.

Interviews and other data from this User's Survey indicate, that if the AERS II system is substantially delayed, or does not receive the funding needed to go forward, resources *must* be dedicated to increasing the functionality of the AERS I system. This includes corrective action on the data dictionary, improving data quality and integrity, labeled versus unlabeled issues, data retrieval, heuristic search capabilities, ability to produce reports, ability to cut and paste, the ability to do batch printing, and the ability to download the data that appear on an AERS I screen into the Microsoft Office suite of products which would give Safety Evaluators the ability to perform expanded data analysis with tools such as Excel and Access. Many users who were interviewed expressed the concern that they might be disappointed with the

AERS II system's level of functionality, much like they were disappointed with the loss of functionality that occurred when they migrates from the previous SRS to AERS I.

User Support

During the 2003 survey, there was an extremely high level of dissatisfaction with BAH and they are no longer the contractor for the AERS Program. Interviews and other data show that the current contractor (SAIC/PSI) is doing a great job. For example, they were very responsive during testing periods. Also, the new contractor has done a superior job in managing the MedDRA upgrades. The previous contractor took about 35-40 hours to perform a MedDRA upgrade and uploading it on the desktops of users was always problematic. SAIC/PSI takes 3-4 hours to do the same work and uploading is automatic – point and click. Also the contractor will be uploading 6,000 reports that will improve the ability of the Safety Evaluators in DMETS to do their job. The serious problem in terms of User Support with the lack of current documentation and training for existing or new Safety Evaluators has already been mentioned in the section that lists Observations.

Summary of Verbatim Comments

The last 5 questions on the AERS User's Satisfaction Survey were written questions. 21% of the people surveyed did not answer these questions. The unedited verbatim text from those who did respond can be found in Appendix C, where the responses have been categorized into the three areas of Functionality, User Support, and Program Management. In addition, we've sorted them into Categories within the three areas, namely the Drug Dictionary, Technology, and Training. This section summarizes the significant themes present in the responses.

1. *How many hours per day do you deal with AERS-related inefficiencies (for example, rework, work-arounds, timeliness, downtime, lack of functionality, inability to get user support etc.)?*

Responses ranged from zero to 4 hours per day. Of those who responded to the question, the average amount of time reported was 3/4 hour per day. For the 75 users polled in this survey, this translates to about \$700,000 per year or a loss 6 FTEs worth of work time.⁷¹ Some people commented in interviews that they have been doing the work-arounds for the AERS I system for so long, that they have come to seem these tasks as a part of doing the job. This means that the *actual* time wasted on AERS I inefficiencies is probably much larger than 3/4 of an hour per day.

2. *Describe three areas in which you personally observe these AERS-related inefficiencies occurring.*

With respect to the overall functionality of the system, significant themes regarding inefficiencies included:

- Drug Dictionary – lack of a quality drug dictionary, with specific weaknesses in the area of CBER-regulated products
- Data Quality/Integrity – inconsistent results in searches due to lack of data clean-up
- Batch Printing
- Reporting – see detailed comments for many difficulties reported in this area
- System/Performance – system locking up and slow response time
- Searching – limitations in custom searches

With respect to user support, common themes were:

- Lack of documentation
- Lack of training
- Too long to get problems resolved

3. *List the AERS system's top three strengths.*

With respect to the overall functionality of the system, significant themes regarding strengths included:

- User Interface – easy to use
- Reporting – ability to save reports, good list of “canned” reports
- Overall Functionality – most extensive AE reporting system in world, timely availability of data in a desktop-accessible repository
- Searches – ability to save search criteria
- Data Quality/Integrity – despite data errors, data is pretty good
- Technology – Ability to view images

The program management for AERS was seen as another strength.

⁷¹ We assume the average fully-loaded salary of an FDA Safety Evaluator to be about \$125,000 per year (2,000 hours), which translates to \$62.50 per hour or about \$47 per 3/4 hour unit per day. This is about \$9,400 per year per Safety Evaluator and about \$700,000 per year for the 75 users involved in this survey. This also translates to about 187 hours of lost work time per Safety Evaluator per year (4.6 weeks) and about 14,062 lost work hours for the 75 users (7 FTEs).

4. *List the AERS system's top three weaknesses.*

With respect to the overall functionality of the system, significant themes regarding weaknesses were similar to those of the inefficiencies, including:

- Drug Dictionary – lack of a good Drug Dictionary
- Data Quality/Integrity – lack of careful data entry, multiple entries for a drug name due to misspellings, duplicates, and other data quality issues
- Searching – specialized/complex searches are difficult or not possible, need to be savvy to understand different search strategies, have to search by verbatim names, no generic ingredient search
- Reporting – a variety of issues, as can be seen in the detailed comments

With respect to User Support, the same issues surfaced as in the inefficiencies question: the lack of training, the lack of documentation and the long response time for fixing problems and adding features.

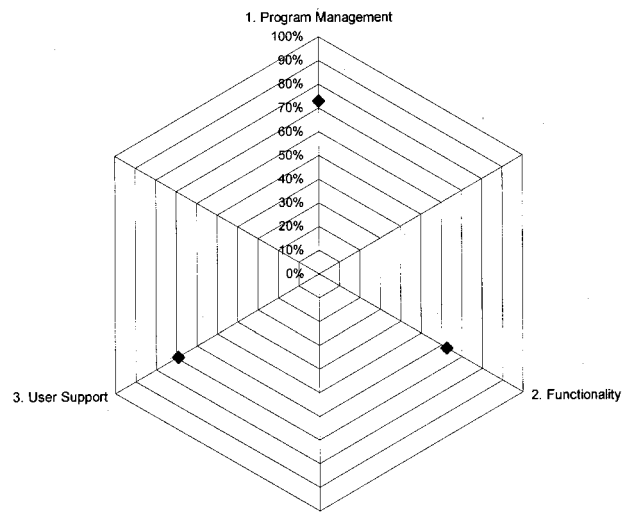
5. *How would the proposed AERS II system positively impact your ability to do your job?*

Of the 24 responses to this question, 11 of the responses fell into the category of “Don’t Know”, indicating a lack of knowledge in the organization about AERS II and what its capabilities are going to be.

Significant themes in the remaining responses included:

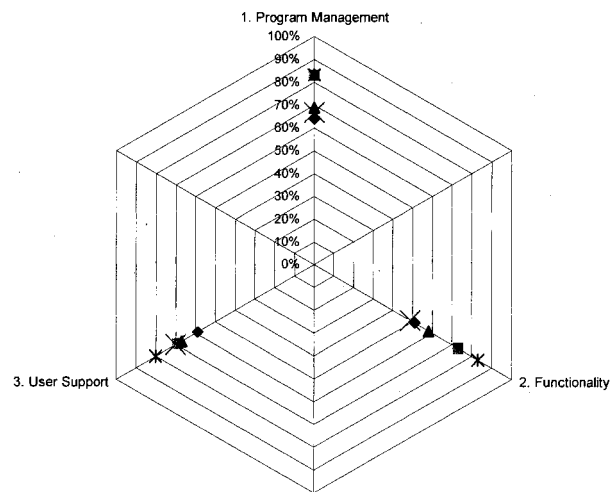
- Technology – web access, which will allow remote access to the system, and the ability “cut and paste” data into offline documents
- Data Quality/Integrity – more timely access to higher quality data
- Drug Dictionary – availability of an improved drug dictionary to decrease effort required for searches and improve search results
- Searching – more powerful search capabilities

AERS Program Survey



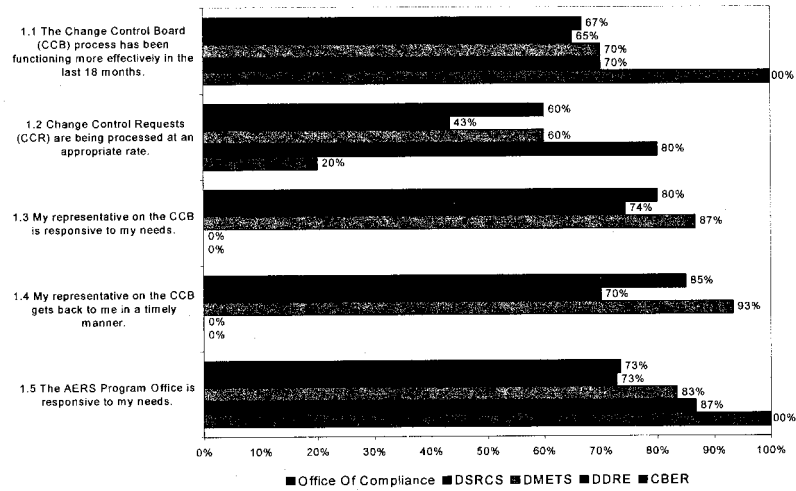
Average Score of the 5 Subgroups(43 Responses):
CBER, DDRE, DMETS,DSRCS,
Office of Compliance

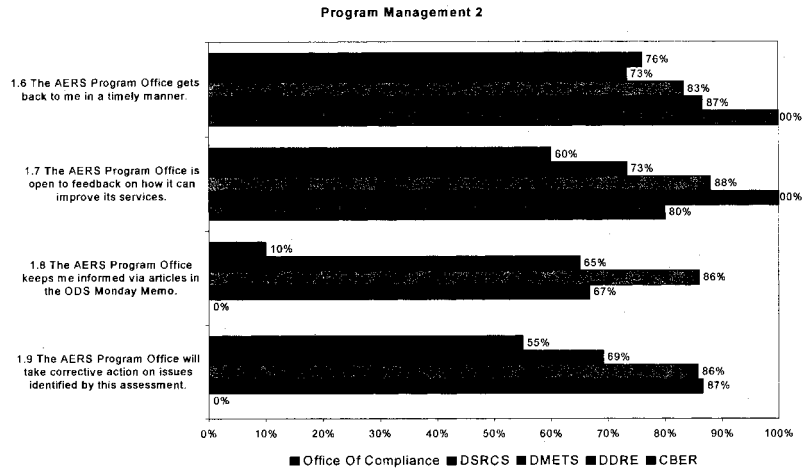
AERS Program Survey

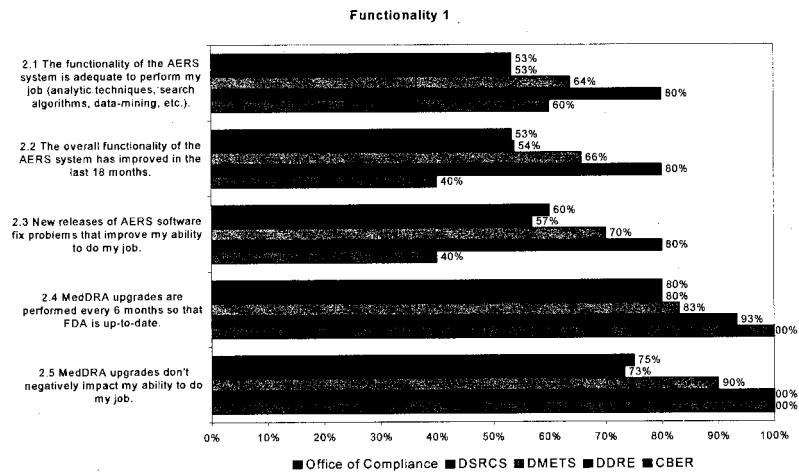


Diamond(red) = CBER; 6 Responded out of 11 Requested
 Triangle(blue) = DDRE; 15 Responded out of 36 Requested
 Square(green) = DMETS; 17 Responded out of 18 Requested
 Star(purple) = DSRCS; 3 Responded out of 5 Requested
 X(orange) = Office of Compliance; 2 Responded out of 3 Requested

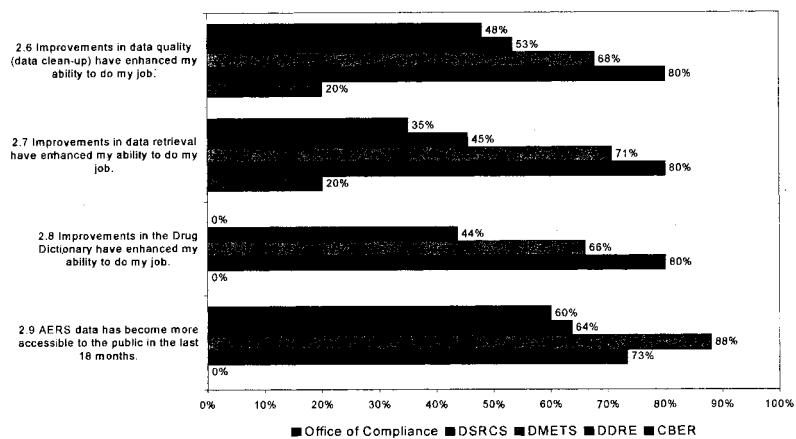
Program Management 1

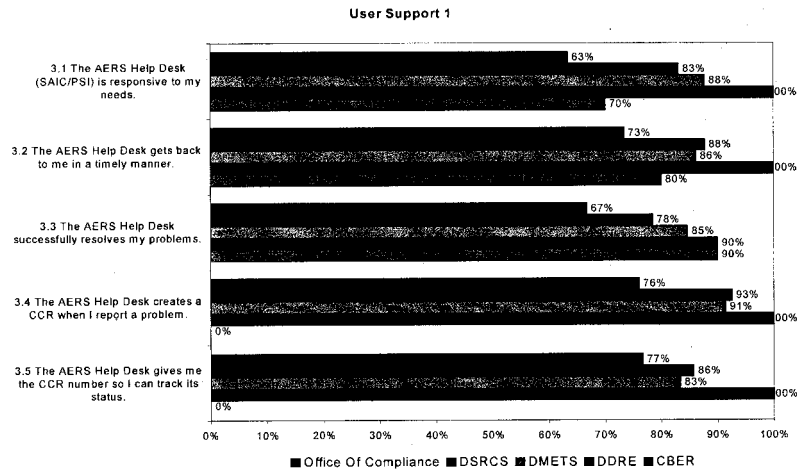




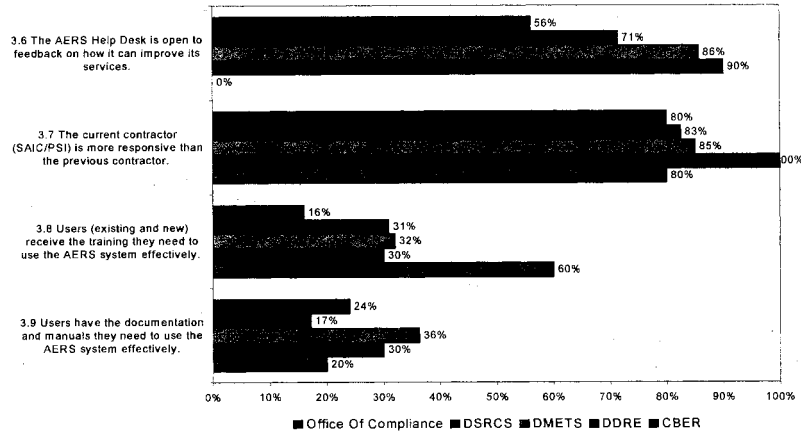


Functionality 2





User Support 2



APPENDIX A

AERS User's Satisfaction Survey Questions

This questionnaire is designed to collect information about the operation of the AERS Program from the perspective of a user. Read all questions carefully and give the most accurate and honest response you can, based on your *personal knowledge* of:

The functionality of AERS system,
The performance of the AERS Program Office, e.g. Charles Stone, and
The performance of the AERS Help Desk, e.g. SAIC/PSI.

There are 27 radio button questions and five open ended questions. Remember that answering "Don't Know/No Opinion" is as valid an answer as any of the other choices are. Since the questionnaire is asking for your *personal knowledge* about the three bullets listed above, if you have *second hand knowledge* or no knowledge at all, then your answer should be "Don't Know/No Opinion."

Mark your answers by moving your cursor to the radio button associated with your response, "click" the mouse and a bullet will appear. If you change your mind, click a new choice and your original selection will automatically be removed.

If you save this file while taking the survey your answers will be saved. You can resume taking the survey at a later time by opening the saved file and continuing.

After you have completed the survey, save your results to your computer. Attach the saved file to an e-mail and send it to elinbcg@aol.com.

If you have any questions, please contact Elin Larson with the Breckenridge Consulting Group at 719-836-9797 ext. 3 or elinbcg@aol.com.

Your Answers are Confidential

In accordance with Public Law 93-579 (Privacy Act of 1974) providing personal information is completely voluntary. Collection of this information has been authorized by Sections 1302, 3301, and 3304 of Title 5 US Code. Your answers are COMPLETELY CONFIDENTIAL. Completed surveys are sent directly to the Breckenridge Consulting Group Inc. for analysis. No one in FDA will have access to your individual responses. Your individual responses will be compiled and summarized with the responses of other participants into an overall summary report, so no one will be able to identify your individual answers.

Program Management

- 1.1 – The Change Control Board (CCB) process has been functioning more effectively in the last 18 months.
- 1.2 – Change Control Requests (CCR) are being processed at an appropriate rate.
- 1.3 - My representative on the CCB is responsive to my needs.
- 1.4 - My representative on the CCB gets back to me in a timely manner.
- 1.5 - The AERS Program Office is responsive to my needs.
- 1.6 – The AERS Program Office gets back to me in a timely manner.
- 1.7 - The AERS Program Office is open to feedback on how it can improve its services.
- 1.8 – The AERS Program Office keeps me informed via articles in the ODS Monday Memo.
- 1.9 – The AERS Program Office will take corrective action on issues identified by this assessment.

Functionality

- 2.1 – The functionality of the AERS system is adequate to perform my job (analytic techniques, search algorithms, data-mining, etc.).
- 2.2 - The overall functionality of the AERS system has improved in the last 18 months.
- 2.3 – New releases of AERS software fix problems that improve my ability to do my job.
- 2.4 – MedDRA upgrades are performed every 6 months so that FDA is up to date
- 2.5 – MedDRA upgrades don't negatively impact my ability to do my job.
- 2.6 – Improvements in data quality (data clean-up) have enhanced my ability to do my job.
- 2.7 – Improvements in data retrieval have enhanced my ability to do my job.
- 2.8 - Improvements in the Drug Dictionary have enhanced my ability to do my job.
- 2.9 – AERS data has become more accessible to the public in the last 18 months.

User's Support

- 3.1 – The AERS Help Desk (SAIC/PSI) is responsive to my needs.
- 3.2 – The AERS Help Desk gets back to me in a timely manner.
- 3.3 - The AERS Help Desk successfully resolves problems I contact them about.
- 3.4 - The AERS Help Desk creates a CCR when I report a problem.
- 3.5 - The AERS Help Desk gives me the CCR number so I can track its status.
- 3.6 – The AERS Help Desk is open to feedback on how it can improve its services.
- 3.7 - The current contractor (SAIC/PSI) is more responsive than the previous contractor.
- 3.8 – Users (existing and new) receive the training they need to use the AERS system effectively.
- 3.9 – Users have the documentation and manuals they need to use the AERS system effectively.

Written Questions

How many hours per day do you waste on AERS-related inefficiencies (for example, rework, work-arounds, timeliness, downtime, lack of functionality, inability to get user support etc.)?

Describe three areas in which you personally observe these AERS-related inefficiencies occurring.

List the AERS system's top three strengths.

List the AERS system's top three weaknesses.

How would the proposed AERS II system positively impact your ability to do your job?

APPENDIX B
Interviews Conducted

The Breckenridge Consulting Group conducted fourteen interviews to gather more detailed information on the Program Management, Functionality, and User Support dimensions of the AERS Program. These interviews were conducted on-site at FDA's Parklawn Building on May 24-25, 2005 and by phone on June 1-2, 2005. The following list of people were interviewed:

- Charlie Stone
- Paul Seligman
- Ralph Lillie
- Marilyn Pitts
- Andrea Feight
- Carol Holquist
- Ann Mackey (Corken)
- Denise Toyer
- Lynette Swartz
- Martin Pollock
- John Quinn
- Anne Gaines
- Miles Braun
- Lise Stevens

APPENDIX C
Unedited
Verbatim Comments

AERS Inefficiencies

"Describe three areas in which you personally observe these AERS-related inefficiencies occurring."

Area	Category	Specific Comments
Functionality	Drug Dictionary	<p>Lack of drug dictionary (requires entering verbatim trade and active ingredients)</p> <p>Too many names in the drug dictionary due to typos</p> <p>Drug dictionary and the ability to properly capture CBER-regulated products</p> <p>Drug name searches</p> <p>Drug Dictionary</p> <p>Biological products in drug dictionary are incompletely supported.</p> <p>Poor Drug Dictionary work-around: Inconsistent coding of the fields "Trade Name" and "Active Ingredient", especially for Biologics (I am in CBER), force users to spend hours creating an extensive "drug list" for each product. These lists are created using as many variations as the user can think of (spelling, nicknames, generic names, trade names, common names, etc.) so they are obviously not entirely scientific and not even these are comprehensive.</p>
	Data Quality And Integrity	<p>Data clean-up, which should be performed routinely but is not (e.g., MFR cases that should have been merged but were not, suspect products that have not been validated).</p> <p>Resolution of data discrepancies in different canned searches (e.g., differing # of cases retrieved depending on which canned program is run, especially when using identical search criteria).</p> <p>Inconsistency in retrieval of AERS cases</p> <p>Some of the things we find out later (date of birth calculation errors, etc) make one lose a lot of faith in the system.</p> <p>Data dictionary and data clean up problems take years to correct</p> <p>Inconsistency in data counts</p> <p>Get different counts on cases series depending upon when you search</p>
	Batch Printing	<p>Batchprinting used to be a problem, but it is much improved.</p> <p>Batch print</p> <p>Batch printing nonimaged reports</p> <p>Batch printing e-sub reports</p> <p>Having to reprint reports due to the AERS printer not functioning</p> <p>Batch printing.</p> <p>Printing reports via batch.</p> <p>Printing of the same ISR twice when sending to batch print</p> <p>Printing issues with e-subs</p>
	Reporting	<p>Mismatch of total report numbers with a total number of gender or age columns for the same run. They do not always add up to the total number of reports.</p> <p>Inability to directly query requires running individual canned reports that do not supply the appropriate data and then trying to manually piece together bits of data.</p> <p>Multiple runs to cover all means of capturing all cases for a particular drug and particular AE(s) or set of MedDRA terms.</p> <p>Downloading to Excel using AERS DataMart.</p> <p>Recurrent need to re-evaluate duplicate/multiple reports each time case-series need updating</p> <p>No easy way to update a case series because of the latency (timeliness) in entering periodic reports.</p> <p>When updating follow-up reports to create the best rep, need to maintain the first report date for other further analysis.</p> <p>Inability to create custom reports</p> <p>Inability to retrieve canned reports on saved searches</p> <p>Inaccurate counting of reports</p> <p>Finding correct reports - drug, drug qualities, reactions</p> <p>Delay in reports getting in to the system</p>
	Searching	<p>Inability to do customized searches from text</p> <p>Data retrieval, data searching, standard report discrepancies, and other new areas of searching that have not been previously identified</p> <p>Manual, offline case analysis (e.g., Excel spreadsheet) because AERS can't run searches needed</p>

		to answer seemingly routine postmarketing surveillance questions. Inability to conduct more specific searches accurately (e.g. unable to retrieve single ingredient only reports or combination only reports)
	System Performance	Running a query and the system locks up Locked out of database, significant time to get back in AERS down Screen freezes... need to re-boot Printing or Previewing Standard Reports takes a long time - don't know if the function is frozen or if it's just taking a long time so you end up repeating it and then come to find out that it's just taking a long time (need an hour glass to let us know it's "working on it" rather than something is wrong). FOI request - slow response time and printing The slow retrieval appears to slow down the overall performance and speed of other applications on my computer. Timeliness of search results and the inability to predict when they will be completed Timeliness: AERS searching is so slow that it often ties up even the fastest computers. Our CBAERS contractor tell us that he has identified many optimization problems that have been remedied in CBAERS, making CBAERS queries much faster.
	Technology	Since AERS is not web based, have to use a coworker's computer if there are program file problems with my computer.
	Upgrades	Losing functionalities when AERS is updated QC/audit of individual saved MedDRA reaction lists following MedDRA upgrades, instead of that having that been performed as part of MedDRA upgrades.
	Inbox	Scrolling down to the bottom of my Inbox and the entire Inbox jumps up to the top of the screen. Functionality of inbox is abysmal. DMETS has to print all of the medication error reports since the SEs don't have inboxes
	Functionality Missing	Can't get the data I want out of AERS because CCBs not implemented. Case Linking CBER drugs with PLA/STN Number possibilities We use CBAERS extensively at CBER for access to AERS data in ways that AERS software does not support and for faster response time. Analysis work-around: There is no way to create a case series in AERS than can be saved and imported into another data format for analysis. In CBER, we use CBAERS to conduct detailed queries of AERS data, then use business objects download these case series into excel (or any other format) for statistical analyses. CBAERS is excellent- its much faster than AERS, and the contractor is able to continually customize the data retrieval options per our exact needs. At our request, CBAERS has added a field for "Date that first ISR was received by FDA" which more closely approximates event date and has the ability to search the narrative for specific words or text strings, and many other enhancements.
User Support	Documentation	No user documentation/manuals, need to ask help from other users Very little system documentation seems to exist
	Training	Training references, course offerings Users generally receive no formal training in AERS
	Other	Too long to get AERS problems solved Workarounds to problems that have never been addressed The development cycle to fix problems and add enhancements is also much faster with CBAERS than with AERS.
Program Management	Other	Continue to invest CBER IT resources to support a CBER AERS datamart

AERS Strengths

"List the AERS system's top three strengths."

Area	Category	Specific Comments
Functionality	User Interface	User friendly Easy to use Fairly easy to use. Autocode very helpful. Ability to retrieve adverse event reports and/or reports associated with drug x without learning a programming language (No documentation available however)

		Screens are easy to read Friendly, point and click If trained appropriately, it's easy to use
	Reporting	Good for quick counts Ability to save query Ability to save case series Stores electronic reports Moderate capability to retrieve information Reasonably comprehensive list of "canned programs." Cases are generally easily retrieved. Report Generation Saving files
	System Performance	Speed (most of the time) Mostly quick retrieval of results Speed
	Drug Dictionary	Update of the MedDra dictionary PSI coding superior to sponsor coding
	Functionality Overall	Good repository system Allow for electronic search of large database Volume of data Most extensive AE reporting system in the world. Computerized. Timely availability for serious, non-label adverse event retrieval One of the worlds largest systems for Adverse event data Shares data with the WHO and with researchers who take the time to create a database out of ascii download data 150,000 reports entered per year/ data from 1969 that was reported to FDA Overall, it is impressive given the complexity of the system and number of reports Generally supports the mission of the group Electronic central repository Desktop access Addition of indications field (previously not entered under the SRS) Reviewer specific drug lists: ability to create and save product lists and reaction lists are critical for our work. Retrieving these by name fo the list of by reviewer is also helpful.
	Searches	Good for simple searches. Flexible search strategies (vs SRS) Saved Searches Saved Search Criteria Searchable
	Other	BAH is GONE!
	Data Quality And Integrity	Attempts to combine duplicates Some ability to identify multiple (updated) reports from a single reporter Great data Although we don't get all of the cases because of possible miscoding, it gives us a pretty good idea of the number of cases we have. MedDRA Coding Accuracy
	Technology	Ability to create pdfs of AERS reports & ISRs. This has gotten faster, more reliable. Ability to view images easily. Oracle based system Electronic Submissions Images: the ability to retrieve complete and clear images of the original reports is critical for our events (which usually occur in small but important numbers).
	Inbox	Interaction: Here at CBER, we recently discovered that each reviewer could examine other reviewers inboxes, helping us to cover products while folks are away on vacation, etc.
	User Support	

Program Management	Other	Responsiveness of new program staff (Charlie & Tim) Program/project management

AERS Weaknesses

"List the AERS system's top three weaknesses."

Area	Category	Specific Comments
Functionality	Drug Dictionary	<p>Lack of "drug dictionary."</p> <p>No drug dictionary</p> <p>Drug Dictionary</p> <p>Needs a good Drug Name dictionary so we don't have to check trade & ingredient names nor each multiple ingredient drug name.</p> <p>Drug name dictionary makes drug retrieval questionable especially when you start searching at the ingredient level</p> <p>Accurate and adequate drug dictionary</p> <p>No drug dictionary or manufacturer reference</p> <p>Drug dictionary issues with combination products</p> <p>Drug and Company Dictionary</p> <p>The drug dictionary is unreliable. Coders need better rules for exactly how to classify a report based on the verbatim entry for product name. There should be exact specifications for what to put into "trade name" and active ing.". Further, training on what these coding rules are should be provided to the safety evaluators. Input for these rules should be provided by the safety evaluators responsible for each product; that should include the safety evaluators for biologics in CBER!</p>
	Data Quality And Integrity	<p>Duplicates</p> <p>Archaic data retrieval system (may be due to data entry)- unsure if you have captured all cases</p> <p>Fear that data retrieval is not duplicable</p> <p>Data integrity</p> <p>Lack of consistency between # of cases retrieved with different canned programs, even when using the same search criteria</p> <p>Data entry emphasis is on speed, not quality, and correction of data is discouraged.</p> <p>Difficult to determine duplicates electronically</p> <p>Duplicate/multiple reports for one case and no routine way to identify matches other than manually reviewing images each time the case series needs to be evaluated particularly those sent by different reporters.</p> <p>Non-transparent rules about what gets into AERS and what does not get into AERS.</p> <p>Concern that I do not have all the cases because of a lack of data entry standards (leaking blanks, extra comma, misspellings etc.)</p> <p>Misspellings in drug names</p> <p>Multiple entries for same drug because of misspellings</p> <p>Only Japan and US code at the PT level. We need to code at the drug level like everybody else.</p> <p>Drug dictionary is scary - someone needs to clean up the typos and custom names. I don't know if I am getting all the case reports...</p> <p>CBER drug tracking</p>
	Batch Printing	<p>Printing out cases is a hassle. There are always glitches with printing, takes time to make sure you have all the cases. We used to have all reports printed out (via microfilm of course) by a technician. Now, SEs and Epis are spending a lot of time gathering up reports before starting a review and there are ALWAYS batch printing glitches.</p> <p>Needs to be connected to a high speed printer.</p>
	Reporting	<p>You can never be sure if you captured all reports</p> <p>Report number changes if you repeat the same search another day with same criteria</p> <p>Cannot link reports</p> <p>Inability to print out microfiche reports</p> <p>Wastes LOTS of paper on Standard Reports</p> <p>Lack of ability to directly query data</p> <p>Sometimes difficult to eliminate unwanted reports, requiring excess "weeding" through reports</p> <p>Data Mining: To my knowledge there is no capability to directly compare the degree of adverse event reporting from any particular product with the reporting for other products within</p>

		a class or all products.
	Searching	<p>One needs to be quite savvy with different search strategies i.e., search under NDA numbers, fuzzy search and how one should select drug names</p> <p>Can not search within a search (data limiting)</p> <p>Can not merge hitlist</p> <p>Inability to allow word search</p> <p>Returning searches</p> <p>Inability to modify programs/search results (e.g., can't easily restrict search results to specific subset of cases; therefore, summary statistics for subsets of cases need to be calculated manually or maintained in separate Word/Excel documents</p> <p>Saved case series is very hard to use. No way to subdivide into folders, etc, so end up with dozens of searches mixed up together.</p> <p>No generic ingredient search capability</p> <p>You have to enter in verbatim names</p> <p>Difficult to do specialized searches</p> <p>Unable to perform complex searches</p>
	System Performance	<p>Difficulty with being locked out when searching for reports</p> <p>Can be very slow.</p> <p>Slow at times</p> <p>System stalls and becomes unresponsive at times</p>
	Technology	<p>Unable to download directly from AERS into Excel.</p> <p>Lack of transportability to other platforms (Excel) for data manipulation.</p> <p>Didn't find functionality that allows me to export data into excel spreadsheet</p>
	Inbox	<p>Inbox format is awful, very user-unfriendly. Great for data processing, and getting reports into electronic database. TERRIBLE for real humans to use as their primary way to read Serious ADRs.</p> <p>Reports go to one Inbox</p>
	Functionality Missing	<p>Inability to single out dosage forms as product characteristic</p> <p>Inability to capture data from text</p> <p>No standard data fields</p> <p>Lack of data field identification and mapping</p> <p>Can't export custom reports (e.g. create reports with an ability to sort by SOC, HLGT, etc.)</p> <p>Can't export narratives to do searches for text strings</p> <p>No trend analysis or data mining module</p> <p>Limits on the ability to "Select All" when products are listed.</p>
	Other	<p>Timeliness of data entry for periodic reports.</p> <p>Complicated data architecture/structure</p> <p>MedDRA browser function is not easy to use nor is the whole system user friendly</p> <p>Down Sampling of Electronic Submissions</p>
User Support	Documentation	Lack of documentation
	Training	<p>Lack of proper training</p> <p>Lack of user training</p> <p>If there is an online or similarly accessible training program for AERS, I have never heard of it. TRAINING!: We never received any. (Except informally from other safety evaluators. But there are so few AERs users in CBER that's not an effective way of learning.) . I've been here 6 months and learned how to do a risk assessor summary last week. I've seen my inbox but I'm not really sure how to use it. I can retrieve cases and do queries but I have no idea how to save data or do analysis in AERs (I think it can actually do these things). I'm still not sure how to merge files. I learned how the database was set up by using CBAERs (trade name, active ingredient, verbatim, drug lists, etc.). I'm not sure I ever would have figured it out otherwise.</p>
	Other	<p>Glacial movement of CCB resolution</p> <p>Exceedingly lengthy development cycle to fix problems and add features</p> <p>Exceedingly costly development, so that many originally designed features were omitted, and refinements often seem too expensive to warrant addition now</p>

AERS II*"How would the proposed AERS II system positively impact your ability to do your job?"*

Area	Category	Specific Comments
Functionality	Don't Know	<p>I have not assessed AERS II yet.</p> <p>I am unfamiliar with AERS II</p> <p>I'm not sure, I'll have to evaluate it when it comes out.</p> <p>I don't know anything about the AERS II system</p> <p>I don't know the details of the proposed AERS II system.</p> <p>Don't know.</p> <p>I don't know.</p> <p>Do not know</p> <p>I don't know enough about it yet.</p> <p>Not Sure</p> <p>We have not had any formal training on the capabilities of AERS II, or personal input into its development, so I cannot say. (Of course, we never had any training on the current AERS system either).</p>
	Data Quality And Integrity	<p>Access to all reported records sooner</p> <p>Ability of the system to standardized data entry and correct misspellings, leading/trailing blanks at time of entry so that we can feel more assured of retrieving all records in a series.</p> <p>Ability to identify duplicate ISRs</p>
	Drug Dictionary	<p>Inclusion of "drug dictionary."</p> <p>Standardize drug queries with the use of a drug dictionary to be assured of retrieving all mentions of the drug being reviewed.</p> <p>Improved drug dictionary will decrease the level of effort required to build custom drug lists for CBER product queries</p> <p>Control of the drug dictionary</p>
	Reporting	Add long-needed reports and functionalities.
	Searching	<p>Ability to run searches tailored to specific post-marketing surveillance needs.</p> <p>Ability to define or otherwise specify data fields, search requirements, search output, and so forth.</p> <p>100% make post-marketing searches easier to conduct, review, etc</p> <p>Searching capabilities enhanced</p>
	COTS	<p>Hard to say what AERS II will be. I think the strong economics of COTS will push them in that direction. I think the initial cost of the system will be very reasonable but FDA will not own source code and cannot dictate changes in a COTS product.</p> <p>In the past we were frustrated by not having the people to do data clean up projects, new types of reports etc. I think we will end up moving to COTS but in this case the program providers will say things like</p> <p>"our users feel the current data structure is ok, and so our the reports so we have no plans to implement the change FDA has suggested."</p> <p>"Some of our users have suggested the change that FDA put forward, we might move in this direction in a couple years, we will see"</p>
	Technology	<p>Ability to "cut and paste" DRUGLISTS and REACTIONLISTS from database into offline documents.</p> <p>Web access from anywhere (office, home, etc.).</p> <p>Web access will allow off-site work</p> <p>Web Based Product to be accessed remotely</p> <p>Ability to share redacted data on the web</p>
	System Performance	Improved system/data architecture will make it easier to perform system maintenance or implement new functionality without negatively affecting other parts of the system
	Functionality	<p>Improved FOI module will reduce the time required to produce FOI listings</p> <p>AERS II is just a name; there needs to be medically intelligent data capture and intelligent product and manufacturer subsystems integrated in any newer system</p> <p>Improve efficiency</p>
	Other	<p>Improve on the current AERS system with lessons learned.</p> <p>I think as the number of reports that FDA gets increases through legislation that mandates</p>

		reporting, the old way of reviewers with mailboxes and the reading of individual reports will become unworkable and they will need to start looking at data mining as a way to review ever larger data. This may be ok for industry where they get only a relatively small number of reports each. It may not work for FDA. I think AERS data will always be an important tool in initial signal detection but as we look more and more at the long term impact of drugs other data sources that we buy (IMS, CMS, etc) we will use AERS more and more for signal detection and other data bases for regulatory decision making
User Support	Documentation	
	Training	
	Other	Include solutions to longstanding CCBs.
Program Management	Other	If it integrates the positive elements of AERS along with those of CBAERS, including expedited turnaround time for fixes and enhancements, it could improve efficiency by allowing us to concentrate on a single system, instead of having to learn and use and maintain two in parallel.

APPENDIX D

Initial Observations for Improvement

An initial set of interviews was conducted by BCG on March 11 and 12, 2003, with about 25 people being interviewed from ODS, DSRCS, DMETS, CBER, DDRE, OB, CDER OIT, CDER OIM. We used the then current version of the CDER OIT/OIM Strategic Plan (February 2003), as a guide for what the FDA needed from the AERS system. The interviews resulted in Initial Observations for Improvement that helped focus the ODP process. The complete list of these observations is listed below.

Observation 1-2003 (Description and Purpose)

This project is not strictly speaking a "strategic planning" effort because strategic planning assumes that there is an organization that is doing the planning. The organizational flux of OIT, OIM, a temporary home for the AERS system in OPSS, and the move to its eventual home in OIM is more like a business process reengineering project (BPR) combined with a strategic planning effort. I tried to take all of this in mind when laying out Organizational Design and Planning Process (ODP).

Observation 2-2003 (Project Management)

The management oversight of the BA contract has been frustrating to OIT and users alike. This needs to be corrected through the planning process. OIT is taking many positive steps to do what can be done now by moving the BA people on site so they will be more accountable and OIT can download information that BA now has sole possession of. They are also having Oracle come in and back-engineer the existing AERS system to get as much documentation as is possible. The consensus of the people I talked to was that the structure of the BA contract, the CCB, and the CCR systems all need to be reengineered.

Observation 3-2003 (Communication)

As is so often the case, the IT people and the users have different professional paradigms and talk past each other. Although the OIM plans to hire business analysts to "mediate" between these groups, this is a function that has been and continues to be missing, complicating communications. I developed the proposal using: a) typical team building, and consensus building techniques that will be familiar to non-IT people, and b) The CASE Method: Tasks and Deliverables text by Richard Barker, published by Oracle. This is a standard text that IT people use to plan and implement large data systems.

Observation 4-2003 (Poor System Design)

The brief technical discussions that I had seemed to indicate that the Oracle back-end of AERS was not designed properly and would not be a suitable foundation for a future system (e.g. the data are not normalized, many data tables were designed using embedded information which limits data flexibility, etc). This probably eliminates the possibility of just putting a new front end on the existing AERS system to increase functionality, but one of the initial tasks in the proposal would be for an OIT/OIM working group to determine this to first order. A formal alternative analysis is part of the proposal. Interviews indicated that what could have been a well-designed relational database, became a kind of two-dimensional flat file system that produces lists of information but lacks even the analytical capabilities of an Excel spread sheet. While things like the Data Mart, CBEAR, etc have been able to increase analytical capabilities on a user-group, by user-group basis, and while the data-mining project appears to be a more complete solution, these are expensive and time consuming work-arounds that would probably not be necessary with a well-designed system.

Observation 5-2003 (Lack of Documentation and Training)

The difficulties of back-engineering the AERS system because of a lack of documentation, pale in the light of trying to reconstruct the history of what the original specifications and system functionality were and

developing up-to-date user documentation and training. This is important because it defines a) what functionality was not delivered by BA that was promised, from b) "functionality creep" where users want more and more bells and whistles after the fact - beyond the scope of the original system. The documentation on how to use the system that does exist is badly out of date and currently there is no formal training on how to use the system.

Observation 6-2003 (Electronic Submissions)

Electronic submissions will increasingly become a serious problem (especially given the requirement in the recent rulemaking). Interviews suggest that the main problem with increasing the number of electronic submission from its current rate of about 25% is on FDA's end. If everyone went to electronic submissions tomorrow (let's say as a result of rule making), the IT structure at the agency could not handle it because of limitations of the data lines into the central IT structure (mainly due to attachments). Interviews also indicated that this limiting aperture could be eliminated with about a \$200K upgrade to FDA systems. Of the \$8M per year spent on AERS, about \$6M goes to data input. One approach might be to invest the \$200K, encourage electronic input to radically reduce the amount of data input need, then leverage the \$6M by using it to pay for the design and construction of a new system.

Observation 7-2003 (AERS Ownership)

Ownership of the AERS system is a problem. If everyone is responsible, then no one is responsible. My proposal addresses this.

Observation 8-2003 (AERS Activity)

Estimates of the "usability" of the system range from 60-90% depending on who was asked. What seemed clear was that the system is useable, but there are multiple work-arounds that users must do in order to make it usable (cleaning up data, depending on their memory and knowledge for heuristics and analysis, etc). Given this level of usability, all revisions might be frozen, and this time and energy could be invested in the ODP process and looking toward a new system.

Observation 9-2003 (IT Consolidation)

The role of the IT consolidation effort within FDA needs to be taken into consideration regardless of whatever path is taken, especially if this results in a 3-5 year strategic plan. The centralization of IT/IM resources and line management responsibility to the CIO must be factored into any future AERS system.

Observation 10-2003 (System Interfaces)

The possibility of interfacing with other systems inside the FDA (Drug Quality Reporting System, Clinical Trials system), and outside the FDA (AHRQ safety net, etc) needs to be seriously considered.

Observation 11-2003 (Identify All Users)

All users' needs and requirements must be taken into account including, safety evaluators in OPSS, biologics, medical errors, epidemiologists, compliance people, FOI, and the 15 Review Divisions. The consensus on system requirements must be part of the written documentation of the next AERS system so that the baseline of functionality and user requirements can be teased apart from, the normal course of functionality creep of systems of this size.

Question. Please provide a breakdown of all expenditures on AERS II since inception.

Answer. Approximately \$1,405,000 has been spent on the Adverse Events Reporting System II, or AERS II, project since its inception and the breakdown of expenditures is: development of high level requirements, \$140,000; system requirements specification, \$315,542; contract support, \$54,558; development contract support, \$578, 000; and program management support, \$219,996; Organizational Design and Planning work, \$10,000; and Independent Verification and Validation work, \$97,340.

Question. Please discuss any and all actions FDA is taking in response to this report.

Answer. The Breckenridge report made three recommendations. The first two recommendations allude to problems with organizational culture which are being ad-

dressed on a higher, more inclusive level than the cultural problems related to this particular report. FDA and CDER recognize the need to improve our culture, and we are addressing the issues raised on that topic by the Institute of Medicine, or IOM, Drug Safety Report. I refer you to the FDA response to the IOM Drug Safety report at <http://www.fda.gov/oc/reports/iom013007.html> for more details.

The third recommendation suggests FDA begin the process of acquiring a replacement for Adverse Events Reporting System I, or AERS I, immediately. Despite allegations in the Breckenridge report that we differ with, AERS II development has continued to move ahead, and a timeline has been developed with initial operations projected for fiscal year 2008. Materials such as the requirements mapping associated with the Breckenridge report are being used in developing AERS II, in addition to other requirements documents that are already available.

USER FEES

Question. Please provide us with a brief update on the reauthorization of both the Prescription Drug and Medical Device User Fee Acts. What is status of MDUFMA negotiations?

Answer. On March 23, 2007, the Secretary transmitted to key House and Senate authorizing committees the HHS/FDA recommendations for changes to the statute and to the performance commitment letter for the Prescription Drug User Fee Act IV, or PDUFA IV. These recommendations reflected the results of FDA's discussions with the pharmaceutical and biotechnology industry, which concluded in November 2006, and further revisions to the commitment letter based on public input received in response to the January 16, 2007 Federal Register R notice publishing FDA's proposed recommendations, and received at the PDUFA IV public meeting FDA held on February 16, 2007. FDA's recommended changes to the statute and commitment letter are currently being reviewed by the Senate Health, Education, Labor and Pensions, or HELP, Committee staff and House Energy and Commerce Committee staff.

FDA and the medical device industry have been discussing legislative recommendations for the Medical Devices User Fee and Modernization Act, or MDUFMA, reauthorization since the fall of 2005. Almost all issues of interest to FDA and to industry have been resolved. We are working to resolve the outstanding issues very quickly.

Question. How will you work to ensure that any "triggers" included in these pieces of legislation are continually, and fully, funded in your budget request?

Answer. We will work to ensure that the Agency's annual budget enables FDA to meet the performance goals it has committed to under PDUFA IV and MDUFMA II.

PROPOSED USER FEES

Question. The budget includes new proposed mandatory user fees for reinspection costs and for export certification, which if enacted, would bring in an additional \$27 million to FDA. Please explain the need for these user fees.

Answer. FDA is re-proposing from fiscal year 2007 two user fees that would fund activities currently supported by budget authority dollars. The proposed user fees for Reinspections and Food and Animal Feed Export Certification are mandatory user fees. These fees will replace budget authority in FDA's budget. In fiscal year 2008, if Congress enacts these user fees, any fees collected for these two proposed user fees will result in an equal transfer of budget authority back to the U.S. treasury. In fiscal year 2009 FDA will not need any budget authority resources for these activities if Congress enacts the user fees.

When a company fails an FDA inspection, we are asking Congress to impose the cost of conducting follow-up inspections on the company. When we find a violation, FDA typically conducts a follow-up inspection to ensure that the problem is corrected. Currently, if companies fail to comply with FDA standards, then FDA must shift resources from other public health activities to reinspect the company and confirm they have corrected the problem. What we recommend is that the company pays the cost of follow-up inspections when FDA finds health or safety violations. It is important for companies to ensure the safety of products before the products reach consumers and this user fee provides an additional incentive for companies to meet FDA safety standards.

In the case of food export certificates, we are asking Congress to impose the cost of preparing export certificates, required by foreign governments, on the companies that export products. Currently, FDA charges exporters for certificates in all other FDA product areas except foods for this service. As with the reinspection user fee

proposal, we recommend that the company benefiting from this service pay for this service.

Question. If these user fees were enacted, would there be a subsequent decrease in discretionary budget authority needs?

Answer. Yes, there would be a subsequent decrease in discretionary budget authority needs if the user fees are enacted. However, the current proposals are structured in such a way that budget authority of \$27 million is initially requested by FDA at the beginning of fiscal year 2008 to continue these activities in case the user fee proposals are not enacted in a timely fashion. If the user fee proposals are enacted and become fully operational in fiscal year 2008, the collection of these user fees will result in decreases of equal amounts in discretionary budget authority that will be returned to the Treasury. If enacted, no budget authority resources will be needed for these activities in fiscal year 2009, as they will be fully funded by user fees.

Question. How would the additional revenue be used at FDA? Is this reflected in the budget?

Answer. Revenue will not be used to fund new activities at FDA. The purpose of the user fee proposals is to charge industry FDA's current costs for reinspections and issuance of food export certificates. In FDA's budget request, \$27 million is initially requested at the beginning of fiscal year 2008 to continue these activities in case the user fee proposals are not enacted in a timely fashion. If the user fee proposals are enacted and become fully operational in fiscal year 2008, the collection of these user fees will result in decreases of equal amounts in discretionary budget authority that will be returned to the Treasury. If enacted, no budget authority resources will be needed for these activities in fiscal year 2009, as they will be fully funded by user fees.

PAY COSTS

Question. Will the funding requested for pay costs meet the actual need for pay and benefit increases at FDA in fiscal year 2008? Part of the reason there was such a hole that had to be filled in the Joint Resolution was because for several years, FDA has had to cut into program funding to fully fund their pay and rent costs. We would like to prevent finding ourselves in a similar situation 5 years from now.

Answer. The funding requested for the pay costs in fiscal year 2008 cover the mandatory government-wide annualized pay raise of 2.8 percent.

RENT

Question. The President's budget includes an increase of nearly \$30 million for Rent and Rent-related costs. It is a breathtaking amount, and it is interesting to note that the increase requested for rent alone is more than the requested increases for drug safety, food safety and medical device safety combined. Further, if the rent costs aren't accurate in the budget, as has happened in the past, increased rental needs have to come out of FDA program activities. How does the FDA rent costs compare to other Federal agencies of the same size? What actions have you taken to try to decrease these costs?

Answer. The President's budget includes a substantial increase for Rent-related costs due to the new White Oak facility and higher costs for essential services, such as utilities, security and service contracts to operate and maintain FDA's facilities. FDA is not privy to other Federal agencies' rent costs. GSA sets rental rates for all of its Federal tenant agencies as a pass-through of the underlying GSA lease contract rent for their leased facilities, and by appraisal based on comparable properties for GSA-owned facilities. Rent is charged per square foot occupied. Aside from the White Oak consolidation of headquarters locations, FDA has made considerable efforts in the past several years to consolidate, reduce space, or close existing offices. For example, the Office of Criminal Investigations recently co-located its Metropolitan Washington Field Office in Laurel, MD, and its Special Prosecution Task Force in Beltsville, MD, saving over \$50,000 in annual rent costs. Additionally, the Office of Regulatory Affairs (ORA) closed seven resident posts in fiscal year 2006, saving the Agency \$150,000 annually in GSA rent. We have notified GSA that we will be closing five additional offices in the coming months. Finally, ORA has developed a comprehensive proposal to centralize laboratory management. ORA plans to consolidate staff, equipment, and other resources from ORA's 13 laboratories into six existing laboratories located across the country. Seven lab facilities will be closed and returned to GSA. If approved as currently planned, these closures will save the Agency almost \$5 million in annual GSA rent.

Question. When can we expect to see decreases in these rent costs, as White Oak continues to be occupied?

Answer. Consolidation of the FDA in the field and at headquarters will result in operational efficiencies and improved quality of the work environment. For the headquarters consolidation, the total number of locations will be significantly reduced. However, the headquarters consolidation does not result in a reduction of space for the Agency's current occupancy. This is partially due to staffing increases provided by FDA's prior appropriations and industry funding of additional staff through user fees. Further, because the White Oak space is often replacing outdated facilities with leases that are from 15 to 20 years old, rents in the consolidated facilities exceed the rents that were paid for the outdated facilities. The White Oak consolidation does effect a savings when compared to replacing the FDA headquarters inventory through new leases acquired on an incremental basis as older building leases expire. Additionally, when consolidating to Government-owned space controlled by the GSA, there is typically a savings because GSA bills only the fair market value of space, with no administrative or overhead fees that would be added for a private-sector lease.

WHITE OAK

Question. The budget includes an increase of \$13.2 million for continued White Oak Consolidation. This will prepare the facility for 1,300 employees to move in during fiscal year 2009. Could you please speak to this increase and provide an update on White Oak. When do you expect everyone to be there?

Answer. The budget increase of \$13.2 million will make it possible for FDA to prepare Office Building 66 for the occupancy of approximately 1,300 staff from the Center for Devices and Radiological Health and support personnel from the Office of the Commissioner. The funding will enable FDA to provide furniture and furnishings for staff offices, support areas, and conference rooms; security system cabling and equipment; and IT and telecom equipment, cabling and services. There are five completed and occupied buildings at White Oak: Life Sciences I Laboratory; Office Buildings 21 and 22; Central Shared Use Building and the Engineering and Physics Laboratory which was just occupied in March 2007. Under construction are Office Building 51 scheduled to be complete in early 2008 and Office Building 66 scheduled to be complete spring 2009. Historic Building I and Office Buildings 31 and 32 are currently in design and construction completion is expected in November 2008 and November 2009, respectively. FDA plans to have everyone at White Oak in fiscal year 2013, depending upon funding included in the General Services Administration's and FDA's future appropriations.

RESEARCH REDUCTION

Question. The budget includes a requested decrease in funding of nearly \$4 million for outreach, coordination and research. Even more than that, I was surprised to read that part of that reduction was to come from the FDA Animal Drugs and Feeds program—including, and I quote from your budget, “research on prohibited materials in animal feed, research on microbiology of animal feed and feed commodities, and research on drug residues. In addition, the program will reduce Field activities supporting enforcement, investigations and compliance.” Canada very recently found a new BSE case. Please explain these proposed reductions. Have we really done all of the research necessary on animal feeds, and is it prudent to decrease enforcement and compliance activities?

Answer. The Center for Veterinary Medicine, or CVM, completed development of a real-time Polymerase chain reaction, or PCR, based method. Once field validation of the real-time method is completed, the field has a necessary tool to support enforcement of the feed ban. Companies are not marketing new rapid test kits for detecting prohibited proteins in animal feeds; therefore, CVM does not have additional test kits to evaluate.

The Office of Regulatory Affairs, ORA, intends to absorb the reduction of \$593K in the Animal Drugs and Feeds Program by reducing both personnel and operating funds for coordination activities in either the ORA Office of Enforcement; ORA Headquarters; or Compliance Officers and Public Affairs Specialists located in the Region and District Offices. Operating fund reductions will be taken in travel, training and meetings with State or industry officials to perform outreach activities in support of the Field Animal Drugs and Feed Program. Management and coordination functions will continue by using electronic media/technology and realigning and consolidating coordination responsibilities to improve efficiencies.

The research reduction allows CVM and ORA to fund the full cost of fiscal year 2008 priority initiatives.

OFFICE OF WOMEN'S HEALTH

Question. Please provide a list of all research activities funded by the Office of Women's Health in 2006 and 2007, including all recipients of the funds.

Answer. I would be happy to provide that for the record.

[The information follows:]

Recipient	Research Funding	Fiscal Year 2006	Fiscal Year 2007
IAG/NIH-ORWH	Specialized Centers of Research on Sex and Gender Factors Affecting Women's Health (SCOR)..	\$100,000	\$100,000
CDER	Prevalence study of all drugs used in pregnancy? ...	35,000
IAG/WHO&CFSAN	Develop and evaluate an effective COMBI program on sanitation and personal hygiene practices.	152,000
CDER	The MATT Consortium (Molecular Assays & Targeted Therapies) within the OBQI (Oncology Biomarker Qualification Initiative) specifically for a project on lung cancer.	25,000
GNSI	Development of the Clinical Review Template	100,065
CDER	Gender Differences & Impact of Pharmacogenomics in Rheumatoid Arthritis.	16,000	6,500
CDER	Women in Clinical Trials and Gender Analysis of Data in New Molecular Entities (NME) approved 2000-2002.	13,000
CDER	Impact of gender and pharmacogenomics on clinical efficacy, safety and pharmacokinetics of drugs used for treatment of alzheimer's disease.	16,000	7,500
CDRH	Evaluation of equality and availability of information on females included in mechanical circulatory support device trials.	32,900
CDER	Women in HIV Trials: A Comprehensive Review and Meta-Analysis.	9,500	9,000
CFSAN	Modulating effects on estrogens on food allergens induced lung inflammation in a highly sensitive rat model for postmenopausal asthma.	33,000
NCTR	Molecular mechanisms underlying gender-associated differences in the adverse reactions to the anti-retroviral agent, zidovudine (AZT): role of mitochondria toxicity.	93,800	87,000
NCTR	Sex Differences in chemotherapeutic toxicity: profiling of transporter genes in humans.	110,100	88,000
CDRH	Assessment of the accuracy of the Troponin Assay in the Diagnosis of Myocardial Infarction by Gender and How Gender Influences Treatment.	30,000
NCTR	Protective effect of vaginal Lactobacillus species against Staphylococcus aureus-mediated toxic shock syndrome.	42,500
CBER	HIV-SELECTEST: A novel assay for diagnosis of HIV infections in the presence of antibodies induced by candidate HIVE vaccines: Evaluation of gender bias in sensitivity and specificity.	135,000	38,000
UN of Arizona	University of Arizona: Dr. Marlene Freeman: PK/PD Sertraline in Pregnancy.	71,600
OC/OPPL	K.Morgan—Evaluation of How Best to Communicate to Health Care Providers about the Risks.	55,000
UN of Boston	50,000
UN of Wisconsin	University of Wisconsin: Dr. Gloria Sarto—PK/PD of selected antibiotics during pregnancy.	32,900
CDER	Quantitative Tumor Size—Survival Relationship in Oncology Clinical Trials.	52,000
CDER	Statistical analyses of gender-specific data from New Drug Application (NDA) submissions.	11,300
CBER	Gender Dimorphism in HIV Infection in Primary Macrophages and T-Lymphocytes: Kinetics of.	16,200

Recipient	Research Funding	Fiscal Year 2006	Fiscal Year 2007
AHRQ	JAG with AHRQ: Research on the Effects of Drug Exposures in Pregnancy.	25,000
CDER	Cardiac safety, and specifically to build on ongoing activities re: the ECG Warehouse and the.	50,000
CDER	Development of an HL 7 standard for the exchange of protocols, protocol summaries, and study.	50,000
UN of Wisconsin	PK/PD of selected antibiotics during pregnancy	16,300
CDER/OTCOM	Pregnancy Seminar: Pathways to Drug Development—A focus on Women's Health..	3,400
Total	1,384,165	339,400

Question. Please explain the process by which OWH determines how to fund research activities.

Answer. The FDA Office of Women's Health, or OWH, determines research funding priorities by coordinating with other FDA and HHS activities around women's health issues to leverage existing funds and target projects to meet Agency and Departmental priorities. OWH created a Women's Health Advisory Council with numerous Agency representatives to help identify areas of highest priority with respect to women's health and a better understanding of sex/gender differences. By participating with the HHS OWH, FDA OWH is able to identify cross cutting activities. The Office sends an announcement out to all Centers in the FDA announcing the availability of intramural funding for research projects aimed at protecting and improving women's health. The announcement specifies the research focus for the fiscal year (e.g. sex related differences in safety or efficacy of FDA regulated products) and the application due dates. Research Proposals, called Concept Papers, are drawn up within individual Centers and go through an initial screening by the respective Center's Women's Health Coordinator to evaluate the proposal's eligibility for context and institutional involvement. The Concept Papers are sent to OWH and to the Center Coordinators who independently rank the proposals based on the need and priority for women's health issues in the respective Centers. After a thorough assessment of the proposals, selected investigators are asked to further expand their proposals and submit to OWH for evaluation and funding. OWH identifies panels of experts to perform an independent review of the expanded proposals rating specific criteria such as Research Question, Study Design, Feasibility, Relevance, Performance History, Investigator Qualifications, and Budget. Final decisions on funding are based on scientific reviews (Center Scientists, external experts and OWH Scientists) and available funds.

Question. For fiscal year 2008, why are you proposing reducing the research funds of OWH?

Answer. To be clear, research funds for women's health activities are not reduced in our fiscal year 2008 budget request. Our budget proposes to transfer \$350,000 from the Office of Women's Health, which is located within the Office of the Commissioner, to the National Center for Toxicologic Research, or NCTR. This transfer has been proposed to augment ongoing women's health research within NCTR. In particular, NCTR research has focused on our ability to understand unique risks that women face when exposed to drugs, particularly on the risks to women's cardiac health. This transfer should not, by any means, be interpreted as a reduction of FDA's commitment to women's health. This transfer represents an amplification of an existing research portfolio to examine pharmacological effects on women's susceptibility to heart damage. It is not a diminishing of the Women's Health Initiative.

Question. The office was created in part because the Centers were not placing a priority on women's health. What research will NCTR fund on women's health?

Answer. NCTR research will continue to focus on our ability to understand unique risks that women face when exposed to drugs, particularly the risk to women's cardiac health. This transfer of research resources to NCTR will augment an already-robust portfolio of toxicology research focused on examining a wide variety of health-related topics.

Question. Why is it necessary to pull the funds from OWH if it is simply being transferred to NCTR, as opposed to letting OWH make the decision?

Answer. As stated earlier, this transfer has been proposed because the National Center for Toxicological Research, or NCTR, is where we have been using those funds to do research in women's health. The Office of Women's Health, or OWH,

serves as a champion for women's health both within and outside the agency. To achieve its goal, the OWH undertakes the following five activities:

- ensures that FDA regulatory and oversight functions remain gender sensitive and responsive
- works to correct any identified gender disparities in drug, device and biologics testing, and/or regulation policy
- monitors progress of priority women's health initiatives within FDA
- promotes an integrative and interactive approach regarding women's health issues across all the organizational components of the FDA
- forms partnerships with government and non-government entities, including consumer groups, health advocates, professional organizations, and industry, to promote FDA's women's health objectives.

I can assure this subcommittee that the proposed transfer of funds to NCTR, specifically for women's health research, will not in any way diminish the ability of the OWH to achieve its goal. Specifically, the OWH will have full input as an equal partner with regards to women's health research activities at NCTR.

DIRECT TO CONSUMER ADVERTISING

Question. What is the current funding level of DDMAC? Please provide a breakdown of staff.

Answer. The current funding level for the Division of Drug Marketing, Advertising, and Communications, or DDMAC, is \$4,991,000. DDMAC consists of 44 FTE. There are nine people within the immediate office of the director, which includes the director, deputy director, associate director, program specialist, 3 policy and enforcement team members, one labeling specialist, and one information-technology specialist. In addition there are four professional review groups totaling 20 reviewers and two technical information assistants; two direct-to-consumer review groups with seven reviewers and two researchers, and 2 vacancies; and one training and support group consisting of one person on board and a vacancy. The staff breakdown represents all full-time and part-time onboard staff and the current vacancies. The funding level does not include full payroll expenditures for all positions listed above.

Question. What percentage of DTC television advertisements are currently being reviewed?

Answer. In 2006, the Division of Drug Marketing, Advertising, and Communications, or DDMAC, reviewed and provided advisory comments on 27 percent of television ads before they were publicly aired.

Question. If the FDA's proposed user fee for DTC advertisements is not enacted, what additional funding amount would be required for FDA to double the productivity of the office? What would a doubling of DDMAC allow FDA to accomplish?

Answer. The Prescription Drug User Fee Act IV, or PDUFA IV, currently includes provisions for \$6.25 million a year for the advisory review of DTC television ads. If we do not receive the \$6.25 million a year as proposed in user fees, we would not be able to increase our productivity in the advisory review of direct-to-consumer, or DTC, television ads. With a doubling of the Division of Drug Marketing, Advertising, and Communications, or DDMAC, we estimate that we could cut our review time for these television ads nearly in half and review about two-thirds more of these materials than was possible in 2006.

Question. A recent GAO report stated that DDMAC should stop using informal criteria when prioritizing material for review, and should develop and publish criteria for prioritization and review. Please provide a cost and time estimate for FDA to develop and formalize this process?

Answer. FDA, like other regulatory agencies, exercises enforcement discretion in order to focus its resources on enforcement actions that would most impact public health. Although the Division of Drug Marketing, Advertising, and Communications, or DDMAC, does not document the criteria it uses to prioritize each direct-to-consumer, or DTC, piece received for review, DDMAC has identified criteria that are systematically applied to identify workload priorities for review of both draft and final DTC materials that have the greatest impact on public health. The DDMAC management team, and in particular the DTC group leaders, works with all the DTC reviewers to ensure consistent application. DDMAC exercises judgment in continually reevaluating its workload in light of these priorities, contingent on emerging scientific and regulatory events. The suggestion that each piece be reviewed under specified criteria, and that all reviews be documented, would require vastly increased staff to essentially review every piece in detail. What now happens is that experienced reviewers scan pieces for problems, recognizing our priorities, and choose the ones to pursue. We are currently evaluating this process to determine what, if any, changes are needed.

PROBIOTICS IN YOGURT

Question. Why does FDA require an IND when studying probiotics in food that is readily available on grocery shelves? Is this appropriate?

Answer. The determining factor as to whether an investigational new drug application, or IND, is required for a probiotic product is the intended use to be studied. Under the Federal Food, Drug, and Cosmetic Act, or FD&C Act, if a probiotic product is intended to be used as a drug, it is regulated as a drug, and an IND would be required. The FD&C Act defines a drug as, among other things, an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, as well as an article (other than food) intended to affect the structure or any function of the body. The Public Health Service Act definition of a biological product includes products containing microorganisms applicable to the prevention, treatment, or cure of disease or condition of human beings, and to which the FD&C Act applies.

On the other hand, where a food, including a dietary supplement, is studied to determine its effect on the structure or function of the body, without reference to any effects on disease, an IND would not be required.

Any clinical investigator or probiotic manufacturer interested in evaluating a probiotic product for the diagnosis, cure, mitigation, treatment, or prevention of a disease is encouraged to request a pre-IND meeting with FDA prior to submitting an IND.

Question. Since this research would not require the use of a drug manufacturing ability, because the product is already on the shelves, how can a researcher secure an IND?

Answer. The Investigational New Drug, or IND, regulations are provided in Title 21 of the Code of Federal Regulations, Part 312. The FDA internet site provides many informational resources concerning how to submit an IND and how to conduct a clinical trial under IND. Also, the Center for Biologics Evaluation and Research's Office of Communication, Training, and Manufacturer's Assistance may be contacted directly at 301-827-1800 for assistance in the process.

Question. Is there a way to allow for this research to move forward without requiring an IND that still provides the safety and assurance expected by the FDA from the public when conducting research?

Answer. If a probiotic product is to be studied for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, it needs to be evaluated under an Investigational New Drug, or IND.

CARBON MONOXIDE

Question. In FDA's March 2007 fresh fruit and vegetable guidance, FDA states that the use of low oxygen Modified Atmosphere Packaging (MAP) systems for perishable foods can promote the growth of spoilage organisms and pathogens that may be present. In light of this publication, and since MAP systems are also being used in fresh meat products, does FDA anticipate withdrawing its acceptance of the GRAS notifications that have been submitted to the agency regarding the use of carbon monoxide in fresh meat?

Answer. FDA is currently evaluating a pending citizen petition which requests that the agency withdraw its response letters to the "generally recognized as safe" notifications regarding the use of carbon monoxide in fresh meat. While our review of that petition is ongoing, we cannot comment on whether we anticipate withdrawing the response letters.

Question. Please provide a status on FDA's response to a citizen petition filed on November 15, 2005 (Docket No. 2005P-0459) regarding carbon monoxide in fresh meat? Please provide a date by which this citizen petition will receive a response?

Answer. On November 15, 2005, FDA opened a docket on a citizen's petition submitted by Kalsec, Inc. In their petition, Kalsec requests that FDA rescind the acceptance of a number of "generally recognized as safe" notices related to the notifiers' determinations that carbon monoxide (CO) is "generally recognized as safe" under specific conditions of use as a component in Modified Atmosphere Packaging systems (MAPs) used in fresh meat. FDA has received and continues to receive numerous submissions commenting on the Kalsec petition. We are evaluating the petition and place a high priority on preparing a timely response. However, due to other priorities and the ongoing review of the submissions commenting on the petition, FDA does not have a specific date when it will complete its review of the citizen's petition submitted by Kalsec, Inc.

OFFICE OF THE COMMISSIONER

Question. Do contractors and consultants report to the Commissioner or Chief of Staff? If so, what are their roles? Could these functions be done by existing permanent staff? If so, why are these individuals hired as consultants rather than as Federal employees?

Answer. There is one contractor who reports to the Commissioner. The contractor's role is to provide professional services in executive leadership development for all of the senior FDA leadership within the Office of the Commissioner and the Centers. Specific tasks include strengthening executive leadership, enhancing cross-agency integration, improving communication, mentoring and developing staff. These functions could not be performed by existing staff as the existing staff does not possess the breadth of knowledge and level of expertise as the contractor in the areas of executive development, coaching and organizational culture.

There is one contractor who reports to the Chief of Staff. This contractor has an extensive background in media and strategic communications and a thorough understanding of how outside organizations perceive critical FDA policies and initiatives. This outside perspective cannot be provided by existing permanent staff.

Question. Does the Office of the Commissioner have sufficient funds to pay for all of these staff with payroll dollars? Is there a "payroll deficit" for the Office of the Commissioner?

Answer. Yes, the Office of the Commissioner, or OC, has sufficient funding for approved staffing. In fiscal year 2007, OC does not have a "payroll deficit".

OFFICE OF COSMETICS AND COLORS

Question. What is the proposed fiscal year 2008 budget for the FDA Office of Cosmetics and Colors (OCAC) within the Center for Food Safety and Applied Nutrition (CFSAN) and the proposed number of FTE positions? How does this compare with fiscal year 2006 and fiscal year 2007?

Answer. The Center for Food Safety and Applied Nutrition (CFSAN) estimates that its appropriated fiscal year 2008 budget for the Office of Cosmetics and Colors (OCAC) will support 13 full time equivalent (FTE) positions and provide \$2.0 million for the cosmetics activities conducted by OCAC. Additionally, the non-appropriated Color Certification Program within OCAC will support 32 FTE positions with a budget of \$7.568 million in fiscal year 2008.

By comparison, in fiscal year 2006, the Agency's Cosmetics program was staffed at 30 FTEs with a budget of \$3.2 million which included staff in OCAC (not including the color certification program). In fiscal year 2007, all compliance and research components that were in individual program offices within CFSAN, including those in OCAC, were realigned to the Office of Compliance or the Office of Regulatory Science to concentrate these similar activities. Other FTEs within the Cosmetics Program left the Agency for various reasons, including retirement and buyouts. As a result, the estimated fiscal year 2007 budget for cosmetic activities conducted by OCAC is 13 FTEs/\$1.825 million.

Question. Is CFSAN planning to change the size or organizational structure of OCAC, and if so, what is the new organizational plan and how would OCAC be structured within CFSAN?

Answer. In February 2007, as part of CFSAN's proposed reorganization, CFSAN changed the size and organizational structure of OCAC. In fiscal year 2006, the entire cosmetics program was located in the Division of Cosmetics and Compliance. In fiscal year 2007, compliance and research components that were in individual program offices within CFSAN, including those in OCAC, were realigned to the Office of Compliance and to the Office of Regulatory Science to concentrate staff in offices with a particular focus. As a result, there was a significant reduction in personnel within OCAC.

Question. The size of the personal care products industry is \$60 billion, with over 11 billion products sold annually, and with over 2,500 facilities in the United States. In the last 25 years there has been a vast expansion of personal care products. However, the number of FTEs in the OCAC has decreased dramatically during this same timeframe. Does FDA believe that there will be a sufficient number of FTEs in the Office of Cosmetics and Colors enough to regulate this industry and insure the safety of these consumer products?

Answer. Thus far, FDA has been able to keep pace with developments, averting any serious or widespread public health problems. While it is difficult to predict, precisely, what the future will bring, there are several areas that loom large for cosmetic safety. Key examples include the safe use of nanotechnology in cosmetics; a need for more scientific information to ensure the safe use of tattoos, which has greatly expanded over a wider segment of the population than formerly; and the in-

creasingly global nature of the industry with a corresponding need for FDA engagement in the development of international safety standards.

PSEUDOEPHEDRINE

Question. The Senate and House Appropriations Committee Report on the fiscal year 2007 FDA Appropriations Bill included language regarding "Expedited Filing". In the context of this Appropriations provision, and in light of the initiatives undertaken by FDA following enactment of the Combat Meth Act, would you please outline the steps that the Agency has taken to enhance access to new prescription combinations of safe and effective marketed drugs that could provide alternative therapies to replace pseudoephedrine-containing products and thereby address the major public health and safety concerns arising from meth production?

Answer. The Office of Non-Prescription Products, or ONP, is interacting with manufacturers to help them interpret the Combat Meth Act provisions regarding reformulation of both New Drug Applications, or NDA, and over-the-counter, or OTC, monograph products. Products that require NDA or a supplement to an NDA, or sNDA, may qualify for a priority review. We are willing to meet with applicants to determine if such applications qualify to be considered under priority review. We interact with such applicants to ensure that only essential testing is required to demonstrate that the reformulations will be safe and effective. For instance, clinical trials are not required in any instance in which a demonstration of bioequivalence in humans can be appropriately applied. This may help shorten the time necessary to provide data for the NDA or sNDA. We also respond to submissions and meeting requests quickly so that access is not delayed based upon the ability of a company to get feedback or to interact with the Agency. If applications do not qualify for priority review, they are reviewed under the specific timelines and procedures associated with the Prescription Drug User Fee Act, or PDUFA, and other pertinent regulations.

OTC products that are marketed under the OTC Drug Review may be reformulated following the stipulations for active ingredients, manufacturing, and labeling that are set out in the regulations associated with the OTC monographs. These reformulations do not require approval by the FDA prior to marketing. For example, an immediate release tablet containing pseudoephedrine as a decongestant in combination with an antihistamine could be reformulated under the monograph to contain an alternative decongestant phenylephrine, in combination with the same antihistamine. This reformulation does not require preapproval, supporting a rapid transition from products containing pseudoephedrine to products using other antihistamines. In addition, a new salt of phenylephrine was recently added to the monograph to allow manufacturers more flexibility in formulating products.

COLOR CERTIFICATION FEES

Question. What is the anticipated balance that will remain in the Color Certification Fund at the end of fiscal year 2007?

Answer. The anticipated balance that will remain in the Color Certification Fund at the end of fiscal year 2007 is \$1,410,134.

Question. What are the anticipated revenues to this fund in fiscal year 2008?

Answer. The anticipated revenues to this fund in fiscal year 2008 are \$7,000,000.

Question. Please provide a list of all anticipated expenses for this program in fiscal year 2008?

Answer. The following is a list of anticipated expenses for the Color Certification Program in fiscal year 2008:

Operating Expenses: \$3,309,740 (Funds the day to day operations of the Color Certification program including equipment purchases, supplies, travel, contracts and rent and rent related costs)

Payroll Expenses: \$4,258,384 (Funds the salaries and benefits of Color Certification employees)

QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

ADVERSE EVENT REPORTING ON DIETARY SUPPLEMENTS

Question. The Dietary Supplement and Nonprescription Drug Consumer Protection Act require manufacturers and distributors of dietary supplements and OTC drugs to report all serious adverse events to the FDA. The legislation requires the FDA to issue guidance by September 18, 2007 on the minimum data elements that should be included in a serious adverse event report.

Has the FDA begun that process?

Answer. Yes, FDA has begun work on the guidance required by the new law. Before issuing final guidance, the agency intends to publish draft guidance describing in detail the minimum data elements that should be included in a serious adverse event report for both dietary supplements and OTC drugs, using the current FDA 3500A MedWatch form for mandatory reporting.

Question. Will the FDA be issuing a proposed guidance to solicit comment from stakeholders?

Answer. Yes. In accordance with the agency's good guidance practice regulations, FDA will announce the availability of the draft guidance in the Federal Register and invite comment on the guidance from interested parties.

The Dietary Supplement and Nonprescription Drug Consumer Protection Act supersedes the Center for Food Safety and Nutrition's (CFSAN's) Adverse Event Reporting System, or "CAERS", which allows voluntary reporting of dietary supplement adverse events.

Question. Since the legislation requires manufacturers and distributors to report serious adverse events, does FDA expect to use more resources to process Adverse Event Reports?

Answer. Yes, the FDA expects to use more resources to process significant adverse event reports (AERs) which are submitted in response to this law.

With respect to resources for Public Law 109-462, no funding for implementation was provided in the fiscal year 2007 appropriation and no funding was requested in the President's fiscal year 2008 budget.

Currently the agency has been performing tasks that will contribute to the full implementation of the new law. For example, FDA performed a gap analysis between the FDA3500A MedWatch form and the capabilities of the current CFSAN Adverse Events Reporting System (CAERS). This analysis shows that CAERS needs software modifications to receive fields on the 3500A MedWatch form.

In addition, the agency is planning the additional work activities needed to fully implement the law. These work activities will include developing several business processes, making significant Information Technology (IT) improvements to CAERS, and modifying contracts providing records management and IT support. To accommodate the increased numbers of significant AERs expected to result from mandatory reporting, CFSAN plans to modify CAERS to accept AERs electronically via the MedWatch Plus initiative, which will include modifications to accommodate dietary supplements.

CFSAN already has processes in place to consolidate duplicate AERs and new medical information on existing AERs so that all information about a given adverse event appears in a single report, as required by the new law.

The Administration has proposed only \$4 million above last year's enacted level for CFSAN. This funding is directed to increases in food safety programs generally, not the CAERS system or a revised version of it.

Question. What additional resources will FDA require for fiscal year 2008 to prepare for the full implementation of the Act?

Answer. No funding for implementation was provided in the fiscal year 2007 appropriation and no funding was requested in the President's fiscal year 2008 budget.

GOOD MANUFACTURING PRACTICES OF DIETARY SUPPLEMENTS

Question. It has been over 12 years after the enactment of Dietary Supplement Health and Education Act and the FDA has yet to finalize the Good Manufacturing Practice (GMP) regulations authorized by the 1994 law. The Senate Health, Education, Labor and Pensions Committee Report that accompanied The Dietary Supplement and Nonprescription Drug Consumer Protection Act encouraged the FDA to act quickly to finalize a GMP regulation for supplements. The Committee also noted that FDA has taken action against products that arguably could not have been sold in the first place if strong GMPs had been promulgated.

What date will GMP regulations be issued?

Answer. FDA is committed to publishing this final rule. I can assure you that there has been significant work done on the final rule since the comment period for the proposed rule ended in August 2003. The Administration is currently reviewing the final rule.

We have worked extremely hard to draft the final rule in such a way that would assure quality products for the consumer while balancing societal costs and benefits. I can assure you that full attention is being given to the completion of the rule as soon as possible.

FOOD SAFETY INSPECTIONS

Question. Between 2003 and 2006, FDA food safety inspections have dropped by 47 percent as reported last month by the Associated Press.

Will an increase of just \$10 million increase the number of food safety inspections for products regulated by FDA?

Answer. The number of domestic food inspections used to calculate the 47 percent decrease in inspections since 2003 (from 7,218 in 2003 to 3,833 in 2006) represents only a subset of total domestic food inspections. This subset does not include such high risk areas as Seafood HACCP inspections; Juice HACCP inspections; Cheese inspections; Low Acid Canned Foods; and, Acidified Food inspections. When ALL domestic food inspections are included, the reduction in inspections between 2003 and 2006 is 19 percent.

In addition, the decreases quoted are for FDA inspections only and do not recognize FDA leveraging with States to conduct contract/grant and partnership inspections. For instance, in fiscal year 2006 the States performed 8,566 food inspections for FDA which is an increase from 8,390 conducted by the States in fiscal year 2003.

The \$5.5 million that the Office of Regulatory Affairs, or ORA, requested as part of the Strengthening Food Safety Initiative in the fiscal year 2008 President's Budget request will not result in an increased number of food safety inspections. Funding will be used to enhance ORA's ability to more rapidly trace back foodborne disease outbreaks and to work proactively to encourage growers and processors to implement good agricultural practices and other interventions designed to prevent contamination of food. ORA will develop, train, and equip teams to work with State partners in large produce-growing regions. Funding will also be used to accelerate development of an import decision-making IT system capable of detecting high-risk food shipments before they enter U.S. commerce. While FDA already has systems that are used to identify and target certain high-risk import shipments the new system will increase current capabilities by providing for automated review and trending of the results of field examinations and analyses of samples, identifying candidates for detention without physical examination; it will score each entry line on the basis of risk factors and surveillance requirements, for an automated, real-time decision on action to be taken; and, it will incorporate exogenous data with available FDA operational data to create a broader picture for each shipment.

The \$4.0 million and 16 FTEs that the Center for Food Safety and Applied Nutrition, or CFSAN, requested in the fiscal year 2008 President's Budget request will be used to improve its Food Safety program particularly focused on produce safety. CFSAN plans to utilize the fiscal year 2008 funds for resources to support four core critical functional areas of the FDA Food Safety Program: (1) methods development to detect and attribute foodborne illness outbreaks related to fresh produce, (2) expand traceback capabilities by hiring environmental epidemiologists to work with FDA and State and local agencies and facilitate on-farm investigations, (3) development of cost-effective regulations and/or guidance, and (4) obtain additional expertise in the production and processing of fresh produce.

The National Center for Toxicological Research, or NCTR, will direct \$165,000 to provide additional staff and \$335,000 for supplies and services to improve methods for rapid screening and complete identification of foodborne pathogens. NCTR will also develop a genomic database to identify and assess the biological threat of foodborne pathogens. The total cost is \$500,000.

Also included is \$644,000 for FDA's Office of Crisis Management, or OCM, to enhance FDA's ability to help industry mitigate the risks of foodborne outbreaks.

Question. What will be the number of inspections as compared to fiscal year 2006 and fiscal year 2007?

Answer. The Office of Regulatory Affairs, or ORA, currently estimates it will perform 19,212 food inspections, including inspections performed by the States for FDA under State contracts and partnerships in fiscal year 2008. This represents a slight increase over the fiscal year 2007 estimate of 19,137 food inspections. In fiscal year 2006, FDA and the States performed 17,730 food inspections.

Question. Is \$10 million enough money to ensure public safety?

Answer. Ensuring the safety of the food supply is a top priority for FDA and the Administration and we will continue to strive to reduce the incidence of foodborne illness, and the associated impact of public health to the lowest level possible.

The \$5.5 million that the Office of Regulatory Affairs, or ORA, requested as part of the Strengthening Food Safety Initiative in the fiscal year 2008 President's Budget request will be used to enhance ORA's ability to more rapidly trace back foodborne disease outbreaks and to perform on farm investigations. Once the outbreak and food involved has been identified, the ability to deploy rapid response teams trained in outbreak response and traceback procedures will prevent addi-

tional exposure of consumers to contaminated produce and reduce the number of illnesses by more quickly identifying implicated shipments and removing them from the market. In addition, the development of these teams enhances FDA's ability to perform on farm and at processor investigations and thereby help prevent future outbreaks. Funding will also be used to accelerate development of an import decision-making IT system capable of detecting high-risk shipments before they enter U.S. commerce which will improve ORA's ability to intercept contaminated products at the border and before they enter U.S. commerce. While FDA already has systems that are used to identify and target certain high-risk import shipments, the new system will increase current capabilities by providing for automated review and trending of the results of field examinations and analyses of samples, identifying candidates for detention without physical examination; it will score each entry line on the basis of risk factors and surveillance requirements, for an automated, real-time decision on action to be taken; and, it will incorporate exogenous data with available FDA operational data to create a broader picture for each shipment.

The \$4.0 million and 16 FTEs that the Center for Food Safety and Applied Nutrition or CFSAN, requested in the fiscal year 2008 President's Budget request will be used to improve its Food Safety program particularly focused on produce safety. In a continued commitment to improve the safety of the U.S. food supply, FDA is taking action to prevent or reduce foodborne outbreaks and the number of illnesses and deaths due to consumption of contaminated food, bolstering public confidence in the safety of fresh produce, the consumption of which the U.S. Government has been encouraging as part of a healthful diet, and encouraging the States and industry to respond to new information on potential food contamination.

The National Center for Toxicological Research, or NCTR, will direct \$165,000 to provide additional staff and \$335,000 for supplies and services to improve methods for rapid screening and complete identification of foodborne pathogens. NCTR will also develop a genomic database to identify and assess the biological threat of foodborne pathogens. The total cost is \$500,000.

Also included is \$644,000 for FDA's Office of Crisis Management, or OCM, to enhance FDA's ability to help industry mitigate the risks of foodborne outbreaks.

Since September of last year, there have been multiple large-scale outbreaks of foodborne illness in the United States. Press reports suggest the reason for the recent outbreak of foodborne illness is FDA's lack of resources in the area of food safety. The President's fiscal year 2008 budget calls for an increase of \$10.6 million for food safety at FDA.

Question. What changes will FDA make with this money to ensure future outbreaks of foodborne illness are prevented?

Answer. The fiscal year 2008 budget requests funds for food safety improvements in the Center for Food Safety and Applied Nutrition, or CFSAN (\$4 million), the Office of Regulatory Affairs, or ORA (\$5.5 million), the National Center for Toxicological Research, or NCTR (\$500,000) and the Office of Crisis Management, or OCM (\$644,000).

CFSAN expects to utilize the fiscal year 2008 increase for resources to support four core functional areas of the FDA Foods Program:

- Methods Development (\$1 million).*—Funds will develop better methods to detect and attribute foodborne illness outbreaks related to produce and allow for quicker intervention to reduce the illnesses and deaths from contaminated food and quicker resumption of marketing of uncontaminated food.
- Surveillance (\$1 million).*—Funds will increase sampling and traceback capabilities, including conducting produce sampling surveys of imported and domestic produce to examine pathogens along the distribution chain to establish a baseline.
- Regulations and Guidance (\$1 million).*—Funds will help develop cost-effective regulations and/or guidance to prevent and reduce outbreaks, thus reducing the instance of illness and death.
- Produce Experts (\$1 million).*—Funds will obtain additional expertise in the production and processing of fresh produce, with emphasis on microbiological safety issues.

Also included is \$644,000 for FDA's Office of Crisis Management, or OCM, to enhance FDA's ability to help industry mitigate the risks of increased foodborne outbreaks.

The National Center for Toxicological Research, or NCTR, will direct \$165,000 to provide additional staff and \$335,000 for supplies and services to improve methods for rapid screening and complete identification of foodborne pathogens. NCTR will also develop a genomic database to identify and assess the biological threat of foodborne pathogens.

The Office of Regulatory Affairs, or ORA, plans to allocate \$3.5 million to develop the capacity for more rapid traceback of produce-related outbreaks and the capacity to determine the root cause of an outbreak. ORA will develop teams trained in traceback technologies, incident command, and root cause analysis. These teams will be strategically positioned in areas with large produce-growing regions. In addition, ORA will provide training, equipment, and other assistance to States so that they can be full partners with FDA in responding to and preventing produce-related outbreaks. After the first year, ORA will have 12 fully equipped and trained FTEs with traceback equipment.

ORA also plans to allocate \$2 million towards developing an import decision-making system capable of detecting high risk shipments of FDA-regulated products before they are admitted or released into U.S. commerce. While FDA already has systems that are used to identify and target certain high-risk import shipments the new system will increase current capabilities by providing for automated review and trending of the results of field examinations and analyses of samples, identifying candidates for detention without physical examination; it will score each entry line on the basis of risk factors and surveillance requirements, for an automated, real-time decision on action to be taken; and, it will incorporate exogenous data with available FDA operational data to create a broader picture for each shipment.

From what I can see, the FDA needs a far greater investment in food safety in order to effect real improvements in actual practice.

Question. If given more than \$10 million for food safety, which programs would benefit most from additional money to increase the safety of our food supply, especially in fresh produce?

Answer. FDA is committed to ensuring that America's food supply continues to be among the safest in the world, but we face challenges. For example, consumption of produce, particularly "ready-to-eat" products, has increased dramatically during the past decade. Americans usually consume these products in their raw state, harvested from the vine, stem, or soil without processing to reduce or eliminate pathogens that may be present. Consequently, the manner in which these products are grown, harvested, packed, processed, and distributed is crucial to ensuring that microbial contamination is minimized, thereby reducing the risk of illness to consumers. Even if a small percentage of what is harvested is contaminated, it can result in severe illness. FDA is taking a "farm-to-fork" systematic risk management approach to food safety to reduce the risk of food illness at all points in the food chain.

For fiscal year 2008, we propose a \$10.644 million increase for a food safety initiative focused on fresh produce. FDA will develop methods to prevent food outbreaks from occurring by rapidly detecting contamination that leads to illness, more quickly tracking contamination to its source, and more effectively conducting root cause analysis of the contamination. We will also provide training to our State and local partners and develop a geographic information mapping system for faster emergency response. Finally, we will develop a decision-making system to detect high-risk imports before they enter U.S. commerce, so they can be evaluated by FDA.

Due to the increased consumption of fresh produce and the current outbreaks of contamination, FDA would allocate additional funding for specific areas where we could expand the food safety program in order to promote and improve the public health. FDA has identified the following five critical areas as targets for future growth:

- preventing contamination and produce safety research
- preventing outbreaks and mitigating outbreak impact
- monitoring antibiotic usage and antibiotic resistance in bacteria from farm-raised aquatic animals and their environments
- developing efficient techniques for identifying foodborne pathogens that cause outbreaks
- providing additional field support for the Foods and Animal Drugs and Feed Programs.

SALT

Question. In 1979, the Federation of American Societies for Experimental Biology submitted a final report to FDA, Evaluation of the Health Aspects of Sodium Chloride and Potassium Chloride as Food Ingredients. This report reviewed the adverse biological effects of dietary sodium and concluded that these effects might be harmful to the health of a significant proportion of the public. It further concluded that "it is the prevalent judgment of the scientific community that the consumption of sodium chloride in the aggregate should be lowered in the United States."

Since that time, additional studies have demonstrated with much greater certainty that diets high in sodium promote high blood pressure. In 2003, the National Heart, Lung and Blood Institute's high blood pressure committee called for a 50-percent reduction in sodium in processed and restaurant foods over the next 10 years, or 5 percentage points a year for 10 years. In a January 2004 commentary in the *American Journal of Public Health*, the director of the National Heart, Lung and Blood Institute (NHLBI) and two colleagues estimated that halving sodium levels in packaged and restaurant foods would save 150,000 lives a year in the United States.

In the early 1980s, likely based in part on the 1979 FASEB report, FDA agreed that a reduction in the consumption of salt would be beneficial, and it initiated a modest campaign of public education and expanded labeling provisions to encourage consumers and food manufacturers to use less salt. Around that time, FDA also rejected calls to revisit the GRAS status of salt. However, in 1984, a Federal district court ordered FDA to reconsider the GRAS status of salt if voluntary measures did not succeed in reducing salt intake.

Per the instructions of the Federal district court in 1984, has FDA taken steps to reconsider the GRAS status of salt?

Answer. In response to a 1979 review on salt by the Select Committee on GRAS Substances (SCOGS) of the Federation of American Societies for Experimental Biology, and concern about the health effects of salt in the U.S. diet, FDA reviewed the regulatory status of salt and issued Federal Register (FR) publications discussing salt's status in a 1982 notice (47 FR 26580; June 18, 1982) and a 1984 final rule (49 FR 15510; April 18, 1984). In these documents, FDA outlines its voluntary review of salt and the decision not to alter salt's status as a GRAS ingredient.

The question references the "instructions of the Federal district court in 1984." These instructions were contained in a court ruling¹ that granted summary judgment to FDA in response to a suit filed by Center for Science in the Public Interest (CSPI) seeking the court's review of FDA's denial of the CSPI citizen petition to reclassify salt as a food additive. The cited "instructions" were non-binding instructions for FDA to make a decision on the GRAS status of salt after it had completed its review of the effectiveness of several FDA initiatives for salt. FDA had concurrently completed a voluntary review of salt and subsequently opted not to alter its regulatory status. The conclusions of FDA's review that are the basis of our decision are documented in the 1982 and 1984 FR documents.

Question. If so, what is the result of those deliberations? If not, why has FDA not done so?

Answer. The results of those deliberations in the early 1980s regarding the GRAS status of salt ultimately led to a decision not to alter GRAS status (47 FR 26580, June 18, 1982; 49 FR 15510, April 18, 1984). FDA opted instead to pursue a consumer information-based approach where declarations of the salt (listed on the food label as the sodium ion) content of foods would encourage individuals to control their own salt intake as well as encourage food manufacturers to limit the salt content of their products. FDA explained in the 1982 FR notice its rationale for choosing this approach. FDA cited several legal and regulatory issues that confounded the regulation of salt as a food additive. These legal and regulatory issues include the complexity of determining limitations of salt in foods and the complexity of the diet in general (i.e., changing the salt content of a particular food or foods may not impact a person's total intake of salt). Furthermore, "prior sanctions"—sanctions or approvals of a use of a food ingredient that were granted by either FDA or the U.S. Department of Agriculture before the Food Additives Amendment to the FDCA was enacted in 1958—exist for uses of salt; revocation of prior sanctions presents further complications.

Question. What resources does FDA currently devote, both budget resources and FTSs, to sodium and sodium reduction?

Answer. Unfortunately, the Agency's financial system does not track programmatic resources to this level of detail.

Question. What would the FDA do, if it had increased resources, to lower sodium levels in processed and restaurant foods?

Answer. Food label education remains a key priority for FDA. In 2006, FDA released a web-based program, "Make Your Calories Count," to assist consumers understand and use the food label to help manage their calorie and nutrient intake. Sodium is one of the nutrients featured on the program.

Additionally, in 2005 FDA amended its regulations concerning the maximum sodium levels permitted for foods that bear the implied nutrient content claim

¹ *Center for Science in the Public Interest v. Novitch*, Food, Drug, and Cosm. L. Rep. (CCH) ¶ 38,275 (D.D.C. June 11, 1984)

“healthy.” In this rule the agency retained sodium levels of 480 mg or less for all food categories, including individual foods, and 600 mg or less for meals and main dishes. Most of the comments from industry suggested that it was difficult to make certain products, particularly soups, which would be both palatable and marketable at lower levels. Many consumer groups, including Center for Science in the Public Interest (CSPI), supported this decision. The agency had concluded that going to more restrictive sodium levels could result in the substantial elimination of meal and main dish products bearing the claim “healthy” from the marketplace and that the proposed sodium levels would help consumers achieve a total diet that would be consistent with dietary recommendations.

Moreover, the fiscal year 2006 CFSAN Program Priorities include publishing an advance notice of proposed rulemaking (ANPRM) to solicit comments on updating daily values in nutrition labeling. All nutrients, including sodium, will be taken into consideration as part of the development of the ANPRM. We will be encouraging comments on this ANPRM from a broad range of stakeholders.

The FDA is currently preparing for a public hearing to discuss issues related to FDA’s regulation of salt. As part of this hearing, FDA will invite comment on the effectiveness of current measures and discuss potential initiatives aimed at reducing salt intake in the United States. Additional resources might be used to further any of the FDA efforts related to reducing sodium levels identified above.

TRANS FAT

Question. The FDA considers partially hydrogenated oil, with its trans fat, to be “generally recognized as safe,” even though the agency’s own evaluations indicate that the ingredient is causing thousands of premature deaths and significant economic costs each year.

Is there any reason that the FDA should not seek to eliminate trans fat, other than naturally occurring trans fat, from the food supply?

Answer. FDA is currently evaluating this issue in its review of a citizen petition from the Center for Science in the Public Interest (CSPI), requesting that FDA revoke the “generally recognized as safe” status of trans fat. In response to this petition, we have received comments from industry that show that revoking the “generally recognized as safe” status of trans fat is a complex issue.

We note that when FDA affirmed partially hydrogenated oils as “generally recognized as safe,” the data on trans fats were very limited. Since then, additional research has shown that some trans fats are unhealthful. Research in this area is ongoing to determine the identity, levels, safety and other variables of trans fats in food.

We are considering all options to address concerns regarding trans fat in foods, including those raised in the citizen petition currently under review. For example, one approach we have already taken is to give consumers the information they need to make healthier food choices and provide industry with an incentive to produce healthier foods. Due in part to FDA’s trans fat labeling regulation that went into effect in January 2006, and FDA’s education and outreach efforts, there has been an increase in consumer demand for trans fat-free products. Therefore, these activities are having a positive effect on reducing trans fat intake.

Question. What steps is the FDA taking to reduce or eliminate trans fat in the food supply?

Answer. The level of trans fatty acids in the diet affects risk of coronary heart disease. To assist consumers in choosing foods with lower amounts of trans fat, the FDA issued a final rule in 2003 (68 FR 41434, July 11, 2003) that requires the amount of trans fat to be declared on the Nutrition Facts panel directly below the saturated fat line. This rule became effective January 1, 2006, for all food under the jurisdiction of FDA.

Americans face a plethora of food choices in grocery stores and at restaurants. Our responsibility is to empower consumers to make informed decisions about their food selections and to encourage them to make changes in their diets for better health. The Nutrition Facts panel, along with other education campaigns, provides invaluable information to the consumer. At the same time, FDA’s public health mission is to foster the development of healthier food products for American consumers. The requirement to declare trans fat on product labeling is changing consumer demand and prompting reformulation, which was anticipated by FDA. FDA is monitoring industry progress in developing and using alternative ingredients and processing techniques for reducing trans fat.

At the same time that the final rule published, FDA issued an advance notice of proposed rulemaking (ANPRM) (68 FR 41507; July 11, 2003) to request comment on establishing trans fat nutrient content claims, disqualifying/disclosure levels, and

a possible footnote about cholesterol raising lipids to help consumers make heart healthy food choices.

FDA is currently reviewing a citizen petition from the Center for Science in the Public Interest requesting FDA to revoke the “generally recognized as safe” status of partially hydrogenated vegetable oils (see Docket No. 2004P-0236).

Question. Does the FDA plan to reconsider the GRAS status of partially hydrogenated vegetable oil given that it contains trans fat?

Answer. FDA is currently evaluating this issue in the review of a citizen petition from the Center for Science in the Public Interest, requesting that FDA revoke the GRAS status of trans fats.

Question. If so, what is the result of those deliberations? If not, why has FDA not done so?

Answer. There is no change in the conclusion made in the trans fat labeling regulation that trans fat represents a health concern. The trans fat information provided on food labels will enable consumers to make healthier food choices. As part of our ongoing review of the citizen petition from the Center for Science in the Public Interest, requesting that FDA revoke the GRAS status of trans fats, we are considering all available options to address concerns regarding consumption of trans fat. FDA plans to monitor the effect of the trans fat labeling regulation on consumer behavior and industry practices to help determine what, if any, additional action should be taken.

QUESTIONS SUBMITTED BY SENATOR BYRON L. DORGAN

DIRECT-TO-CONSUMER ADVERTISING

Question. The United States is one of only two nations that allow DTC advertising. The other is New Zealand. The amount of money spent on DTC ads has increased by 20 percent per year since 1997. In 2005, drug companies spent \$4.2 billion on DTC ads.

I think we have to take a hard look at whether these ads have value to consumers. I have seen some ads that don't even mention what the product does. I remember an ad for Levitra—an erectile dysfunction drug—that showed a man trying to throw a football through a tire swing. He had no luck until the word Levitra flashed on the screen. In the next scene, the man is being embraced by a woman.

Do you believe this type of ad is beneficial to consumers? Should pharmaceutical companies be required to clearly state what the product is for in addition to listing the risks and benefits associated with the product?

Answer. FDA believes consumer-directed advertisements can play an important role in advancing the public health. There are a number of serious medical conditions that are undertreated in the United States. Conditions such as diabetes, depression, hyperlipidemia, and hypertension, left untreated, can have devastating effects in patients. We believe the public health is benefited when consumer-directed promotion provides information that encourages patients to speak with their doctors and get their serious medical conditions treated. The benefit depends critically on the participation of the physician, who must devise a treatment plan, consider alternative treatments, and monitor the patient's response to treatment. But we believe the role of DTC advertising in initiating contacts is important for these serious conditions. The advertisement you described, which is a so-called “reminder ad,” however, contains little useful information.

There are 2 types of product promotion for prescription drugs. The first type is full product promotion, which must clearly state the indication (approved use) of the advertised drug and must provide balancing risk information about the drug. In addition, any claims that are presented in the advertisement must be substantiated. These ads can remind patients to see physicians about serious illness. The second type is reminder promotion. Reminder advertisements are advertisements that call attention to the name of the drug product but do not include indications or dosage recommendations for use of the product, or any other representations or suggestions about the product. Reminder advertisements contain the proprietary name of the drug and the established name of each active ingredient. They may also contain additional limited information, such as the name of the company, price, or dosage form. These advertisements are exempt from the FDA regulations that require that the indication and risks of the product be presented. However, if a supposed reminder advertisement includes more information than is allowed, it is considered to be a full product advertisement and must include the indication and risk information or it is in violation of FDA regulations.

Although reminder advertisements are legal, PhRMA has encouraged companies not to run reminder television advertisements to consumers but rather to run only full product ads. Principle #10 of PhRMA Guiding Principles—Direct to Consumer Advertisements About Prescription Medicines states “DTC television advertising that identifies a product by name should clearly state the health conditions for which the medicine is approved and the major risks associated with the medicine being advertised.” Note that these are voluntary guidelines and only apply to television advertisements. Below is the link to PhRMA Guiding Principles. <http://www.phrma.org/files/DTCGuidingprinciples.pdf>. The Agency encourages companies to follow these guidelines so that consumer-directed television ads provide the public with both indication and risk information for advertised drugs.

Question. In fiscal year 2006, the FDA spent slightly more than \$1 million to monitor DTC ad content. A total of 8 full time staff are responsible for reviewing all DTC ads. Do you believe that the FDA has adequate resources to review DTC ad content?

Answer. The Center for Drug Evaluation and Research devotes 13 full time equivalents (representing some full-time staff and portions of time spent by other staff). With these resources, we cannot review every one of the nearly 11,000 DTC promotional pieces disseminated by companies annually. We are proposing to recommend a program (separate from, but related to PDUFA IV) assessing user fees for advisory reviews of DTC television advertisements. These new fees would provide sufficient resources for FDA to hire additional staff to review television advisory submissions in a predictable, timely manner. FDA anticipates collecting \$6.25 million in annual fees during the first year of the program to support 27 additional staff.

Question. According to a recent GAO report, from 2004 to 2005, by the time the FDA acted to stop misleading ad campaigns, more than half of the ad campaigns had already ended. Should the FDA be required to approve DTC ads before they are broadcast?

Answer. FDA does not have the legal authority to require that broadcast ads be approved before they are publicly used. In the event that FDA was given the authority to pre-approve certain ads, as noted in Question 3 above, it would require an increase in staff resources to perform this review and approval in a timely manner.

DRUG IMPORTATION

Question. Do you believe that prescription drugs sold in brick and mortar pharmacies in Canada are safe?

Answer. Prescription drugs sold in brick and mortar pharmacies in Canada are regulated by Health Canada, the Canadian Federal department responsible for their approval. For this reason, the Administration can only comment on those products that fall under FDA regulatory authority. FDA can only assure the safety and efficacy of products that have been approved for marketing in the United States.

Question. Under current law, drug companies are free to manufacture prescription drugs in other countries and import them for sale in the United States. About one-quarter of the drugs sold in the United States today are made in other countries and imported to the United States for sale by pharmaceutical manufacturers. If importation can be deemed safe for manufacturers, why can't it be made safe for consumers?

Answer. Drug companies can manufacture prescription drugs in other countries and import them for sale in the United States only if they fulfill FDA's regulatory requirements. Foreign drug establishments must be registered with FDA and comply with all regulations that apply to domestic drug establishments. This includes submission of all qualifying information with each drug product and being subject to inspections to insure the integrity of the product and the manufacture, process, handling, and storage of the product. It is only under these conditions that FDA can confirm the integrity of the product and allow importation of these products.

Unapproved products pose a public safety concern since they are produced outside of this closed regulatory system. Unapproved products may include counterfeit drug products that may be making their way into the United States distribution system through consumers purchasing drug products from unregulated sources, such as the internet. Patients are at risk when they purchase these products from rogue websites, as it is uncertain whether the product they receive is genuine or counterfeit, contains inert or harmful ingredients, or contains sub-potent or super-potent amounts of the active ingredient. FDA does not have the resources to expand inspection capabilities to all possible sites from which a consumer may obtain unapproved drug products.

The HHS Drug Importation Task Force Report issued in December 2004 outlined the measures that would be needed to implement an importation program that provides adequate safeguards and resources to ensure that the imported drugs are safe and effective. A program that does not take these measures into consideration, regulated or not, would perpetuate the “buyer beware” situation that is currently occurring and consumers would continue to put themselves at risk for harm by importing unapproved drugs into the United States for personal use.

The Task Force found that under such a system, importing drug products would yield minimal cost savings. Based on observations during a recent survey of packages intercepted at an international mail facility, FDA Office of Criminal Investigations suggests that cost savings for imported drugs is already questionable. Of over 400 drug products assessed, approximately 50 percent were available as United States approved generic drug products. Further examination revealed that more than 40 percent of the generic drug products were available through national retail pharmacy chain programs that offer generic prescriptions for \$4 each—which is likely less than the cost of shipping.

Question. Wouldn't a regulated system be safer than what is occurring today?

Answer. The current system is regulated; the Food Drug and Cosmetic Act, or FD&C Act, gives the Secretary of HHS the authority to regulate drug products in the United States through FDA. Currently FDA does not have the resources or a regulatory mechanism to assess the safety and effectiveness of drug products imported into the United States outside of the existing closed distribution system. To effectively assess the safety and efficacy of these imported drug products, a new mechanism for the review and approval of these products would need to be created. This could entail creating a program similar to the generic drug program, which determines therapeutic equivalence of generic drug products. This is achieved by a thorough scientific review of chemistry, manufacturing and controls, clinical bioequivalence studies comparing the innovator product to the generic product, and labeling. Clinical, analytical, and manufacturing sites are subject to inspection by the agency. Creation of this program is impractical since it would require additional resources well beyond those currently available and allow for the approval of foreign generic products without regard to intellectual property protections of the innovator drug product.

Consumers are likely to continue to purchase drug products from foreign or rogue websites. It is important to recognize that many who attempt to purchase medications from foreign sources are not doing so as a cost-savings measure, but are seeking to circumvent the need for a legitimate doctor's prescription. As a public health agency, FDA understands the importance of protecting the public health not only through regulation and enforcement, but also through education and collaboration. FDA's website is replete with consumer information about drug importation, buying drugs online, counterfeit drugs, enforcement activities, potential public health threats, as well as resources to report problems with FDA regulated products or websites that could be selling counterfeit or harmful products.

PENDING APPROVAL OF CEFQUINOME

Question. The Washington Post recently reported that the FDA is on the verge of approving cefquinome for use in animals, despite a warning from the FDA's Veterinary Medical Advisory Committee that approving cefquinome for use in animals may erode the effectiveness of a related drug that is used to treat human infections. I understand that that FDA will likely approve cefquinome because of a guidance document (Guidance #152) that was issued in 2003. The guidance makes it hard for the FDA to reject any drug unless it is clear that the use of the drug in animals will reduce the effectiveness of antibiotics that are used to treat food-borne illnesses in humans. Why is the threat assessment in Guidance #152 limited to food-borne illnesses?

Answer. First, we would like to clarify that Guidance 152 is “guidance” and, therefore, provides nonbinding recommendations on an approach for evaluating antimicrobial drugs as part of the new animal drug approval process. In developing this guidance, FDA obtained broad stakeholder input through public meetings and through publication of a draft document. The guidance document was first published as a draft for public comment in September 2002, consistent with the Agency's Good Guidance Practices Regulations.

After considering public comment on the draft document, FDA issued a final guidance in October 2003. The guidance outlines an approach for conducting a qualitative risk assessment to evaluate the likelihood that an antimicrobial drug used to treat an animal may cause an antimicrobial resistance problem in humans consuming food from that animal. The guidance focuses on food-borne pathogens be-

cause FDA believes that human consumption of animal-derived foods represents the most significant pathway for human exposure to antimicrobial resistant bacteria that have emerged or been selected as a consequence of antimicrobial drug use in animals. Nonetheless, as stated in the guidance, although FDA's primary focus will be food-borne pathogens, other bacteria may be considered when deemed necessary. The risk assessment approach recommended in the guidance includes three key elements that are collectively considered in determining an antimicrobial drug's potential risk to humans if used to treat food-producing animals. The first is the "release assessment," which estimates the probability that resistant bacteria will be present in animals as a result of the proposed use of the new antimicrobial drug. The second is the "exposure assessment," which gauges the likelihood that humans would ingest the resistant bacteria from the relevant food product. The third is the "consequence assessment," which assesses the probability that human exposure to the resistant bacteria would result in adverse human health consequences.

The input for the "consequence assessment" component is based on a system, developed as part of the guidance, for ranking the importance of antimicrobial drugs in human medicine. The ranking system, included as Appendix A of the guidance, results in a drug being ranked as Important, Highly Important, or Critically Important to human medicine. This ranking system was developed in collaboration with physicians at FDA's Center for Drug Evaluation and Research (CDER), CDER's Anti-Infective Drugs Advisory Committee, and the Centers for Disease Control and Prevention (CDC). The criteria for ranking human importance considers factors including whether the antimicrobial (1) is used to treat food-borne infection; (2) is a sole therapy or one of limited therapies to treat serious human disease, or is an essential component among many antimicrobials in the treatment of human disease; (3) is used to treat enteric pathogens in non-food-borne disease; and (4) is a drug for which cross-resistance or co-resistance to other drugs is a concern. Therefore, the human importance ranking process and, hence the consequence assessment component, considers a number of relevant factors in addition to whether the drug is important for treating food-borne disease.

Based on a consideration of the release, exposure, and consequence components of the assessment, the guidance outlines an approach by which the animal drug in question is placed into one of three risk categories. The guidance outlines examples of risk management steps that FDA may apply to an antimicrobial drug based on the risk category such as the level of concern to human health. These range from denying the approval if the drug is not shown to be safe to approving the application with certain restrictions on its use.

We reiterate that the final decision regarding the safety of an antimicrobial drug is not driven solely by Guidance 152. Pursuant to the Federal Food, Drug, and Cosmetic Act, FDA's decision regarding whether to approve a new animal drug application is driven by factors that include (1) whether such application included adequate tests to determine whether or not the drug is safe, (2) whether the results of such tests show the drug is unsafe or do not show the drug to be safe, or (3) whether, based on information either in the application or otherwise available to FDA, there is sufficient information to determine that the drug is safe.

In regard to the drug cefquinome, FDA has not made a final decision regarding its approval. FDA is currently reviewing the comments from its Veterinary Medical Advisory Committee, carefully reviewing the drug's assessment under Guidance 152, and considering any and all other information relevant to the safety of the drug.

Question. I understand that the World Health Organization recommends that animal drugs should only be approved if the use of the drug would not result in resistance to any antibiotic that is important to fighting human disease. Why is the scope of the FDA standard much narrower?

Answer. FDA recognizes that food-borne human exposure to antimicrobial resistant bacteria is complex and often involves contributions from other sources of exposure, for example, direct contact between animals and humans, introduction of resistant bacteria, and resistance determinants into the environment. However, FDA believes that evaluating antimicrobial new animal drug safety relative to the most significant exposure pathway, such as the food-borne pathway, is the best way to qualitatively assess the risk of antimicrobial drug use in food-producing animals. Nonetheless, as stated in Guidance 152, non-food-borne bacteria may be considered when deemed necessary; for example, uncertainties regarding the contribution of other exposure pathways may be considered during the development of appropriate risk management strategies.

In developing criteria for ranking antimicrobial drugs with regard to their importance in human medicine, FDA considered broad issues associated with the efficacy of drugs in human medicine and factors influencing the development of antimicrobial resistance. Specific factors include the usefulness of the drug in food-borne

infections, the types of infections treated, the availability of alternative therapies, the uniqueness of the mechanism of action, and the ease with which resistance develops and is transferred between organisms.

The World Health Organization (WHO) has also developed a system for ranking antimicrobial drugs with regard to their importance to human medicine. However, the WHO approach differs somewhat than the approach adopted by FDA. WHO determines the critical nature of an antimicrobial drug based on its use as the sole therapy or one of few alternatives to treat serious human disease, and on its use to treat diseases caused by organisms that may be transmitted via non-human sources or diseases caused by organisms that may acquire resistance genes from non-human sources. WHO is looking broadly at diseases worldwide that may not be present in the United States.

As mentioned previously, FDA believes that human consumption of animal-derived foods represents the most significant pathway for human exposure to antimicrobial resistant bacteria that have emerged or been selected as a consequence of antimicrobial drug use in animals.

Question. Should the burden be on the drug companies to prove that using a drug to treat animals poses no risks to human health?

Answer. Drug companies are required to submit as part of a new animal drug application (NADA) full reports of adequate tests by all methods reasonably applicable to show whether or not the new animal drug is safe and effective. For animal drugs intended for use in food-producing species, this requirement includes safety with regard to human health.

FDA does not normally do the actual testing, but rather evaluates the results of testing that is submitted as a component of an NADA. In the case of NADAs for antimicrobial drugs intended for food-producing animals, FDA's Guidance 152 provides recommendations to industry on an approach for evaluating safety concerns related to antimicrobial resistance. FDA considers an antimicrobial new animal drug to be "safe" with regard to human health if it concludes that there is reasonable certainty of no harm to human health from the proposed use of the drug in food-producing animals.

QUESTIONS SUBMITTED BY SENATOR RICHARD J. DURBIN

DIETARY SUPPLEMENTS

Question. Late last year, Congress enacted a law that requires manufacturers of dietary supplements to report serious adverse events that result from the use of their products. The supplement ephedra caused seizures and strokes and the loss of over 150 lives before it was finally taken off the market. The new law will provide an important early warning system and is a first step in addressing safety concerns with supplements. Have you developed a timeline for developing regulations? What resources will the Food and Drug Administration (FDA) need to implement the law?

Answer. The Dietary Supplement and Nonprescription Drug Consumer Protection Act requires by December 22, 2007, that the labels of dietary supplements include a domestic address or phone number which persons can use to submit adverse event reports (AERs) to the manufacturer, packer, or distributor of the product, and declares dietary supplements misbranded if they are labeled on or after this date without this information. In addition, the firm whose name and address appears on the supplement label must submit to FDA any serious adverse event reports associated with the use of the supplement within 15 business days of receiving the report. Any new medical information received within a year of the initial report must also be submitted to the Secretary within 15 days of receipt. The reporting and labeling requirements for industry are self-implementing.

The new law directs FDA to issue guidance by September 18, 2007, on the minimum data elements that should be included in a serious adverse event report for a dietary supplement, and to develop systems to consolidate duplicate reports of, and new medical information related to, a serious adverse event into a single AER. Before issuing final guidance on the minimum data elements that should be included in a serious adverse event report for a dietary supplement, CFSAN intends to publish draft guidance and solicit comments from the public, in accordance with FDA's good guidance practice regulations. CFSAN already has processes in place to consolidate duplicate AERs and new medical information on existing AERs so that all information about a given adverse event appears in a single report, as required by the new law.

With respect to resources for Public Law 109–462, no funding for implementation was provided in the fiscal year 2007 appropriation and no funding was requested in the President's fiscal year 2008 budget.

Currently, the agency has been performing tasks that will contribute to the full implementation of the new law. For example, FDA performed a gap analysis between the FDA 3500A MedWatch form and the capabilities of the current CFSAN Adverse Events Reporting System (CAERS). This analysis shows that CAERS needs software modifications to receive fields on the 3500A MedWatch form.

In addition, the agency is planning the additional work activities needed to fully implement the law. These work activities will include developing several business processes, making significant Information Technology (IT) improvements to the existing CAERS, and modifying contracts providing records management and IT support. To accommodate the significant adverse event reports expected to result from mandatory reporting, CFSAN plans to modify CAERS to accept AERs electronically via the MedWatch Plus initiative, which will include modifications to accommodate dietary supplements.

ADVISORY COMMITTEES

Question. The credibility of FDA's decisions is seriously undermined when its advisory committee members have financial ties to the industries whose products they are reviewing. I think the FDA has too readily granted waivers to existing conflict of interest laws. In July, FDA announced a plan to strengthen the advisory committee process. And in January, as part of its response to drug safety recommendations from the Institute of Medicine, FDA said it would issue three guidances on advisory committees in 2007. Can you tell me what issues FDA is looking at and when we can expect to see those guidances?

Answer. FDA has been engaged in a high level review of our advisory committee processes. We are committed to making the FDA advisory committee process even stronger and better understood so that the public has confidence in the integrity of advisory committee recommendations. Our goals are to increase the consistency, predictability, and transparency of the process. As part of our efforts to improve advisory committee processes, we announced that we would develop three new guidance documents in furtherance of these goals. One of these guidances has already gone on display at the Federal Register, and we plan to issue the other two in the near future. The first guidance will help ensure that briefing materials prepared for advisory committee members are made available to the public and will assist sponsors and others in preparing and submitting such briefing materials to FDA. The second draft guidance will provide guidelines for reviewing conflicts of interest and determining who may participate in FDA advisory committee meetings. This draft guidance will also simplify the process for determining who may participate in advisory committee meetings and will recommend a consistent and predictable decision-making process for all FDA advisory committees. FDA's third draft guidance document on disclosure of conflicts of interest and waivers for advisory committee members will bring increased transparency to FDA's waiver process by making additional information about waivers and members' conflicts of interest available on FDA's website.

FOOD SAFETY

Question. The Government Accountability Office (GAO) recently designated food safety as one of the high risk Federal Government programs. In addition to the GAO's report, the spinach and Taco Bell E. coli outbreaks last year and the recent outbreak of salmonella in peanut butter underscore the need for increased food inspections.

Although FDA's overall funding has been steadily increasing since 2001, the budget for FDA's core functions, including the Center for Food Safety and Applied Nutrition has been slowly eroding since 2002. FDA regulates 80 percent of the food supply. According to FDA, staffing is the main barometer of FDA resources. The total staff is not increasing even though the workload continues to increase. What is FDA doing to ensure that the incidence of food-borne illnesses decreases? Does FDA have any plans to increase the number of food inspectors on its staff?

Answer. FDA uses a risk-based approach to allocate available resources. When outbreaks occur FDA moves resources to address the immediate need to protect public health. Since 1998, FDA has increased efforts toward minimizing food safety hazards associated with fresh produce. For example, we have been and are working with industry as it develops commodity-specific safety guidelines for a number of fresh produce products, including lettuce and leafy greens, melons, and tomatoes; food safety guidelines for green onions and herbs are being drafted. We also recently

issued the draft final guidance for fresh-cut produce. We are holding public meetings to allow us to gather comments, data, and other useful scientific information about current agricultural and manufacturing practices, risk factors for contamination of fresh produce, and possible steps we can take to enhance the safety of fresh produce. In addition, FDA launched a multi-year Leafy Greens Safety Initiative with assessment, research and communication components. This Initiative is a collaboration between FDA, the California Department of Health Services and the California Department of Food and Agriculture, intended to reduce public health risks by proactively focusing on the product, agents, and areas of greatest concern in advance of an outbreak. We are looking at using this Initiative as a model for other commodities, such as tomatoes.

For fiscal year 2008 we have requested a total of \$10.6 million for additional food safety activities. We consider this amount as an initial deposit on the many activities that are necessary to continue our campaign for improved food safety. Funds will be used to begin to address the lifecycle of produce production; to develop better methods to detect and attribute foodborne illness outbreaks, to increase sampling and traceback capabilities; to develop and update guidance to prevent and reduce outbreaks; to obtain additional expertise in the production and processing of fresh produce; and to enhance our response to foodborne outbreaks.

The \$5.5 million that the Office of Regulatory (ORA) requested as part of the Strengthening Food Safety Initiative in the fiscal year 2008 President's Budget request will not result in an increased number of food safety inspections. Funding will be used to enhance ORA's ability to more rapidly trace back foodborne disease outbreaks and to work proactively to encourage growers and processors to implement good agricultural practices and other interventions designed to prevent contamination of food. ORA will develop, train, and equip teams to work with State partners in large produce-growing regions. Funding will also be used to accelerate development of an import decision-making IT system capable of detecting high-risk food shipments before they enter U.S. commerce. While FDA already has systems that are used to identify and target certain high-risk import shipments, the new system will increase current capabilities by providing for automated review and trending of the results of field examinations and analyses of samples, identifying candidates for detention without physical examination; it will score each entry line on the basis of risk factors and surveillance requirements, for an automated, real-time decision on action to be taken; and, it will incorporate exogenous data with available FDA operational data to create a broader picture for each shipment.

QUESTIONS SUBMITTED BY SENATOR JACK REED

SUNSCREEN MONOGRAPHS

Question. The FDA Reform Act of 1997 directed your agency to complete a sunscreen monograph, which will guide UVA and UVB labeling information for over-the-counter (OTC) sunscreen products. The fiscal year 2006 Agriculture Appropriations conference report again included language directing the FDA to complete the sunscreen monograph, within 6 months of passage of the agriculture appropriations bill. That bill was signed into law on November 10, 2005. The FDA began drafting this monograph for sunscreen products in 1978 and has yet to complete it. Meanwhile, another summer season is approaching and millions of consumers will again use sunscreen products that provide half the protection. As you know, around 60,000 people worldwide die each year from skin cancer caused by too much sun exposure.

Why is the FDA unable to complete this monograph despite repeated requests from Congress, the public health community, and health care providers?

Answer. Revisions to the stayed final sunscreen monograph that address the issue of measuring protection against UVA rays, including UVA and UVB labeling requirements, involve the resolution of complex scientific and legal issues, both of which have contributed to this lengthy process.

Question. What is the status of the monograph and how much longer can we expect to wait before a final monograph will be available?

Answer. On May 12, 1993, FDA published a tentative final monograph (TFM) that included UVB testing and labeling requirements. On May 21, 1999, FDA published a final monograph (FM) for OTC sunscreen drug products. The FM included UVB testing and labeling requirements, but deferred UVA testing and labeling requirements to a future publication. On December 31, 2001, FDA stayed the December 31, 2002, effective date of the FM to develop a comprehensive monograph that addresses formulation, labeling and testing requirements for both UVB and UVA radi-

ation protection. The proposed rule that addresses formulation, labeling and testing requirements for both UVB and UVA radiation protection has been written and is in final FDA clearance.

Question. Once the final monograph is completed, how much longer will it take for skin screen manufacturers and makers of skin care products that include sunscreen to adopt necessary changes to their products?

Answer. FDA cannot provide an exact time estimate, but the agency is aware there are many factors involved for manufacturers to implement necessary changes to their products, such as the seasonal nature of the sunscreen industry, time required for product testing and relabeling and economic impact considerations for the industry and consumers. All of these factors affect the speed with which changes can be made to products and how quickly the products reach the market.

Question. As the former Director of the National Cancer Institute, could you talk about the potential health impact of excess exposure to UVA rays?

Answer. Ultraviolet (UV) rays are a part of sunlight that is an invisible form of radiation. UV rays can penetrate and change the structure of skin cells. UVA is the most abundant source of solar radiation at the earth's surface and penetrates beyond the top layer of human skin. Scientists believe that UVA radiation can cause damage to connective tissue and increase a person's risk for developing skin cancer. UV exposure appears to be the most important environmental factor in the development of skin cancer. A person's risk of skin cancer is related to lifetime exposure to UV radiation. Most skin cancer appears after age 50, but the sun damages the skin from an early age.

Skin cancer is the most commonly occurring cancer in the United States. Basal cell carcinoma and squamous cell carcinoma are the most common forms of skin cancer, but are easier to cure than melanoma. The number of new cases of skin cancer appears to be increasing each year.

It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen.

QUESTIONS SUBMITTED BY SENATOR ROBERT F. BENNETT

COUNTERFEIT DRUGS

Question. Dr. von Eschenbach, earlier this month, FDA notified consumers that a number of Americans who had placed orders over the internet for common prescription drugs instead received a product that contained a very powerful anti-psychotic drug. As a result of taking these fake products, consumers had to seek emergency medical treatment for symptoms such as difficulty in breathing, muscle spasms and muscle stiffness. FDA warned consumers not to purchase prescription drugs off the internet unless they were certain that the internet sites were legitimate pharmacy sites.

In your opinion, how prevalent are counterfeit drugs in the United States?

Answer. We believe that in the United States, counterfeit drugs are quite rare. By all accounts, the overwhelming majority of prescription drugs sold in the United States are genuine, FDA-approved drug products. While we have no direct quantitative evidence about the prevalence of counterfeit drugs, we believe that counterfeit drugs represent significantly less than 1 percent of the total U.S. drug supply.

Question. Please explain the steps FDA is taking to find and prosecute counterfeit drug manufacturers.

Answer. The FDA Office of Criminal Investigations, OCI, actively elicits and receives information from many entities to identify counterfeit drug sources, including industry, the public and other domestic law enforcement agencies. OCI also coordinates counterfeit drug investigations with several foreign counterparts, especially those in China, Israel, the Netherlands, and Canada, to enhance criminal investigations. These efforts continue to produce positive outcomes for both OCI and its foreign counterparts. OCI will continue to aggressively pursue counterfeit drug investigations with law enforcement partners in foreign countries as well as with Federal, State, and local law enforcement here in the United States.

As an example, in September 2006, an individual from China was arrested by officers of the Hong Kong Customs and Excise Department based on a Federal arrest warrant issued by the U.S. District Court for the District of Colorado. The defendant was arrested in Hong Kong after meeting with an undercover OCI agent who posed as a buyer of over 400,000 counterfeit Cialis® and Viagra® tablets. This investigation also involved the sale of several thousand counterfeit Tamiflu® capsules that were manufactured in China and shipped to the United States. Information developed by OCI and Immigration and Customs Enforcement, or ICE, was shared with

Chinese authorities had already led to the August 2006 arrests of four individuals in China. In addition to the arrest in Hong Kong, three other defendants in the United States have pled guilty to counterfeit drug charges. Furthermore, information developed during this joint OCI, ICE counterfeit drug investigation was the basis for another counterfeit Percocet® investigation in Philadelphia, Pennsylvania which resulted in a sentence of 32 months incarceration for the defendant.

Question. Since many counterfeit products come from other countries, does FDA receive adequate assistance from foreign governments to find and prosecute drug counterfeiters?

Answer. The adequacy of assistance the Office of Criminal Investigations, or OCI, receives from foreign governments depends on the respective governments involved. OCI has had success with foreign governments regarding counterfeit drug investigations, but increased cooperation, collaboration, and strengthening of relationships with foreign governments would lead to enhanced identification and prosecution of counterfeit drug operations. Our success is limited because OCI does not have a foreign presence in countries such as China and therefore, OCI must leverage its resources with other agencies such as the Immigration and Customs Enforcement, or ICE and the Drug Enforcement Administration or DEA, which do have a presence in other countries.

In another example of assistance OCI receives from foreign governments, an individual from the State of Washington was indicted and arrested in September 2005 for his involvement in the importation from China and subsequent distribution of counterfeit drugs, including Viagra®, Cialis® and Lipitor®. The defendant pled guilty to distributing counterfeit drugs and was sentenced in October 2006 to 10 months of incarceration. In this joint OCI and ICE investigation, cooperation was sought and received from the Chinese government. As a result of this cooperation, the Chinese authorities arrested eleven individuals in China and recovered significant amounts of counterfeit drugs and counterfeit drug packaging.

FDA PAY COSTS

Question. During user fee negotiations this year, FDA and industry agreed that annual inflation for pay and benefit costs is approximately 5.8 percent. This calculation was based on a moving 5-year average. However, the budget request includes only a 3.0 percent increase for pay costs.

Why does the budget request not include the total amount for pay?

Answer. In the fiscal year 2008 President's Budget FDA requested an increase of \$21.77 million for the 3 percent mandated cost-of-living increase for employees, which is in concurrence with the Administration's policy. Funding the annual pay increase enables FDA to perform its public health mission.

Question. What is the rationale for shortchanging basic inflationary costs in the budget?

Answer. In the fiscal year 2008 President's Budget FDA requested an increase of \$21.77 million for the 3 percent mandated cost-of-living increase for employees, which is in concurrence with the Administration's policy. Funding the annual pay increase enables FDA to perform its public health mission.

Question. How do pay shortfalls affect the ability of FDA to utilize initiative increases, such as food safety or drug safety, to the fullest extent?

Answer. In the fiscal year 2008 President's Budget FDA requested an increase of \$21.77 million for the 3 percent mandated cost-of-living increase for employees, which is in concurrence with the Administration's policy.

Funding the annual pay increase enables FDA to perform its public health mission. Without these funds, FDA must reduce the number of inspectors, medical and consumer safety officers, food safety technologists, medical product reviewers, postmarket safety experts, and other public health experts to meet higher payroll obligations. These workforce reductions would limit FDA's ability to safeguard the American public.

Question. How does under-budgeting for pay affect FDA staffing and future budget requests?

Answer. In the fiscal year 2008 President's Budget FDA requested an increase of \$21.77 million for the 3 percent mandated cost-of-living increase for employees, which is in concurrence with the Administration's policy.

Funding the annual pay increase enables FDA to perform its public health mission. Without these funds, FDA must reduce the number of inspectors, medical and consumer safety officers, food safety technologists, medical product reviewers, postmarket safety experts, and other public health experts to meet higher payroll obligations. These workforce reductions would limit FDA's ability to safeguard the American public.

GENERIC DRUG REVIEW FISCAL 2007 FUNDING

Question. The fiscal 2007 joint resolution provided an increase of \$5 million for the Office of Generic Drugs.

How does FDA plan to use this funding and how will generic drug review performance be enhanced as a result of the additional funding?

Answer. The \$5 million increase to the office of generic drugs in fiscal year 2007 will allow FDA to help make up for lost performance, due to the loss of 10 FTE under the continuing resolution. The Center for Drug Evaluation and Research, or CDER, currently is recruiting to backfill these lost positions. In fiscal year 2008 this \$5 million increase is expected to yield an additional 10 approvals a month, once all of the reviewers have been hired and trained to conduct reviews. FDA expects that it will take at least 1 year to recruit and train staff for the Office of Generic Drugs.

Question. What is the current backlog for generic drug applications?

Answer. There is currently a backlog of about 1,300 original generic applications as of the end of February 2007.

FDA ALLIANCE REQUEST FOR FDA FUNDING

Question. Dr. von Eschenbach, a couple groups, the FDA Alliance and the Coalition for a Stronger FDA, have been lobbying for more money for FDA. They estimate that Congress needs to add \$250 million in non-user fee funding this year to effectively fund FDA's needs. This estimate is obviously well above the budget request for FDA.

Are you aware of their analysis of FDA funding needs?

Answer. We have read accounts of their analysis that has been reported in the press.

Question. What do you think about their suggestion that FDA needs an increase of \$250 million this year?

Answer. This is an amount that greatly exceeds the President's budget request.

PROPOSED GENERIC DRUG USER FEE

Question. The budget request includes a proposal to implement a generic drug user fee in fiscal 2008. According to FDA's calculations, the fee will generate \$15.7 million in the first year.

Has industry been receptive to this fee proposal?

Answer. We are currently exploring with industry the possibility of user fees for generic drugs.

PROPOSED RE-INSPECTION USER FEE

Question. For the second year, FDA is proposing a re-inspection user fee, which will require manufacturers to pay for the full cost of follow-up inspections when FDA must revisit facilities because of initial bad inspection reports. FDA plans to collect \$23.2 million in fiscal 2008 as a result of this fee.

Please explain for what services these fees are intended to be collected.

Answer. When FDA finds that a firm fails to comply with applicable FDA law, then FDA may take various regulatory actions to ensure the firm's compliance. Often, the firm's voluntary corrective action can address these compliance failures and thus preclude the need for FDA initiating any regulatory action. In other cases, agency regulatory action will mean that the firm can no longer market some or all of its products. For example, in some cases FDA will not grant export certificates, approve product applications, or award government contracts because of the firm's compliance status. If a firm undertakes corrective action to achieve compliance, FDA will verify the appropriateness and completeness of the corrective action. For the firm to satisfy FDA's concerns and, if regulatory action was taken, to resume its full ability to market products, FDA must reinspect the firm to confirm compliance.

When a firm believes it has corrected its noncompliance and addressed FDA's concerns, the timely reinspection by FDA to evaluate such compliance benefits the firm by allowing a quicker resolution of these compliance questions and, where applicable, allowing the firm to resume its full ability to market products.

These user fees will permit FDA to act in a timely manner to ensure that non-compliant firms have taken appropriate corrective action and to facilitate the return of compliant firms to full marketing. Some of the activities that FDA performs in conducting reinspections include the scheduling and preparatory reinspection work by the FDA investigator, the reinspection itself, collecting and analyzing samples, preparing reports on the inspection, review and analysis by compliance officers, consulting with experts, and travel and administrative time.

Question. How does FDA determine the costs that each facility must pay for re-inspection?

Answer. The Office of Regulatory Affairs determined the costs that each facility must pay for re-inspections based on the number of violative inspections in fiscal year 2006; the average length of time performing those inspections; and, the average cost of each Office of Regulatory Affairs FTE.

Question. Would FDA charge small or start-up companies differently than larger, more established companies?

Answer. The Secretary of Health and Human Services will establish reinspection fees to be collected based on the Secretary's estimate of the cost to conduct reinspections for a particular year. The legislation submitted to the Congress in fiscal year 2007 for this proposal allows the Secretary to provide for waivers, reductions, or other adjustment of fees based on financial hardship or other circumstances as determined appropriate by the Secretary.

Question. Has industry been receptive to this fee proposal?

Answer. We are currently exploring with industry the possibility of user fees for reinspections.

USER FEE REAUTHORIZATION

Question. FDA is currently in the process of renegotiating the user fee agreements for prescription drugs and medical devices. These two user fee programs are crucial to maintaining FDA review times and bring in almost \$400 million in revenue annually.

Please provide us with an update on the progress FDA and industry are making toward reauthorizing these programs.

Answer. On March 23, 2007, the Secretary transmitted to key House and Senate authorizing committees the HHS/FDA recommendations for changes to the statute and to the performance commitment letter for the Prescription Drug User Fee Act IV, or PDUFA IV. These recommendations reflected the results of FDA's discussions with the pharmaceutical and biotechnology industry, which concluded in November 2006, and further revisions to the commitment letter based on public input received in response to the January 16, 2007 Federal Register notice publishing FDA's proposed recommendations, and received at the PDUFA IV public meeting FDA held on February 16, 2007. FDA's recommended changes to the statute and commitment letter are currently being reviewed by the Senate Health, Education, Labor and Pensions, or HELP, Committee staff and House Energy and Commerce Committee staff.

FDA and the medical device industry have been discussing legislative recommendations for the Medical Devices User Fee and Modernization Act, or MDUFMA, reauthorization since the fall of 2005. Almost all issues of interest to FDA and to industry have been resolved. We are working to resolve the outstanding issues very quickly.

PANDEMIC INFLUENZA

Question. In the fiscal 2006 supplemental, we provided \$20 million for pandemic influenza preparedness. This funding was continued in the fiscal 2007 joint resolution.

What has FDA accomplished with this funding?

Answer. FDA reports the following 12 activities have been accomplished with the funding:

- engaged in efforts to build and enhance our infrastructure to support new vaccine development and licensure for pandemic influenza, hired 75 employees with expertise in essential clinical, product safety, and manufacturing areas; initiated contracts to ensure facilities have needed surge capacity and being prepared to handle viruses at the Biosafety Level 3, which include laboratories critical for vaccine testing
- approved another influenza vaccine under the new accelerated approval pathway, giving consumers five FDA-licensed influenza vaccines
- approved 35 influenza vaccine BLA supplements, which contribute to capacity building for seasonal and pandemic influenza vaccines
- involved in activities to determine the potency of vaccines against a pandemic strain, develop tests and assays to ensure safety of cell cultures used to manufacture vaccines, and explore requirements to prepare libraries of pandemic influenza viral strains, so the strains are available for manufacturing vaccines
- published two draft guidance documents outlining approaches that influenza vaccine developers can follow to ensure the safety and effectiveness of new vaccines

- developed a Lot Release Information Technology System to support testing and release of vaccines to ensure safety and effectiveness
- hosted a meeting with foreign regulatory authorities to discuss harmonizing regulatory pathways for pandemic influenza vaccines
- participated in meetings on issues such as existing and “next generation” vaccine production technologies, current Good Manufacturing Practices and research needs, and participated in a public-private working group to develop guidelines to assure the public of the safety of the food supply during an outbreak in animals
- provided technical assistance to support HHS decision making on the mix of antiviral medications to include in the Strategic National Stockpile
- served as technical advisor to HHS and others on FDA regulation of masks and other personal protective equipment (PPE) and workplace guidance on the use of PPE during an influenza pandemic
- conducted investigations and covert surveillance operations to detect counterfeit, impure, contaminated, sub-potent, or super-potent products that claim to prevent or treat seasonal or pandemic influenza
- issued 41 warning letters to internet sellers of unproven bird flu cures and preventatives.

Question. How many pandemic influenza products have been approved?

Answer. With the funding associated with the \$20 million supplemental funding CBER has approved one influenza vaccine biologics license application, or BLA, Flulaval, which was a priority review, and 35 influenza vaccine BLA supplements, which contribute to capacity building for seasonal and pandemic influenza vaccines. In this same time frame, CBER held 28 meetings with influenza vaccine manufacturers and received and reviewed 21 investigational new drug applications, or INDs, for influenza vaccines.

In October 2006, CBER received the first U.S. BLA for a vaccine against H5N1 influenza virus. FDA also designated this application as a priority review, which means that FDA will take an action on the application within 6 months of receiving it. In February 2007, CBER presented this application to the Vaccines and Related Biological Products Advisory Committee to obtain the Committee’s input regarding the safety and effectiveness of the vaccine. The action due date for this H5N1 vaccine is April 17, 2007. If approved, this will be the first vaccine approved for H5N1, a potential pandemic influenza strain.

FDA has also approved other pandemic influenza products with base funding used in both CDER and CDRH. There are four antiviral drugs currently approved by CDER at FDA to treat acute, uncomplicated influenza. Two related drugs, amantadine (approved 1966; Trade Name Symmetrel, also available as generic Amantadine Hydrochloride) and rimantadine (approved 1993; Trade Name Flumadine, also available as generic Rimantadine Hydrochloride), are approved for treatment and prevention of influenza A; however, many recent influenza viruses are resistant to these drugs, seriously limiting their usefulness. Two newer drugs, zanamivir (approved 1999; Trade Name Relenza; no approved generics) and oseltamivir phosphate (approved 1999; Trade Name Tamiflu; no approved generics), are approved for treatment of acute uncomplicated illness due to influenza A and B. Both zanamivir and oseltamivir are approved for preventive use.

CDRH approved a diagnostic device for the detection of novel influenza (H5N1) which is directly related the Pandemic Influenza. This product is called the Influenza A/H5 (Asian lineage) Virus Real-time RT-PCR Primer and Probe Set. The test provides preliminary results on suspected H5 influenza samples within four hours once a sample arrives at the lab and testing begins. Previous testing technology would require at least 2 to 3 days to render results. If the presence of the H5 strain is identified, then further testing is conducted to identify the specific H5 subtype (e.g., H5N1).

There are a number of devices regulated by FDA that would be in increased demand in a pandemic. Examples include devices such as ventilators, bacterial filters for breathing circuits, resuscitators, infusion pumps, IV administration sets, vaccination needles, surgical masks, surgical respirators, gloves and gowns. None of these is specifically cleared for use in a pandemic, but carry more general labeling claims. CDRH assessed types, number and the increase in submissions for cleared products in increased demand during a pandemic. CDRH observed an increase in the number of clearances from an average of 0.5 respirators per year prior to October 1 2005 to an average of 5.6 respirators per year between October 1, 2005 and February 27, 2007—for a total of 8 respirators cleared in the latter time period.

RESEARCH REDUCTIONS TO BSE

Question. Dr. von Eschenbach, the budget request includes a proposal to reduce research by \$3.8 million. According to the budget request, one area where FDA plans to reduce research is on prohibited materials in animal feed.

Why is FDA reducing funding for this research, especially when it is so critical to FDA's role in reducing the risk that cattle will contract mad cow disease?

Answer. The Center for Veterinary Medicine, or CVM, completed development of a real-time Polymerase chain reaction, or PCR, based method. Once field validation of the real-time method is completed, the field has a necessary tool to support enforcement of the feed ban. Companies are not marketing new rapid test kits for detecting prohibited proteins in animal feeds; therefore, CVM does not have additional test kits to evaluate.

The Office of Regulatory Affairs, or ORA, intends to absorb the reduction of \$593,000 in the Animal Drugs and Feeds Program by reducing both personnel and operating funds for coordination activities in either the ORA Office of Enforcement; ORA Headquarters; or Compliance Officers and Public Affairs Specialists located in the Region and District Offices. Operating fund reductions will be taken in travel, training and meetings with State or industry officials to perform outreach activities in support of the Field Animal Drugs and Feed Program. Management and coordination functions will continue by using electronic media/technology and realigning and consolidating coordination responsibilities to improve efficiencies.

The research reduction allows CVM and ORA to fund the full cost of fiscal year 2008 priority initiatives.

MEDICAL DEVICE USER FEE AND MODERNIZATION ACT (MDUFMA)

Question. I have paid close attention to the Medical Device User Fee and Modernization Act (MDUFMA) review program, and this subcommittee has provided substantial appropriated dollars for the review of medical devices.

How is FDA doing in regards to meeting the performance goals associated with the user fee program with the user fee and appropriated funding it has received to date?

Answer. FDA has made excellent progress towards meeting the Medical Device User Fee and Modernization Act's, or MDUFMA, complex and demanding performance goals, and particularly so for the decision goals that both FDA and industry regard as the key indicators of performance. We review our performance at the end of each quarter, and I am providing a table for the record that summarizes total FDA progress on each goal through December 31, 2006. As soon as we have prepared similar information for the quarter that ends March 31, 2007, I will send you an updated table.

Let me cite just three examples of our progress in meeting MDUFMA's performance goals from fiscal year 2003 through the end of 2006. For premarket approval applications and panel-track PMA supplements, we made 169 "FDA decisions" during that period, and we made 94.7 percent of those decisions within our target of 320 days. For 180-day PMA supplements, we made 532 "FDA decisions" and we made 95.7 percent of those decisions within 180 days. And for 510(k) premarket notifications, we made 13,670 decisions, and we made 86.1 percent of these decisions within 90 days.

I believe the performance we have achieved to date clearly demonstrates FDA's strong commitment to pursuing and meeting MDUFMA's performance goals. The proposals FDA and industry have developed to reauthorize medical device user fees for fiscal years 2008 through 2012 build on the progress we have made, and include a refined set of performance goals that provide a clear pathway to further improvements in our review of medical devices.

[The information follows:]

QUARTERLY REPORT ON PROGRESS TOWARDS ACHIEVING MDUFMA PERFORMANCE GOALS

Summary Tables

[Actions through December 31, 2006—Data for FDA]

Activity	Review Time Goal	Performance Goals and Actual Performance to Date												Overall Fiscal Year 2003 to Date (Actual)
		Fiscal Year 2003			Fiscal Year 2004			Fiscal Year 2005			Fiscal Year 2006			Fiscal Year 2007
		Goal Percent	Actual Percent	Goal Percent	Goal Percent	Actual Percent	Actual Percent	Goal Percent	Actual Percent	Actual Percent	Goal Percent	Actual Percent	Goal Percent	
Vias, Panel-Track Supplements, Premarket Reports: FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	320 days	91.7	91.7	97.9	80	100	94.7
First action—major deficiency letter	150 days	84.6	82.1	75	91.9	80	92.9	90	87.5
First action—all other first actions (approval, approvable, approvable pending GMP inspection, not approvable, or denial)	180 days	95.8	95	75	90	80	90.5	90	92.9
Second or later action—major deficiency letter	120 days	100	100	75	70.6	80	100	90	81.5
Action on an amendment containing a complete response to a major deficiency or not approvable letter	180 days	92	88.9	75	90.2	80	90	90	90.3
Action on an amendment containing a complete response to an approvable letter	30 days	90	33.3	90	90	70	90	90	44.4
Expedited PMAs: FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	300 days	100	92.3	70	50	80	90	85
First action major deficiency letter	120 days	100	80	70	80	80	90	82.4
First action—all other first actions (approval, approvable, approvable pending GMP inspection, not approvable, or denial)	170 days	100	25.0	70	100	80	100	90	57.1
Second or later action—major deficiency letter	100 days	70	100	80	90	50
Action on an amendment containing a complete response to a major deficiency or not approvable letter	170 days	100	62.5	70	100	80	90	80
Action on an amendment containing a complete response to an approvable letter	30 days	90	100	90	90	50	90	90	90	66.7
180-day PMA Supplements: FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	180 days	94.1	96.2	80	95	80	98.3	90	95.7
First action—not approvable letter	120 days	18.8	83.7	80	90	85	81.1	90	71.1
First action—all other first actions (approval, approvable, approvable pending GMP inspection, not approvable, or denial)	180 days	95.3	96.8	80	98.4	85	98.9	90	96.9
Action on an amendment containing a complete response to a not approvable letter	160 days	96	97.6	80	86.1	85	92.3	90	93.1

	90 days	76.1	83.9	75	91.3	75	95.3	80	100	86.1
FDA decision (SE/NSE)
First action—additional information letter	75 days	58.6	78.6	70	93.8	80	92.8	90	98.1	81.9
Second or later action	60 days	50.9	81.9	70	91.5	80	96	90	100	80.7
Biologics Licensing Applications BLAs:										
Review and act on standard original BLAs (issue complete action letter)	10 months	100	100	75	100	90	100	100
Review and act on priority original BLA submissions (issue complete action letter)	6 months	75	90
BLA Supplements:										
Review and act on standard BLA efficacy supplements (issue complete-action letter)	10 months	100	75	90	100
Review and act on priority BLA efficacy supplements (issue complete action letter)	6 months	75	90
Review and act on BLA manufacturing supplements that require prior approval (issue complete action letter)	4 months	98.6	100	96	75	100	90	100	98.9
BLA Resubmissions:Supplement Resubmissions:										
Review and act on a Class 1 resubmission to an original BLA or BLA efficacy supplement (issue complete action letter)	2 months	75	100	80	90	100
Review and act on a Class 2 resubmission to an original BLA or BLA efficacy supplement (issue complete action letter)	6 months	100	80	75	100	80	100	90	95

Question. Would you be willing to adopt a method to determine incremental direct and indirect costs associated premarket application (PMA) and 510(k) device approvals?

Answer. FDA is committed to providing a full accounting of our use of those resources entrusted to us. To that end, we have established cost accounting systems that meet or exceed generally-accepted government accounting practices. As required by the Chief Financial Officers Act of 1990, as amended, our records are subject to periodic independent audits by the Office of Inspector General, or OIG. The OIG issued unqualified audit opinions on FDA's financial statements for fiscal years 1998 through 2004. This is the most favorable category of audit opinion. Auditors did not render an opinion on FDA's financial statements for fiscal year 2005, primarily due to the mid-year conversion to the new HHS Unified Financial Management System. In fiscal year 2006, HHS incorporated the FDA financial audit as part of the HHS financial statement audit. We are pleased to report that HHS received an unqualified opinion on its financial statements. Our implementation of the Medical Device User Fee and Modernization Act of 2002, or MDUFMA, has been addressed by three reports by the U.S. Government Accountability Office, which made no adverse findings and provided no recommendations for change. We have also provided a MDUFMA financial report to Congress each year since the program was enacted.

FDA and industry discussed whether additional information was required for adequate oversight of our MDUFMA initiatives. Our joint recommendations for reauthorization 6 months to discuss issues relating to performance and medical device user fees includes an agreement to meet informally every expenditures, including an FDA update on how funding is being used for the device review process, including investments in information technology and training.

I believe these systems, safeguards, audits, oversight, reports, and commitments provide the necessary transparency concerning our costs and our use of resources.

Question. What criteria does the agency use to determine the allocation and priority for the distribution of staff and funding increases across FDA components, including offices, divisions, or branches resulting from the medical device user fees and related appropriated funding?

Answer. I would describe our general approach as combining a risk-based assessment of our needs, and a focus on accomplishing our public health missions through the most efficient and effective means possible. FDA allocates medical device user fees and other medical device appropriations to best achieve FDA's public health objectives, performance goals and other expectations established under the Medical Device User Fee and Modernization Act of 2002 and its amendments. The user fees and additional appropriations provided to FDA under MDUFMA have been allocated to reflect the workload balance between the Center for Devices and Radiological Health, or CDRH, and the Center for Biologics Evaluation and Research, or CBER. Soon after Congress enacted MDUFMA, FDA estimated the percent of the device review workload that was performed in CDRH and the percent that was performed in CBER. FDA allocated its MDUFMA resources to CDRH and CBER using those percentages.

Field resources are allocated among districts by the Office of Regulatory Affairs according to each district's projected workload, such as Quality Systems Regulation and preapproval inspections of medical device establishments.

Each Center and ORA is responsible for apportioning its overall resource allocation to its offices, divisions, and branches. The general approach is to prioritize additional needs and to allocate additional resources accordingly.

Question. Are third party review and third party inspection programs useful? Is there anything that can be done to improve these programs?

Answer. I believe that both the third-party inspection program and third-party reviews of 510(k) premarket notifications have the potential to be useful adjuncts to the corresponding FDA processes, helping us conserve and focus FDA's resources.

In implementing the third-party inspection program, FDA met all of the Medical Device User Fee and Modernization Act's, or MDUFMA, statutory requirements and deadlines. We accredited 17 well-qualified organizations to conduct third-party inspections. We trained third-party inspectors so they would fully understand FDA's inspectional requirements. We prepared guidance to facilitate the understanding of the statutory requirements and the processes FDA would use to administer the program. We wrote to device establishments to make them aware of the program. Despite these efforts, establishments have been reluctant to participate because of perceived procedural burdens. So far, only two establishments have requested and received a third-party inspection.

FDA is currently working on changes to this program as part of the MDUFMA reauthorization negotiations. I look forward to communicating these recommendations to you and working with you to see that these changes are made.

Although the third party 510(k) review program has grown significantly since it was established, the program has not yet saved FDA the resources that we had hoped we could reallocate to other 510(k) reviews. This is because all third party submissions undergo FDA quality review and because the training and continuing education of third parties remains resource intensive.

Nonetheless, more than 1,300 510(k)s have undergone third-party review since the inception of the program, and the number of submissions has been rising steadily. During fiscal year 2006, the third-party program was responsible for 287 submissions, compared with just 107 5 years earlier, and accounted for about 7 percent of all 510(k)s. For some types of devices, third-party submissions account for a much larger share of our overall workload. For example, during the past 3 years, over 80 percent of radiology devices have been reviewed through the third-party program.

We have worked hard to ensure that third-party reviews meet our expectations for quality and completeness. When we observed some unevenness in the quality of third-party submissions, we provided additional guidance to FDA staff and third-party reviewers. We also believe that quarterly teleconferences with third-party reviewers and continuous quality feedback from FDA review divisions will contribute to further quality improvement over time. We believe the program may further improve as third parties gain further review experience and proficiency that can be applied to subsequent reviews, and as FDA develops guidance documents for more devices.

BIOLOGIC LICENSE APPLICATION APPROVALS

Question. According to a recent news article, the Center for Biologics Evaluation & Research's average time to approval of biologic license applications (BLAs) was 18.9 months in 2006, almost doubling the previous year's average of 9.3 months. This is a troubling statistic.

What has caused the increase in review times and what steps is FDA taking to make improvements?

Answer. The approval number quoted in the Pink Sheet article does not reflect a doubling of Agency review time from 2005 to 2006. Time to approval is the time from initial submission to final approval, including all the time that elapses while a company revises its application to correct deficiencies in its initial application. In fiscal year 2005, the Center for Biologics Evaluation and Research, or CBER, had eight biologics license application, or BLA, approvals, with all eight approved during the first review cycle. The review cycle is the time between application receipt and issuance of an action letter. Sometimes an application contains deficiencies that prevent CBER from approving the license application in the first review cycle. In this event, CBER issues what is known as a complete response letter. A complete response letter describes the deficiencies in the application, stops the review clock, and gives the company an opportunity to correct the deficiencies and resubmit its application. Sometimes companies can correct the deficiencies quickly by explaining or clarifying existing data or methods; other times companies must submit more data or even conduct completely new clinical trials before the application can be approved. In 2005, because CBER was able to approve all BLAs in the first review cycle, total approval times were considerably shorter than if a complete response letter had been issued.

In fiscal year 2006, CBER had five approvals: three during the first review cycle; one in the second review cycle; and one in the third review cycle. The approval that went through three review cycles took almost 53 months. Thirty-two of those months did not involve FDA review time. They were time between review cycles that the applicant used to address CBER's complete response letters. With only five total approvals in fiscal year 2006, that one application—along with the other application that required more than one review cycle—skewed the average approval time significantly. The difference between the median approval time, which was 13 months, and the average approval time, which was 19.4 months—the Pink Sheet's figure differs because it includes Center for Drug Evaluation and Research-approved licenses, reflects the effect of the two applications that could not be approved in the first review cycle.

In contrast, the CBER approvals in fiscal year 2005 were completed in extremely short times with no second review cycles required. The average CBER approval time was 9.1 months, and the median CBER approval time was 9.9 months. CBER reviewers completed those reviews expeditiously through intense review effort but also were aided considerably by the quality of the submissions. While CBER reviewers

made similar intense review efforts in 2006, and continue those efforts today, we also continue to explore ways to improve the quality of submissions and shorten review times further.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

FOLLOW-ON BIOLOGICS

Question. There is concern among biologic drug companies that the FDA does not have the resources to handle the regulatory procedures necessary to ensure safe and effective follow-on or generic biologics. In your opinion does the FDA have the regulatory ability to ensure the safety and efficacy of follow-on biologics?

Answer. FDA has the scientific expertise to determine the safety and effectiveness of follow-on biologics. This is demonstrated by FDA's approval of certain follow-on protein products under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act and the agency's substantial expertise and experience in approving biologics license applications under section 351 of the Public Health Service Act, or PHS Act. FDA will address the scientific challenges related to follow-on protein products in a manner consistent with its approach in other scientific arenas: on a case-by-case basis as issues arise, in accordance with FDA's statutory authority and its mission to both advance and protect the public health. If a new regulatory pathway is enacted by statute for the approval of follow-on biologics under section 351 of the PHS Act, it will be necessary to consider the adequacy of agency resources needed to efficiently and effectively implement such a program.

ORA CONSOLIDATION

Question. It is my understanding that FDA plans on consolidating the FDA's Office of Regulatory Affairs laboratories. I appreciate your response to a joint letter to you sent on January 29, 2007. Could you elaborate in more detail on the proposal to include which labs are planned on being closed and the number of employees that would be affected. Further, what does the agency plan on offering those employees that work at labs that are proposed to be closed? Finally, will the consolidation plan negatively impact our Nation's safety of food, medical equipment, and cosmetics?

Answer. FDA's Office of Regulatory Affairs, or ORA, plans to enhance its laboratory capabilities by strengthening six of ORA's regulatory labs, moving to these six labs the personnel, equipment and other resources from seven other existing labs. The seven labs are older facilities in need of costly renovations, cannot expand to accommodate merging with another lab, have expiring leases, and meet a range of other criteria which have led FDA to consolidation in these areas. This transformation will allow ORA scientists to work more closely together and improve collaboration and synergy. This will allow us to invest in state-of-the-art equipment and processes in the remaining laboratories and to increase investment in other critical areas. Because the ORA restructuring is still early in its planning phase, the number of employees impacted has not yet been determined.

Strengthening these six labs will help FDA better meet its mission to protect and promote the public health. Currently, FDA must pay the costs associated with approximately 40 percent more laboratory space than is needed to conduct the laboratory work to support all of FDA's field programs and activities. These six labs will accommodate and exceed the capacity of testing conducted in the existing 13 labs. Although overnight delivery services diminish the need for laboratories to be in close proximity to sample collection sites, the consolidated laboratories will be dispersed geographically. In addition, the six labs will continue to provide supporting layers of expertise with appropriate redundancies to protect against unforeseen operational problems, and surge capacity to deal with emergencies.

This proposed restructuring of ORA would begin in fiscal year 2008. Costs for the restructuring in fiscal year 2008 are covered within the fiscal year 2008 budget level. All analysts from closing labs will be offered jobs in the labs to which their work is transferred. We realize that some employees will not relocate and in order to retain as many of these valued employees as possible, we will seek to place them in other jobs in their current location. ORA needs to invest intellectual and financial capital in new approaches to emerging challenges such as the increasing complexity of the products and processes we regulate. ORA transformation provides an opportunity to staff teams of national experts in a variety of disciplines. Towards this end, the transformation plan provides for Centers for Excellence in those geographic regions of the country where labs will be closed.

The seven closing laboratories include Denver District Laboratory (Denver, Colorado); Detroit District Laboratory (Detroit, Michigan); Kansas City District Labora-

tory (Lenexa, Kansas); Philadelphia District Laboratory (Philadelphia, Pennsylvania); San Francisco District Laboratory (San Francisco, California); San Juan District Laboratory (San Juan, Puerto Rico); and, the Winchester Engineering and Analytical Center (Winchester, Massachusetts).

In the seven areas where there have been laboratories, FDA is planning to utilize the significant expertise that already exists and focus on the 21st Century challenges unique to each region. The ORA transformation provides the opportunity to address the specific challenges that ORA is facing in each of these regions, and to respond to the rapidly changing profile of the products it regulates. These regions, and the capability of the FDA employees who are stationed there, will continue to play a critical role in ensuring the safety of our Nation's food and drugs.

CONCLUSION OF HEARING

Senator KOHL. This hearing is recessed.

[Whereupon, at 12:18 p.m., Tuesday, February 27, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RE- LATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2008

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

NONDEPARTMENTAL WITNESSES

[The following testimonies were received by the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies for inclusion in the record. The submitted materials relate to the fiscal year 2008 budget request for programs within the subcommittee's jurisdiction.]

PREPARED STATEMENT OF THE AD HOC COALITION

Mr. Chairman, Members of the Subcommittee, this statement is respectfully submitted on behalf of the ad hoc coalition¹ composed of the organizations listed below. The coalition supports sustained funding for our Nation's food aid programs, including Titles I and II of Public Law 480, and therefore strongly opposes the administration's twice-rejected proposal to convert Public Law 480 food aid funding into cash donations for commodities purchases in overseas markets.

GUIDING PRINCIPLES OF FOOD AID POLICY

The coalition recognizes that American food assistance policy is well-established and founded on certain guiding principles, including the following:

- Meeting America's humanitarian obligation to sustain food assistance programs, with U.S. participation in such programs constituting more than 50 percent of all food aid worldwide.
- Employing food assistance programs as stepping stones for economic growth and development.
- Employing food assistance programs to promote respect worldwide for American values and our economic system, thereby enhancing goodwill toward America among disadvantaged populations that may be breeding grounds for terrorism.

THE SHARP DECLINE IN OVERALL FOOD AID PROGRAM LEVELS

The programs needed to implement these principles have enjoyed broad, bipartisan support for many decades. The strength of our commitment has made the United States the world's leading food aid supplier. In the process, American agriculture is bolstered as food aid recipients strengthen and stabilize their economies.

¹The ad hoc coalition is composed of the American Maritime Congress, American Maritime Officers, American Maritime Officers' Service, American Soybean Association, International Food Additives Council, International Organization of Masters, Mates & Pilots, Liberty Maritime Corporation, Marine Engineers' Beneficial Association, Maritime Institute for Research and Industrial Development, National Association of Wheat Growers, National Corn Growers Association, National Council of Farmer Cooperatives, National Oilseed Processors Association, North American Millers' Association, Seafarer's International Union, Sealift, Inc., TECO Ocean Shipping, Inc., Tosi Maritime Consultants, LLC, Transportation Institute, U.S. Dry Bean Council, USA Rice Federation, and U.S. Wheat Associates, Inc.

In recent years, however, food aid shipments have declined sharply. The United States shipped 5.9 million tons of commodities in fiscal year 2002, 4.2 million tons in fiscal year 2005, and 3.7 million tons in fiscal year 2006. For fiscal year 2008, the administration's proposal would support only 2.975 million tons of commodities.

We respectfully request that this steady erosion of food aid be reversed, and that funding be restored to sustainable levels to assure the continued effectiveness and stability of these important and historically successful programs.

THE ADMINISTRATION'S BUDGET FOR FISCAL YEAR 2008

The administration proposes to continue last year's total elimination of funding for Title I.

Over the last several years, as funding for Title I has disappeared, the vast majority of food aid donations have been provided through the Food for Peace Title II program, which the administration proposes to further reduce by \$413 million from fiscal year 2006 levels, supporting the shipment of only 2.5 million tons of commodities in fiscal year 2008. Moreover, under the President's budget, Title II food aid would be reduced by up to \$305 million and converted to overseas purchases of food aid at the discretion of the Administrator for the U.S. Agency for International Development ("USAID").

Our coalition strongly opposes the administration's proposal to convert essential American food assistance to a program under which USAID would use appropriated funds to procure food supplies overseas. It has provided no sound basis for doing so, and there are many reasons why this proposal should be rejected again, just as it was rejected by the Congress in 2005 and 2006.

Under authority provided by Section 416(b) of the Agricultural Act of 1949, the administration states that no surplus commodities will be made available for donation in 2008. This represents another year of diminished reliance on the 416(b) program, which is funded through the Commodity Credit Corporation ("CCC").

In its fiscal year 2008 Budget Summary, the Department of Agriculture ("USDA") estimates that CCC-funded Food for Progress ("FFP") shipments will be 385,000 metric tons of grain equivalent. Unfortunately, this falls short of the 400,000 ton level established for CCC-funded FFP shipments in the 2002 Farm Bill.

Finally, the administration has requested \$100 million for the McGovern-Dole International Food for Education and Child Nutrition Program ("IFEP"), representing approximately 90,000 tons of commodities. This increase of only 3 percent from fiscal year 2006 is far overshadowed by the decreases in other programs.

The administration's recommendations, taken together, would lead to further reductions in food aid. Of even more significance, the administration's recommendation to reduce Title II funding in favor of USAID cash assistance undermines the foundation upon which U.S. food aid policy has been built in the post-World War II era. For the reasons set forth below, the coalition urges this subcommittee to sustain Title II funding, reinvigorate the Title I program, and reject, for a third time, the administration's unwise and unnecessary proposal to siphon off a quarter of Title II appropriations into a discretionary account for USAID.

RESTORATION OF OVERALL FOOD ASSISTANCE PROGRAM LEVELS

The coalition recommends that food aid be restored over time to sustainable levels in the range of 5.0 million to 6.0 million metric tons of grain equivalent in each fiscal year. In fiscal year 2008, this would require restoration of Title I funding, incremental increase in the Title II funding to \$1.6 billion, and greater use of existing authorities of the CCC.

USDA's Budget Summary justifies the elimination of Title I as necessary because recipient countries have been more interested in direct grants than concessional sales. Of course, the demand for donated food will always exceed the supply and the coalition recognizes that recipient countries would prefer grants over concessional sales—even sales at extremely favorable terms.

In order to ensure that the most desperate countries have sufficient donated food aid, the coalition recommends that USDA offer the Title I concessional sales program to countries that can afford the terms. Among the countries receiving Title II-funded grants in recent years, there are surely some who reasonably could afford to make the transition from grant assistance to concessional sales, using the direct loan authority of Title I. And to the extent that the Title I funding truly cannot be used for concessional sales, it may be converted to donations on full grant terms through FFP.

ELIMINATION OF TITLE II FUNDING FOR LOCAL PURCHASE

The coalition is strongly opposed to the administration's attempts to eliminate up to 25 percent (\$305 million) of Public Law 480 Title II funding in favor of an experimental program whereby the USAID Administrator will be granted unchecked discretion to divert U.S. tax dollars to foreign producers. Congress has wisely rejected this proposal in each of the last two budget cycles, and there is no authority for this program.

The administration intimated that its cash-based proposal was prompted by concerns regarding the timeliness of shipments from the United States in times of crisis. However, USAID already has adequate options for overcoming time constraints in appropriate circumstances, including:

- using the existing authority in the International Disaster and Famine Assistance Program ("IDFA");
- borrowing commodities from a nearby available source and later replacing them with Title II commodities once shipped into the region;
- transferring commodities between approved Title II programs before they are distributed;
- expanding the existing prepositioning program by developing forward deployed food stocks closer to areas of need; and
- diverting commodities already in transit to areas in extreme need, as was done when a shipload of aid was diverted to the tsunami-damaged areas of Asia in 2005.

Surely some combination of these solutions could be developed to address any timeliness concerns, obviating the justification for raiding our Nation's longest-running and most successful food aid program.

Little study has been conducted regarding the dangers of purchasing aid locally, near areas of food insecurity. USAID has admitted that local purchases threaten to destabilize local food markets. Additionally, discretionary expenditures of large sums for aid in third world countries raise the specter of corruption and abuse, including theft, kick-backs, and market manipulation by local traders. Local markets lack adequate seasonal storage capacity in many instances, putting relief efforts at the mercy of the very market fluctuations they are designed to alleviate, and cannot be counted upon to provide the high-quality, fortified blend products that are most essential to saving lives in severe food crises.

Moreover, the administration's proposal to eliminate up to a quarter of in-kind aid under Title II would undermine our position in the World Trade Organization ("WTO") where the United States has spent the last several years defending our current food assistance programs as a necessity if the world is committed to reducing hunger.

Lastly, the proposal to buy commodities overseas, instead of from American farmers and processors, threatens to undermine the broad-based political and support framework that has made Title II a success over the last half century. Indeed, Europe's conversion to cash-based aid resulted in a dramatic drop in aid levels.

CONCLUSIONS AND RECOMMENDATIONS

Mr. Chairman, the coalition is committed to maintaining U.S. food assistance programs at responsible levels in order to meet humanitarian needs and enhance the potential for economic growth in recipient countries. Our recommendation is to increase, over time, annual food assistance at combined program levels of between 4.0 million and 6.0 million metric tons of grain equivalent. This can be accomplished, as in the past, with a blend of programs supported by direct appropriations and CCC program authorities.

The coalition respectfully recommends the following:

- Title I program levels should be restored, and responsibly increased again in succeeding years, so that the unique advantages of the program are not lost.
- The Title II program should be restored to its fiscal year 2006 level of \$1.632 billion, and funding should not be diverted to programs relying primarily on the purchase of foreign commodities for food assistance. These actions will also help ensure that the United States fulfills its moral obligation to provide not less than one-half of the world's donated food aid.
- In committee report language, the House Appropriations Committee should reiterate its directive to the FAS in the fiscal year 2003 cycle to make greater use of existing CCC authorities to expand food aid to regions in critical need, and explicitly reject the administration's proposal to convert American food aid to so-called "local purchase" initiatives.

The in-kind food programs of Public Law 480 have been a bulwark of American food aid policy since the days of the Marshall Plan, and they deserve the strong support of your subcommittee, the Congress, and the entire Nation.

Thank you, Mr. Chairman.

PREPARED STATEMENT OF THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION

AdvaMed is pleased to provide this testimony on behalf of our member companies and the patients and health care systems we serve around the world. AdvaMed is the largest medical technology trade association in the world, representing more than 1,300 medical device, diagnostic products and health information systems manufacturers of all sizes. AdvaMed's members manufacture nearly 90 percent of the \$86 billion of health care technology products purchased annually in the United States, and more than 50 percent of the \$220 billion purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies and directly employ about 350,000 workers in the United States. More than 75 percent of our members have \$30 million or less in domestic sales annually.

AdvaMed supports the President's fiscal year 2008 budget request of \$240,122,000 for the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH). This inflationary increase amount maintains the annual inflationary increases for the agency that have helped meet the requirements of the Medical Device User Fee and Modernization Act (MDUFMA—Public Law 107-250) and the Medical Device User Fee and Stabilization Act (MDUFSA—Public Law 109-43) to date, and is crucial to ensure patients have timely access to lifesaving and life-enhancing products.

Medical Device User Fees

We are pleased that the President's budget proposal includes a 5 percent increase in FDA funding over 2007, which will help maintain a reasonable balance between user fees and appropriated funds in the device center and expand other resources to address key public health needs.

The increasing number and complexity of medical device submissions have overwhelmed CDRH over the last decade. When MDUFMA was crafted, review times for breakthrough products often exceeded over 400 days, despite a statutory ceiling of 180 days. To address these chronic delays, Congress passed MDUFMA in October of 2002 to supplement FDA's resources and expertise and reduce review times for medical technologies. MDUFMA creates a predictable and adequate funding base for CDRH through a combination of industry-paid user fees and an increase in Congressional funding for the agency. Congress passed MDUFSA in 2002 to ensure the continuance of this critical program, and we are hopeful that MDUFMA will be reauthorized this summer to continue the program for another 5 years.

Medical technology companies will have added over \$150 million to CDRH resources during the first 5 years of the historic MDUFMA agreement. Although the additional appropriations did not materialize in the first 2 budget years of the MDUFMA agreement, Congress provided nearly \$26 million in fiscal year 2005 and inflationary required amounts for fiscal year 2006 and fiscal year 2007. The fiscal year 2008 requested amount shows the strong support by the Administration to maintain the MDUFMA program.

CDRH must be funded adequately to ensure the goals of MDUFMA are met, maintain the United States' position in the rapidly advancing field of medical technology, and ensure patients' timely access to needed medical breakthroughs. AdvaMed requests that the fiscal year 2008 Agriculture Appropriations bill fully fund CDRH at \$240,122,000 to accomplish these important goals.

Additional Fees and Issues

AdvaMed notes with interest that the President's budget calls for collecting over \$23 million for re-inspection fees. We are interested to learn more about the nature of these fees and to which services currently provided by the FDA they will apply. As noted above, we are in the process of reauthorizing the MDUFMA program this year. This reauthorization will include significant increases in the current user fees the industry pays already for the review process. Given the significant number of small companies within our industry, we have strong concerns about additional fees being applied, especially before any substantial dialogue between the industry and the Agency over the level and intended use of the fees. Any additional fees must be additive to the baseline and must be associated with clearly identified performance goals above and beyond current levels.

Additionally, AdvaMed is concerned that, as in years past, attempts will be made in the fiscal year 2008 appropriations process to alter FDA policy and procedures related to the regulation of new and existing devices, including the advisory panel process. AdvaMed generally opposes such attempts to alter fundamental FDA regulatory policy for medical devices on appropriations bills. We stand ready to offer our expertise on such matters should the need arise in the coming months.

Background on the Medical Device User Fee Program

America is on the cusp of an unprecedented revolution in medical technology driven by major private and public investments in scientific research and computer technology. Congress has also made a multi-billion dollar commitment to double medical research at NIH and unravel the human genome. Medical technology companies also doubled research and development spending in the decade of the 90's.

The vibrant medical technology sector has driven employment gains and a strong balance of trade much to the benefit of the American patient and economy over the last several years. At the same time, the growing number and complexity of new medical devices throughout the last decade, coupled with a drop in the absolute number of reviewers at CDRH has resulted in severe budget strain and increasing delays in approval of new medical technologies for patients.

Prior to passage of MDUFMA, CDRH faced increasing challenges as a result of dwindling resources and accelerating innovation. Staff levels had dropped by eight percent between 1995 and 2001. By 2001, the average total review time for pre-market approval applications had risen to 411 days, more than twice the statutory review time. An FDA science panel warned at the time that increasingly rapid advances in technology "threaten to overwhelm" CDRH's limited resources.

On October 26, 2002, President Bush signed MDUFMA, which was unanimously passed by Congress, into law to give CDRH additional resources and expertise to help provide timely patient access to new medical technologies. It established an industry-funded user fee program to provide up to \$35 million each year to help the agency meet rigorous new performance goals.

Key regulatory reforms in MDUFMA are designed to:

- Eliminate bureaucratic delays in review of combination products by establishing a new office to oversee these technologies
- Authorize FDA to accredit third-party inspectors to audit medical technology companies with a good track record of compliance;
- Encourage timely, thorough premarket reviews by codifying the PMA "modular review" program and extending the third-party review program for 510(k)s;
- Permit paperless device labeling and electronic facility registration.
- Strengthen FDA regulation of reprocessed disposable devices.

From bioengineered organs and implantable artificial hearts to gene-based diagnostic tests and molecular imaging systems, America's medical technology companies are developing thousands of promising new tests and treatments. AdvaMed believes full implementation of MDUFMA will help ensure these advances reach the millions of patients who need them.

The user fee provisions in the law set fees for premarket approval applications, supplements and 510(k) submissions. Under the original law, these fees, combined with funds from increased appropriations, will provide FDA's device program with more than \$225 million in additional resources over the 5 years of the program. A letter agreement accompanying the bill sets review performance goals for the agency.

To assure that these user fees would have an additive effect on the CDRH budget, MDUFMA required that CDRH receive a \$15 million appropriations increase in each of the first 3 years of the program (fiscal year 2003, fiscal year 2004 and fiscal year 2005) for a total of \$45 million by the end of fiscal year 2005, or the user-fee program would have terminated in fiscal year 2006. These funds were designed to allow CDRH to upgrade information technology and other infrastructure necessary to carry-out a user-fee program and to meet the performance goals.

MDUFMA passed both houses of Congress on the last day of the regular session in October 2002. Owing to the extremely late timing of MDUFMA passage and a very tight budget climate, MDUFMA funding targets were not met in either of the first 2 years of the MDUFMA agreement. MDUFSA was passed last year to allow the program to continue despite the funding shortages in the early years of the program. MDUFSA also addressed the significant rate of increases in fees paid by industry. As Congress has struggled to provide its funding, industry paid user fees (per submission) that far exceed what was expected by MDUFMA. Increases of 35 percent, 15.7 percent and a projected 20 percent for fiscal year 2006 for individual PMA submissions were troubling to industry, and we appreciate the steps Congress

took to limit the rates of increase until the program can be reauthorized by September 30, 2007.

To maintain the MDUFMA program and protect investments made by the Agency, American consumers and a leading source of job growth in our economy, we ask Congress to again meet the President's fiscal year 2008 budget request for CDRH.

Conclusion

AdvaMed appreciates the Subcommittee's efforts last year and urges them to continue on this path to fully fund MDUFMA and ready FDA for the coming era of biomedical innovation and patients that await timely access to the coming dramatic breakthroughs in medicine. AdvaMed requests that the fiscal year 2007 Agriculture Appropriations, Rural Development, Food and Drug Administration and Related Agencies bill fully fund CDRH at \$240,122,000 to accomplish these important goals. We have concerns about the inclusion of new fees for the FDA to carry out core mission activities and urge the committee to refrain from altering FDA policy and procedures related to the regulation of new and existing devices in the fiscal year 2008 appropriations process.

AdvaMed thanks the committee for this opportunity to present our views and we look forward to working with you to help prepare FDA for the coming revolution in medical technology.

PREPARED STATEMENT OF THE AMERICAN FOREST & PAPER ASSOCIATION

The American Forest & Paper Association¹ (AF&PA) supports the sustainable management of our Nation's forests and encourages increased funding to advance forestry research, combat invasive species, and enhance food packaging innovations. The following recommendations concern fiscal year 2008 appropriations for the U.S. Department of Agriculture.

Cooperative State Research, Education, and Extension Service (CSREES)

There is a critical need to focus resources on research and outreach that addresses forest productivity, wood utilization, inventory, and conversion of wood to produce bioenergy/bioproductions. This practical research and outreach will advance our capacity to produce and measure healthier, faster-growing forests. CSREES and its partnering universities play a key role on-the-ground in meeting this need.

—*McIntire-Stennis (Cooperative Forestry Research) Program.*—AF&PA recommends an increase over the President's fiscal year 2008 request of \$20.5 million. This program is the foundation of forest resources research and scientist education efforts at universities. It supports cutting-edge research on forest productivity, wood utilization, and development of new technologies. AF&PA opposes the President's proposal to divert 63 percent of existing funds to competitive funding, as it would undermine valuable forestry research being conducted by our Nation's universities. Instead, we encourage a phased approach to building in a competitive grants component to the program.

—*National Research Initiative (NRI) Competitive Grants Program.*—AF&PA supports the President's request of \$256 million, but with increased focus on forestry research. These grants are a significant source of funding for basic and applied research on forest resources, including their management and utilization. In recent years, however, less than 6 percent of available funding has been allocated for forestry-related research. Given the considerable potential of the program to contribute to the Nation's sustainable forestry research needs, that percentage should be increased, with specific focus on grants that support Agenda 2020 research, such as the Pine Genome Initiative.

—*Renewable Resources Extension Act (RREA) Program.*—AF&PA recommends an increase over the President's request of \$4 million. RREA provides the foundation for extension and outreach efforts delivered to private landowners through universities. Cutting-edge forestry research is of limited benefit unless it can be effectively delivered to the Nation's forest landowners.

¹ AF&PA is the national trade association of the forest, paper and wood products industry. AF&PA represents more than 200 companies and related associations that engage in or represent the manufacture of pulp, paper, paperboard and wood products. The U.S. forest products industry accounts for approximately 6 percent of the total U.S. manufacturing output, employs more than a million people, and ranks among the top 10 manufacturing employers in 42 States with an estimated payroll exceeding \$50 billion.

Animal and Plant Health Inspection Service (APHIS)

Emerging Plant Pests Program.—AF&PA encourages increased funding to ensure adequate research, eradication, and control efforts targeting the Sirex woodwasp, emerald ash borer, Asian longhorned beetle, and sudden oak death pathogen. All four introduced organisms have already done significant damage and threaten further damage to trees in our forests and communities. For example, the Sirex woodwasp is now found across much of New York State and parts of Pennsylvania, and threatens valuable pine timber resources, especially those of the Southeast. Without sufficient funding to prevent movement of these insects and diseases through infested wood, nursery stock, and other materials, the economic cost could escalate to hundreds of billions of dollars.

Food and Drug Administration (FDA)

Food Contact Notification (FCN) Program.—AF&PA urges restoration of funding at \$6 million for this program, which is proposed for elimination in the President's fiscal year 2008 budget request. This highly successful program provides efficient review and timely approval of new food packaging materials and additives. New food-contact materials have enhanced the safety and security of the U.S. food supply while increasing the availability of environmentally friendly products. The elimination of the FCN program would be an enormous detriment to manufacturers seeking clearances for new food-contact materials to be introduced in the U.S. marketplace. The FCN program is essential for continued paper and paperboard food packaging innovation, and for ensuring the most effective protection of packaged foods during transportation, storage and ultimate use by the consumer.

Conclusion

AF&PA appreciates the opportunity to provide the Subcommittee with testimony regarding the fiscal year 2008 budget for the U.S. Department of Agriculture. If implemented, increased funding for the programs listed above will help promote the sustainable management of our Nation's public and private lands and the products that are produced from these lands.

PREPARED STATEMENT OF THE AMERICAN HONEY PRODUCERS ASSOCIATION, INC.

Chairman Kohl and Members of the Subcommittee: My name is Mark Brady from Waxahachie, Texas, and I currently serve as President of the American Honey Producers Association ("AHPA"). I am pleased today to submit the following statement on behalf of the AHPA, a national organization of commercial beekeepers actively engaged in honey production throughout the country. The purpose of this statement is bring to your attention both new and continuing serious threats to the domestic bee industry and to request your continued assistance in supporting Agricultural Research Service ("ARS") research to address the many challenges that face the domestic beekeeping industry.

First, we wish to thank again the Subcommittee for the strong support you have provided in past fiscal years for agricultural research activities on behalf of the beekeeping industry. As you know, in the fiscal year 2003 cycle, the Subcommittee rejected a proposal that would have resulted in the elimination of three ARS laboratories that are indispensable to the survival of our industry. In the years since then, the Subcommittee has worked to restore proposed cuts in honey bee research. Such support has enabled the ARS to address the critical research needs of the industry.

For fiscal year 2008, the Administration's budget again proposes to eliminate certain funding for ARS that it did not request but that the Congress provided in the appropriations process. To continue the research that is critical to honey bees, however, the AHPA requests that Congress maintain the funding for the ARS Honey Bee Research Laboratories at Baton Rouge, Louisiana; Weslaco, Texas; Tucson, Arizona; Beltsville, Maryland; and the ARS Wild Bee Research Laboratory at Logan, Utah. We also support increased funding for honey bee genome research at the ARS laboratory in Baton Rouge, as proposed before by the Administration.

In addition to the maintenance of these ongoing efforts, we strongly urge the Subcommittee to provide at least \$1 million in new funding through the ARS laboratories at Beltsville and Tucson, and possibly in conjunction with researchers at the University of California in Davis, to address a new threat to domestic honey bees: Colony Collapse Disorder (CCD). CCD is currently ravaging bee colonies across the United States. The causes of CCD are unknown and appear to be complicated mix of factors, including the stresses caused by continuing infestations of mites and pests and by the high demands of pollination today. I provide a more detailed description of CCD in this statement.

The President's Budget Proposal

Our understanding is that while OMB has not yet agreed to the ARS funding levels under the fiscal year 2007 Continuing Resolution, the most likely outcome will be a continuation of honey bee research at the fiscal year 2006 levels. As the Subcommittee reviews the proposed fiscal year 2008 budget and the fiscal year 2007 baseline, we urge you also to consider that in its fiscal year 2007 bill, the House originally provided (H. Rep. 109-463) additional fiscal year 2007 research funding as follows: "Bee Research, Weslaco, TX, \$244,077" and "Honey Bee Research (Varroa Mites), Baton Rouge, LA, \$390,101." The fiscal year 2007 Senate bill (S. Rep. 109-266) provided continued funding for "Bee Research (Chalk Brood)), Logan, Utah," and separately recommended an increase of \$100,000 for Logan, Utah for non-Apis research.

The AHPA is concerned that the President's fiscal year 2008 budget proposal to eliminate ongoing spending set by Congress would reduce funding for critical research at two key ARS Honey Bee Research Laboratories at Baton Rouge and at Weslaco. Such cuts to these ARS Honey Bee Research Laboratories would have a severe effect on the honey industry as well as on all pollination-dependent agriculture and many native plants. This budget recommendation seems particularly inappropriate considering the substantial benefits that flow from these research efforts, which help assure the vitality of the American honey bee industry and is integral to many aspects of U.S. agriculture.

The four ARS Honey Bee Research Laboratories provide the first line of defense against exotic parasite mites, Africanized bees, and brood diseases. Equally, the laboratories are prepared to respond to new pests, pathogens and other conditions as they arise, such as CCD, that pose very serious and growing threats to the viability and productivity of honey bees and the plants they pollinate. If continued funding is not provided, scientists at the Baton Rouge and Weslaco laboratories will be overburdened and forced to discontinue essential research, thereby jeopardizing the U.S. honey bee industry and the production of agricultural crops that require pollination by honey bees.

The Importance of Honey Bees to U.S. Agriculture

Honey bees are a critical element in the production of more than 90 food, fiber, and seed crops, valued at more than \$20 billion a year in the United States, according to the Department of Agriculture. The role of pollination is even more important given today's dietary importance of fruit, vegetables and nuts, most of which are dependent on pollination. Honey bees are necessary for the production of such diverse crops as almonds, apples, oranges, melons, broccoli, tangerines, cranberries, strawberries, vegetables, alfalfa, soybeans, sunflower, and cotton, among others. In fact, honey bees pollinate about one-third of the human diet.

The importance of this pollination to contemporary agriculture cannot be understated—the value of such pollination is 143 times greater than the total value of honey and wax produced by honey bees. More than 140 billion honey bees representing 2 million colonies are transported by U.S. beekeepers across the country every year to pollinate crops.

The importance of honey bees—and the U.S. honey industry which supplies the honey bees for pollination—is illustrated by the pollination of California's almond crop, which is that State's largest agricultural export. California grows 100 percent of the Nation's almond crop and supplies 80 percent of the world's almonds. Honey bees are transported from all over the Nation to pollinate California almonds, which is the largest single crop requiring honey bees for pollination. More than one million honey bee hives are needed to pollinate the 600,000 acres of almond groves that line California's Central Valley. That means nearly half of the managed honey-producing colonies in the United States are involved in pollinating almonds in California during February and early March. As with other agricultural products, having enough bees to pollinate the almond crop can mean the difference between a good crop and disaster. Moreover, almond producers estimate that California may need as many as 2 million hives for pollination by 2012 to pollinate the expected 800,000 acres of almonds that will be in production then. As OnEarth magazine noted recently, the fate of California's almond crop rests "on the slender back of the embattled honey bee."

Many other U.S. agriculture producers rely on extensive honey bee pollination. A Maine blueberry grower recently put it quite succinctly—"without bees in May, there are no blueberries in August." Additionally, avocados—a \$363 million crop in California—receive more than 90 percent of their pollination from the honey bee. Studies on the effect of pollination of cotton by honey bees show an increase of 17 to 19 percent in the yield of seed cotton, as compared to a cotton crop that is not pollinated by honey bees. The cattle and farm-raised catfish industries also benefit

from honey bee pollination, as pollination is important for growing alfalfa, which is fodder for cattle and farm-raised fish.

Unfortunately, due to bee losses caused by pests and mites and other recent problems plaguing the U.S. honey industry, U.S. farmers were forced to import honey bees from other countries (New Zealand and Australia) last year for pollination. This marked the first time since 1922 that honey bees were imported into the United States for pollination services, underscoring the fragile State of the U.S. honey industry and highlighting the critical need for research.

Yet, the health of the beekeeping industry is dependent upon the production of honey and beeswax. Honey bees are responsible for the production of an average of 200 million pounds of honey annually in the United States, the sales of which help sustain this nation's beekeepers.

THREATS TO THE HONEY BEES

Since 1984, the survival of the honey bee has been threatened by continuing infestations of mites and pests for which appropriate controls must continually be developed by scientists at the four ARS laboratories. Within the past year, however, CCD has emerged as an additional and grave new threat with unknown causes but destructive force.

COLONY COLLAPSE DISORDER (CCD)

As chronicled in several recent news accounts, including the attached articles from the New York Times, CNN, ABC News and AP, reports of the sudden death of bees in colonies has been reported in 22 States. Often, most of the adult bees in a colony mysteriously disappear, and soon the colony is completely empty. The news outlets quote various Federal and State researchers who have not been able to determine the cause of the collapse of the colonies. There are also increasing reports that otherwise healthy bee colonies are not reproducing at anywhere near historic levels.

This severe and baffling destruction of domestic honey bee populations will require additional resources for the ARS laboratories as soon as possible to determine the causes of CCD and to develop effective treatment strategies. CCD remains a mystery to both beekeepers and scientists. There are a wide range of factors that—either alone or in combination—may be possible causes of this serious condition. Areas to explore include the stress from the movement of bees to different parts of the country for extensive commercial pollination, the additional stress of pollinating crops, such as almonds, that provide little honey to the bees, and the impact of certain crop pesticides and genetic plants with altered pollination characteristics. Additionally, continuing infestations of the highly destructive Varroa mite, combined with other pests and mites, are also thought to compromise the immune systems of bees and may leave them more vulnerable to CCD. At the same time, researchers will need to focus on the many reported instances in which otherwise healthy, pest-free, stationary bee colonies are also suffering collapse or problems with reproduction.

In many ways, CCD is the latest in a series of threats faced by the modern U.S. honey bee industry as it continues to evolve to both produce honey and meet the ever-increasing demands of crop producers for vital pollination. Unfortunately, CCD will not be the last challenge faced by the industry. But at this time, it is clearly the most critical threat to our industry. As every week goes by, additional members of AHPA report that CCD is affecting their bees.

The AHPA respectfully requests that additional funding of at least \$1 million be provided in a dedicated manner to respond to CCD. Such funding could be allocated to the ARS laboratories at Beltsville, Maryland, and Tucson, Arizona. We would also recommend that funding be considered for the University of California at Davis, because it has particular expertise in honey bee research and is in close proximity to the almond groves of the California Central Valley. Such a joint effort could better analyze the relationship between CCD, pollination and other stress factors. The joint effort would also take advantage of the fact that, in February of each year, almost the entire honey bee industry has its bees in California for pollination purposes.

ONGOING RESEARCH

The research being done at the ARS laboratories is critical in a number of areas. For example, the pinhead-sized Varroa mite is systematically destroying bee colonies and has been considered by many in recent years to be the most serious threat to honey bees. Tracheal mites are another contributing factor to the loss of honey bees. Tracheal mites infest the breathing tubes of adult honey bees and also feed

on the bees' blood. The mites essentially clog the bees' breathing tubes, blocking the flow of oxygen and eventually killing the infested bees. The industry is also plagued by a honey bee bacterial disease that has become resistant to antibiotics designed to control it, and a honey bee fungal disease that has no known medication to control it. These pests and diseases, especially Varroa mites and the bacterium causing American foulbrood, are now resistant to chemical controls in many regions of the country. Further, we have seen that these pests are building resistance to newly-developed chemicals more quickly than in the past, thereby limiting the longevity of chemical controls.

Unfortunately, there is no simple solution to these problems, and the honey bee industry is too small to support the cost of the needed research, particularly given the depressed state of honey prices. Further, there are no funds, facilities, or personnel elsewhere available in the private sector for this purpose. Accordingly, the beekeeping industry is dependent on research from public sources for the scientific answers to these threats. Since the honey bee industry is completely comprised of small family-owned businesses, it relies heavily on the ARS for needed research and development. The key to the survival of the honey industry lies with the honey bee research programs conducted by ARS.

The sequencing of the honey bee genome at Baylor University has opened the door to creating highly effective solutions to these problems via marker-assisted breeding. Marker-assisted breeding would permit the rapid screening of potential breeders for specific DNA sequences that underlie specific desirable honey bee traits. The sequenced honey bee genome is the necessary key that will allow scientists to discover the important DNA sequences. Because of the sequenced honey bee genome, it is now possible to apply molecular biological studies to the development of marker-assisted breeding of honey bees. Marker-facilitated selection offers the first real opportunity to transform the beekeeping industry from one that has been dependent upon a growing number of expensive pesticides and antibiotics into an industry that is free of chemical inputs and that is economically viable in today's competitive global marketplace.

Furthermore, research on honey bees, one of five animals chosen by the National Institutes of Health for genome sequencing, may provide important insight into other areas of science. The honey bee is the first agricultural species to be sequenced, and such work may provide breakthrough advances in many areas of science. In fact, honey bees are being studied by the U.S. Department of Defense as sentinel species that could detect and locate agents of harm, such as chemical or biological threats. According to one researcher, it appears that honey bees' olfactory capabilities are at least on par with those of a dog, if not more sensitive. Thus, the scientific advances achieved by ARS will provide an array of benefits across many disciplines.

The Work of the ARS Honey Bee Research Laboratories

The ARS Honey Bee Research Laboratories work together to provide research solutions to problems facing businesses dependent on the health and vitality of honey bees. The findings of these laboratories are used by honey producers to protect their producing colonies and by farmers and agribusinesses to ensure the efficient pollination of crops. Each of the four ARS Honey Bee Research Laboratories (which are different in function from the ARS Wild Bee Research Laboratory at Logan, Utah) focuses on different problems facing the U.S. honey industry and undertakes research that is vital to sustaining honey production and assuring essential pollination services in this country. Furthermore, each of the four ARS Honey Bee Research Laboratories has unique strengths and each is situated and equipped to support independent research programs which would be difficult, and in many cases impossible, to conduct elsewhere.

Research at the ARS Weslaco Laboratory

Because the AHPA recommends that the appropriation for the Weslaco laboratory be approved at not less than current levels, we respectfully request that Congress again restore an additional \$244,100 in funding for the ARS Honey Bee Laboratory at Weslaco, Texas. This funding would be eliminated under the administration's budget. Retaining the current level of funding for the Weslaco laboratory will enable this facility to continue its work in finding a chemical solution to parasitic mites that are causing a crisis for the U.S. beekeeping and pollination industries. Varroa mites are causing the loss of hundreds of thousands of domestic honey bee colonies annually as well as devastating wild bee colonies. As noted in a February 2005 USA Today article, the Varroa mite has destroyed as much as 60 percent of the hives in some areas.

For example, in Florida, the number of commercial bee colonies has fallen from approximately 360,000 hives in 1990 to just 160,000 in 2005—in large part as a result of the Varroa mite. These tiny parasites—also known as the “vampire mite”—attach themselves to the backs of adult bees and literally suck out their insides. When these mites were first discovered in the United States in the 1980s, beekeepers were able to fight them with strips of the chemical fluvalinate. However, the Varroa mites have evolved into a parasite seemingly immune to current pesticides. The ARS laboratory at Weslaco has been developing alternative chemicals to control the Varroa mite. Presently, there are no other chemicals available for controlling the Varroa mite, and the laboratory is working frantically to develop other means of control. The laboratory also is working with a potent fungus, which may kill the mites without impeding colony development or population size.

Furthermore, the laboratory at Weslaco is researching methods that may control the small hive beetle. Since its discovery in Florida in 1998, this pest has caused severe bee colony losses in California, Florida, Georgia, South Carolina, North Carolina, Pennsylvania, Ohio, and Minnesota. Estimates put these losses in just one season at over 30,000 colonies. The beetles are now spreading all across the United States. The ARS honey bee research scientists at the Weslaco laboratory have been working diligently to find chemicals, techniques, pheromones, or other methods of controlling the beetle. Time is of the essence and a control must be found immediately, because all the bee colonies in the Western Hemisphere are at risk.

This facility also focuses its research efforts on developing technologies to manage honey bees in the presence of Africanized honey bees, parasitic mites, and other pests. In order to ensure that further pests are not introduced into the United States, scientists at the Weslaco facility provide technical assistance to agriculture departments in foreign countries on the control of parasitic mites. The laboratory has worked with officials in Guatemala, Costa Rica, Mexico, and South Africa to protect the U.S. honey bee population from further devastation by infestation of foreign parasites, diseases, and other pests. This inter-governmental cooperation is necessary to ensure the continued viability of the U.S. honey bee industry.

Research at the ARS Baton Rouge Laboratory

We were pleased with past Administration budgets that requested increased funding in the amount of \$500,000 for honey bee genome research at the Baton Rouge Laboratory and applaud the Subcommittee's efforts in fiscal year 2006 to provide \$375,000 of the \$500,000 requested. In light of the importance of genome research, we encourage the Committee to provide additional funds to move this area of research forward. An increase in funding will allow the vital genome research to achieve the breakthrough successes that are closer than ever to realization.

It is also important that Congress fully restore the \$390,101 in “add-on” funding for the Baton Rouge facility that it has provided in previous years. This Baton Rouge facility is the only laboratory in the United States and, we believe, in the world, developing long-term, genetic-based solutions to the Varroa mite. Existing stocks of U.S. honey bees are being tested to find stocks that exhibit resistance to the parasitic mites. Research scientists with the laboratory have also been to the far corners of the world looking for mite-resistant bees. For example, in eastern Russia, they found bees that have co-existed for decades with the mites and survived. Using these bees, the laboratory develops stocks of honey bees resistant to the parasites. Before these new stocks are distributed to American beekeepers, the laboratory ensures that the resistance holds up under a wide range of environmental and beekeeping conditions, testing attributes such as vigor, pollination, and honey production. We believe recent scientific breakthroughs with this genomic research will allow scientists in the near future to breed honey bees that are resistant to the Varroa mite and other parasites.

The Baton Rouge facility also operates the only honey bee quarantine and mating station approved by the Animal and Plant Inspection Service. These stations are necessary to ensure that new lines of bees brought into the United States for research and development are free of diseases unknown in the United States. In addition, Baton Rouge research scientists are focused on the applications of new technologies of genomics. This work has the potential to enhance the proven value of honey bee breeding for producing solutions to the multiple biological problems that diminish the profitability of beekeeping.

Research at the ARS Tucson Laboratory

The American Honey Producers Association appreciates past Administration support for maintaining funding at the ARS Honey Bee Research Laboratory in Tucson at current levels. At the same time, consideration should be given to possibly increased funding at this facility to address the emerging CCD issue, and also to sup-

porting two new research positions at the laboratory. The addition of an insect behaviorist position and a pollination biologist position at the Tucson Honey Bee Research Laboratory will strengthen the research programs conducted at the laboratory, including research related to preventing the spread of Africanized honey bees, which are jeopardizing the queen breeding and packaged bee industry.

This research center is the only ARS honey bee laboratory serving the needs of beekeepers and farmers in the western United States. It also serves as the primary facility developing methods to prevent the spread of Africanized honey bees in our country. The facility works to improve crop pollination and honey bee colony productivity through quantitative ecological studies of honey bee behavior, physiology, pest and diseases, and feral honey bee bionomics. Currently, the Tucson laboratory is working to finalize the development of a pheromone that kills the Varroa mite.

Because more than one million colonies are transported from across the country for pollination into crops grown in the western United States (primarily California), the Tucson research center addresses problems that arise from transporting and introducing colonies for pollination of crops such as almonds, plums, apricots, apples, cherries, citrus, alfalfa, vegetable seed, melons, and berries. The importance of this work is illustrated by the pollination of California's almond crop discussed earlier in this statement. More than one million honey bee hives are needed to pollinate the half a million acres of almond groves that line California's Central Valley. That means nearly half of the managed colonies in the United States are involved in pollinating almonds in California during February and early March.

The work of the ARS Tucson Honey Bee Research Laboratory is indispensable in ensuring the successful pollination of crops in California and other areas of the western United States. This research center has been instrumental in disseminating information on technical issues associated with the transport of bee colonies across State lines. Additionally, in order to ensure that transported colony populations remain stable during transport and also during periods before the crop to be pollinated comes into bloom, scientists at the laboratory have developed an artificial diet that stimulates brood production in colonies. A large bee population is necessary to ensure that efficient pollination occurs, creating superior quality crops.

Research at the ARS Beltsville Laboratory

AHPA strongly supports an increase in funding for the Beltsville Laboratory to help address CCD and other threats to our domestic beekeeping industry. This facility, the oldest of the Federal bee research centers, conducts research on the biology and control of honey bee parasites, diseases, and pests to ensure an adequate supply of bees for pollination and honey production. Using biological, molecular, chemical, and non-chemical approaches, scientists in Beltsville are developing new, cost-effective strategies for controlling parasitic mites, bacterial diseases, and emergent pests that threaten honey bees and the production of honey.

The laboratory also develops preservation techniques for honey bee germplasm in order to maintain genetic diversity and superior honey bee stock. Scientists at the facility also provide authoritative identification of Africanized honey bees and diagnosis of bee diseases and pests for Federal and State regulatory agencies and beekeepers on a worldwide basis. In operating this bee disease diagnosis service, the Beltsville facility receives over 2,000 samples annually from across the United States.

Conclusion

In conclusion, we wish to thank you again for your strong support of honey bee research in the past and for your Subcommittee's understanding of the critical importance of these ARS laboratories.

By way of summary, the American Honey Producers Association strongly encourages at least \$1 million in additional new funding for the ARS laboratories at Beltsville, Maryland, and Tucson, Arizona, as well as possibly for the University of California at Davis, to address the new CCD threat that is suddenly devastating bee colonies across the country. AHPA also appreciates your continued support by (1) restoring the \$390,101 in funding for the ARS Honey Bee Research Laboratory in Baton Rouge, Louisiana, that had previously been added by the Congress but is proposed for elimination in the Administration's budget proposal; (2) continuing the increased funding of \$375,000 for genome research at the ARS Honey Bee Research Laboratory in Baton Rouge, as proposed by the administration and approved by the Congress in fiscal year 2006; (3) increasing the level of funding for the ARS Honey Bee Research Laboratory in Beltsville, Maryland, by at least \$500,000 in new funding for CCD research; (4) restoring \$244,100 for the Weslaco, Texas, facility as previously provided by the Congress but not contained in the President's budget submission; (5) maintaining at least the current level of funding for the ARS Honey Bee

Research Laboratory in Tucson, Arizona, but also considering additional funding of \$500,000 for CDC research; and (6) maintaining the current level of funding for the ARS Wild Bee Research Laboratory at Logan, Utah.

Only through research can we have a viable U.S. beekeeping industry and continue to provide stable and affordable supplies of bee-pollinated crops, which make up fully one-third of the U.S. diet.

Furthermore, we urge you to reject any effort to cut the operating budgets of these vitally important research laboratories by consolidating their functions. Any proposed cuts and their resulting budget and staff reductions would significantly diminish the quality of research conducted by these laboratories, harming bee keepers as well as farmers who harvest pollination-dependent agriculture. Congress cannot allow these cuts to occur and must continue to provide sufficient funding for the ARS Honey Bee Research Laboratories to perform their vital role.

I would be pleased to respond to provide answers to any questions that you or your colleagues may have.

PREPARED STATEMENT OF THE AMERICAN SHEEP INDUSTRY ASSOCIATION

The American Sheep Industry Association (ASI) is a federation of State member associations representing over 68,000 sheep producers in the United States. The sheep industry views numerous agencies and programs of the U.S. Department of Agriculture as important to lamb and wool production. Sheep industry priorities include expanding the United States sheep inventory which has grown two of the past 3 years. We believe strengthening the infrastructure of the industry primarily through the programs of USDA, APHIS, Veterinary Services and Wildlife Services is critical. The industry and the benefits to rural communities will be strengthened by fully funding critical predator control activities, national animal health efforts, and expanding research capabilities.

We appreciate this opportunity to comment on the USDA fiscal year 2008 budget.

ANIMAL AND PLANT HEALTH INSPECTION SERVICE (APHIS)

Scrapie

The American Sheep Industry Association supports the appropriations approved in fiscal year 2006 of \$18.4 million and urges the Subcommittee increase funding to this level in fiscal year 2008.

Through concerted effort, USDA/APHIS, along with industry and State regulatory efforts, is in the position to eradicate scrapie from the United States with a multi-year attack on this animal health issue. As the collective and aggressive efforts of Federal and State eradication efforts have expanded into slaughter-surveillance and other methods and systems, the costs are, as expected, escalating.

Scrapie is one of the families of transmissible spongiform encephalopathies (TSEs), all of which are the subject of great importance and interest around the globe. USDA/APHIS, along with the support and assistance of the livestock and allied industries, began an aggressive program to eradicate scrapie in sheep and goats four years ago. The plan USDA/APHIS is implementing is designed to eradicate scrapie by 2010. Through a subsequent monitoring and surveillance program, the United States could be declared scrapie-free by 2017. Becoming scrapie-free will have significant positive economic impact to the livestock, meat and feed industries and, of course, rid our flocks and herds of this fatal animal disease.

Essential to the eradication effort being accomplished in a timely manner is adequate appropriated funds. The program cannot function properly without sufficient emphasis on diagnostic support and surveillance activities that are dedicated to scrapie eradication as an animal health priority. We believe adequate funding will help provide for an achievable scrapie eradication program and the eventual scrapie-free status for the United States. As with the other successful animal disease eradication programs conducted by USDA/APHIS in the past, strong programs at the State level are key. We therefore urge the Subcommittee to send a clear message to USDA/APHIS to (A) make scrapie eradication a top disease eradication priority within USDA and the APHIS field staff with a focus on ID compliance and enforcement; and (B) increase the slaughter-surveillance numbers so that the disease can be found and dealt with where it resides.

Wildlife Services

With well over one-quarter million sheep and lambs lost to predators each year, the Wildlife Services (WS) program of USDA-APHIS is vital to the economic survival of the sheep industry. The value of sheep and lambs lost to predators and predator control expenses are second only to feed costs for sheep production. Costs

associated with depredation currently exceed our industry's veterinary, labor and transportation costs.

Wildlife Service's cooperative nature has made it the most cost effective and efficient program within the Federal Government in the areas of wildlife management and public health and safety. Wildlife Services has more than 2,000 cooperative agreements with agriculture, forestry groups, private industry, State game and fish departments, departments of health, schools, county and local governments to mitigate the damage and danger that the public's wildlife can inflict on private property and public health and safety.

ASI strongly supports the fiscal year 2006 appropriations for Wildlife Services operations and methods development programs, particularly as related to livestock protection. We ask the Subcommittee to fund the livestock industry request for the western region of Wildlife Services operations of livestock protection at \$19 million.

The line item of the fiscal year 2006 appropriations for the livestock protection program in the western region of WS was funded at \$10.7 million, an increase of \$700,000 which is very important to our industry and the agency operations. Fuel costs alone for aerial operations and ground vehicles have increased dramatically which burdens the operations budgets.

The additional \$8.3 million increase requested will increase the effectiveness of the livestock protection program. Federal funding available for livestock predation management by the Western Region program has remained relatively constant for approximately 16 years. WS program cooperators have been forced to fund more and more of the costs of the program. WS Western Region base funding has increased only 5.6 percent in the past 10 years while cooperative funding has increased 110 percent. This increase has primarily come from individual livestock producers, associations, counties, and States.

Additionally, new Federal mandates and program investments such as narrow-banding of radios, computer record keeping and compliance with the Endangered Species Act are requiring a larger portion of the already stretched budget and negatively impacting the amount of livestock predation management work that WS can conduct.

We encourage and support continued recognition in the appropriations process for fiscal year 2007 of the importance of aerial hunting as one of Wildlife Service's most efficient and cost-effective core programs. It is used not only to protect livestock, wildlife and endangered species, but is a crucial component of the Wildlife Services rabies control program.

Similar to the increasing needs in the aerial hunting program, we encourage continued emphasis in the programs to assist with management of wolf depredation in the States of Montana, Idaho, Wyoming, Minnesota, Wisconsin, Michigan, New Mexico and Arizona. Additionally, program expenses are expected in the States surrounding the Montana, Idaho and Wyoming wolf populations. It is strongly supported that appropriations be provided for \$586,000 for additional wolf costs anticipated in Washington, Oregon, Nevada, Utah, Colorado and North Dakota.

Economics of Predation Management

The WS Western Region predation management program is one of the few government sponsored programs that is cost-shared, and this provides a significant benefit to both the producers and the government. Predation management, as conducted by the WS program, is cost effective and returns more money to the U.S. treasury than it costs. An analysis of 1998 data shows that for every dollar spent for predation management, \$3 worth of livestock was saved. In that same year the total investment in just the predation management program was \$20 million (\$9 million Federal and \$11 million cooperative funds); therefore, the full impact of this investment was a \$250 million net increase in economic activity. Using today's values for livestock, every Federal dollar spent on predation management results in \$10.84 in livestock saved, conservatively, \$97.5 million in livestock saved (\$52.5 million in calves, \$34 million in sheep and lambs, \$11 million in goats). When cooperative funding is included with federal funds, the benefit cost ratio is \$4.87:1.

Type of Livestock	No protected	No saved from predators	Total value of livestock saved
Calves	2,500,000	70,000	\$52,500,000
Adult Sheep	2,000,000	82,000	8,200,000
Lambs	1,850,000	214,600	25,752,000
Goats	292,000	110,960	11,096,000

The value of livestock saved is much greater in rural economies than any other type of economic development. Livestock dollars, that would have been lost without adequate predation management, generate an additional three fold increase in non-agricultural economic activity in rural America. The total economic activity (both agriculture and non-agricultural sectors) generated by predation management is \$390.2 million.

Emerging Issues

Additional issues are emerging in the West that will challenge the Federal WS program.

—*Wolves*.—Recently a Federal judge struck down the threatened species status for wolves in the Western Distinct Population area eliminating the ability of private land ranchers to deal with wolves, thus requiring additional government intervention.

—*Wildlife*.—The declines in predation management that have already occurred, and that will continue to occur without additional Federal funding, have resulted in negative impacts on many native wildlife populations. Several western States currently need to fund predation management to prevent the listing of sage grouse as an endangered species or to recover mule deer herds.

Without additional Federal funding to support existing western livestock protection programs, predation management expertise will be lost and livestock grazing in some areas will be jeopardized. Rural economies need this support and the return for the investment exceeds the requested assistance.

ASI urges the Subcommittee to provide USDA, APHIS, WS, Western Region an additional \$8.3 million of Federal funds for livestock protection. At a nominal 16 percent tax rate on the economic activity generated by the investment would result in over \$62 million to the Treasury.

Total Livestock Protected	6,642,000
Total Value of Livestock Saved (Using \$10.84:1 Ratio)	\$97,548,000
Value incl. Multiplier	\$390,192,000
16 percent Nominal Tax rate	\$62,430,720

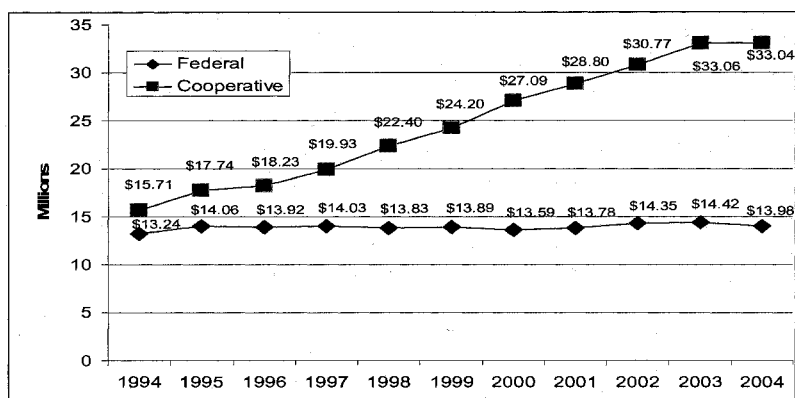


CHART 1.—Ten Year Comparison—WR Federal Base and Cooperative Funds
(Including Livestock Protection)

FARM AND FOREIGN AGRICULTURAL SERVICES

Foreign Agricultural Service (FAS)

The sheep industry participates in FAS programs such as the Market Access Program (MAP), Quality Samples Program (QSP) and the Foreign Market Development Program (FMD). ASI strongly supports appropriations at the full authorized level for these critical Foreign Agricultural Service programs. ASI is the cooperator for American wool and sheep pelts and has achieved solid success in increasing exports of domestic product. Exports of American wool have increased dramatically with approximately 60 percent of U.S. production now competing overseas.

Risk Management Agency (RMA)

Through ASI, the U.S. sheep industry is working with RMA on the development of "Livestock Risk Protection" for lamb (LRP-Lamb), a model-based, price-risk insurance product to help sheep producers manage the primary factor in their operation's financial exposure. The sheep industry is very anxious to participate in a 27 State pilot project with LRP-Lamb as approved in September of 2006. The goal is a market-based, user-friendly risk management tool that effectively and efficiently protects against unexpected price downswings that provides producers and their lenders with a critically needed financial management option.

ASI urges the Subcommittee to support the agency's research and developmental costs to design creative new programs for the livestock sector as well as in the "Administrative and Operating Expenses" category to enable RMA to deliver these products, including appropriate maintenance expenses.

NATURAL RESOURCES CONSERVATION SERVICE (NRCS)

ASI urges increased appropriations for the range programs of the Soil Conservation Service to benefit the private range and pasture lands of the United States with conservation assistance. We support the budget item and recommend an increased level for the Grazing Lands Conservation Initiative, which ASI has worked with, along with other livestock and range management organizations to address this important effort for rangelands in the United States.

RESEARCH, EDUCATION AND ECONOMICS

Our industry is striving to be profitable and sustainable as a user of and contributor to our natural resource base. Research, both basic and applied, and modern educational programming is essential if we are to succeed. We have been disappointed in the decline in resources USDA has been targeting toward sheep research and outreach programs. In order for the sheep industry to continue to be more globally competitive, we must invest in the discovery and adoption of new technologies for producing, processing and marketing lamb and wool. We urge the Subcommittee to send a strong message to USDA supporting sheep research and educational funding increases.

Agricultural Research Service

We continue to vigorously support the administration's funding of research concerning emerging and exotic diseases. Emerging and exotic diseases continue to have significant impact on our industry due to animal health and trade issues. The animal disease portion should be substantial and is urgently needed to protect the U.S. livestock industry. We note the President's request for fiscal year 2007 includes \$9.5 million for BSE and CWD research. We agree that BSE has been an extremely important disease issue; however it is well established that BSE is being controlled globally and research has shown that since BSE is not transmitted by casual contact, actual disease concerns regarding BSE in the United States should be minimal. With this in mind, we respectfully remind the Subcommittee that scrapie along with CWD are Transmissible Spongiform Encephalopathies that are endemic in the United States and unlike BSE are transmitted by casual contact. We recommend that any additional funds for BSE and CWD research also address scrapie with emphasis toward scrapie eradication needs (detection and control methods). We also respectfully remind the Subcommittee that scientists in the Animal Disease Research Unit (ADRU), ARS, Pullman Washington, have made significant progress in the early diagnosis of TSEs, in understanding genetic resistance to TSEs and in understanding mechanisms of TSE transmission, which are important in eradication of all TSEs. The programs of these scientists at ADRU should be enhanced and expanded to include, for instance, the development of further improvements in rapid and accurate TSE detection methods and to provide an understanding of the role of other small ruminants as environmental sources of the TSE agent in the transmission of TSEs within the United States and world and to further understand the basis of genetic resistance and susceptibility to these devastating diseases.

We note and strongly support the ARS 2008 priority initiative (3.8 million) entitled "Functional Genomics to Improve Nutrient Utilization in Beef Cattle". Due to the extreme importance of this approach to enhancing the economics of sheep production and the recent progress in acquiring the sheep genome, we respectfully request that this initiative be expanded to include sheep genomics. Since 2001, Congress has had the foresight to appropriate \$756,553 each year to this unit for "Microbial Genomics." Microbial genomics is the cornerstone project for their genomic research infrastructure and has resulted in very important genomics based research advancements for infectious diseases of livestock such as Ovine Progressive Pneu-

monia virus (OPPV), caseous lymphadenitis and foot rot. OPPV, caseous lymphadenitis and foot rot cause infections and environmental contaminations that continue to have significant economic impact for U.S. sheep producers. Also, pneumonia of big horn sheep continues to be a major concern for the domestic sheep industry. Regulatory impact on the use of public lands by domestic sheep producers due to the perceived possibility of disease transmission events between big horn and domestic sheep continues to be significant. Most recently genomics based research has yielded advancements in the understanding of the pneumonia complex affecting big horn sheep. This research is consistent with the ARS 2008 priority initiative (4.9 million) entitled "Livestock Immunology and Microbial Genomics to Improve Animal Health". Very promising on-going genomic research efforts are directed at early determination of which sheep are susceptible to disease and responsible for economic losses. High throughput genomics has ushered in a new era of integrated research regarding the ability to link control of chronic, economically important diseases such as OPPV and important production traits. There are a number of infectious diseases across domestic and wild animals that will benefit from this research focus. It is becoming clear that not all infected animals transmit diseases with equal efficiency; in fact it appears that the "super shedders" are a small proportion of an infected population. In addition to aiding in the control of chronic infectious diseases such as OPPV, caseous lymphadenitis and foot rot, control of Big Horn Sheep pneumonia and internal parasitism may well be aided by this genomics approach. Early detection of susceptibility and resistance will lead to practical intervention strategies. We respectfully request the Subcommittee to recommend the restoration and enhancement of microbial genomics to ADRU for the fiscal year 2008 budget. With this in mind, we respectfully request the subcommittee to recommend restoration of the \$764,195 and enhancement of the microbial genomics budget of ADRU by \$900,000 to a total of \$1,664,195 to use in collaboration with the University of Idaho, Washington State University and the U.S. Sheep Experiment Station in Dubois and other collaborators to expand research concerning causation and transmission of the pneumonia complex of big horn sheep and link predictive genomics based tests with the genetics of production.

We also urge the Subcommittee to recommend the restoration of \$484,292 for Malignant Catarrhal Fever (MCF) at the ARS/ADRU in Pullman for the fiscal year 2007 budget. MCF is a viral disease of ruminants that is of great concern to our livestock industries. The exotic variant of MCF is considered a high priority select agent. This funding is provided for collaborative research with the U.S. Sheep Experiment Station, Dubois ID and the University of Idaho, for vaccine development directed at preventing transmission and economic losses caused by MCF.

Research into Johne's disease has received additional funding through ARS over the past several years with a focus on cattle. Johne's disease is also endemic in the U.S. sheep population and is not well understood as a sheep disease. The same food safety concerns exist in both sheep and cattle; other countries are also very concerned about Johne's in sheep. We urge the Subcommittee to send a strong message to ARS that Johne's disease in sheep should receive more attention with an emphasis on diagnostics.

We appreciate and support USDA's strategic goals and note that strategic goal (3) "Enhance Domestic Rural and Farm Economies States in part as follows: "Work to expand production and market opportunities for bioenergy and biobased products". In response to this strategic goal of the USDA we request that the Subcommittee recommend \$350,000 as a targeted increase for ARS/ERRC research at Wyndmoor, PA to be directed toward research on wool at the molecular level focusing on antimicrobial properties, flame retardation and enhancement of fiber properties through enzyme treatments targeting high priority military needs and other niche market applications for consumers.

Cooperative State Research, Education, and Extension Service (CSREES)

The Minor Use Animal Drug Program is funded through a "Special Research Grant" that has had great benefit to the U.S. sheep industry. The research under this category is administered as a national program "NRSP-7" cooperatively with FDA/CVM to provide research information for the approval process on therapeutic drugs that are needed. Without this program, American sheep producers would not have effective products to keep their sheep healthy. We appreciate the fiscal year-2006 funding level of \$582,000 for this program, and we urge the Subcommittee to recommend that it be funded at least at this level in fiscal year 2008 to help meet the needs of our rapidly changing industry and increasing costs for research necessary to meet the requirements for approving additional therapeutics for sheep.

On-going funding for the Food Animal Residue Avoidance Databank (FARAD) program is critically important for the livestock industry in general and especially for

“minor species” industries such as sheep where extra-label use of therapeutic products is more the norm rather than the exception. We urge the Subcommittee to recommend that it be funded at least at the fiscal year 2006 level of \$806,000 in 2008 to help meet the needs of the animal industries. FARAD provides veterinarians the ability to accurately prescribe products with appropriate withdrawal times protecting both animal and human health.

On-going research to improve value quantification and marketing of wool is critically important to the sheep and wool industry. ASI urges the Subcommittee's support to restore and continue the CSREES special grants program for wool research at least to the fiscal year 2006 level of \$298,000 for fiscal year 2008.

Research for the Montana Sheep Institute is important to the sheep and wool industry. Sheep grazing is being used as an important tool for natural resource management to improve the competitiveness of lamb and wool in the marketplace and reduce the impacts of invasive plant species. ASI encourages the Subcommittee's support to continue funding at the fiscal year 2006 level of \$591,000 for 2008.

The Livestock Marketing Information Center (LMIC) is a unique and very effective cooperative effort. This is not a State specific effort; it operates as a national virtual “Center of Excellence” for Extension education, research, and public policy. Members of the LMIC represent 26 Land Grant Universities, 6 USDA agencies, and a variety of associate institutions. In conjunction with the USDA's Economic Research Service (ERS), this cooperative effort started in the mid-1950's. This effort is an integral part of U.S. livestock marketing and outlook programs for cattle, hogs, sheep, dairy and poultry. Demands on the LMIC staff continue to increase from other USDA agencies, Land Grant Universities, State governments, commodity associations and directly from producers. We strongly support funding be continued at least at the previously funded level of \$194,000 for the Livestock Marketing Information Center (LMIC) in fiscal year 2008. The coordinating office for this national Land Grant University directed effort is located in Lakewood, Colorado. As in the past, line-item funding will be directed through the USDA CSREES.

The Joe Skeen Institute for Rangeland Restoration is an on-going collaborative research program with Texas A&M University, New Mexico State University and Montana State University. Federal support is sought to help correct critical degradation of public lands, especially desertification of rangelands through research and education.

The rangelands of the United States have been degraded for decades impacting water runoff and production of amenities enjoyed by the general public. Innovative methods for control of invasive plants though goats and sheep are providing biological solutions while improving the environment. We urge the Subcommittee to support the Institute at \$2 million for fiscal year 2008.

Grants to Train Farm Workers in Technologies and Specialized Skills Necessary for Higher Value Crops

The shortage of skilled sheep shearers has increasingly become a problem for U.S. sheep producers and strong interest has been expressed in utilizing this grant program through USDA as authorized in section 6025 of the 2002 Farm Security and Rural Investment Act. Grant funds are authorized; however appropriations would be necessary for the program to allow the U.S. sheep industry the opportunity to apply for funds to train U.S. workers as sheep shearers.

PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR MICROBIOLOGY

The American Society for Microbiology (ASM) is pleased to submit the following testimony on the fiscal year 2008 appropriation for the U.S. Department of Agriculture (USDA) research and education programs. The ASM is the largest single life science organization with more than 42,000 members. The ASM mission is to enhance the science of microbiology, to gain a better understanding of life processes, and to promote the application of this knowledge for improved health and for economic and environmental well-being.

The ASM is concerned with the fiscal year 2008 proposed budget of approximately \$2 billion for agricultural research and development, a \$245 million decrease from fiscal year 2007, and a \$428 million cut from fiscal year 2006. The steady decline in Federal funding for agricultural research will have detrimental effects on both public health and the Nation's economy. Agricultural research is critical to USDA's role in oversight of domestic and imported food production to ensure a safe food supply and to the Nation's stake in domestic and global markets. In 2006, U.S. agricultural exports reached a record \$71 billion, an \$8 billion increase over 2005. There are strong correlations between food safety, food markets, and the U.S. economy.

The estimated costs of five foodborne bacterial diseases alone total nearly \$7 billion per year, with more than \$71 million just for *E. coli* O157 in contaminated ground beef. Recent outbreaks of disease linked to spinach and peanut butter and subsequent product recalls illustrate the effects of contaminated food on private sector markets.

The ASM asks Congress to increase support for the USDA Agricultural Research Service (ARS), the lead scientific agency that conducts intramural research, and the USDA National Research Initiative (NRI), the competitive, peer-reviewed grants program that supports extramural research. USDA research efforts in food safety, climate change, crop production, alternative fuels, the environment and other strategic areas are producing tangible returns on past federal investments. U.S. agricultural output has more than doubled in the last 50 years, attributed by economists almost entirely to increased productivity by U.S. producers who benefit from the Nation's investment in research and technology. Genetic improvements, for example, have accounted for half the yield gains in major cereal crops since the 1930s. The net gain from crop genetics research is estimated to be about \$385 million per year in the United States and more than \$600 million globally. The world's population likely will reach 9 billion by about 2050 but agricultural experts foresee shortfalls in cropland expansion for food production, thus the increased food supply will need to come from enhanced yields based on basic and applied research.

The President's fiscal year 2008 budget request would reduce funding for the ARS by 11 percent from fiscal year 2007 and fiscal year 2006. The ASM urges Congress to provide at least \$1.15 billion for the ARS in fiscal year 2008, the same level as fiscal year 2007 and fiscal year 2006. The President proposes funding the NRI at \$257 million in fiscal year 2008, an increase of \$67 million over fiscal year 2007; however, \$61 million of the increase will be allocated to the integrated programs transferred into the NRI and biofuel research, providing the NRI with an actual increase of only \$6 million for its base programs.

Food Safety

Strong support for the NRI and ARS is needed to provide the fundamental research essential to creating efficient and accurate technologies for the protection of human health and agricultural quality. This research is critical considering there are approximately 76 million foodborne illness cases in the United States per year. The United States has recently suffered from several bacterial foodborne illness outbreaks, including a widespread *E. coli* outbreak in spinach last summer that sickened more than 200 people and killed three. Several other outbreaks of salmonella and *E. coli* also occurred last year. The most recent problem resulted in a large recall of all Peter Pan and certain Great Value peanut butter contaminated with salmonella.

Recently, USDA supported scientists identified a safe and effective new sanitizer (acidified sodium chlorite, or SANOVA) that achieved a 5-log reduction of *E. coli* O157:H7, *Listeria monocytogenes*, and *Salmonella* on produce even in the presence of large organic loads. The researchers optimized sanitation treatment procedures to ensure good quality of shredded carrot and fresh-cut lettuce while maintaining the effective killing power of the sanitizer.

Because livestock and poultry are often the original source of pathogens (even in the case of produce-borne outbreaks), additional research is needed to strengthen production safeguards that can protect animal and human health. Other ARS research groups have been developing interventions using bacteriocins (natural antimicrobial agents) and bacteriophage (bacteria-killing agents) that upon commercialization will contribute to a reduction in campylobacter on chicken, leading to greater food safety.

Additionally, there is concern that some food borne bacterial pathogens may become resistant to certain antimicrobial agents. It is necessary to have continued support for antimicrobial resistance monitoring programs, such as the National Antimicrobial Resistance Monitoring System (NARMS) the Collaboration on Animal Health Food Safety Epidemiology (CAHFSE) program to generate data that will guide appropriate interventions in the food production chain to minimize and contain antimicrobial resistant bacterial pathogens in the food supply.

Through the Food Safety and Inspection Service (FSIS) and the Animal and Plant Health Inspection Service (APHIS), the USDA is ensuring the Nation's food quality, providing safety interventions, and contributing to pathogen reduction. The ASM supports the President's fiscal year 2008 requested increases above fiscal year 2007 of 4.8 percent and 35.4 percent for FSIS and APHIS respectively.

In 2002, the import share of total U.S. food consumption was 13 percent and continues to grow today. As agricultural imports increase, it is important to develop better systems to screen produce and other food imports at the borders. Federal sup-

port of research is needed to develop better methods for rapid detection, sampling, and intervention to protect the public from food borne pathogens.

Bioeconomy Based Systems

Agricultural research is a critical component of discovering biobased products such as polymers, lubricants, solvents, composites, and energy. The USDA research programs expand science-based knowledge and technologies to support the efficient, economical and environmentally friendly conversion of biomass, more specifically agricultural and municipal residuals into value-added industrial products and biofuels. Microbial research is essential to understanding and thus creating efficient conversion and production methods of biomass.

As research in the area of biofuels and bioenergy expands, it also affects other aspects of food production such as the fact that corn prices for livestock will increase as more is diverted to biofuel production potentially affecting the food supply, exports, and agricultural practices overall. The ASM urges the USDA to expand further the research programs on alternative bioenergy production to explore new resources and methods that would not compete with the food system, such as cellulose-based fermentation.

The ASM notes that more research is needed to understand the impact that removing biomass for energy and other products has on the sustainability of soils and water. Since soil sustainability is intrinsically linked to the microbial health of the soil, and the health of soil can directly affect its ability to filter and clean water, a greater understanding of soil microbiology is essential to ensuring sustainability.

Greater support for the NRI and ARS is essential to address the challenges of the emerging biobased industry with programs that support research, development and demonstration.

Climate Change

One of the most pressing issues faced by plant and animal producers is adapting to the impact of global change and climate on crop or animal production. Changing climate may alter bacterial and fungal pathogen pressures on plant and animal production and nutrient cycling and availability. Agriculture can contribute to a reduction in greenhouse gases that are microbial driven. The agricultural community needs scientific information for planning and decision making, to ensure economic viability. Scientific information on global change and climate and its impacts on soils, water, air, microbial biology, as well as plant and animal biology, and the general environment will produce robust simulation models to provide guidance on the relative benefits associated with agronomic decisions.

Current NRI-funded weather and climate projects focus on determining the effects of global change and climate on land-based systems and the global carbon cycle and on identifying agricultural and forestry activities that can help reduce greenhouse gas concentrations. Research can help identify, describe, and quantify processes involved in the cycling of organic and inorganic carbon in soil. Strong support of NRI is needed to develop new tools for accurately measuring greenhouse gases, methods for measuring and estimating carbon in ecosystems at different scales, and effective ways to sustain productivity in a changing environment. Information from this research can be used to achieve national goals on carbon dioxide and methane emissions reductions.

Genomics

The Microbial Genome Sequencing Program has been supported jointly by the NRI and the National Science Foundation (NSF) since fiscal year 2001. The program supports high-throughput sequencing of the genomes of a broad range of microorganisms and the development and implementation of strategies, tools, and technologies to make currently available genome sequences more valuable to the user community. Over 100 microbial genomes have been sequenced to date because of this program. The broad availability of these sequences has led to important insights into how the structure and content of microbial genomes affect the ability of microorganisms to function and adapt to the environments in which they live. The USDA/CSREES and NSF Microbial Genome Sequencing Program will lead to improved breeding strategies, increased disease resistance, and enhanced yield and nutritive value of agriculturally important plants and animals. The ASM urges Congress to provide strong support for the USDA genomics initiative.

Soil Processes

Microbial research is essential in protecting the Nation's natural resources, soil and water, and the subsequent impact on the supply and quality of food. The NRI is currently supporting research that will potentially lead to an effective treatment to entrap, remove, or inactivate cryptosporidia oocysts, which persist in soil and

water. Cryptosporidia are a potentially fatal protozoan that infects humans, livestock, and wildlife. When an effective control mechanism is developed, it may prove to be effective in dealing with all pathogens, including Salmonella, enteric bacteria, and viruses. The ASM urges Congress to increase support for the NRI to continue and expand on opportunities in soil processes research that is critical for the health and well-being of the Nation.

Workforce Development and Training

Studies project that over the period 2005–2010, employment opportunities for U.S. college graduates with expertise in the food, agricultural, and natural resources systems are expected to average over 52,000 openings per year, with some 49,300 qualified graduates available each year for these positions; with approximately 32,300 new graduates available from the U.S. colleges of agriculture and life sciences, forestry, and veterinary medicine and 17,000 qualified graduates from allied higher education programs such as biological sciences, engineering, business, health sciences, communication, and applied technologies will be available. It is essential to foster programs that assess what the future workforce demands will be in agricultural research and contribute to workforce development and training to meet these demands.

The ASM urges Congress to increase support for the NRI. As grant applications have increased, and funding has remained flat essentially for the last 4 years, young scientists are discouraged by the low funding rate of just 16 percent. Increasing funding for the NRI will increase the funding rate, providing greater opportunity for young scientists.

Conclusion

The ASM urges Congress to increase research funding for the USDA. The 2002 Farm Bill stated the sense of Congress to double funding for agriculture research over the next 5 years. The ASM is concerned that we are losing ground in the important field of agricultural research, just as the challenges the Nation faces in competitiveness, food safety, energy, and climate change, places more emphasis on the need for greater research to answer these demands.

The ASM appreciates the opportunity to provide written testimony and would be pleased to assist the Subcommittee as it considers the fiscal year 2008 appropriation for the USDA.

PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR MICROBIOLOGY

The American Society for Microbiology (ASM) appreciates the opportunity to comment on the fiscal year 2008 budget submission for the Food and Drug Administration (FDA). The ASM is the largest single life science Society with over 42,000 members, who work in academic, clinical, government and industry laboratories and are involved in research and diagnostic testing. The Society has a special interest in the activities of the FDA which are critical to safeguarding the health and welfare of the public. The ASM supports an increase in funding for FDA activities, which are expanding because of scientific innovations, rapid globalization and new and re-emerging diseases. The ASM urges that the FDA budget be increased and specifically recommends a significant increase for FDA Food Safety activities. An increase in the FDA budget will better equip the agency to address new public health issues and additional funding for food safety programs will help to protect the safety and quality of food consumed in the United States.

The FDA has enormous responsibilities that affect the public every day. About 20 percent of consumer spending in the United States buys FDA regulated products, an annual expenditure of nearly \$1.5 trillion. The FDA plays a critical role in overseeing and evaluating new products with significant potential to greatly improve public health and reduce costs to society. Annual spending on health care in the United States reached nearly \$2 trillion in 2005. Last year, FDA approved an array of new cost containing medical advances, including vaccines to fight cervical cancer, shingles, and gastroenteritis. FDA scientific and support staff must be prepared to respond to disease outbreaks, like those recently linked to contaminated salad greens and peanut butter. It is essential that FDA receive the federal funding which it needs to meet its changing and expanding regulatory responsibilities.

The proposed fiscal year 2008 budget for FDA includes \$1.64 billion in budget authority and nearly \$444 million to be collected as industry user fees, an overall 6.8 percent increase above the fiscal year 2007 request. The fiscal year 2008 budget authority includes a net increase of \$95.3 million to subsidize high priority initiatives identified as crucial by the FDA and external reviewers. The ASM agrees that this is a justifiable and wise investment in these priority initiatives, which include

strengthening food safety, modernizing FDA drug safety programs, and assuring FDA expertise and infrastructure upgrades.

Strengthening Food Safety

Foodborne disease continues to be a problem in the United States. In 2006, FDA investigators helped pinpoint the sources of pathogens in familiar products sold at grocery stores and restaurants, by testing contaminated spinach and lettuce, oysters, and peanut butter. More than 250 foodborne illnesses are recognized by the FDA's Center for Food Safety and Applied Nutrition (CFSAN). Federal officials estimate that each year about 76 million become sick, more than 300,000 are hospitalized, and 5,000 die from foodborne illnesses. The high priority initiative to enhance food safety includes much needed improvements like hiring experts in fresh produce microbiology, enhancing geographic information systems (GIS/GPS) to better map disease outbreaks, and expanding genomic databases used in screening imported foods.

The FDA's food program regulates \$417 billion worth of U.S. produced foods, \$49 billion in imported foods, and \$59 billion in cosmetics, from point of entry or production to point of sale. Global marketing, the threat of bioterrorist agents added to foods, changing American diets, and the rapidly growing diet supplement industry converge to further complicate FDA efforts toward a safe food supply. CFSAN personnel oversee consumer products as diverse as tattoo inks and infant formula. In fiscal year 2006, they inspected lettuce farming and processing operations in California, completed construction of a high level containment laboratory to develop methods for identifying biothreat agents, established a repository of pathogenic *Escherichia coli* O157:H7, and augmented advanced research tools for pinpointing sources of contamination by specific bacterial strains.

The fiscal year 2008 budget request includes \$10.6 million to strengthen the FDA's food safety activities, as part of the overall \$467 million allocated to the agency's Foods Program (a 4 percent increase over fiscal year 2007). The proposed increase in FDA's food safety activities is not sufficient to provide the resources needed to ensure adequate protection and programs based on the best science. The FDA is responsible for ensuring the safety and quality of 75 percent of the food consumed in the United States. Despite the fact that additional funding was provided to FDA in the 2007 Joint Resolution, no increase was provided for food safety. The food safety program must, therefore, absorb infrastructure and payroll costs at the expense of funding critical program needs. When the fiscal year 2008 CFSAN food safety request is compared to funding for food safety in the 2007 Joint Resolution, the net increase in fiscal year 2008 is only \$1 million. The proposed increase for food safety activities at CFSAN would be at the expense of current CFSAN programs.

FDA food safety activities are not able to keep pace with the demands to protect food in this country. The two primary centers within FDA that address food safety are CFSAN and the Office of Regulatory Affairs (ORA). In fiscal year 2004, CFSAN was authorized 901 FTEs, with a major focus on addressing food safety issues. Since then, several additional responsibilities have been delegated to the Center for regulatory oversight, including nutritional claims, food allergens, nanotechnology, and food security, and major reductions in appropriated personnel positions have occurred. In fiscal year 2008, only 756 FTEs have been proposed for CFSAN. In addition, in fiscal year 2004 2,086 FTEs were appropriated for ORA, the inspection program of FDA. About 30 percent of the ORA is allotted to food inspection, which equates to 626 inspectors. In fiscal year 2008, 1,946 FTEs have been proposed for ORA, which equates to 584 for food inspectors. Currently, the United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) has approximately 7,600 inspectors for approximately 6,500 meat and poultry processing facilities. FDA has about 600 food inspectors for over 50,000 food processing facilities which the agency oversees. The FDA would need at least 58,500 inspectors to be on par with the USDA-FSIS meat and poultry inspection program. Both FDA's CFSAN and the foods program within ORA are woefully under funded to adequately accomplish the tasks required to verify the safety of the U.S. food supply. Addressing gaps in inspection and compliance, enhancing scientific risk assessment, management and analysis, and science based food standards are examples of areas in need of new resources to provide adequate public health protection to the nation's food supply. The ASM recommends the FDA Food Safety programs be appropriated an additional \$75 million to strengthen CFSAN and ORA Food Safety activities.

The FDA's Center for Veterinary Medicine (CVM) regulates animal drugs and feeds used to care for a momentous number of animals: 9 billion chickens, 266 million turkeys, 97 million cattle, 61 million pigs, 11 million sheep and goats, 130 million dogs and cats, and 5 million horses. The current recall of 60 million containers of pet food by a major Canadian manufacturer, following reports of kidney failure

in dogs and cats, is the most recent example of CVM's rapid response to consumer complaints. The FDA quickly alerted the public and the media of the potential threat to pet health, while CVM personnel are onsite at the company's U.S. plants to search for any connection between the reported cases and product processing. The fiscal year 2008 budget requests \$106 million to support FDA's supervision of animal drugs and feeds, roughly a 7 percent increase. CVM programs slated to receive a funding increase include an interagency effort against the rising incidence of drug resistant microorganisms. In September 2006, the FDA released its third annual retail meat report, based on laboratory testing for resistance among meat associated microorganisms, part of the interagency National Antimicrobial Resistance Monitoring System. The FDA also issued an order last year that prohibits the extra label use in poultry of two classes of human anti influenza drugs, to avoid emergence of resistant strains of type A influenza that include the avian H5N1 virus. Other fiscal year 2008 funding targets are vigilance against Bovine Spongiform Encephalopathy (BSE) in cattle and evaluation of genetically modified animals as human food sources. Emerging infectious diseases and cutting edge science force regulators to adapt, to acquire new scientific methods and evaluate previously unknown food safety issues. Last December, the FDA issued three draft documents on the safety of animal cloning, concluding that meat and milk from clones and their offspring are safe as food, but asking producers to refrain from selling such products until final documents are released following public comment. The three documents illustrate the breadth and complexity of FDA oversight of specific food sources: a draft risk assessment, a proposed risk management plan, and a draft guidance for industry.

Modernizing Drug Safety

In 2006, two reports released by the Institute of Medicine (IOM) warned health officials about high numbers of prescription drug dispensing errors and about problems with drug safety oversight. The first report estimated that at least 1.5 million preventable adverse drug events (ADEs) occur each year in the United States. The report also concluded that preventable ADEs in hospitals alone could be costing the U.S. economy about \$3.5 billion annually in treatment expenses, adding that the extra cost of drug error related illness and death in the ambulatory setting had already reached an estimated \$177.4 billion by 2000. In response to these crises in prescription errors, the proposed fiscal year 2008 budget specifically requests nearly \$9 million to modernize FDA's drug safety programs. The FDA expects the fiscal year 2008 initiative to revolutionize the agency's ability to identify drug safety issues, by collecting surveillance numbers from more databases, acquiring the latest scientific tools to evaluate drugs and patient reactions, hiring specialist investigators to detect and resolve problems, and improving communication on safety to all stakeholders.

The proposed fiscal year 2008 budget sets aside nearly \$571 million for the FDA's ongoing oversight of human drugs, a 10 percent increase over fiscal year 2007. Without adequate funding, the quality of drug oversight will deteriorate at the same time as regulatory demands are expanding steadily. Each year, the FDA's Center for Drug Evaluation and Research (CDER) evaluates growing numbers of new and on-market drug products, routinely investigating adverse medical events and clarifying consumer information included in packaging. In 2006, the FDA approved several significant new drugs after extensive research and review, including the first inhaled insulin for self treatment by adult patients, the first drug patch for depression, the first drug treatment for a rare glycogen storage disease (Pompe disease, designated an FDA orphan drug), and the first drug for dementia of Parkinson's disease. Throughout the year, the agency announced a number of drug labeling changes based on adverse event reports. The FDA also contributed to ongoing counterbioterrorism initiatives, approving a nerve agent treatment for use by civilian emergency personnel and generic versions of a drug already FDA approved for inhalational anthrax.

Improving Generic Drug Review

The budget requests \$5.6 million to improve the evaluation of new generic drugs and \$15.7 million in new generic drug user fees to be collected from drug manufacturers to underwrite the rapidly expanding generic drug industry. In 2005, prescription drug sales accounted for roughly 10 percent of the \$2 trillion in total health care spending (about \$200.7 billion), making medications the third largest spending category. During the past six years, generic drug applications to the FDA's Office of Generic Drugs (OGD) increased by 158 percent (793 in fiscal year 2006), and the OGD estimates that 857 applications will be filed in fiscal year 2008. The fiscal year 2008 request to fund the FDA's generic drug initiative recognizes this expanding demand on FDA oversight. The agency already has implemented steps to improve pro-

gram efficiency, to shorten turn around time for applications. It estimates that funding for the fiscal year 2008 initiative will permit approval of as many as 550 generic drugs annually, reducing U.S. prescription drug costs and making more treatments available to more patients. In fiscal year 2006, the FDA approved or tentatively approved a record 510 new generic drug applications. Among those approved were 13 HIV/AIDS drugs and medications for hyperlipidemia, depression, osteoarthritis, and high cholesterol.

Modernizing Biologics Safety

The initiative to modernize drug safety, which is allocated \$11.2 million in the fiscal year 2008 budget, includes more than \$2.2 million to enhance safety assessments of biologics, blood and blood products, human tissue, cell and gene therapies, vaccines, and allergenic products. Statistics from 2006 reveal the extent of products regulated by the FDA's Center for Biologics Evaluation and Research (CBER): more than 14 million units of blood and blood products transfused, over 235 million vaccinations administered, and more than one million human tissues transplanted. Funding would expand postmarket surveillance, strengthen adverse event assessment, and improve communication with the medical community and other partners. The overall fiscal year 2008 budget for the Biologics Program would be \$216 million, a 10.8 percent increase over fiscal year 2007 that properly recognizes safe biologic products save lives and economic resources. CBER scientists must be able to evaluate cutting edge product development, including their involvement in the nearly 250 new gene therapy studies presently overseen by the Center. CBER oversight has been highly effective; for example, the risk of HIV and hepatitis C transmission through blood transfusion has been reduced from 1 in 100 units in the 1980s to less than 1 in a million units today. Cost effective vaccines in particular are credited with saving thousands of lives and millions of dollars in health care costs. In 2006, CBER approved new vaccines against three pathogenic viruses that cause significant death and disability: human papillomavirus (cervical cancer, sexually transmitted disease), herpes zoster virus (shingles), and rotavirus (gastroenteritis in infants and children).

Improving Medical Device Safety

A high priority initiative proposed in the fiscal year 2008 budget would help the FDA better evaluate the safety of a wide range of medical devices marketed in the United States. Of the \$285 million allocated to the Medical Devices Program, about \$7.2 million will fund specific advances in safety analysis and consumer information provided by the Center for Devices and Radiological Health (CDRH). As elsewhere in the FDA, demands on CDRH staff are being intensified by global market forces, rapidly advancing technologies, and shifting population demographics. In fiscal year 2006, CDRH received over 150,000 adverse event reports requiring review and in some cases follow up actions to protect the public health. Last year, FDA personnel continued collaboration with the Federal Trade Commission and eBay to make certain that unapproved medical devices were not being sold on the website. The CDRH also approved innovative devices with significant health enhancing potential, including the first easy to use portable lead poisoning test system, a device that will reduce brain damage in some hospitalized infants by keeping the head cool, a rapid diagnostic test for avian influenza viruses based on polymerase chain reaction (PCR) technology, and a sensor that wirelessly transmits blood glucose readings in real time for use by diabetics at home. The CDRH recently provided the scientific support for a large clinical trial of digital mammography, showing that the new technology was significantly more accurate than standard film mammography among patients with dense breasts, under age 50, or pre and perimenopausal. In fiscal year 2008, CDRH expects to certify new mammography facilities after evaluation of their technological expertise, plus examine and recertify one third of the more than 8,900 existing mammography facilities in the United States.

ASM Supports the Proposed FDA Budget for Fiscal Year 2008

The ASM supports an increase of \$75 million in the proposed budget for food safety and asks the Congress to appropriate the funding necessary to strengthen FDA regulation of foods, drugs, medical devices and other products that affect the public health. The ASM reminds the Congress that without its highly skilled staff of scientists and professionals, the FDA will not succeed in fully protecting U.S. public health with activities that are based on the best science available. If the agency does not receive adequate funding, it will be forced to reduce the number of safety officers, onsite inspectors, product reviewers, and laboratory researchers so necessary to effective and efficient oversight of FDA regulated products.

PREPARED STATEMENT OF THE ANIMAL HEALTH INSTITUTE

Dear Mr. Chairman: I write today to request that you include funding for priorities important to the animal health industry in the fiscal year 2008 Agriculture Appropriations Bill.

The Animal Health Institute strongly endorses the Administration's fiscal year 2008 budget request of \$19.867 million for the U.S. Department of Agriculture's Center for Veterinary Biologics, an increase of about \$4.4 million over its fiscal year 2007 funding level. For the past three fiscal years, CVB's funding has not included cost of living increases, so no progress has been made in filling vacant positions for reviewers, inspectors, and laboratory personnel. The CVB Inspection and Compliance division is currently at about 65 percent of its authorized personnel level, and the Policy, Evaluation, and Licensing division (including the laboratory) is below 50 percent. CVB's leadership anticipates that another year of level funding would force staff cutbacks in order to absorb the new activities relating to beginning operations in the new laboratories and added security responsibilities.

Every year, U.S. animal health companies produce 83 billion doses of animal vaccines. These vaccines are critical to protecting the health of America's flocks, herds, and pets from domestic and foreign animal diseases. Animal health companies, for instance, are developing new and innovative biologic to greatly reduce the presence of food-borne pathogens in animals just prior to slaughter, resulting in less pressure on pathogen reduction programs during processing. These new products represent a step forward in on-farm contributions to food safety. The lack of funding at CVB is dire, and threatens the innovation and availability of these products.

Additionally, Congress has authorized the Animal Drug User Fee Act, implementing a system of performance standards and user fees to improve the new animal drug review process at FDA's Center for Veterinary Medicine. Now in the fourth year of ADUFA implementation, CVM continues to make steady progress toward its performance goals. Animal producers will benefit from a supply of new and innovative products being brought to market more efficiently. The Committee has generously funded the fees in the previous four appropriations cycles. The President's budget proposal includes \$13.696 million that needs to be appropriated for fiscal year 2008, the last year of ADUFA authorization. The fiscal year 2008 user fee request includes the first quarter of fees for fiscal year 2009, funds which would be needed to ramp down the program if it were not reauthorized. The industry and Administration have not yet begun to negotiate a re-authorization agreement, but we are confident that ADUFA will be reauthorized. We ask for the user fees to be included in this year's appropriations bill. Similar to appropriations for the Prescription Drug User Fee Act, this appropriation is entirely budget neutral as the money will be provided by animal health companies.

The Animal Health Institute also endorses the President's budget request of \$94.809 million for FDA's Center for Veterinary Medicine (CVM). This amount includes the additional budget authority that is needed to make sure that user fee triggers are met. The additional funding will ensure that CVM is able to continue essential post market safety programs that would otherwise be adversely affected in order to meet ADUFA trigger fee requirements.

Finally, the Animal Health Institute strongly urges the Committee to fund the Administration's request of \$1.8 million for the Collaboration for Animal Health and Food Safety Epidemiology (CAHFSE), a joint effort of the Animal and Plant Health Inspection Service, the Food Safety and Inspection Service, and the Agricultural Research Service. CAHFSE will enable USDA to identify and track emerging diseases and identify and implement mitigation strategies in a timely manner thereby averting economic, animal health, and public health consequences. Further, it will provide comprehensive, science based answers regarding animal health and public health and will serve as a model for future surveillance efforts on a national level. Finally, it is the only pre-harvest food safety request included in the President's budget request.

Thank you for your consideration. Please do not hesitate to contact me if you have any questions or need additional information.

PREPARED STATEMENT OF THE ANIMAL WELFARE INSTITUTE

Dear Mr. Chairman: We are writing in support of an fiscal year 2008 appropriation of \$1.8 million for the Animal Welfare Information Center (AWIC) at the National Agricultural Library. The AWIC was established in 1986 in response to a mandate in the Improved Standards for Laboratory Animals amendment to the Animal Welfare Act. The Center serves as a clearinghouse, training center, and education resource for those involved in the use of animals for research, testing and

teaching, and the need and demand for its services continue to outstrip its ability to respond. The AWIC's subject areas include husbandry, handling, and care of animals; personnel training; animal behavior; alternatives; improved methodologies; environmental enrichment of non-human primates, and pain control via anesthesia and analgesia. Further information on the Center is on the web at: <http://www.nal.usda.gov/awic>.

The AWIC staff also compiles and distributes information resources from the scientific literature on zoonotic diseases such as avian influenza, transmissible spongiform encephalopathies, tuberculosis, etc.

An appropriation of \$1.8 million would be used as follows:

- \$1,273,000—Staff salary and benefits, including 2 critical new positions to support and enhance the use and usability of AWIC's most essential tool, its database. A Technical Information Specialist is needed to meet growing demand for complex AWIC database searches; to train the research community to meet the AWA's information requirements; and to produce large topical information resources. A new Information Technology Specialist would build, manage, and improve use of the AWIC database.
- \$61,400—Present exhibitions at conferences, including 3 regional AALAS conference in underserved areas of the country
- \$36,000—Present workshops in cooperation with Animal Care to assist licensees/registrants frequently cited for AWA violations
- \$28,000—Prepare and conduct informational workshops at research institutions across the country
- \$4,100—Prepare and conduct local workshops
- \$38,000—Acquisition of and electronic access to data
- \$29,200—Printing and reproduction (paper and electronic)
- \$26,000—Office supplies (software, hardware, etc.)
- \$20,400—Internet services
- \$13,900—NAL staff training
- \$270,000 overhead to ARS and NAL

AWIC's services are vitally important to the nation's biomedical research enterprise because they facilitate compliance with specific requirements of the Federal animal welfare regulations and policies governing animal-related research. In addition, the AWIC provides extensive research services for us, thereby greatly benefiting our work on animal research issues. We appreciate and look forward to a continued working relationship with the Animal Welfare Information Center and hope you will support our modest request for appropriations.

PREPARED STATEMENT OF THE CALIFORNIA INDUSTRY AND GOVERNMENT CENTRAL
CALIFORNIA OZONE STUDY COALITION

Mr. Chairman and Members of the Subcommittee, on behalf of the California Industry and Government Central California Ozone Study (CCOS) Coalition, we are pleased to submit this statement for the record in support of our fiscal year 2008 funding request of \$400,000 from the Department of Agriculture for CCOS. These funds are necessary for the State of California to address the very significant challenges it faces to comply with new national ambient air quality standards for ozone and fine particulate matter. The study design incorporates technical recommendations from the National Academy of Sciences (NAS) on how to most effectively comply with Federal Clean Air Act requirements.

First, we want to thank you for your past assistance in obtaining Federal funding for the Central California Ozone Study (CCOS) and California Regional PM₁₀/PM_{2.5} Air Quality Study (CRPAQS). Your support of these studies has been instrumental in improving the scientific understanding of the nature and cause of ozone and particulate matter air pollution in Central California and the Nation. Information gained from these two studies is forming the basis for the 8-hour ozone, PM_{2.5}, and regional haze State Implementation Plans (SIPs) that are due in 2007 (ozone) and 2008 (particulate matter/haze). As with California's previous and current SIPs, all future SIPs will continue to be updated and refined due to the scientific complexity of our air pollution problem. Our request this year would fund the completion of CCOS to address important questions that won't be answered with results from previously funded research projects.

To date, our understanding of air pollution and the technical basis for SIPs has largely been founded on pollutant-specific studies, like CCOS. These studies are conducted over a single season or single year and have relied on modeling and analysis of selected days with high concentrations. SIPs are now more complex than they were in the past. The National Academy of Sciences (NAS) now recommends a

weight-of-evidence approach that will involve utilizing more broad-based, integrated methods, such as data analysis in combination with seasonal and annual photochemical modeling, to assess compliance with Federal Clean Air Act requirements. This will involve the analysis of a larger number of days and possibly an entire season. In addition, because ozone and particulate matter are formed from some of the same emissions precursors, there is a need to address both pollutants in combination, which CCOS will do.

Consistent with the NAS recommendations, the CCOS study includes corroborative analyses with the extensive data provided by past studies, advances the state-of-science in air quality modeling, and addresses the integration of ozone and particulate pollution studies. In addition, the study will incorporate further refinements to emission inventories, address the development of observation-based analyses with sound theoretical bases, and includes the following four general components:

- Performing SIP modeling analyses—2005–2011
- Conducting weight-of-evidence data analyses—2006–2008
- Making emission inventory improvements—2006–2010
- Performing seasonal and annual modeling—2008–2011

CCOS is directed by Policy and Technical Committees consisting of representatives from Federal, State, and local governments, as well as private industry. These committees, which managed the San Joaquin Valley Ozone Study and are currently managing the California Regional Particulate Air Quality Study, are landmark examples of collaborative environmental management. The proven methods and established teamwork provide a solid foundation for CCOS.

For fiscal year 2008, our Coalition is seeking funding of \$400,000 from the Department of Agriculture/CSREES in support of CCOS. Domestic agriculture is facing increasing international competition. Costs of production and processing are becoming increasingly more critical. With the recent SJV PM₁₀ SIP and the upcoming ozone and PM_{2.5} SIPs, the agricultural industry within the study area is facing many new requirements to manage and reduce their air quality impacts. The identification of scientifically validated, cost-effective options for reducing the environmental impacts of on-field and livestock related air emissions will contribute significantly to the long-term health and economic stability of local agriculture. Funding will support livestock and crop-related research that will help maintain a vital agricultural industry within the state. Research will be focused to measure baseline emissions, and to study the most economical and effective approaches for reducing the impacts of agriculture on air quality. These studies also have nationwide benefits.

The funding request is for: (1) Study of agricultural volatile organic compound (VOC) emissions from pesticide application that will help answer questions relevant to farmers and regulators throughout the Nation, (2) Evaluation of baseline livestock emissions (VOCs, PM₁₀, ammonia) and effective methods to reduce these emissions, (3) Development of livestock facility emissions models as recommended by the National Academy of Sciences and (4) Improvement of emissions estimates for agricultural related diesel engines, both on-road and off-road. This includes emission factors, activity data, fleet characteristics, seasonality of emissions, and benefits of incentive programs to accelerate the introduction of cleaner engines.

Thank you very much for your consideration of our request.

PREPARED STATEMENT OF THE COALITION ON FUNDING AGRICULTURAL RESEARCH MISSIONS

The Coalition on Funding Agricultural Research Missions (CoFARM) appreciates the opportunity to submit testimony on the fiscal year 2008 appropriation for the United States Department of Agriculture (USDA). CoFARM is a coalition of 24 professional scientific organizations with over 200,000 members dedicated to advancing and sustaining a balanced investment in our nation's research portfolio.

The USDA sponsors research and education programs which contribute to solving agricultural problems of high national priority and ensuring food availability, nutrition, quality and safety, as well as a competitive agricultural economy. Agriculture faces new challenges, including threats from emerging infectious diseases in plants and animals, climate change, and public concern about food safety and security. It is critical to increase the visibility and investment in agriculture research to respond to these challenges, and we appreciate the efforts of Congress to fund the National Research Initiative (NRI) at \$190 million in fiscal year 2007. We urge the Subcommittee to support the Administration's fiscal year 2008 request of \$257 million for this program.

USDA National Research Initiative Competitive Grants Program

The National Research Initiative Competitive Grants Program (NRI) was established in 1991 in response to recommendations outlined in the report, *Investing in Research: A Proposal to Strengthen the Agricultural, Food and Environmental System*, by the National Research Council's (NRC) Board of Agriculture. This report called for increased funding by USDA of high priority research through a competitive peer-review process directed at:

- Increasing the competitiveness of U.S. agriculture.
- Improving human health and well-being through an abundant, safe, and high-quality food supply.
- Sustaining the quality and productivity of the natural resources and the environment upon which agriculture depends.

Stakeholders of the research community continue their interest in and support of the NRI, which is reflected in two subsequent NRC reports, *Investing in the National Research Initiative: An Update of the Competitive Grants Program* of the U.S. Department of Agriculture, published in 1994, and *National Research Initiative: A Vital Competitive Grants Program in Food, Fiber, and Natural Resources Research*, published in 2000.

Today, the NRI, housed within USDA's Cooperative State Research, Education, and Extension Service (CSREES), supports research on key problems of national and regional importance in biological, environmental, nutritional, physical, and social sciences relevant to agriculture, food, health and the environment on a peer-reviewed, competitive basis. Additionally, NRI enables USDA to develop new partnerships with other Federal agencies that advance agricultural science like its current collaborations between NRI and DOE and NSF.

CoFARM urges Congress to support the Administration's requested increase for NRI in fiscal year 2008. NRI's proposed increase comes from the shifting of CSREES Integrated Activities, such as food safety, pest management, and water quality, making up \$42 million of the proposed increase, providing a net increase of \$25 million for NRI. The Administration also requests \$19 million of the NRI budget be used for bioenergy research. CoFARM supports the Administration's effort to increase competitively awarded funding mechanisms.

By increasing the funding for this program, the United States is investing in our nation's future. Failure to make this investment will imperil the future of agriculture in the United States by reducing competitiveness and decreasing productivity. With limited dollars our scientists already produce an annual rate of return of at least 40 percent.¹ This high rate of return suggests that an increase in funds to agricultural research would be beneficial to the U.S. economy.

Because of Federal investment, we have made since 1991, we have gained valuable new knowledge in areas such as:

Food Safety and Nutrition

USDA funded competitive research has supported studies to understand incentives for firms to adopt food safety controls and industry response to losses when products are recalled for food safety violations.

USDA supported scientists identified a safe and effective new sanitizer (SANOVA) that achieved a 5-log reduction of *E. coli*, *Listeria*, and *Salmonella* on produce even in the presence of large organic loads. The researchers optimized sanitation treatment procedures to ensure good quality of shredded carrot and fresh-cut lettuce while maintaining the effective killing power of the sanitizer. This research is critical considering there are approximately 76 million foodborne illness cases in the U.S. per year and the findings from this research is especially useful to the fresh produce industry as they provide practical information in selecting a suitable sanitizer to maintain microbial safety and quality of fruits and vegetables.

Iowa State University researchers have studied fatty acid composition in beef and dairy cattle through a NRI funded grant. They have discovered a single nucleotide polymorphism that is correlated to content of C14:0 (myristic acid, the most atherogenic of saturated fatty acids) of beef. Thus, the marker in the thioesterase domain in fatty acid synthase gene can be used to select for healthier beef.

University of Illinois scientists are involved with the assessment of general risk posed from transgenic animals, which is important to their future contributions to society. Identification of potentially harmful properties of transgenic livestock is the initial step in a risk assessment. Direct and indirect impacts of potential harmful properties of transgenic livestock are being evaluated at three levels: (1) character-

¹ "Agricultural Research and Productivity: Questions and Answers," USDA Economic Research Service, December 2005. <http://www.ers.usda.gov/Briefing/AgResearch/Questions/APRDQA6.HTM>

ization of how the transgene, the transgene product, and the transgenic livestock behave in their immediate environment, that is, in their barn or pen, (2) determination of possible impacts of large scale release of transgenic livestock, that is, if they were to be integrated into the larger population of food animal livestock, and (3) determination of the more complex environmental and safety consequences of their release into the livestock population. This study will determine whether a mammary specific transgene, bovine a-lactalbumin (Ba-LA) is expressed in tissues other than the mammary gland and whether the transgene (Tg) itself, the transgenic RNA or the transgenic protein cross over into non-transgenic (C) animals under various physiological and physical conditions.

Renewable Energy and Fuels

In a time of volatile gasoline prices, USDA dollars have helped provide economic and policy analyses for specific renewable energy technologies and will estimate national impacts of certain renewable energy policy alternatives.

An April 2005 joint study of the U.S. Departments of Energy and Agriculture found that with continued advances in research there will be enough renewable biomass grown in the United States, to meet more than one-third of the current demand for transportation fuels in the nation, without diverting from food crop production.² With advances in plant and microbial research, land in every state in the nation could be used to grow plants that produce clean-burning cellulosic ethanol resulting in decreased dependence on foreign oil, reduction of the trade deficit, reduced emissions of stored greenhouse gases, revitalized rural economies and strengthened national security.

Plant and Animal Health and Well-Being

Pennsylvania researchers are developing rapid diagnostic tests to curb avian influenza, a disease that could cripple the state's \$700 million poultry industry.

Entomologists and Nematologists developed a vaccine for the protection of cattle from the horn fly, a major insect pest in many parts of the world costing the North American cattle industry alone more than \$1 billion annually.

Iowa State University researchers studied fatty liver syndrome in dairy cattle. They found that daily injections of glucagon can be used to prevent and treat fatty liver in transition dairy cows. A patent has been issued for this technology.

Waste Remediation

Researchers in Florida have tested a common fern's ability to soak up arsenic, a cancer-causing heavy metal, from contaminated soils. The market for plant-based remediation of wastes is estimated to be \$370 million in 2005.

With the support of Congress, increased funding for research will continue to boost the American agricultural enterprise and improve our economy by increasing food safety, boosting production, protecting the environment, finding new uses for renewable resources, and enhancing food itself so that food and agricultural systems contribute to a stronger and more healthful society. Research programs in nutrition and food science help to ensure high-quality, safe, and affordable food for consumers, and contribute to the success of a food and agricultural system that creates jobs and income in the United States.

CoFARM appreciates the opportunity to provide written testimony and would be pleased to assist the Subcommittee as the Department of Agriculture bill is considered throughout the appropriations process.

PREPARED STATEMENT OF THE COLORADO RIVER BASIN SALINITY CONTROL FORUM

The Congress concluded that the Colorado River Basin Salinity Control Program (Program) should be implemented in the most cost-effective way. Realizing that agricultural on-farm strategies were some of the most cost-effective strategies, the Congress authorized a program for the United States Department of Agriculture (USDA) through amendment of the Colorado River Basin Salinity Control Act in 1984. With the enactment of the Federal Agriculture Improvement and Reform Act of 1996 (FAIRA), the Congress directed that the Program should continue to be implemented as one of the components of the Environmental Quality Incentives Program (EQIP). Since the enactment of the Farm Security and Rural Investment Act (FSRIA) in 2002, there have been, for the first time in a number of years, opportunities to adequately fund the Program within the EQIP.

²"Biomass as Feedstock for a Bioenergy and Bioproducts Industry: The Technical Feasibility of a Billion-Ton Annual Supply, April 2005" http://www1.eere.energy.gov/biomass/pdfs/final_billionton_vision_report2.pdf

The Program, as set forth in the Colorado River Basin Salinity Control Act, is to benefit Lower Basin water users hundreds of miles downstream from salt sources in the Upper Basin as the salinity of Colorado River water increases as the water flows downstream. There are very significant economic damages caused by high salt levels in this water source. Agriculturalists in the Upper Basin where the salt must be controlled, however, don't first look to downstream water quality standards but look for local benefits. These local benefits are in the form of enhanced beneficial use and improved crop yields. They submit cost-effective proposals to the State Conservationists in Utah, Wyoming and Colorado and offer to cost share in the acquisition of new irrigation equipment. The Colorado River Basin Salinity Control Act provides that the seven Colorado River Basin States will also cost share with the Federal funds for this effort. This has brought together a remarkable partnership.

After longstanding urgings from the States and directives from the Congress, the USDA has concluded that this program is different than small watershed enhancement efforts common to the EQIP. In this case, the watershed to be considered stretches more than 1,200 miles from the river's headwater in the Rocky Mountains to the river's terminus in the Gulf of California in Mexico and receives water from numerous tributaries. The USDA has determined that this effort should receive a special funding designation and has appointed a coordinator for this multi-state effort.

In recent fiscal years, the Natural Resources Conservation Service (NRCS) has directed that over \$19 million be used for the Program. The Colorado River Basin Salinity Control Forum (Forum) appreciates the efforts of the NRCS leadership and the support of this subcommittee. The plan for water quality control of the Colorado River was prepared by the Forum, adopted by the States, and approved by the United States Environmental Protection Agency (EPA). The Colorado River Basin Salinity Control Advisory Council has taken the position that the funding for the salinity control program should not be below \$20 million per year. Over the last three fiscal years, for the first time, funding almost reached the needed level. State and local cost-sharing is triggered by the Federal appropriation. In fiscal year 2007, it is anticipated that the States will cost share with about \$8.3 million and local agriculture producers will add another \$7.5 million. Hence, it is anticipated that in fiscal year 2007 the State and local contributions will be 45 percent of the total program cost.

Over the past few years, the NRCS has designated that about 2.5 percent of the EQIP funds be allocated to the Colorado River salinity control program. The Forum believes this is the appropriate future level of funding as long as the total EQIP funding nationwide is around \$1 billion. Funding above this level assists in offsetting pre-fiscal year 2003 funding below this level. The Basin States have cost sharing dollars available to participate in funding on-farm salinity control efforts. The agricultural producers in the Upper Basin are waiting for their applications to be considered so that they might improve their irrigation equipment and also cost share in the Program.

Overview

The Program was authorized by the Congress in 1974. The Title I portion of the Colorado River Basin Salinity Control Act responded to commitments that the United States made, through a Minute of the International Boundary and Water Commission, to Mexico specific to the quality of water being delivered to Mexico below Imperial Dam. Title II of the Act established a program to respond to salinity control needs of Colorado River water users in the United States and to comply with the mandates of the then newly-enacted Clean Water Act. This testimony is in support of funding for the Title II program.

After a decade of investigative and implementation efforts, the Basin States concluded that the Salinity Control Act needed to be amended. The Congress agreed and revised the Act in 1984. That revision, while keeping the Department of the Interior as lead coordinator for Colorado River Basin salinity control efforts, also gave new salinity control responsibilities to the USDA. The Congress has charged the Administration with implementing the most cost-effective program practicable (measured in dollars per ton of salt controlled). It has been determined that the agricultural efforts are some of the most cost-effective opportunities.

Since Congressional mandates of three decades ago, much has been learned about the impact of salts in the Colorado River system. The Bureau of Reclamation (Reclamation) has conducted studies on the economic impact of these salts. Reclamation recognizes that the damages to United States' water users alone are hundreds of millions of dollars per year.

The Forum is composed of gubernatorial appointees from Arizona, California, Colorado, Nevada, New Mexico, Utah and Wyoming. The Forum has become the seven-

state coordinating body for interfacing with Federal agencies and the Congress in support of the implementation of the Salinity Control Program. In close cooperation with the EPA and pursuant to requirements of the Clean Water Act, every 3 years the Forum prepares a formal report evaluating the salinity of the Colorado River, its anticipated future salinity, and the program elements necessary to keep the salinity concentrations (measured in Total Dissolved Solids—TDS) at or below the levels measured in the river system in 1972 at Imperial Dam, and below Parker and Hoover Dams.

In setting water quality standards for the Colorado River system, the salinity concentrations at these three locations in 1972 have been identified as the numeric criteria. The plan necessary for controlling salinity and reducing downstream damages has been captioned the "Plan of Implementation." The 2005 Review of water quality standards includes an updated Plan of Implementation. In order to eliminate the shortfall in salinity control resulting from inadequate Federal funding for a number of years from the USDA, the Forum has determined that implementation of the Program needs to be accelerated. The level of appropriation requested in this testimony is in keeping with the agreed upon plan. If adequate funds are not appropriated, significant damages from the higher salt concentrations in the water will be more widespread in the United States and Mexico.

Concentrations of salts in the river cause \$330 million in quantified damages and significantly more in unquantified damages in the United States and result in poorer quality water being delivered by the United States to Mexico. Damages occur from:

- a reduction in the yield of salt sensitive crops and increased water use for leaching in the agricultural sector,
- a reduction in the useful life of galvanized water pipe systems, water heaters, faucets, garbage disposals, clothes washers, and dishwashers, and increased use of bottled water and water softeners in the household sector,
- an increase in the use of water for cooling, and the cost of water softening, and a decrease in equipment service life in the commercial sector,
- an increase in the use of water and the cost of water treatment, and an increase in sewer fees in the industrial sector,
- a decrease in the life of treatment facilities and pipelines in the utility sector,
- difficulty in meeting wastewater discharge requirements to comply with National Pollutant Discharge Elimination System permit terms and conditions, and an increase in desalination and brine disposal costs due to accumulation of salts in groundwater basins, and
- increased use of imported water for leaching and cost of desalination and brine disposal for recycled water.

For every 30 mg/L increase in salinity concentrations, there is \$75 million in additional damages in the United States. The Forum, therefore, believes implementation of the USDA program needs to be funded at 2.5 percent of the total EQIP funding.

Although the Program thus far has been able to implement salinity control measures that comply with the approved plan, recent drought years have caused salinity levels to rise in the river. Predictions are that this will be the trend for the next several years. This places an added urgency for acceleration of the implementation of the Program.

State Cost-Sharing and Technical Assistance

The authorized cost sharing by the Basin States, as provided by FAIRA, was at first difficult to implement as attorneys for the USDA concluded that the Basin States were authorized to cost share in the effort, but the Congress had not given the USDA authority to receive the Basin States' funds. After almost a year of exploring every possible solution as to how the cost sharing was to occur, the States, in agreement with Reclamation, State officials in Utah, Colorado and Wyoming and with NRCS State Conservationists in Utah, Colorado and Wyoming, agreed upon a program parallel to the salinity control activities provided by the EQIP wherein the States' cost sharing funds are being contributed and used. We are now several years into that program and, at this moment in time, this solution to how cost sharing can be implemented appears to be satisfactory.

With respect to the Basin States' cost sharing funds, the Basin States felt that it was most essential that a portion of the Program be associated with technical assistance and education activities in the field. Without this necessary support, there is no advanced planning, proposals are not well prepared, assertions in the proposals cannot be verified, implementation of contracts cannot be observed, and valuable partnering and education efforts cannot occur. Recognizing these values, the "parallel" State cost sharing program expends 40 percent of the funds available on these needed support activities made possible by contracts with the NRCS. Initially,

it was acknowledged that the Federal portion of the Program funded through EQIP was starved with respect to needed technical assistance and education support. The Forum is encouraged with a recent Administration acknowledgment that technical assistance must be better funded.

PREPARED STATEMENT OF THE COLORADO RIVER BOARD OF CALIFORNIA

This testimony is in support of funding for the U.S. Department of Agriculture (USDA) with respect to its on-farm Colorado River Basin Salinity Control Program for fiscal year 2008. This program has been carried out through the Colorado River Basin Salinity Control Act (Public Law 93-320), since it was enacted by Congress in 1974. With the enactment of the Federal Agricultural Improvement and Reform Act (FAIRA) in 1996 (Public Law 104-127), specific funding for salinity control projects in the Colorado River Basin were eliminated from the federal budget and aggregated into the Department of Agriculture's Environmental Quality Incentives Program (EQIP) as one of its program components. With that action, Congress concluded that the salinity control program could be more effectively implemented as one of the components of the EQIP.

The Program, as set forth in the Act, benefits both the Upper Basin water users through more efficient water management and the Lower Basin water users, hundreds of miles downstream from salt sources in the Upper Basin, through reduced salinity concentration of Colorado River water. California's Colorado River water users are presently suffering economic damages in the hundreds of million of dollars per year due to the River's salinity.

The Colorado River Board of California (Colorado River Board) is the state agency charged with protecting California's interests and rights in the water and power resources of the Colorado River system. In this capacity, California along with the other six Colorado River Basin states through the Colorado River Basin Salinity Control Forum (Forum), the interstate organization responsible for coordinating the Basin States' salinity control efforts, established numeric criteria in June 1975 for salinity concentrations in the River. These criteria were established to lessen the future damages in the Lower Basin states of Arizona, California, and Nevada, as well as assist the United States in delivering water of adequate quality to Mexico in accordance with Minute 242 of the International Boundary and Water Commission.

The goal of the Colorado River Basin Salinity Control Program is to offset the effects of water resources development in the Colorado River Basin after 1972 as each state develops its Colorado River Compact apportionments. In close cooperation with the U.S. Environmental Protection Agency (EPA) and pursuant to requirements of the Clean Water Act (Public Law 92-500), every 3 years the Forum prepares a formal report analyzing the salinity of the Colorado River, anticipated future salinity, and the program elements necessary to keep the salinity concentrations (measured in Total Dissolved Solids—TDS) at or below the levels measured in the Colorado River system in 1972 at Imperial Dam, and below Parker and Hoover Dams. The latest report was prepared in 2005 titled: 2005 Review, Water Quality Standards for Salinity, Colorado River System (2005 Review). The plan necessary for controlling salinity and reducing downstream damages has been captioned the "Plan of Implementation." The 2005 Review includes an updated Plan of Implementation.

Concentrations of salts in the River annually cause about \$330 million in quantified damage in the United States (there are significant unquantified damages as well). For example, damages occur from:

- A reduction in the yield of salt sensitive crops and increased water use for leaching in the agricultural sector;
- A reduction in the useful life of galvanized water pipe systems, water heaters, faucets, garbage disposals, clothes washers, and dishwashers, and increased use of bottled water and water softeners in the household sector;
- An increase in the use of water for cooling, and the cost of water softening, and a decrease in equipment service life in the commercial sector;
- An increase in the use of water and the cost of water treatment, and an increase in sewer fees in the industrial sector;
- A decrease in the life of treatment facilities and pipelines in the utility sector;
- Difficulty in meeting wastewater discharge requirements to comply with National Pollutant Discharge Elimination System permit terms and conditions, and an increase in desalination and brine disposal costs due to accumulation of salts in groundwater basins, and fewer opportunities for recycling due to groundwater quality deterioration; and

—Increased use of imported water for leaching and the cost of desalination and brine disposal for recycled water.

For every 30 milligram per liter increase in salinity concentrations, there are \$75 million in additional damages in the United States. Although the Program, thus far, has been able to implement salinity control measures that comply with the approved plan, recent drought years have caused salinity levels to rise in the River. Predictions are that this will be the trend for the next several years. This places an added urgency for acceleration of the implementation of the Program.

Enactment of the Farm Security and Rural Investment Act of 2002 provided an opportunity to adequately fund the Salinity Program within EQIP. The Colorado River Basin Salinity Control Advisory Council has taken the position that the USDA portion of the effort be funded at 2.5 percent of the EQIP funding but at least \$20.0 million annually. Over the past few years, the Natural Resources Conservation Service (NRCS) has designated 2.5 percent of EQIP funds be allocated to the Colorado River Salinity Control program. The Forum suggests that this is an appropriate level of funding as long as it does not drop below \$20.0 million. Funding above this level assists in offsetting pre-fiscal year 2003 funding below this level. The Colorado River Board supports the recommendation of the Forum and urges this Subcommittee to support funding for the Colorado River Basin Salinity Control Program for 2008 at this level.

These Federal dollars will be augmented by the State cost sharing of 30 percent with an additional 25 percent provided by the agricultural producers with whom USDA contracts for implementation of salinity control measures. Over the past years, the Colorado River Basin Salinity Control program has proven to be a very cost effective approach to help mitigate the impacts of increased salinity in the Colorado River. Continued Federal funding of this important Basin-wide program is essential.

In addition, the Colorado River Board recognizes that the federal government has made significant commitments to the Republic of Mexico and to the seven Colorado River Basin States with regard to the delivery of quality water to Mexico. In order for those commitments to continue to be honored, it is essential that in fiscal year 2008, and in future fiscal years, that Congress continues to provide funds to USDA to allow it to provide needed technical support to agricultural producers for addressing salinity control in the Basin.

The Colorado River is, and will continue to be, a major and vital water resource to the 18 million residents of southern California as well as throughout the Colorado River Basin. As stated earlier, preservation and improvement of the Colorado River water quality through an effective salinity control program will avoid the additional economic damages to users of Colorado River water in California, Arizona, and Nevada.

PREPARED STATEMENT OF FLORIDA STATE UNIVERSITY

Summary of Request

Florida State University is requesting \$4,500,000 from the U.S. Department of Agriculture; Cooperative State Research, Education and Extension Service/Research and Education Activities/Federal Admin. Account for the Risk Reduction for Agricultural Crops project for fiscal year 2008.

Mr. Chairman, I would like to thank you and the Members of the Subcommittee for this opportunity to present testimony before this Committee. I would like to take a moment to briefly acquaint you with Florida State University.

Located in Tallahassee, Florida's capitol, FSU is a comprehensive Research I university with a rapidly growing research base. The University serves as a center for advanced graduate and professional studies, exemplary research, and top-quality undergraduate programs. Faculty members at FSU maintain a strong commitment to quality in teaching, to performance of research and creative activities, and have a strong commitment to public service. Among the current or former faculty are numerous recipients of national and international honors including Nobel laureates, Pulitzer Prize winners, and several members of the National Academy of Sciences. Our scientists and engineers do excellent research, have strong interdisciplinary interests, and often work closely with industrial partners in the commercialization of the results of their research. Florida State University had over \$190 million this past year in research awards.

Florida State University attracts students from every State in the nation and more than 100 foreign countries. The University is committed to high admission standards that ensure quality in its student body, which currently includes National

Merit and National Achievement Scholars, as well as students with superior creative talent.

At Florida State University, we are very proud of our successes as well as our emerging reputation as one of the Nation's top public research universities.

Mr. Chairman, let me summarize our primary interest today. The Southeast Climate Consortium (SECC), which consists of Florida State University, the University of Florida, the University of Miami, the University of Georgia, Auburn University, and University of Alabama at Huntsville, has been at the forefront of research and extension for the applications of climate predictions to risk reduction for agriculture. With support from NOAA and USDA, the SECC has developed new methods to predict the consequences of climate variability for agricultural crops, forests, and water resources in the southeast United States. In recent real-life tests, these methods have been applied to the problems that farmers raising specialty crops face arising from variable rainfall, temperature, and wild fires.

In the SECC, Florida State University will provide the climate forecasts and risk reduction methodology. The University of Florida and University of Georgia will translate this climate information into risks associated environmental impacts on agriculture and, with Auburn University, will work with Extension Services to provide information to the agricultural community. The University of Miami will provide economic modeling of agricultural systems. Together UM, UF, and the University of Alabama-Huntsville are developing new tools to help minimize climate risks to water quality and quantity, especially for agriculture. FSU, on behalf of the SECC, seeks \$5.0 million in fiscal year 2008 for this activity. Utilization of these tools and their application to agricultural problems has the strong support of extension managers.

Mr. Chairman, FSU is seeking \$4,500,000 in fiscal year 2008 to continue our important work. The new tasks for fiscal year 2008 include the development flood forecasting methods to help farmers and producers plan for reducing risks of economic losses and environmental damage; developing partnerships and methods for incorporating climate forecasts and other climate information into agricultural and water policy decisions, and beginning development of a prototype decision support system for the application of climate forecasts to water resource management, especially for agricultural water use. We are also working with the committees on agriculture on the upcoming farm bill, seeking to secure authorization for this program.

Mr. Chairman, we believe this research is vitally important to our country and would appreciate your support.

PREPARED STATEMENT OF FOOD & WATER WATCH

My name is Wenonah Hauter. I am the Executive Director of Food & Water Watch, a non-profit consumer organization. We welcome this opportunity to present our views on the fiscal year 2008 Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations Bill.

USDA—Food Safety and Inspection Service (FSIS)

Risk-Based Inspection

We have the following concerns about this proposal:

We believe that the agency lacks the statutory authority to execute a risk-based inspection scheme, especially one that contemplates food processing plants receiving less than daily inspection. According to both the Federal Meat Inspection Act (21 U.S.C. 603) and the Poultry Products Inspection Act (21 U.S.C. 455), the United States Department of Agriculture is required to provide continuous inspection in all establishments that produce meat and poultry products that enter the food supply.

FSIS' own glossary defines continuous inspection as:

—USDA's meat and poultry inspection system is often called "continuous" because no animal destined for human food may be slaughtered or dressed unless an inspector is present to examine it before slaughter (antemortem inspection), and its carcass and parts after slaughter (postmortem inspection). In processing plants, as opposed to slaughter plants, inspectors need not be present at all times, but they do visit at least once daily. Processing inspection is also considered continuous.¹

Under Secretary for Food Safety Richard Raymond has been quoted in the press advocating "virtual inspections," whereby food establishments would merely transmit daily production records to FSIS inspectors either via facsimile or electronically

¹ See <http://www.fsis.usda.gov/Help/glossary-C/index.asp>.

without a physical inspection visit.² This is not what the meat and poultry inspection statutes establish, and we believe that the agency is treading on dangerous legal ground as it proceeds with this proposal.

Furthermore, we believe that this new system could spark legal challenges by food establishments that believe they are being singled out for more intense inspections. Without a statutory basis for instituting changes to the inspection process, the agency might be hard-pressed to implement this new program in light of such legal challenges.

Risk-based inspection needs a reliable database upon which to make judgments about which meat and poultry plants meet or exceed performance standards. At the present time, there are problems with the data collected by FSIS. The USDA Office of Inspector General (OIG), in a November 2004 audit report, said the following about the agency's Performance Based Inspection System (PBIS) database:

Due to the lack of controls noted during our audit, FSIS cannot be assured that PBIS data is complete, accurate, and reliable. As a result, FSIS management may not have the information it needs to effectively manage its inspection activities. Without effective controls over data integrity, the PBIS system may be an unreliable repository that gives FSIS management a false sense that inspection activities are adequately carried out and sanitation of plant operations is accurately reported.³

In September 2006, the OIG released an audit of the agency's Pathogen Reduction Enforcement Program (PREP). PREP is used to collect information from the FSIS salmonella testing program. The OIG found the following:

—We found a significant number of establishments that were excluded from the Salmonella sampling database because of ineffective controls to identify eligible establishments and also because district office personnel did not fully understand the process for including the establishments in the database. At the district we visited, 28 percent of the establishments that should have been subject to Salmonella testing were excluded from the sampling database. This problem was particularly apparent at establishments inspected under Federal-State Cooperative Programs (Talmadge-Aiken establishments) in the one State we visited. The State supervisors responsible for program oversight at these establishments were not provided with the eligibility reports that could have allowed them to identify establishments that needed to be included in the sampling database.⁴

The agency is also lacking one critical piece of information that we consider vital before it can move forward with any proposal to change its inspection system—attribution data that links specific foods under the agency's jurisdiction to food borne illness outbreaks. Congress has repeatedly asked the agency about this issue, and the agency has repeatedly responded that it is working on it.⁵

We have long suspected that the real reason the agency is pressing to implement risk-based inspection is that it would serve to mask shortages in inspection staffing that has plagued the agency for years. We have heard of chronic shortages in the number of processing inspectors. For example, just last year, we heard of one inspector in the Albany District of FSIS being assigned to 19 food plants that stretched from New York City to Connecticut; in the Philadelphia District, one inspector was assigned 26 plants to cover. These sorts of assignments fly in the face of testimony provided by the agency during last year's appropriations hearings in which it asserted that FSIS inspectors spend an average of 2 hours and 40 minutes per processing plant each day.⁶ Just this week, Under Secretary Raymond testified before the House Agriculture Appropriations subcommittee that at least 250 establishments have not been receiving daily—or even weekly—inspection for the last 30 years.

The Hazard Analysis Critical Control Points (HACCP) inspection system still has serious problems. The authority of inspectors to prevent adulterated products from entering the food supply has been severely hampered. Company HACCP plans do not require pre-approval from FSIS before they are implemented. Under HACCP, inspectors have been relegated to verifying whether company-written HACCP plans are being followed. Even when FSIS issues directives to companies to reassess their HACCP plans to take into account new food safety policies (e.g., the 2002 directive

² Morton, Joseph. "USDA Looks at 'Virtual' Inspections," *Omaha World Herald*, October 23, 2006.

³ See <http://www.usda.gov/oig/webdocs/24501-01-FM.pdf>.

⁴ See <http://www.usda.gov/oig/webdocs/24601-07-CH.pdf>, p. i.

⁵ Hearings before the House Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for fiscal year 2007, Food Safety and Inspection Service, Part 1, March 8, 2006, pp. 215–216.

⁶ *Ibid.*, p. 296.

requiring companies to deal with *E. coli* 0157:H7 as an adulterant likely to occur in beef processing), companies often take a long time to implement the new policy.

In its fiscal year 2008 budget submission, the agency states that it would like to begin implementing risk-based inspection in slaughter facilities. We assume that its proposal means expansion of the HACCP-Based Inspection Models Project (HIMP) in poultry slaughter. HIMP still has fewer than two-dozen plants participating in the program. The Government Accountability Office issued the last comprehensive analysis of this project in December 2001 and pointed out a number of serious problems.⁷ Inspectors assigned to these plants report that they are not able to perform food safety functions because they are assigned to stationary positions on the slaughter lines (e.g., they are not able to look inside the cavity of poultry carcasses where there may be contamination). Furthermore, defects that are considered to be “other consumer protection,” such as blemishes, scabs, tumors, feathers, and bruises, and would not pass muster in poultry slaughter plants using conventional inspection techniques are being permitted to enter commerce under the HIMP system. In a recent national public opinion survey conducted for Food & Water Watch by Lake Research Partners, nearly two-thirds of American consumers favor having Federal government inspectors evaluate meat and poultry products for wholesomeness as well as food safety issues.⁸ We do not believe that the Agency is prepared to extend this inspection model to the entire poultry industry at this time. There should be a thorough examination of HIMP project before it is expanded.

Because there has not been a full evaluation of HIMP recently, we filed a Freedom of Information Act request on December 14, 2005 requesting certain documents so that we could conduct our own study. FSIS initially responded that they wanted us to pay more than \$10,000 for the information. The agency has since relented on the fee, but we still have not received all of the information we requested. We believe that Congress should request full disclosure of this information so that it can make an informed judgment on the agency’s readiness to expand this program.

In January 2006, the USDA Inspector General released an audit report entitled, “Food Safety and Inspection Service Assessment of the Equivalence of the Canadian Inspection System” (Report No. 24601-05-Hy). The report indicates that Canada was continually exporting meat and poultry products to the United States that had been subject to less than daily inspection—in violation of U.S. standards. While those responsible for enforcing our equivalency agreements at FSIS recommended taking disciplinary action against Canada for their repeated violations, in 2004 the Secretary overruled them. We find this most troubling. FSIS has repeatedly testified before Congress that countries that wish to export their meat and poultry products to the United States must maintain inspection standards that are identical to those for domestic producers. Yet, in this instance, USDA has chosen to look the other way.

While Canada has agreed to institute daily inspection in those establishments that export to the United States, Canada is in the process of conducting a study to justify less-than-daily inspections for processed food exports to the United States that would serve as the basis for a request for an equivalency determination by FSIS. We believe that granting Canada equivalency for less-than-daily inspection would establish a dangerous precedent and mark a radical departure from current U.S. policy.

We have also learned that Australia is in the process of considering a “trial” of its controversial Meat Safety Enhancement Program (MSEP) for a beef processor that would like to export its products to the United States. MSEP is a privatized inspection system for beef for which there is no comparable system here in the United States. MSEP trials were last conducted in 1999, but were stopped since the inspection system raised consumer concerns both here in the United States and in Europe. We can only surmise that someone at USDA has signaled to Australia that we would accept beef products produced under a privatized inspection system.

We view both the Canadian pilot project and the Australian MSEP trial as vehicles by the current USDA policymakers to institute backdoor changes to our inspection system through our international trading partners. Last year, Congress was compelled to warn USDA on changing the programs authorized under the 2002 Farm Security and Rural Development Act through the Doha round of WTO negotiations. We suspect that USDA may be attempting to do the same with food safety policy.

For all of these reasons, we do not believe that the Agency is prepared to make radical changes to the current inspection system, no matter what terms they use to describe it. The concept of “continuous” government inspection has been the core

⁷ See <http://www.gao.gov/new.items/d0259.pdf>.

⁸ See <http://www.foodandwaterwatch.org/about/press/meat-inspection-poll>.

of our meat inspection system for 100 years, and the Agency should not be permitted to abandon this principle.

Expansion of processed poultry imports from the People's Republic of China (PRC)

In January 2007, we learned that FSIS was in the process of developing a proposed rule that would expand the import of processed poultry products from PRC to include poultry that was raised in the PRC.

We have several concerns about any imports of poultry products from the PRC:

—The April 24, 2006 regulation that permitted the import of poultry products from the PRC that were processed from slaughtered poultry of United States or Canadian origin was approved under suspicious circumstances and Congress should conduct an investigation into this matter. The fact that the Office of Management and Budget approved this regulation in record time—within 24 hours of its receipt of the rule from USDA—and the day before the arrival of PRC President Hu Jintao in Washington on April 20, 2006 clearly indicated that its approval was orchestrated.

—There is no track record to show that the April 24, 2006 regulation has been working. In a recent Global Agriculture Information Network (GAIN) report issued by USDA's Foreign Agriculture Service, the PRP has complained that the rule has been a non-starter because it is economically burdensome.⁹ We consider that to be a weak argument to justify the expansion of the current trade situation for several reasons. First, we have concerns about the sanitation practices in the slaughter and processing facilities in the PRC. The audit reports filed by FSIS inspectors describe unsanitary conditions in some of the facilities in the PRC that might be eligible to export product to the United States.¹⁰ Second, the PRC still has an avian flu problem.¹¹ Third, by USDA's own admission, much of the smuggled poultry that is intercepted coming to the United States originates from the PRC.¹² Why should we reward illegal activity by expanding trade?

USDA-Agricultural Marketing Service

Large seafood companies and trade associations have complained about the costs of implementing country of origin labeling for fish, while fishermen, environmental and consumer groups contend that the costs of compliance are fair and worthwhile. AMS recognized that most fishermen already keep sufficient records to document country of origin and wild-caught versus farm-raised claims, making a \$241 per year estimation "within reason."

All sellers, not only supermarkets, should be included in the program. Exempting processed seafood from the program does not accurately reflect the law, given that processed foods count for up to 50 percent of the finished product. The USDA should ensure that all seafood sold at all retailers is labeled with the proper country and means of origin.

Food and Drug Administration

We recommend increased funding for the Food and Drug Administration's seafood inspection program. Eighty percent of the seafood consumed by Americans now originates in foreign countries, yet according to a January 30, 2004 Government Accountability Office report entitled "FDA's Imported Seafood Safety Programs Shows Some Progress, but Further Improvements Are Needed," only 1.2 percent of imported seafood shipments are tested at ports of entry. Recent import inspection data from the FDA indicates that inspection rates are woefully low to ensure that consumers are protected from unsafe drugs and chemicals used in fish farming in other countries, as well as decomposed and filthy seafood—the number one inspection violation since 2003. We recommend that the FDA improve testing of seafood products, implement new regulatory programs, tighten its standards, provide incentives for producers to reduce drug and chemical use, and give consumers enough information to make informed decisions.

PREPARED STATEMENT OF FRIENDS OF AGRICULTURAL RESEARCH—BELTSVILLE

Mr. Chairman, and Members of the Subcommittee, thank you for this opportunity to present our statement regarding funding for the Department of Agriculture's Ag-

⁹ See <http://www.fas.usda.gov/gainfiles/200703/146280447.pdf>, p. 6.

¹⁰ See <http://www.fsis.usda.gov/OPPDE/FAR/China/China2005.pdf> and <http://www.fsis.usda.gov/OPPDE/FAR/China/China2004.pdf>

¹¹ See <http://www.cidrap.umn.edu/cidrap/content/influenza/avianflu/news/feb2807avian.html>

¹² See <http://www.usda.gov> and search for Release 0065.07.

gricultural Research Service (ARS), and especially for the Agency's flagship research facility, the Henry A. Wallace Beltsville Agricultural Research Center (BARC), in Maryland. Our organization—Friends of Agricultural Research—Beltsville—promotes the Center's current and long-term agricultural research, outreach, and educational missions.

Our testimony will emphasize two main themes: First, we begin by adding our strongest endorsement for high-value "new" research items proposed in the President's fiscal year 2008 budget. We provide additional support for each new research item in Part I.

Second, we recommend and urge continuing full support for on-going research that the Congress has previously mandated to be carried out at BARC. Support for these items is essential to sustaining irreplaceable research momentum now and fundamental to the success of American agriculture in the future. We will elaborate on the basis for our recommendations in Part II.

PART I. NEW RESEARCH ITEMS PROPOSED IN THE FISCAL YEAR 2008 BUDGET

Obesity Prevention Research, \$1,150,000.—Obesity is a growing health menace in the United States. Today, an estimated 64 percent of all Americans are overweight or obese. Obesity has been linked to heart disease, stroke and cancer, and thus to spiraling health problems and rapidly rising health care costs. These funds would provide critical support for BARC and its collaborators to pursue vital clinical and translational research on the efficacy of the Dietary Guidelines and to develop improved strategies for preventing unhealthy weight gain in the diverse American population. We urge support for this research.

Food Safety, \$708,000.—Maintaining consumer confidence in the safety of the U.S. food supply is a primary goal for producers and marketing managers. Recent isolated food safety incidents highlight the need for research to identify points in the food chain where food can become contaminated by chemical residues, pathogenic bacteria or toxins that are capable of causing severe illness, even death in worst case situations. These funds provide the resources to examine production systems and pre-harvest crop management practices thoroughly, especially for leafy vegetables and organic produce. We endorse full funding for this work.

Research to Support the Animal and Plant Health Inspection Service, APHIS, Citrus Canker and Ralstonia, \$850,000.—APHIS needs effective diagnostic tools to identify emerging citrus and tree fruits diseases, to confirm infections in epidemiological studies, and to carry out regulatory programs. This research also strengthens the National Citrus Pathogen Collection, which is essential for effective citrus disease research. Some of this research may be directed to Ralstonia, a bacterial pathogen not known to occur in the United States. Ralstonia causes wilt in potatoes, tomatoes, peppers, eggplant, and other crop plants. APHIS and ARS need to design survey protocols to detect and track plant disease agents and to identify crop pathogen threats. Research on diseases of citrus, tree fruits, and other crops is extremely under funded. We strongly urge support for strengthening plant disease research and for supporting the action mission of the Animal and Plant Health Inspection Service.

Emerging Diseases and Animal Health, \$1,165,000.—Globalization of trade and the growing movement of people and goods around the world steadily raise the threat of disease outbreaks in the United States. Diseases such as avian influenza, bovine diarrhea, transmissible spongiform encephalopathies, and porcine reproductive and respiratory disease are among many such disease threats. Effective control strategies require a more complete understanding of not only the basic biology of pathogens and their mode of transmission but also of the animal's immune system for resisting infections. BARC has one of the country's premiere groups of scientists engaged in livestock immunology research. This funding would strengthen their research effort to more fully unravel the complexity of the animal's immune system and protect the health of U.S. livestock. This research is vital to advancing our understanding of livestock immunology, and for protecting and improving animal health. We support full funding for these studies.

Emerging Diseases of Livestock, \$195,000.—This research is vital to further understanding genetics and genomics methods to improve disease resistance in livestock. We recommend full funding.

Emerging Diseases in Crops, \$500,000.—We confirm and support the proposal to develop diagnostics for rapid, practical, and specific identification of pathogens. This is an under funded research area, and we recommend full support.

Soybean and Wheat Stem Rust, \$300,000.—This goal here is to identify and incorporate diverse sources of genetic resistance into new grain and soybean varieties and germplasm. We fully support this research.

Plant Introduction Stations and the National Plant Germplasm System, \$500,000.—These funds are necessary for making germplasm and associated information more readily available to research programs and user stakeholders. These funds are needed to support the activities of the Germplasm Resources Information Network, or GRIN, which provides germplasm information about plants, animals, microbes and invertebrates. We recommend full funding.

Specialty Crops Genetic Resources, \$250,000.—These funds will provide floral and nursery plant research to support the research mission of the U.S. National Arboretum. Full funding is recommended.

Part II. Now we turn to the urgent need to continue support for specific research areas that the Congress has mandated at BARC in previous fiscal years. These mandates address research that has enormous national impact. We list them here with brief descriptions and our recommendations for continued funding.

Dairy Genetics.—For over 75 years, the Animal Improvement Programs Laboratory has created statistical genetic predictions to aid the dairy industry in identifying the best bulls for dairy breeding. Genetic improvement in dairy cattle has steadily increased milk yield per cow and feed efficiency (milk produced per pound of feed) over many years. The result is lower milk prices for consumers and less animal waste to contaminate the environment because fewer cows are needed to produce the Nation's milk supply. We confirm that this mission critical research should continue.

Barley Health Food Benefits.—Barley contains soluble fiber compounds, called beta-glucans, that are beneficial for health. Beta-glucans can lower cholesterol and improve control of insulin and blood sugar. These funds support human-volunteer studies designed to help us better understand how barley could be used in a healthful diet to reduce the incidence of chronic disease. We recommend continued support.

Biomineral Soil Amendments for Control of Nematodes.—Plant nematodes are microscopic worms that feed on the roots of plants. Nematodes can cause substantial losses in crop yields. This research focuses on using such industrial byproducts as environmentally benign soil additives for controlling nematodes. We recommend funding for these promising approaches.

Foundry Sand Byproducts Utilization.—Waste sands from the metal-casting industry currently are dumped in landfills. This project is working with industry on guidelines for beneficial uses of these sands. We recommend continuation.

Poultry Disease (Avian Coccidiosis).—Coccidiosis, a parasitic poultry disease, costs the industry \$2–3 billion per year. This research focuses on understanding the genetics of both the parasite and the host chicken to identify targets that will allow better disease control. We recommend this funding.

Biomedical materials in plants: Plants can be used as factories to manufacture vaccines and other pharmaceuticals for both animals and humans. This research focuses on development of tobacco as a crop with this beneficial use. This research should continue.

National Germplasm Resources Program.—Sources of germplasm for all agricultural crops are maintained either as seed or live plant material at several locations across the country. Much of this germplasm is the result of plant exploration around the world. This group maintains the computer database that indexes all crop germplasm in our repositories with critical information as to where it was obtained, the specific scientific identification, and information on useful traits for plant breeding. We strongly support continued funding for this mission-critical program.

Bovine Genetics.—This research focuses on bovine functional genomics, especially for dairy cattle. Scientists are identifying specific genes for quality traits such as easier calving, higher milk production, and resistance to mastitis. We recommend this funding.

Minor-use Pesticides (IR-4).—“Minor-use” pesticides are those that are used on crops such as fruits and vegetables that are not one of the “big four” crops like corn, wheat, and soybeans, and cotton. Because markets are much smaller than for major crops, chemical manufacturers have little incentive to obtain all the safety data needed to obtain EPA registration for pesticides used on minor crops. Nevertheless, producers of minor crops find certain agrochemicals to be essential. This project produces the data needed for EPA registration of minor-use pesticides. We recommend continued funding.

National Nutrition Monitoring System.—Scientists at BARC have the unique responsibility of carrying out the national surveys of food consumption by individuals. This is now done in collaboration with HHS's health surveys. BARC scientists also maintain the National Nutrient Database, which includes information on 126 nutrients in thousands of foods. This work supports the school lunch program, WIC, Food

Stamps, senior nutrition programs, food labeling, dietetic practices, and even the EPA. We urge continuation of this funding.

Coffee and Cocoa.—Producers of chocolate candy are the single largest users of fluid milk, sugar, peanuts, and almonds in the United States. U.S. specialty coffee shop chains also are one of the major markets for fluid milk. Events that limit the availability of cocoa or coffee can have significant impacts on major U.S. commodity markets. Candy producers need a stable supply of cocoa, but smallholders in developing countries produce most cocoa. Several devastating diseases and insects threaten cocoa. This research is aimed at developing environmentally friendly ways to control pests and diseases. Some insects that threaten coffee are very similar to those that attack cacao, thus work on the two crops benefits from being together. We recommend continuation of this funding.

John's Disease.—John's disease is a contagious bacterial disease of the intestinal tract of ruminants. It occurs most often in dairy cattle, causing weight loss and diarrhea. Nearly one-fourth of dairy herds are infected. Producers lose \$54 million annually from reduced milk production. The disease is spread in manure. This research focuses on disease control. We recommend continuation of this funding.

Food Safety—Listeria, E.Coli, and Salmonella.—Food-borne illness annually costs \$3 billion in health-care costs, and annually costs the economy up to \$40 billion in lost productivity. This research focuses on diagnostics for food-borne pathogens, and on ways to control pathogens in fruits and vegetables. We recommend continuation of this funding.

Weed Management Research.—All farmers must contend with weeds. For organic farmers, weeds are the single biggest challenge to crop production. This research, in collaboration with the Rodale Institute and Pennsylvania State University, focuses on developing systems for controlling weeds in organic production systems. Organic crop production was valued at \$400 million per year in the 2002 Census of Agriculture. These research funds will improve non-chemical weed control.

Mr. Chairman, that concludes our statement. We again thank you for the opportunity to present our testimony and for your generous support.

PREPARED STATEMENT OF THE HARDWOOD FEDERATION, NATIONAL ASSOCIATION OF STATE DEPARTMENTS OF AGRICULTURE, NATIONAL ASSOCIATION OF STATE FORESTERS, THE NATURE CONSERVANCY, AND SOCIETY OF AMERICAN FORESTERS

Dear Mr. Chairman and Ranking Member, the Hardwood Federation, National Association of State Departments of Agriculture, National Association of State Foresters, The Nature Conservancy, and Society of American Foresters urge the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies to increase funding substantially for the USDA Animal and Plant Health Inspection Service (APHIS) Emerging Plant Pests program. A sharp increase in funding is necessary in order to ensure adequate funding for eradication and control efforts targeting the emerald ash borer, Asian longhorned beetle, sudden oak death pathogen, and Sirex woodwasp. All four foreign and invasive species threaten trees in our forests and communities and related economic values worth hundreds of billions of dollars.

This coalition represents a widely diverse group of stakeholders that are unified in support of the following program areas. This statement of common goals supplements individual letters to the Subcommittee submitted by several of these organizations. Some of these individual letters address additional issues.

We seek an appropriation of \$45 million for fiscal year 2008 to contain the emerald ash borer. The emerald ash borer threatens twelve species of ash across the continent, especially in the upper Midwest and Southeast. At risk are the \$25 billion ash timber industry in the Northeast, street trees across the Nation valued at \$20 to \$60 billion, and myriad trees found in our neighborhoods and parks. The emerald ash borer outbreak is large, but the core of the infestation remains in the lower peninsula of Michigan and neighboring portions of Indiana and Ohio. It is absolutely crucial that APHIS and its partners carry forward detection surveys and regulatory and educational programs aimed at preventing movement of infested firewood, nursery stock, and other materials that spread the insect. APHIS and its State partners need additional funding in fiscal year 2008 to enable affected States to eradicate limited and isolated outbreaks found in Illinois, Maryland, Ohio, Indiana, and Michigan's Upper Peninsula. Education, effective quarantine, and elimination of isolated infestations are necessary to create the potential to contain the core outbreak in and around Michigan.

We seek an appropriation of \$30 million for fiscal year 2008 to carry forward eradication of the few remaining populations of the Asian longhorned beetle. The

Asian longhorned beetle poses an alarming threat to hardwood forests reaching from New England into Minnesota and in the West, and to the hardwood timber, maple syrup, and autumn foliage tourism industries dependent on these forests. Also at risk are street trees across the Nation valued at more than \$600 billion. Eradication has been successful in Chicago, proving the efficacy of this approach. Beetle populations in New Jersey are well on track for eradication. Only the populations in New York persist—and that is because funding for the New York effort has been reduced in past years to focus the inadequate overall resources on Illinois and New Jersey. It is essential to provide sufficient funding now and in coming years to complete eradication in New Jersey and New York. The identification of another population on an island near Staten Island just this past week is an indication of the risk placed on the environment due to chronic under-funding of these programs.

We support a request for \$10 million in appropriations for fiscal year 2008 to contain a third damaging forest pest, the sudden oak death pathogen (also called the phytophthora leaf and stem blight pathogen). This disease is a major threat to the nation's nursery industry as it readily attacks species such as rhododendron, camellias and a long list of other common ornamentals. In addition, if sudden oak death does escape confinement, it threatens oaks in forests in Oregon and Washington as well as throughout the Appalachians, Ozarks, and even into southern New England. Many wildlife species are dependent upon oaks for forage—the potential for devastating impacts on forests and wildlife is very real.

The Sirex woodwasp is now found across much of New York State and two counties in Pennsylvania, as well as in Ontario, Canada. The woodwasp threatens valuable pine timber resources, especially those of the Southeast. It is essential that APHIS receive \$3.6 million in fiscal year 2008 to implement a program including regulatory and educational programs aimed at preventing movement of infested wood, nursery stock, and other materials that spread the insect.

In addition to the appropriations needed to support these line items in APHIS's Emerging Plant Pest program, the Hardwood Federation, National Association of State Departments of Agriculture, National Association of State Foresters, The Nature Conservancy, and Society of American Foresters also strongly support the Congress' numerous statements urging the Administration to release emergency funds from the Commodity Credit Corporation (CCC) sufficient to enable full implementation of these management plans. The combination of the appropriations and the release of CCC funds is necessary to accomplish the needed tasks.

Action now at the funding level requested would help ensure that these forest pests do not reach populations so large as to threaten trees in our forests and communities, garden nursery stock, and related economic activities worth hundreds of billions of dollars.

PREPARED STATEMENT OF THE HEART RHYTHM SOCIETY

Dear Mr. Chairman, The Heart Rhythm Society (HRS) thanks the Subcommittee for considering our comments regarding the need for increased funding of the Food and Drug Administration (FDA), in particular the Center for Devices and Radiological Health (CDRH). The Heart Rhythm Society recommends that the FDA receive an additional \$20 million in appropriations for medical device oversight, as recommended by the Coalition for a Stronger FDA. These dollars would in part go to reform and update the current post-market surveillance system, which is currently ill-equipped to handle the complex challenges of responding to product safety issues and providing timely information to physicians, patients and the public.

The Heart Rhythm Society, founded in 1979, is the international leader in science, education and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders. Our mission is to improve the care of patients by promoting research, education and optimal health care policies and standards. We are the preeminent professional group, representing more than 4,400 specialists in cardiac pacing and electrophysiology. The Heart Rhythm Society serves as an advocate for millions of American citizens from all 50 States, since arrhythmias are the leading cause of heart-disease related deaths, with Sudden Cardiac Arrest (SCA) taking 325,000 lives annually. Other, less lethal forms of arrhythmias are even more prevalent and account for 14 percent of all hospitalizations of Medicare beneficiaries.

Background

Implantable Cardioverter Defibrillators (ICD's) are 99 percent effective in stopping life-threatening arrhythmias and are the most successful therapy to treat ventricular fibrillation, the major cause of Sudden Cardiac Arrest (SCA). However, less

than 2 years ago, there was a crisis in the patient and physician community regarding the ability of the current post-market surveillance system to react to information on implanted cardiac devices and to communicate the essential data to physicians and patients in a timely manner. In 2005, recalls and advisories issued by the three largest pacemaker defibrillator manufacturers and the untimely death of a patient with a device malfunction, led the Heart Rhythm Society to focus attention on the post-market system and the critical need for reform. It quickly became apparent to the Heart Rhythm Society, that leadership was necessary to convene members of our community, industry and patients to discuss the inherent issues with the current post-market surveillance system and work together to make recommendations for improvement. In September 2005, HRS convened a policy conference, co-sponsored with the FDA, of 300 experts in industry, the law, FDA, physician community, risk communication and patients to explore improvements for post market surveillance of pacemakers and ICDs. As a result of that meeting, the Society assembled a 15-member task force of leading cardiac care providers and experts charged with the development of recommendations to address concerns raised at the conference. In September, 2006, the Heart Rhythm Society published the Device Performance Recommendations to improve the post-market surveillance system for implanted devices. The guidelines have been officially endorsed by the American College of Cardiology Foundation, American Heart Association and the International Coalition of Pacing and Electrophysiology Organizations (COPE).

Current Limitations of Post Market Surveillance for Implanted Devices

As described in the Recommendations, changes to the current post-market surveillance system are required to improve the timely identification of cardiac rhythm management devices that do not perform according to design and that may pose a danger to patients. The current Manufacturer and User Device Experience (MAUDE) system assists with adverse event reporting and information dissemination for medical devices of all types. It contains hundreds of thousands of adverse event reports. Selected information is publicly searchable via the internet. However, because submitted adverse event reports are often cryptic or incomplete, it is often difficult to determine if a true device malfunction or patient injury has occurred. Poor organization and retrieval tools within MAUDE frustrate the users' ability to retrieve useful information. It is particularly difficult to distinguish multiple reports about the same adverse event from several sources (from the manufacturer, physician and patient) and recognize updated information. It has been noted by many that MAUDE has other inherent problems including the issue of under reporting, out of date information, and having inadequate resources to meet the current needs for medical device surveillance. Registries have been created by physician groups to begin to meet gaps in FDA efforts in medical device surveillance. The current MAUDE system also utilizes a one-size-fits-all form for all medical devices, making it difficult to collect meaningful information.

Needed Changes

The Heart Rhythm Society recommends that the FDA design and implement a more robust reporting system for observed device malfunctions that could overcome many of the MAUDE shortcomings and strengthen the voluntary reporting system by:

- Utilizing a specialized form for cardiac rhythm management devices to permit better and more precise reporting of adverse events.
- Facilitating the reporting of all unexpected device malfunctions through the adoption of remote monitoring technologies.
- Tracking devices that are returned to manufacturers for analysis and updating publicly available adverse event reports with root cause analyses. The system should allow individuals to track devices through the manufacturers' analysis online, analogous to tracking an overnight package.
- Including in the database the adjudication of root cause analysis once that has been determined.
- Facilitating links to data from international sources which may permit earlier detection of device malfunction.
- Employing an internet based reporting system with a user friendly format to encourage submission of reports by health care providers.
- Including standardized data elements and definitions for each device malfunction such as manufacturer model and serial numbers, dates of implant and failure, signs of failure and clinical consequences.
- Including a search engine available for public use.

Additionally, the FDA should establish standing post-market advisory committees that meet on a regular basis to analyze data regarding cardiac rhythm management

device performance and to advise when and what action should be taken to address device malfunctions that are identified. The Heart Rhythm Society supports a centralized, rather than the current regional, system for communication of device advisory notifications to promote a broader and more inclusive interpretation of the advisory issues. In addition, the unique and specialized nature of cardiac rhythm management device advisories requires a centralized, rather than regional, intake mechanism to enable accurate interpretation of data on an ongoing basis by key knowledgeable FDA staff and by the other parties such as a post-market physician advisory panel. The Heart Rhythm Society believes that a centralized system will facilitate timely FDA classifications and urges the FDA to classify all advisory notifications and include these data on the Physician Device Advisory Notification form within 30 days.

Budget Justification

To implement the above suggested changes, the FDA will need additional resources. The FDA's resources in recent years have diminished while Congress has mandated increases in FDA's oversight responsibilities. The number of regulated products, imports and adverse event reports has grown rapidly in the past 6 years and FDA is asked to do more with less. Furthermore, public confidence in the agency's effectiveness has taken an unfortunate hit. We urge Congress to recognize that post-market surveillance, analysis, and reporting of ICD and pacemaker performance is a high priority for ensuring patient safety. Additionally, we urge you to recognize and address the issue that the FDA does not currently have adequate resources to perform this function. The enhancements to the surveillance system that HRS recommends, particularly those to the Manufacturer and User Facility Device Experience (MAUDE) database, will require additional resources. By providing such resources, Congress will enable the FDA to achieve its mission, enhance the lives of the rapidly growing number of Americans with these devices and their families, and may decrease costs associated with delayed identification of device malfunction.

It is for this reason that we are asking for your support to increase the FDA's medical device budget by \$20 million for fiscal year 2008 budget. We believe that these additional funds will assist the FDA in addressing concerns that have been raised about the safety and effectiveness of pacemakers and ICDs and the post-market surveillance of these life saving devices. We believe patient and physician knowledge, confidence and trust can be enhanced and strengthened through greater transparency in post-market surveillance, analysis, reporting and communication of this information. Thank you very much for your consideration of our request.

If you have any questions or need additional information, please contact Nevena Minor, Coordinator, Health Policy at the Heart Rhythm Society (nminor@hrsonline.org or 202-464-3431) or Amy Melnick, Vice President, Health Policy (amelnick@hrsonline.org or 202-464-3434).

PREPARED STATEMENT OF THE IMPERIAL VALLEY CONSERVATION RESEARCH CENTER COMMITTEE

My name is John R. Kershaw, President of the Imperial Valley Conservation Research Center Committee (IVCRCC). This is a group of Imperial Valley agricultural producers who volunteer to provide support to the ARS Brawley Research Station in Imperial County, California. These farmers provide financial assistance and provide necessary equipment to augment the station's annual operating budget. We are a 501(c)(5) nonprofit organization. This is a unique industry-government partnership that has been successfully operating since 1951 when the station was founded.

The many achievements of this research facility rank it with the more successful ARS/USDA stations in the United States. For example, it is one of the lowest-cost field stations in the entire USDA network of agriculture research sites. This is true even though it is situated in one of the most challenging areas for farming and ranching due to the intense heat and dry conditions. Producers in our area farm land high in salinity content that is irrigated by water containing large amounts of salt.

The region where the Brawley station is situated has an incredible variety of vectors for insect and crop disease pests. The agriculture industry could not exist without strategic research programs dealing with soil, water, pest and disease problems that habitually confront producers. These programs, which are and have been addressed in Brawley, range from salt tolerance studies on food crops to new crop management studies using high salinity water, whitefly pest densities, virus transmission and ecological genetics of pest populations, biological control programs and

IPM programs using parasites and predators in conjunction with microbial pesticides.

With the help of crucial federal funding, the Brawley station is pioneering projects beneficial not only to agriculture, but, perhaps more importantly, to urban interests as well. It is participating with the New River Congressional Task Force addressing the quality of the New and Alamo Rivers. The focus of this study is to demonstrate the effectiveness of using constructed wetlands to improve water quality in the Imperial Valley and inflows to the Salton Sea, whose water elevation is maintained by agricultural drainage from the tributaries of the Alamo River, New River and Whitewater Rivers.

Expanding its traditional research in order to assist USDA in its desire to establish greater focus on forage research in the West, the Brawley Research Station has been conducting tests on a low-cost, high yield forage plant with multiple potential uses, including phytoremediation. This forage plant's characteristics allow it to be used to improve agricultural runoff and tailwater. The plant is called Elephant Grass, also known as Napier Grass (*Pennisetum* Sp) and has a trademark name of Promor A. It was discovered in Brazil and brought to the United States through the USDA Beltsville Quarantine Station in 1991. Experimental investigations in the San Joaquin Valley indicated that the plant, when irrigated exclusively with dairy lagoon water, exhibited significant phytoremediation with respect to high absorption of nitrates and phosphates. This unique variety is also regarded as a real candidate for biomass, including a specific capability for ethanol production.

A large group of pregnant beef cattle cows and their calves grazed the leaves of the grass to the ground in an experiment demonstrating its palatability and lack of toxicity. An additional large-field phytoremediation trial for irrigation was conducted at a raisin packing facility using processed wash water with significant nitrate levels. The grass used in this experiment was harvested after 60 days. Forage samples and weight measurements indicated a nitrate uptake of almost 55 pounds per acre per day. The harvested green chop forage was fed to dairy calves with no ill effects.

Additional research at the Brawley station, including a cooperative project with the University of California at Meloland, show the palatability and acceptability of this grass as use in finishing diets for feedlot cattle. Further research being conducted at the Brawley station utilizing elephant grass fed to lactating cows under the direction of the University of California were also very positive.

These experiments utilizing *Pennisetum* SP elephant grass have drawn the interest and financial support of the California State Quality Control Board. This Board regards the grass as a serious candidate for a barrier crop designation to improve water quality. Ongoing research with the City of Fresno on its waste water support the finding that this grass may have major benefits for city water supplies. Urban use of the grass may result as additional cities work to clean up their water.

All of the above projects fall directly under the mandate for research designated by the National Program 201 Water Quality administered by ARS. This research is part of ARS current policy and future focus. To terminate the project prematurely due to lack of funding would severely limit the conclusions and potential benefits.

This research facility is continuing the ongoing research on its popular Rhyzomania resistant sugar beet seeds. This research is conducted under the supervision and direction of ARS scientist Dr. Llewellyn from Salinas. The resultant sugar beet seed has doubled sugar beet production yields. This research is benefiting sugar beet producers nationwide.

The research station additionally serves as a work site and regional office for APHIS/USDA and the California Department of Food & Agriculture.

The research facilities are also utilized by several local agricultural entities including cotton committees and the California Farm Bureau. We continue as a support laboratory for the unique Salinity Assessment Vehicle and also serve as a weather station reporting location.

In addition to the station's diversified agricultural research agenda, it is strategically located to provide quick response support to biosecurity and agroterrorism detection work. It is situated less than 90 miles from six Mexican border crossings; one of which is only 16 miles from Brawley, and is the busiest crossing anywhere. The constant supply of international traffic puts Imperial Valley on the front line of protection of the American food supply from the introduction of disease, insects and many invasive species. The station currently headquarters research facilities and personnel from USDA and the California Department of Food & Agriculture which can quickly implement control and eradication programs in coordination with local authorities, thereby making use of the best capabilities of local, State and Federal agencies.

As for its research agenda, the station performs many trials associated with the arid saline conditions of the region. Specific experiments may be conducted on, but not limited to, water management, irrigation techniques, soil salinity, crop production, plant breeding, agricultural systems, control of aquatic weeds and integrated pest management.

Our salinity trials are conducted in conjunction with the U.S. Salinity Lab based in Riverside, California. The salinity work done at the Brawley station could not effectively be performed at Riverside because smog there negates scientific validity of the findings. The Brawley Research Station is geared to be a contributor, if asked, to the National Salt Cedar Demonstration Project. The station has been monitoring native species that could be used in the revegetation of Salt Cedar that will be removed or mitigated.

There is a date palm repository at the Imperial Valley Research Center. This is the largest repository of date palms in the world. It contains every known variety of date palm. This repository is used for research. Additionally, this repository is used to provide varieties of date palms to various countries where the United States is encouraging farmers to grow dates.

The Imperial Valley Conservation Research Center Committee specifically requests that \$334,514 be appropriated to fund the Water Management Research Laboratory in Brawley, CA.

The funds for this ARS/USDA research facility were deleted from the President's proposed budget. As you know, the President's budget deleted over \$200 million for ARS research facilities nationwide. Loss of these research facilities would be a blow to U.S. agriculture nationwide. Specifically it would be a blow to California agriculture and especially to agriculture in the Imperial Valley.

The ARS research station in Brawley is in very good condition and has been well managed. The research provided by this facility far exceeds the value of the funds requested. The farmers in the Imperial Valley continue to support this facility with matching funds amounting to approximately \$100,000.

We urge you, Mr. Chairman, to support the continued funding for this important ARS research station in the fiscal year 2008 agricultural appropriations bill.

PREPARED STATEMENT OF THE MULTI-CROP AFLATOXIN WORKING GROUP

As members of the Multi-Crop Aflatoxin Working Group, the undersigned associations appreciate the opportunity to share with you our agricultural research priorities for fiscal year 2008.

As you know, corn, cotton, peanuts and tree nuts are all affected by aflatoxin, a toxin caused by the *Aspergillus flavus* fungus. Aflatoxin is the costliest, most pressing mycotoxin problem affecting each of these crops. Widespread drought conditions in 2005 resulted in aflatoxin contamination levels in excess of earlier levels, and more troubling in areas of the country that are not usually prone to the problem.

Aflatoxin also dramatically decreases U.S. global competitiveness and farm income. Most of our export customers have more stringent aflatoxin tolerances than the U.S., resulting in closed markets. Likewise, an aflatoxin level in excess of FDA guidelines significantly limits the marketability of the product.

Despite the dire consequences aflatoxin has on agricultural marketing and human safety, Federal research budgets in this area have been declining for the past decade. Given recent events and the spread of the disease, the Multi-Crop Aflatoxin Working Group recommends \$1.25 million for aflatoxin research through the Pre-Harvest Control of Aflatoxin research program. Specifically, this is an increase of \$500,000 over fiscal year 2007 funding levels. These funds will be administered by the Agricultural Research Service (ARS) and dispersed on a competitive basis for aflatoxin research. These grants are awarded on both crop specific and aflatoxin-wide research. Some examples of current research are conventional crop breeding, use of atoxigenic strains, host and fungal genomics, genetic blocks of toxin production and transgenic resistances. Although each of these projects have different approaches, they all share one common goal, the elimination of aflatoxin from the world's food supply. Following this statement, we have provided the Committee with an example of previous work funded by ARS.

Thank you for the support and assistance you have provided to agricultural research over the years. Please contact Lisa Kelley with the National Corn Growers Association at 202-628-7001 or Howard Valentine with the Peanut Foundation at 706-579-1755 if you need any additional information.

APPENDIX

Previous Work Funded By ARS:

In Dr. Felicia Wu's previous work funded by ARS, "Total Economic Impact of Aflatoxin: Models of Economic Loss and Industry Learning," she developed the conceptual basis for the aflatoxin economic model shown in Figure 1 of the Research Approach. She implemented the following equations under "Noncompliance Adjustment Costs" and "Livestock Health Effects" for corn, by considering two classes of impact: market losses and animal health losses.

High quality corn can be sold as human-food-grade corn at the highest market price. Corn contaminated with aflatoxin levels between the highest-permitted levels of food and feed can be sold for animal feed at a lower price, and corn with high levels of aflatoxin is either sold for non-food-non-feed uses at an even lower price or rejected outright. The proportions of the total crop that are rejected at each of these levels depend on the national or international standards for mycotoxins in food and feed. Thus:

$$Loss_{Market} = M_{crop} * [dP_{food} Q_{food} R_{food} + dP_{feed} Q_{feed} R_{feed}],$$

where

M_{crop} = proportion of total corn production sold

dP_{food} = price difference between food-grade and feed-grade corn

dP_{feed} = price difference between feed grade and lowest-grade corn

Q_{food}, Q_{feed} = quantities intended for food and feed, respectively

R_{food}, R_{feed} = proportions of corn found to be above aflatoxin guidelines for feed and feed

Animal health as a function of aflatoxin contamination is dependent on three factors: the number of animals experiencing mortality or morbidity as a result of aflatoxin consumption, the cost of treatment for sick animals, and the market value of each animal.

$$Loss_{Animal} = \sum_a [(A_{mort,a} * [V_{animal,a} + Treat_a] + A_{morb,a} Treat_a],$$

where

A_{morts}, A_{morb} = number of animals experiencing mortality or morbidity

V_{animal} = market value per animal

$Treat_a$ = medical treatment cost per animal

The subscript a indicates the affected species of animals $a = \{\text{cattle, swine, poultry}\}$

Data for each of these parameters were gathered from the USDA National Agricultural Statistical Service (NASS) and relevant literature on aflatoxin's animal effects (Lubulwa and Davis 1994, Keyl 1978, Wyatt 1991). Annual aflatoxin-related market losses in U.S. corn were estimated to be \$163 million (\$73–332 million; 95 percent CI): \$31 million in food-grade rejections and \$132 million in feed-grade rejections. Annual livestock losses were estimated at \$4 million (\$1–9 million). Sampling and testing costs vary by year, with an average \$25 million cost annually to growers (\$10–250 million; the large confidence interval reflects the high variability in this area). In addition, the following currently "intangible" costs were considered: losses related to ethanol production (and the resulting concentration of aflatoxin in the distillation byproducts), grower disposal of highly contaminated corn, sampling errors, and losses on a geographical basis. The total annual loss to U.S. corn of measurable aflatoxin-related losses was roughly \$200 million (\$192 million, with uncertainty bounds); however, the intangible costs could increase this loss significantly.

Dr. Wu's first year of work with ARS provided her an excellent opportunity to meet key representatives from the major commodities that are affected by aflatoxin contamination. She is grateful to the following commodity experts, who, among others, provided her with useful information regarding aflatoxin's specific impacts on each commodity: Larry Antilla, Scott Averhoff, Peter Cotty, David Gibson, Mike Hurley, Merle Jacobs, Dave Kendra, Bob Klein, Marshall Lamb, Dewey Lee, Howard Valentine, and Phillip Wakelyn. The insights and data she has gained through these collaborations will provide a basis for her economic research in this proposal.

PREPARED STATEMENT OF THE NATIONAL COALITION FOR FOOD AND AGRICULTURAL RESEARCH

Dear Mr. Chairman, Ranking Member Bennett and Members of the Subcommittee: On behalf of the National Coalition for Food and Agricultural Research¹

¹As part of its mission, National C-FAR seeks to increase awareness about the value of food and agricultural research, extension and education. For example, National C-FAR is hosting an educational series of "Lunch-N-Learn" seminars on the hill, featuring leading-edge researchers on timely topics to help demonstrate the value of public investment in food and agricultural research, extension and education. More information about National C-FAR and its programs is available at <http://www.ncfar.org>.

(National C-FAR), we are pleased to submit comments in strong support of enhanced public investment in food and agricultural research, extension and education as a critical component of Federal appropriations for fiscal year 2008 and beyond. National C-FAR serves as a forum and a unified voice in support of sustaining and increasing public investment at the national level in food and agricultural research, extension and education. National C-FAR is a nonprofit, nonpartisan, consensus-based and customer-led coalition established in 2001 that brings food, agriculture, nutrition, conservation and natural resource organizations together with the food and agriculture research and extension community.

SUPPORT FOR FISCAL YEAR 2008 FUNDING FOR FOOD & AGRICULTURAL RESEARCH,
EXTENSION & EDUCATION

CSREES.—National C-FAR urges the Subcommittee and Committee to support the Administration's fiscal year 2008 request for USDA's Cooperative State Research, Education, and Extension Service (CSREES) of \$1.036 billion, augmented at a minimum by restoring the funding equivalent of "earmark" funding incorporated into the fiscal year 2007 CR—and other increases to the extent practicable. The Administration's proposal represents a 10 percent decrease as compared with fiscal year 2007 funding levels, and National C-FAR believes a significant increase is fully warranted.

The Administration's fiscal year 2008 request does not include about \$190 million in funding that Congress in the past has invested in so-called "earmarks" in the CSREES account. In the fiscal year 2007 CR Congress opted to eliminate the earmarks but included the funding equivalent in the CSREES account. National C-FAR strongly urges the Subcommittee and Committee to restore this funding to the fiscal year 2008 budget for CSREES, whether designated for specific projects or for distribution by CSREES.

National C-FAR supports funding the National Research Initiative (NRI) at the authorized level of \$500 million. The Administration's \$256.5 million fiscal year 2008 request represents a significant increase over the fiscal year 2007 Congressional funding level of \$190 million. However, a portion of the proposed increase (\$42 million) results from a shift of CSREES Integrated Activities, such as food safety, pest management, and water quality, providing a net increase of \$25 million for NRI.

The NRI supports research on key problems of national and regional importance in biological, environmental, physical, and social sciences relevant to agriculture, food, and the environment on a peer-reviewed, competitive basis. Additionally, the NRI enables USDA to leverage a portion of its funds for food and agricultural research, extension and education by fostering the development of new partnerships with other federal agencies that advance agricultural science. Examples of successful collaborations include USDA's involvement in the Microbial Genome Sequencing Program, the Maize Genome Program, the Microbial Observatories program, the Plant Feedstock Genomics for Bioenergy program, the Metabolic Engineering program, and the Climate Change Science Plan.

ARS.—National C-FAR urges the Subcommittee and Committee to support the Administration's fiscal year 2008 request for USDA's Agricultural Research Service (ARS) of \$1.056 billion, augmented at a minimum by restoring the funding equivalent of "earmark" funding incorporated into the fiscal year 2007 CR—and other increases to the extent practicable. National C-FAR is concerned that ARS funding has been cut each of the past several years and urges the Subcommittee and Committee to sustain and enhance ARS funding. Research conducted by ARS helps to ensure high-quality, safe food, and other agricultural products, assess the nutritional needs of Americans, sustain a competitive agricultural economy and enhance the natural resource base and the environment. The steady erosion in ARS funding could jeopardize the ability of the agency to carry out its important mission.

According to the Administration, its fiscal year 2008 request of \$1.129 billion for ARS does not include about \$280 million in so-called "earmark" funding [divided about equally between research projects and facilities] that Congress in the past has invested in. In the fiscal year 2007 CR Congress opted to eliminate the earmarks but included the funding equivalent in the ARS account. National C-FAR strongly urges the Subcommittee and Committee to restore this funding to the fiscal year 2008 budget for ARS, whether designated for specific projects or for distribution by ARS.

ERS.—National C-FAR urges the Subcommittee and Committee to support the Administration's fiscal year 2008 request of \$83 million for the USDA, Economic Research Service (ERS), which represents a modest increase over the fiscal year 2006 and fiscal year 2007 appropriated levels and provides additional funding to

strengthen the market analysis and outlook capabilities and bioenergy economic analysis. Many of the research outcomes generated through ERS efforts provide value in both policy and business application terms far in excess of what the modest size of the ERS budget might suggest.

FS.—National C-FAR urges the Committee to support the Administration's fiscal year 2008 funding request of \$263 million for forest and rangeland research. National C-FAR is concerned that this represents a decrease in funding compared with fiscal year 2007. While the Administration may be justified in dropping lower priority projects, stagnant and declining funding is inappropriate in light of major challenges in forest, range and ecosystem management and utilization.

National C-FAR urges that funding for food and agricultural research, extension and education be augmented to the maximum extent practicable, as an important next step toward building the funding levels needed to meet identified food and agricultural research, extension and education needs.

A Sense of the Congress resolution endorsed by National C-FAR to double funding in food and agricultural research, extension and education within five years was incorporated into the 2002 Farm Bill that was enacted into law. However, the major commitment to expanded research has not yet materialized. At the five-year mark, the larger reality is the threat of funding cuts. National C-FAR is urging the Congress to reaffirm a commitment to doubling funding in food and agricultural research, extension and education in the 2007 farm bill.

As a coalition representing stakeholders in both the research, extension and education community and the "customers" who need and depend upon their outcomes, National C-FAR urges expanded public participation in the Administration's research priority setting and funding decision process and stands ready to work with the Administration and other interested stakeholders toward that end.

ENHANCED INVESTMENT IN RESEARCH, EXTENSION & EDUCATION ESSENTIAL TO SUCCESS

The research, extension & education title of the Farm Bill represents the nation's signature Federal investment in the future of the food and agricultural sector. Other Farm Bill titles depend heavily upon the Research Title for tools to help achieve their stated objectives. Public investment in food and agricultural research, extension and education today and in the future must simultaneously satisfy needs for food quality and quantity, resource preservation, producer profitability and social acceptability.

Tools provided through research, extension & education are needed to help achieve safer, more nutritious, convenient and affordable foods delivered to sustain a well nourished, healthy population; more efficient and environmentally friendly food, fiber and forest production; improved water quality, land conservation, wildlife and other environmental conditions; less dependence on non-renewable sources of energy; expanded global markets and improved balance of trade; and more jobs and sustainable rural economic development. Societal demands and expectations placed upon the food and agricultural system are ever-changing and growing. Examples of current and future needs include—strengthened bio-security; food-linked health costs; environment and conservation; farm income and rural revitalization; biofuels and climate change; the world demand for food and natural fiber and improved diets; and biotechnology and genetic resources research and public oversight.

DEMONSTRATED VALUE OF PUBLIC INVESTMENTS IN RESEARCH

Publicly financed research, extension and education are necessary complements to private sector research, focusing in areas where the private sector does not have an incentive to invest, when (1) the pay-off is over a long term; (2) the potential market is more speculative; (3) the effort is during the pre-technology stage; and (4) where the benefits are widely diffused. Public research, extension and education help provide oversight and measure long-term progress. Public research, extension and education also act as a means to detect and resolve problems in an early stage, thus saving American taxpayer dollars in remedial and corrective actions.

Public investment in research is a wise investment. An analysis by the International Food Policy Research Institute of 292 studies of the impacts of ag research and extension published since 1953 (Julian M. Austin, et al, A Meta-Analysis of Rates of Return to Agricultural Research, 2000) showed an average 81 Percent annual rate of return on public investments in ag research & extension!

Food and agricultural research, extension and education to date have helped provide the United States with a food and agricultural system that consistently produces high quality, affordable food, natural fiber and other products, while at the same time:

- Creating Jobs and Income.*—The food and agricultural sector and related industries provide over 20 million jobs, about 17 percent of U.S. jobs, and account for nearly \$1 trillion or 13 percent of GDP.
- Helping Reduce the Trade Deficit.*—Agricultural exports average more than \$50 billion annually compared to \$38 billion of imports, contributing some \$12 billion to reducing the \$350 billion trade deficit in the nonagricultural sector.
- Sustaining Important Strategic Resources.*—This Nation's abundant food supply bolsters national security and eases world tension and turmoil. Science-based improvements in agriculture have saved over a billion people from starvation and countless millions more from the ravages of disease and malnutrition.
- Providing Many Valuable Aesthetic and Environmental Amenities to the Public.*—The proximity to open space enhances the value of nearby residential property. Farmland is a natural wastewater treatment system. Unpaved land allows the recharge of the ground water that urban residents need. Farms are stopovers for migratory birds. Farmers are stewards for 65 percent of non-Federal lands and provide habitat for 75 percent of wildlife.

FUNDING INSUFFICIENT TO ADDRESS PRIORITY NEEDS

By any measure, Federal funding for food and agricultural research, extension and education has failed to keep pace with identified priority needs. Public and private investments in U.S. agricultural research and practical application of results have paid huge dividends to the United States and the world, especially in the latter part of the 20th century. However, these dividends are the result of past investments in agricultural research. The unparalleled success story in the food and agricultural system is a product in large part of past investments in food and agricultural research and extension.

However, Federal funding for food and agricultural research, extension and education has been essentially flat for over 20 years, while support for other Federal research has increased substantially. Public funding of agricultural research in the rest of the world during the same time period has outpaced investment in the United States.

Stagnant public investment in food and agricultural research, extension and education may well be a result of a view that the U.S. food and agricultural system is doing fine and that funds can be redirected to other needs. The U.S. food and agricultural sector has been a world leader and has provided unprecedented value to U.S. citizens, and indeed the world community. However, societal demands and expectations placed upon the food and agricultural system are ever-changing and growing.

National C-FAR believes it is imperative to lay the groundwork now to respond to the many challenges and promising opportunities ahead through Federal policies and programs needed to promote the long-term health and vitality of food and agriculture for the benefit of both consumers and producers. Stronger public investment in food and agricultural research, extension and education is essential in producing research outcomes needed to help deliver beneficial and timely solutions. Multiple examples, such as those highlighted below, serve to illustrate current and future needs that arguably merit enhanced public investment in research, extension and education so that the food and agricultural system can respond to these challenges on a sustainable basis:

- Strengthened bio-security is a pressing national priority. There is a compelling need for improved bio-security and bio-safety tools and policies to protect against bio-terrorism and dreaded problems such as foot-and-mouth and “mad cow” diseases and other exotic plant and animal pests, and protection of range lands from invasive species.
- Food-linked health costs are high. Some \$100 billion of annual U.S. health costs are linked to poor diets, obesity, food borne pathogens and allergens. Opportunities exist to create healthier diets through fortification and enrichment.
- Research, extension and education are key to providing to solutions to environmental and conservation challenges related to global warming, limited water resources, enhanced wildlife habitat, and competing demands for land and other agricultural resources. Rural water conservation and development of drought-resistant crops have evolved from a good idea to a necessity.
- It is a highly competitive world for food and agriculture and rural America. There was considerable debate during the last Farm Bill reauthorization about how expanded food and agricultural research, extension and education could enhance farm income and rural revitalization by improving competitiveness and value-added opportunities.

- Energy costs are escalating, dependence on petroleum imports is growing and concerns about greenhouse gases are rising. Research, extension and education can enhance agriculture's ability to provide renewable sources of energy and cleaner burning fuels, sequester carbon, and provide other environmental benefits to help address these challenges, and indeed generate value-added income for producers and stimulate rural economic development.
- Population and income growth are expanding the world demand for food and natural fiber and improved diets. World food demand is projected to double in 25 years. Most of this growth will occur in the developing nations where yields are low, land is scarce, and diets are inadequate. Without a vigorous response, demand will only be met at a great global ecological cost.
- Regardless of one's views about biotechnology and genetic resources, an effective publicly funded research role is needed for oversight and to ensure public benefits.

If these challenges and opportunities are to be met, then the nation must commit to a stronger investment that reflects the long-term benefits of food and agricultural research, extension and education.

CONCLUSION

National C–FAR respectfully submits that—

- The food and agricultural sector merits Federal attention and support;
- Food and agricultural research, extension and education have paid huge dividends in the past, not only to farmers, but to the entire nation and the world;
- There is an appropriate and recognized role for Federal support of research, extension and education;
- Recent funding levels for food and agricultural research, extension and education have been inadequate to meet pressing needs;
- Federal investments in food and agricultural research, extension and education should be enhanced in fiscal year 2008 and beyond; and
- Actions should be taken to provide for expanded public participation, including during review of programs being considered for possible reforms or cuts.

National C–FAR appreciates the opportunity to share its views and stands ready to work with the Chair and members of this Committee in support of these important funding objectives.

PREPARED STATEMENT OF THE NATIONAL CORN GROWERS ASSOCIATION

The National Corn Growers Association (NCGA) appreciates the opportunity to share with you our agriculture appropriations priorities for fiscal year 2008. NCGA represents more than 32,000 members in 48 States, 47 affiliated State organizations and more than 300,000 corn farmers who contribute to State checkoff programs for the purpose of creating new opportunities and markets for corn growers.

America's corn producers continue to make a significant and important contribution to our nation's economy. Over the last 5 years, the Nation's corn crop has averaged 10.3 billion bushels resulting in an annual average farm gate value of almost \$22 billion. The relatively stable production over the past 10 years, made possible by innovation in production practices and technological advances, has helped to ensure ample supplies of corn for livestock, an expanding ethanol industry, new biobased products and a host of other uses in the corn industry.

Aflatoxin Research

Aflatoxin is a significant problem for corn growers. While the disease is most common in the South, northern corn growers also experience aflatoxin, especially in times of drought. Aflatoxin costs corn growers millions of dollars in lost sales every year.

Currently, the Agriculture Research Service (ARS) receives about \$7 million per year for its entire aflatoxin research program. Of that, ARS awards about \$750,000 in competitive grants each year for pre-harvest aflatoxin research on corn, cotton, peanuts and tree nuts. These figures have been relatively flat for 10 years. NCGA requests an additional \$500,000 for ARS's aflatoxin cooperative agreement program, totaling \$1.25 million. We believe the funds should be used to address cross-cutting issues of concern to all affected crops and the development of nondestructive testing protocols and technologies.

Genomic Research

The entire corn industry, including the academic research community, grain handlers, growers, industry and seed companies strongly believe that research on plant

and plant genomes has substantial long-term benefits. NCGA supports the plant genome research conducted by ARS through its genetic resources, genome sequencing and genome bioinformatics programs. Specifically, this research includes plant and fungal genomics exploration to determine what drives aflatoxin production, what causes susceptibility, and helps us understand plant and fungal nutrient and environmental needs.

NCGA also supports the Cooperative State Research, Education and Extension Service's National Research Initiative. Our research policy supports competitive grants where appropriate.

APHIS Biotechnology Regulatory Service

NCGA supports the President's budget request of \$14.141 million for the Animal and Plant Health Inspection Service's Biotechnology Regulatory Service as well as the separate funding stream requested in the budget from the Office of the Secretary for the same. These resources are necessary to ensure the agency properly manages its functions associated with this expanding technology to maintain consumer and customer confidence in our strong science-based regulatory structure.

FAS SPS Issues Resolution

NCGA supports the President's budget request of \$27.153 million that increases funding by \$6,196,000 within the Foreign Agricultural Service (FAS) for Sanitary and Phytosanitary (SPS) resolution. Unnecessarily restrictive regulations to address plant health risks are major impediments to U.S. market expansion. As trade barriers have been reduced, there has been a dramatic increase in non-tariff trade barriers to trade.

FAS Market Access

NCGA supports the President's budget request of \$200 million for the Market Access Program (MAP) within the Foreign Agricultural Service. This program has been successful in maintaining and expanding U.S. agricultural exports and strengthening farm income. The 2002 farm bill authorizes up to \$200 million in mandatory spending for MAP; NCGA urges that the program be funded at the fully authorized level.

National Corn to Ethanol Research Center

In 2006, fuel ethanol production from corn generated 4.8 billion gallons of ethanol, displacing 3 percent of petroleum imports. Economic forecasting estimates that the United States is capable of producing in excess of 14 billion gallons of ethanol by 2015. Such production is critical to our national economy, energy security and the environment. The National Corn-to-Ethanol Research Center (NCERC) at Southern Illinois University—Edwardsville is in a perfect position to: continue generation of baseline data, serve as training center for Workforce Development and expand as a Lignocellulosic Center of Excellence. To fulfill these objectives, NCGA is seeking additional funding on behalf of NCERC.

Updated baseline data is continuously required to be reflective of industry changes and their impact on product yields and efficiencies. The goal of this objective is to continue generating baseline data under typical industry operating conditions reflective of changing industry practices and changes in inputs (e.g. fractionization, corn hybrids, enzymes, yeast practices). The baseline data generated by the NCERC is of significant interest to academic, government, industry and trade association ethanol researchers as well as ethanol plant operators. The baseline data generated by NCERC is providing a critical benchmark for all industry and institutional comparison testing. We encourage the committee to provide \$400,000 to NCERC for this purpose.

A key component to the success of the ethanol industry over the next decade is to ensure the industry has a ready and available workforce. NCERC is well-positioned to train an immediately productive workforce as it plays a unique role in serving both the educational mission of the university as well as meeting the growing needs of the biofuels industry. NCERC provides a year-long, hands-on workforce training program to student interns while conducting commercial testing trials. Since opening in late 2003, nearly 35 interns have helped with the successful operation of the plant and labs. NCGA requests an additional \$1,000,000 to expand the current internship program to meet the growing needs of the industry. Through this endeavor, NCERC will develop and implement a National Biofuels Workforce Training Center.

For cellulose to be a viable feedstock, the process of converting cellulose to ethanol must be optimized. The three "process points" of optimization in the cellulose to ethanol process are: pre-treatment method, enzyme functionality and fermentation organisms (yeast). The NCERC is a research leader in the conversion of corn to eth-

anol and its co-product. Therefore, the NCERC is able to more cost-effectively stay on the cutting edge of technology as we enter a new era of converting cellulose to ethanol.

The NCERC is well-positioned to work directly with USDA/ARS, the Department of Energy, and Academic and Industry researchers who are conducting scientific discovery research on the conversion of cellulose to ethanol. This work will spur unlimited investment by private industry as they will make that crucially important decision to enter the cellulose to ethanol market. We encourage the committee to consider NCERC as Lignocellulosic Center of Excellence.

Ethanol Coproduct Utilization

One of the major benefits of using corn as a feedstock for ethanol production is the ability to retain the protein, fat, fiber, vitamins and minerals for use as an animal feed. The co-product of ethanol production, distillers dried grain with solubles (DDGS), results from the concentration and drying of the components remaining after the starch portion of corn is converted to ethanol. Strong global demand for DDGS will be critical in maximizing the potential and profitability of fuel ethanol production from corn while ensuring livestock feed needs are met.

While nearly 12 million tons of DDGS was fed domestically or exported in 2006, use of this alternative feed ingredient may be limited in the future because of real and perceived issues relating to DDGS consistency, quality, flowability and feed efficiency. NCGA encourages the committee to dedicate the resources necessary to greatly expand ARS's efforts in this area, particularly as they relate to DDGS flowability, contaminant mitigation, nutritional value, and nutrient and mineral management issues.

Value-Added Grants

Grants from USDA's Value-Added Product Market Development Grant program have been used by corn growers to leverage significant investments in rural communities. NCGA supports this grant program as authorized by the 2002 farm bill at \$40 million per year. Potential technologies include processing identity-preserved corn varieties and adding value to the non-fermentable components of the corn feedstock.

Thank you for the support and assistance you have provided to corn growers over the years. Please feel free to contact Lisa Kelley at 202-628-7001 if you need any additional information.

PREPARED STATEMENT OF THE NATIONAL COMMODITY SUPPLEMENTAL FOOD PROGRAM ASSOCIATION

The Honorable Herb Kohl, Mr. Chairman and Subcommittee members, I am Frank Kubik, President of the National Commodity Supplemental Food Program Association (NCSFPA). Thank you for this opportunity to present information regarding the Commodity Supplemental Food Program (CSFP).

CSFP was our Nation's first food assistance effort with monthly food packages designed to provide protein, calcium, iron, and vitamins A and C. It began in 1969 for low-income mothers and children, preceding the Special Supplemental Nutrition Program for Women, Infants, and Children known as WIC. Pilot programs in 1983 added low-income seniors to the list of eligible participants and they now comprise 91 percent all participants.

CSFP is a unique Federal/State and public/private effort. The USDA purchases specific nutrient-rich foods at wholesale prices for distribution. State agencies such as the departments of health, agriculture or education provide administration and oversight. These agency's contracts with community and faith based organizations to warehouse and distribute food, certify eligibility and educate participants. The local organizations build broad collaboration among non-profits, health units, and area agencies on aging so that seniors and others can quickly qualify to and receive their monthly supplemental food package along with nutrition education to improve their health and quality of life. This unique public/private partnership reaches even homebound seniors in both rural and urban settings with vital nutrition.

The foods provided through CSFP include canned fruits and vegetables, juices, meats, fish, peanut butter, cereals and grain products, cheese, and other dairy products increase healthy food consumption among these low-income populations.

The CSFP is also an important "market" for commodities supported under various farm programs, as well as an increasingly important instrument in meeting the nutritional and dietary needs of special low-income populations.

In fiscal year 2006, the CSFP provided services through 150 non-profit community and faith-based organizations at over 1,800 sites located in 32 States, the District

of Columbia, and two Indian reservations (Red Lake, Minnesota and Oglala Sioux, South Dakota). On behalf of those organizations NCSFPA would like to express our concern and disappointment regarding the reduction of available CSFP resources for fiscal year 2008.

—The prospect of seniors not receiving needed CSFP food in a year when USDA has forecast in excess of \$35.4 million in carryover inventory at the end of the fiscal year 2006 is disturbing. Clearly these inventories could and should be used to serve the areas that were affected by the hurricanes of 2005 and who were given 6 month CSFP supplemental caseload that has since been exhausted.

—At a time when many Americans must choose between food or medicine, utilities, and other basic expenses, the Federal Government should not be reducing benefits for our most vulnerable citizens.

CSFP's 38 years of service stands as testimony to the power of partnerships among community and faith-based organizations, farmers, private industry and government agencies. The CSFP offers a unique combination of advantages unparalleled by any other food assistance program:

—The CSFP specifically targets our Nation's most nutritionally vulnerable populations: young children and low-income seniors.

—The CSFP provides a monthly selection of food packages tailored to the nutritional needs of the population served. Eligible participants are guaranteed [by law] a certain level of nutritional assistance every month in addition to nutrition education regarding how to prepare and incorporate these foods into their diets as prescribed by their health care provider.

—The CSFP purchases foods at wholesale prices, which directly supports the farming community. The average food package for fiscal year 2007 is \$15.85, and the retail value is approximately \$50.00.

—The CSFP involves the entire community in confronting the problem of hunger. There are thousands of volunteers as well as many private companies who donate money, equipment, and most importantly time and effort to deliver food to needy and homebound seniors. These volunteers not only bring food but companionship and other assistance to seniors who might have no other source of support. (See Attachment 1)

The White House proposed budget for fiscal year 2008 would eliminate CSFP completely, and would eliminate all of this effort and support of those 38 years. This proposal has shocked the entire CSFP community as well as legislators, anti-hunger and senior service organizations and the concerned citizens as they have become aware of it. America's Second Harvest, AARP, and FRAC have all voiced their opposition to the elimination of CSFP. It is unconscionable to eliminate benefits for some of our most vulnerable citizens and to eliminate hope of those waiting for participation in the program. It is the cruelest cut for the greatest generation.

In a recent CSFP survey, more than half of seniors living alone reported an income of less than \$750 per month. Of those respondents from two-person households, more than half reported an income of less than \$1,000 per month. Fewer than 25 percent reported being enrolled in the Food Stamp Program. Over 50 percent said they ran out of food during the month. Also, close to 70 percent senior respondents say they use money for medical bills not food.

The Senate Agriculture Appropriations Subcommittee has consistently supported CSFP, acknowledging it as a cost-effective way of providing nutritious supplemental foods. Last year this subcommittee and all of Congress provided funding for CSFP in direct opposition to its proposed elimination. This year, your support is again needed to provide adequate resources for the 485,416 mothers, children and seniors currently receiving benefits, 20,500 low-income participants currently waiting in five new States and 100,827 seniors waiting in current States for this vital nutrition program.

There is no discernible plan to address the long-term needs of those affected by the elimination of CSFP. The proposed transition plan provides that seniors being removed from CSFP will be provided a Food Stamp Program (FSP) benefit of \$20 per month for up to six months, or until the participant actually enrolls in the FSP, whichever comes first. Simply transferring seniors to the FSP is an inadequate solution. It is essential for seniors to have access to services which they feel are offered with dignity and respect. Many will outright reject the idea of applying for FSP benefits. According to the ERS Evaluation of the USDA Elderly Nutrition Demonstrations: Volume I:

The Commodity alternative benefit demonstration in North Carolina was popular both among new applicants and among existing FSP participants. Clients eligible for low FSP benefits were more likely to get the commodity packages, which had a retail value substantially greater than their FSP benefits". "In particular, seniors

described the anxiety of using FSP benefits in stores, where they felt shoppers and store clerks looked down on them". "The demonstrations attracted a particularly large share of clients eligible for the \$10 benefit because the retail value of the commodity packages was worth \$60–\$70.

Depending on their non-cash assets, seniors may not qualify for a FSP benefit level equivalent to the CSFP food package. Seniors receiving the minimum benefit would not be eligible for the \$20/month transitional benefit. The 25 percent of current CSFP participants who already enrolled in the FSP will lose the benefits of CSFP and those benefits will not be replaced at a time when they are struggling to make ends meet. CSFP and FSP are supplemental programs. They work together to make up the shortfall that many of our seniors are facing each month. Both programs need to continue to be available as part of the "safety net" for our low-income participants.

USDA reports that the average benefit paid to senior citizens is about \$67 per month, but in reality, many senior citizens receive only the minimum monthly benefit of \$10, which has not been updated since 1975. USDA figures also report households rather than individual participants and include households with disabled family members.

The proposed transition plan for women, infants and children enrolled in the CSFP is to transfer them to WIC. However, due to increasing coordination between WIC and CSFP at the State and community levels, the number of WIC-eligible mothers and children enrolled in the CSFP is steadily declining. In some States, this figure is less than 2 percent of all enrolled women and children, eradicating supplemental food and nutrition benefits for that population as well.

As referenced earlier, CSFP provides a food package that costs USDA about \$15 per month. It has a retail value of approximately \$50. How does someone use \$20 to purchase \$50 worth of nutritious foods? What happens at the end of 6 months?

The National Commodity Supplemental Food Program Association requested the Senate Agriculture Appropriations Subcommittee take the appropriate actions to funding CSFP for fiscal year 2008 at \$157.4 million as illustrated below:

To continue serving the 485,416 needy seniors (91 percent of participants), women, infants and children (9 percent of participants) currently enrolled in CSFP—\$123 million.

To serve the 22,577 individuals who received a food package through the supplemental caseload provided to hurricane ravaged Gulf States.—\$4.3 million.

To meet USDA's commodity procurement expenses—\$0.7 million.

Appropriation required to serve the 507,993 people who have relied upon CSFP for supplemental nutrition—\$128 million.

To begin meeting the needs of 20,500 eligible seniors in the 5 States with USDA approved plans: Arkansas (5,000), Delaware (2,500), Oklahoma (5,000), New Jersey (5,000) and Utah (3,000)—\$3.9 million.

To serve an additional 100,827 individuals among of our Nation's most vulnerable individuals in the 32 States with existing programs and documented additional needs—\$25.5 million.

Appropriation needed to maximize this program's effectiveness in serving 629,518 seniors and women and their infants and young children challenged by hunger—\$157.4 million.

With the aging of America, CSFP must be an integral part of USDA Senior Nutrition Policy as well as comprehensive plans to support the productivity, health, independence, and quality of life for America's seniors.

Measures to show the positive outcomes of nutrition assistance to seniors must be strengthened. A 1997 report by the National Policy and Resource Center on Nutrition and Aging at Florida International University, Miami—Elder Insecurities: Poverty, Hunger, and Malnutrition indicated that malnourished elderly patients experience 2 to 20 times more medical complications, have up to 100 percent longer hospital stays, and incurs hospital costs \$2,000 to \$10,000 higher per stay. Proper nutrition promotes health, treats chronic disease, decreases hospital length of stay and saves health care dollars.

Rather than eliminating the program, the NCSFPA recommends the following initiatives to strengthen CSFP:

- Develop a formal evaluation process to demonstrate individual and program outcomes of CSFP with Federal, State, and local CSFP managers included in the study design;
- Restore financial guidelines for seniors to the original level of 185 percent of poverty;
- Set "greatest need within a project area" as the priority for service or let each State set its priority for service under a plan approved by the Secretary of Agriculture;

—Support and expand the program in those States that have demonstrated an interest in the CSFP, including the 5 States that already have USDA-approved plans to operate CSFP (Arkansas, Delaware, New Jersey, Oklahoma and Utah) or that have demonstrated a willingness to continue and expand current CSFP services.

This program continues with committed grassroots operators and dedicated volunteers. The mission is to provide quality nutrition assistance economically, efficiently, and responsibly always keeping the needs and dignity of our participants first. We commend the Food and Nutrition Service of the Department of Agriculture and particularly the Food Distribution Division for their continued innovations to strengthen the quality of the food package and streamline administration. We also remain committed to providing quality services in collaboration with the community organizations and volunteers that contribute nearly 50 percent of the resources used in providing these services.

ATTACHMENT 1.—NATIONAL CSFP ASSOCIATION ADMINISTRATIVE EXPENSE VALUE SURVEY FISCAL YEAR 2006

Programs	USDA Reim- bursed Cash	Not Reimbursed by USDA Cash	CSFP Expendi- tures Cash	Goods & Services donated to agen- cy Value	Volunteer Labor Hours Value	Annual Total Pro- gram Value	Percent Paid by USDA	Extra Goods do- nated to CSFP participants
New Hampshire	\$416,648	\$13,227	\$429,875	\$6,650	\$108,235	\$544,760	76	\$2,625
New York	1,804,443	45,000	1,849,443	1,000	296,307	2,146,750	84	12,755
Vermont FB	246,524	300,000	546,524	90,200	636,724	39	2,000
Washington DC	439,098	1,600,000	2,039,098	800,000	172,318	3,011,416	15
Pennsylvania	835,702	53,197	888,899	22,885	186,985	1,088,769	76	92,638
Kentucky	898,857	162,681	1,061,538	22,180	704,282	1,788,000	50	714,055.00
Mississippi	400,448	400,448	160,370	561,766	1,122,584	36
North Carolina	74,583	30,000	104,583	104,583	71	5,000
South Carolina	212,744	212,744	58,883	271,627	78	2,500
Tennessee ¹	804,260	804,260	804,260	100
Illinois	885,767	3,000	888,767	477,447	1,366,214	65
Indiana	246,603	28,072	274,675	22,000	396,880	693,555	36	443
Michigan	4,490,742	601,805	5,092,547	356,773	2,161,385	7,610,705	59	769,301
Minnesota	802,557	103,225	905,782	19,000	173,068	1,097,850	73	199,000
Red Lake, MN	5,841	5,841	5,841	100
Ohio	709,662	94,228	803,890	65,000	368,251	1,237,141	57	302,000
Wisconsin	276,228	56,458	332,686	3,150	300,691	636,527	43	41,845
Louisiana	4,505,386	250,000	4,755,386	452,000	825,330	6,032,716	75
New Mexico	1,009,150	272,139	1,281,289	97,987	350,283	1,729,559	58	446,378
Texas	708,521	70,000	778,521	15,000	405,900	1,199,421	59	12,000
Colorado	1,193,799	204,168	1,397,967	30,474	612,151	2,040,592	59	878,389
Iowa	222,652	520,767	743,419	29,712	773,131	29
Kansas	333,423	45,715	379,138	46,200	209,986	635,323	52	51,400
Missouri	532,997	29,000	561,997	2,400	398,455	962,852	55	1,010,950
Montana	385,402	35,525	420,927	107,333	2,163,357	2,691,617	14	78,825
Nebraska	756,827	87,486	844,313	21,580	308,475	1,174,369	64	89,709
North Dakota	160,216	7,800	168,016	235,729	403,745	40
South Dakota	160,962	33,520	194,482	32,842	227,324	71
Ogala Sioux, SD	37,341	37,341	37,341	100
Alaska	130,334	48,038	178,372	10,000	45,100	233,472	56
Arizona	883,204	450,000	1,333,204	4,516	1,549,401	2,887,121	31	580,460
California	3,078,203	1,265,849	4,344,052	68,600	2,492,966	6,905,618	45	772,308
Nevada	352,044	97,629	449,673	84,788	534,461	66	113,000
Oregon	78,299	48,000	126,299	75,768	202,067	39

Washington	132,094	25,000	157,094	250	39,544	196,888	67
Grand Total	28,211,561	6,581,529	34,793,090	2,335,348	15,916,481	53,044,919	53	6,177,579

¹ No information provided.

FISCAL YEAR 2008 BUDGET REQUEST

On behalf of low-income seniors and women and their infants and young children in need of the prescribed packages of nutritious food made available through the Commodity Supplemental Food Program (CSFP), we request not only the rejection of the proposal to eliminate CSFP, but also consideration of increases in program resources.

At a modest cost of 15.85 per monthly food package, CSFP leverages the efforts and energy of thousands of volunteers at churches and charities across America to deliver essential nutrition with a retail value in excess of 50.00 per month to vulnerable members of "The Greatest Generation" and to help at-risk members of the next generation get a healthy start. The appropriations required and the benefits anticipated are as follows:

To continue serving the 485,416 needy seniors (91 percent of participants), women, infants and children (9 percent of participants) currently enrolled in CSFP—\$123 million.

To serve the 22,577 individuals who received a food package through the supplemental caseload provided to hurricane ravaged Gulf States—\$4.3 million.

To meet USDA's commodity procurement expenses—\$.7 million.

Appropriation required to serve the 507,993 people who have relied upon CSFP for supplemental nutrition—\$128 million.

To begin meeting the needs of 20,500 eligible seniors in the 5 States with USDA approved plans Arkansas (5,000), Delaware (2,500), Oklahoma (5,000), New Jersey (5,000) and Utah (3,000)—\$3.9 million.

To serve an additional 100,827 individuals among of our Nation's most vulnerable individuals in the 32 States with existing programs and documented additional needs—\$25.5 million.

Appropriation needed to maximize this program's effectiveness in serving 629,518 seniors and women and their infants and young children challenged by hunger—\$157.4 million.

PREPARED STATEMENT OF THE NATIONAL ENVIRONMENTAL SERVICES CENTER (NESC)

Chairman Kohl, Senator Bennett, and Members of the Subcommittee: Thank you for the opportunity to offer testimony to the Subcommittee on Agriculture, Rural Development, FDA and Related Agencies.¹ We request funding to support the programs of the National Drinking Water Clearinghouse in providing information and technical assistance to small and rural and underserved communities under the Rural Utilities Service programs of the USDA.

Need for Federal Programs

Clean, safe drinking water and wastewater treatment are critical to public and environmental health. For most of us, it's easy to take water for granted. However, according to U.S. Census Bureau data, half of American homes in 1940 lacked complete plumbing facilities (defined as hot and cold piped water, a bathtub or shower, and a flush toilet). By 2002, EPA found that the number of homes having complete plumbing facilities increased to 91 percent. Much of this improvement can be attributed to Federal infrastructure investment. The U.S. Department of Agriculture's Rural Utilities Service (RUS) has provided more than \$20 billion for water and wastewater projects since 1947. In spite of these improvements, however, 670,000 households (with nearly 2 million people) lack access to water, sanitation, or both. Safe, affordable water infrastructure is an investment in the economic viability and public health of rural America.

Water and Wastewater Challenges

Over 50,000 water treatment systems serve the U.S. population, with 86 percent of these systems being classified as "small" systems (serving fewer than 3,300 people) and "very small" systems (serving fewer than 500 customers). Because smaller systems have lower revenues and fewer resources, they are more likely to have difficulty in meeting regulatory requirements. When the Safe Drinking Water Act was passed in 1974, 18 contaminants were regulated. By 2004, that number had grown to 86. Another eight will be added by 2008.

While significant progress has been made, a number of challenges confront communities as they try to safeguard public health. In many communities, water dis-

¹The National Environmental Services Center is located at West Virginia University. This statement has been prepared by Richard Bajura, Executive Director, with assistance from Pamela Schade and Trina Waffle. For more information, see our Web site at <http://www.nesc.wvu.edu>

tribution systems and wastewater collection systems are 40 to 50 years old, with many dating back more than a century. According to the American Society of Civil Engineers (ASCE), U.S. drinking water system operators are responsible for maintaining an estimated 800,000 miles of water delivery pipelines. In the 2002 report titled *Clean Water and Drinking Water Infrastructure Gap Analysis*, EPA estimated that we need to invest \$265 billion for drinking water systems infrastructure through 2022. Wastewater infrastructure will need an estimated \$388 billion during the same time period. ASCE puts the water infrastructure funding gap at \$534 billion over the same time period, saying that the EPA estimate doesn't adequately address population growth and new construction. In the 2003 update to ASCE's Report Card for America's Infrastructure, both water and wastewater were given a grade of "D." The report suggests that, without new investment, progress made over the last 30 years is threatened.

Federal Assistance Programs

As a partial solution to addressing these challenges, the Water and Wastewater Technical Assistance and Training [TAT] grants under USDA's Rural Community Advancement Program make it possible for small and rural communities to maximize their investments in water infrastructure through assistance with technology selection, operation and maintenance, capacity development, and asset management. The National Drinking Water Clearinghouse has been a strong partner with USDA in providing services to these communities. We are requesting appropriations in fiscal year 2008 to continue our work with USDA by providing the kinds of services described below.

About the National Drinking Water Clearinghouse (NDWC)

For 17 years, the National Drinking Water Clearinghouse at West Virginia University has helped small and rural communities with their water infrastructure management. In 2001, the NDWC also undertook programs related to utility security issues.

The NDWC provides a range of assistance for small communities. Telephone callers can obtain toll-free technical assistance from our staff of engineers and scientists. Our quarterly publication *On Tap*, a magazine about drinking water treatment, financing, and management options, helps communities and small water systems operate, manage, and maintain their facilities, while keeping them financially viable. A comprehensive Web site and databases with thousands of entries provide round-the-clock access to contemporary information on small water system. Training sessions customized for small and rural areas, teleconferences, Web casts, and more than 400 free and low-cost educational products give people the instruction and tools they need to address their most pressing water issues. These services are well received by small community officials and service providers.

In addition to our knowledge base, technical assistance through telephone consultation, and publications which we provide to the public, the NDWC wishes to develop new initiatives targeted to reach underserved communities found in places such as rural Appalachia, the Mississippi Delta, the Colonias in the U.S.-Mexico border region, and Native American Tribes.

Request

In fiscal year 2008, we want to strengthen our core programs in providing information and technical assistance and also develop special initiatives to address problems unique to certain underserved communities as described above. We seek an appropriation of \$1.7 million to support our work in these two important program areas. Thank you for considering our request.

PREPARED STATEMENT OF THE NATIONAL FISH AND WILDLIFE FOUNDATION

Mr. Chairman and Members of the Subcommittee, I appreciate the opportunity to submit testimony regarding the fiscal year 2008 funding request for the National Fish and Wildlife Foundation (Foundation). Since 2000, the Foundation has received \$3 million annually from the U.S. Department of Agriculture's Natural Resources Conservation Service (NRCS). We have worked with NRCS to focus on agency wildlife priorities in the past and look forward to continuing to do so. With a Farm Bill pending, we have a number of outside organizations willing to match federally provided dollars to assist in agricultural wildlife conservation projects.

—The Foundation respectfully requests that this Subcommittee fund the Foundation at \$4 million through the NRCS Appropriation.

These dollars will be focused on mutually agreed upon projects across the country. Furthermore, the appropriated \$4 million will be turned into a minimum of \$8 mil-

lion, according to the Foundation's Congressional Charter which requires a minimum of a one-to-one match. We have been operating on a three-to-one match historically, which means that the \$4 million has the potential to turn into \$16 million or more for on-the-ground conservation. One other note of special interest is that according to the Foundation's Charter, all directly appropriated funds have to be obligated to grants as they are not available to the Foundation for any direct or indirect expenses.

Since 2000 when the grants partnership began, the Foundation has received \$21 million in NRCS Federal funds (\$3 million per fiscal year), which it has dedicated to a matching grant program focused on private land conservation. The Foundation has supported over 470 projects in 49 States, the Caribbean, and the Pacific Islands, by leveraging the \$21 million in NRCS funds into more than \$85 million in on-the-ground conservation. These projects have led to the direct restoration of more than 1,232,000 acres of farmland and rangeland and 1,041 miles of streams and rivers. In fiscal year 2006, the Foundation received \$3 million in NRCS Federal funds, which it leveraged into more than \$14 million in on-the-ground conservation.

Working Landscapes.—Through our partnership, the Foundation works with NRCS to identify and fund projects that have strong support in affected agricultural and rural communities. We place our highest priority on projects integrating conservation practices on ongoing agricultural, ranching, and forestry operations, with the goal of improving the ecological health of working lands. We fund partners and provide expertise by engaging watershed experts, ranchers, foresters, farmers, local governments, and non-profits to undertake on-the-ground private land activities with willing landowners. Through these efforts, the Foundation has helped to reduce agricultural runoff, remove invasive species, and restore native ecosystems.

Conserving Fish, Wildlife, and Plants.—With our NRCS dollars, the Foundation funds projects that directly benefit diverse fish and wildlife species, including salmon in the West, migratory birds in the Midwest, and grassland birds in the South. Habitat for native fish has been restored on private lands throughout the United States, by way of vegetative planting, streambank stabilization, livestock fencing, and nutrient reduction efforts. In addition to improving water quality, efforts have been undertaken by our grantees to reduce water loss caused by invasive species or from outdated irrigation systems. By reducing the water taken from rivers, there is less chance that drought will negatively impact aquatic life.

—*Pulling Together Initiative (PTI).*—In fiscal year 2006, NRCS joined the Foundation's Pulling Together Initiative, a grant program that supports the creation of local cooperative Weed Management Area partnerships. These partnerships bring together local landowners, citizens groups, and weed experts to develop and implement strategies for managing weed infestations on public lands, natural areas, and private working lands. Through this collaborative program, NRCS staff is able to join invasive species experts from the U.S. Fish and Wildlife Service (FWS), USDA-Forest Service (FS), Bureau of Land Management (BLM), Animal and Plant Health Inspection Service, and the Department of Defense to review and jointly select the most innovative weed management projects.

—Due to the successful experience with the PTI program, NRCS has expressed an interest in participating in the Foundation's Bring Back the Natives (BBN) grant program in fiscal year 2007 (depending on appropriations). The BBN program is a public-private partnership, including FS, BLM, FWS, Trout Unlimited and the Foundation; it is focused on restoring native populations of sensitive or listed aquatic species. Priority is provided to aquatic joint ventures and to those projects that directly implement the recommendations of the National Fish Habitat Action Plan.

The National Fish and Wildlife Foundation continues to be one of, if not the most, cost-effective conservation program funded in part by the Federal Government. Congress established the Foundation 23 years ago, and since that time the Foundation's vision for more healthy and abundant populations of fish, wildlife, and plants has flourished through the creation of numerous valuable partnerships. The breadth of our partnerships is highlighted through our active agreements with 14 Federal agencies, as well as various corporations, foundations and individual grantees. Through these unique arrangements, we are able to leverage Federal funds, bring agencies and industry together, as well as produce tangible, measurable results. Our history of collaboration has given way to programs and initiatives such as the North American Waterfowl Management Plan, the Neotropical Migratory Bird Conservation Program, the Chesapeake Bay Small Watershed Grants Program, and the Pulling Together Initiative. With the support of the Committee in fiscal year 2008, we can continue to uphold our mission of enriching fish, wildlife, and the habitat on which they depend.

Federal dollars appropriated by this Committee allow the Foundation to be highly successful in assisting the NRCS in accomplishing its mission to help people conserve, maintain, and improve our natural resources and environment. Whether it involves farm, range or grassland conservation, species management or conservation education, the Foundation strategically invests the Federal funds entrusted to us in sound projects. This request would allow the Foundation to expand its highly successful grant program to better assist NRCS in maximizing private land conservation.

The Foundation's achievements are based on a competitive grant process where Federal funds are matched by the grantee with non-Federal funds and in-kind services. Grantees include Resource Conservation and Development Areas, conservation districts, universities, and non-profit organizations who partner with farmers and ranchers to support conservation efforts on private land. The Foundation also works to further maximize Federal funds by providing private funds through the generosity of our growing number of corporate and foundation partners. These funds are in addition to the non-Federal funds that are provided by the Foundation's grantees. In the Foundation's partnership with NRCS, Federal funds have been supplemented with funding from Shell Oil Company, FMC Corporation, Doris Duke Foundation, the Kellogg Foundation, Wal-Mart, Anheuser-Busch Companies, Inc., Southern Company, Summer T. McKnight Foundation, Charles Stewart Mott Foundation, William Penn Foundation, and the David and Lucile Packard Foundation.

We also measure our success in part by preventing the listing of species under the Endangered Species Act, as well as by stabilizing and hopefully moving others off the list. Some species that have received support through our NRCS grant program include salmonids, golden-cheeked warblers, black-capped vireos, Southwestern willow flycatchers, whooping cranes, sage grouse, lesser prairie chickens, aplomado falcons, black-tailed prairie dogs, Louisiana black bears, bog turtles, tiger salamanders and Karner blue butterflies. We invest in common sense and innovative cooperative approaches to endangered species, building bridges between the government and the private sector.

New Strategic Plan.—During 2006, the Foundation underwent a detailed self-evaluation, which resulted in the development of a new strategic plan for the organization. The strategic planning process revealed that the Foundation maximizes conservation benefits when it targets a series of grants towards a specific geographic region, habitat type, or conservation challenge. To ensure that future grants achieve a sustainable and measurable conservation impact, the Foundation is establishing targeted Keystone Initiatives around the core conservation investment areas in which the Foundation has historically specialized. The Keystone Initiatives represent the new core portfolio of the Foundation's grant making with clearly defined long-term goals, well-articulated strategies, and defined budgets to reach desired outcomes.

The four initial Keystone Initiatives, launched by the Foundation in 2007, include Birds; Wildlife and Landscape Scale Habitats; Freshwater Fish and Habitats; and Marine and Coastal Life and Habitats. Additional Keystone Initiatives being developed include Wildlife and Agriculture, Wildlife and Energy Development, Invasive Species, and Future Conservation Leaders. Each grant approved under a Keystone Initiative will be designed to provide a measurable outcome that brings us one step closer to the final long-term conservation goal of the Initiative. Where appropriate, the strategies and outcomes of the Foundation's Special Grant Programs, such as the Great Lakes Restoration Fund, Bring Back the Natives, and the Coral Reef Conservation Fund, will be designed to directly contribute to the long-term Keystone Initiative goal. Through our targeted grants, the Foundation seeks to achieve measurable success in "moving the needle" on these critical conservation objectives over the next 5 to 10 year period.

Accountability and Grantsmanship.—During the strategic planning process, Foundation staff spent time listening to feedback from our agency partners and grantees. Choke points in our grant making process were identified, and the Foundation is in the process of revising portions of our grant review and contracting process to ensure we maximize efficiency while maintaining strict financial and evaluation-based requirements. The Foundation has also launched a new website that is more user-friendly and content rich than the previous version. This new interactive tool will allow the Foundation to improve communication with our stakeholders and will help streamline our grant making process.

To ensure that only those grants with the greatest likelihood of obtaining conservation outcomes directly related to a Keystone Initiative are funded, the Foundation has implemented a thorough review process. Applicants are required to submit a pre-proposal which allows staff to proactively work with applicants to refine and improve their application before submitting a full proposal. All full proposals are

then submitted to a peer review process which involves five external reviews representing State agencies, Federal agencies, affected industry, environmental non-profits, and academics. Grants are also reviewed by the Foundation's Keystone Initiative staff, as well as evaluation staff, before being recommended to the Board of Directors for approval. In addition, the Foundation provides a 30-day notification to the Members of Congress for the congressional district and State in which a grant will be funded, prior to making a funding decision, according to our Congressional Charter.

Basic Facts About the Foundation.—The Foundation is governed by a 25-member Board of Directors, appointed by the Secretary of Interior and in consultation with the Secretary of Commerce. At the direction of Congress, the Board operates on a nonpartisan basis. Directors do not receive any financial compensation for service on the Board; in fact, most all of our directors make financial contributions to the Foundation. It is a diverse Board, and includes the Director of the U.S. Fish and Wildlife Service, the Administrator of the National Oceanic and Atmospheric Administration, as well as corporate and philanthropic leaders with a tenacious commitment to fish and wildlife conservation.

None of our federally appropriated funds are used for lobbying, litigation, or the Foundation's administrative expenses. By implementing strategic real-world solutions with the private sector, while avoiding regulatory or advocacy activities, we serve as a model for developing cooperative solutions to environmental issues. We are confident that the money you appropriate to the Foundation is making a positive difference.

PREPARED STATEMENT OF THE NATIONAL POTATO COUNCIL

Legislative/Government Affairs

My name is Ed Schneider. I am a potato farmer from Pasco, Washington and current Vice President, Legislative/Government Affairs for the National Potato Council (NPC). On behalf of the NPC, we thank you for your attention to the needs of our potato growers.

The NPC is the only trade association representing commercial growers in 50 States. Our growers produce both seed potatoes and potatoes for consumption in a variety of forms. Annual production is estimated at 437,888,000 cwt. with a farm value of \$3.2 billion. Total value is substantially increased through processing. The potato crop clearly has a positive impact on the U.S. economy.

The potato is the most popular of all vegetables grown and consumed in the United States and one of the most popular in the world. Annual per capita consumption was 136.5 pounds in 2003, up from 104 pounds in 1962 and is increasing due to the advent of new products and heightened public awareness of the potato's excellent nutritional value. Potatoes are considered a nutritious consumer commodity and an integral, delicious component of the American diet.

The NPC's fiscal year 2008 appropriations priorities are as follows:

Potato Research

Cooperative State Research Education and Extension Service (CSREES)

The NPC urges the Congress not to support the President's fiscal year 2008 budget request to eliminate the CSREES Special Grant Programs. This program supports and fine tunes important university research work that helps our growers remain competitive in today's domestic and world marketplace.

The NPC supports an appropriation of \$1,800,000 for the Special Potato Grant program for fiscal year 2008. The Congress appropriated \$1,482,000 in fiscal year 2006 and recommended the same amount in fiscal year 2007. This has been a highly successful program and the number of funding requests from various potato-producing regions is increasing.

—The NPC also urges that the Congress include Committee report language as follows: "*Potato research.*—The Committee expects the Department to ensure that funds provided to CSREES for potato research are utilized for varietal development testing. Further, these funds are to be awarded after review by the Potato Industry Working Group."

Agricultural Research Service (ARS)

The NPC urges that the Congress not support the Administration's fiscal year 2008 budget request to rescind Congressional increases for research projects.

The Congress provided funds for a number of important ARS projects and, due to previous direction by the Congress, the ARS continues to work with the NPC on how overall research funds can best be utilized for grower priorities.

Foreign Market Development

Market Access Program (MAP)

The NPC also urges that the Congress maintain the spending level for the Market Access Program (MAP) at its authorized level of \$200 million for fiscal year 2008 as requested by the Administration.

Foreign Agriculture Service (FAS)

The NPC supports the President's fiscal year 2008 budget request of \$268 million for the USDA Foreign Agriculture Service (FAS). This level is necessary for the agency given the multitude of trade negotiations and discussions currently underway. The Agency has had to absorb pay cost increases as well as higher operating costs for its overseas offices such as increased payments to the Department of State for services provided at overseas posts. Recent declines in the value of the dollar, coupled with overseas inflation and rising wage rates, have led to sharply higher operating costs that must be accommodated if FAS is to maintain its overseas presence.

Food Aid Programs

McGovern-Dole

The NPC supports the Administration's fiscal year 2008 budget request of \$100 million for the McGovern-Dole International Food Aid Program. PVO's have been including potato products in their applications for this program.

Pest and Disease Management

Animal and Plant Health Inspection Service (APHIS)

Golden Nematode Quarantine.—The NPC supports an appropriation of \$1,266,000 for this quarantine which is what is believed to be necessary for USDA and the State of New York to assure official control of this pest. Failure to do so could adversely impact potato exports.

Given the transfer of Agriculture Quarantine Inspection (AQI) personnel at U.S. ports to the Department of Homeland Security, it is important that certain USDA-APHIS programs be adequately funded to ensure progress on export petitions and protection of the U.S. potato growers from invasive and harmful pests and diseases. Even though DHS staffing has increased, agriculture priorities have not been adequately addressed.

Pest Detection.—The NPC supports \$45 million in fiscal year 2008, which is the Administration's budget request. This increase is essential for the Plant Protection and Quarantine Service's (PPQ) efforts against potato pests and diseases such as *Ralstonia* and the potato cyst nematode.

Emerging Plant Pests.—\$93 million was appropriated in fiscal year 2007. The President requests \$124 million in fiscal year 2008 which the NPC supports. This budget request includes an increase of \$4.5 million for potato cyst nematode regulatory, control and survey activity.

The NPC supports having the Congress once again include language to prohibit the issuance of a final rule that shifts the costs of pest and disease eradication and control to the States and cooperators.

Trade Issues Resolution Management.—\$12,457,000 appropriated in fiscal year 2007 and the President requests \$15 million in fiscal year 2008. The NPC supports this increase ONLY if it is specifically earmarked for plant protection and quarantine activities. These activities are of increased importance, yet none of these funds are used directly for plant protection activities. As new trade agreements are negotiated, the agency must have the necessary staff and technology to work on plant related import/export issues. The NPC also relies heavily on APHIS-PPQ resources to resolve phytosanitary trade barriers in a timely manner.

Agricultural Statistics

National Agricultural Statistics Service (NASS)

The NPC supports sufficient funds and guiding language to assure that the potato objective yield and grade and size surveys are continued, as well as for vegetable pesticide use surveys, which provides valuable data to the EPA for use in registration and re registration decisions for key chemical tools.

Rural Development Grants

Since potato growers do not receive direct payments, the 2002 Farm Bill provided for, among other things, grants to allow our growers to expand their business opportunities. One program that has been used by our growers is the value-added grant program. The NPC would urge that the Farm Bill funding level for this program

be maintained. In addition, maintaining adequate farm labor is also important to our growers. The NPC urges that farm labor housing grants be maintained and not reduced.

PREPARED STATEMENT OF THE NATIONAL RURAL TELECOM ASSOCIATION

SUMMARY OF TESTIMONY REQUESTS

Project Involved

Telecommunications lending programs administered by the Rural Utilities Service of the U.S. Department of Agriculture

Actions Proposed

Supporting loan levels for fiscal year 2008 in the amounts requested in the President's budget for 5 percent direct (\$145 million) and cost-of-money (\$250 million) and the associated subsidy, as required, to fund those programs at the requested levels.

Supporting Sec. 306 guaranteed loans in the amount (\$295 million) requested in the budget.

Opposing the budget request that would cut direct loans for broadband facilities and Internet service access by 40 percent from the fiscal year 2006 enacted level of \$500 million to \$300 million.

Supporting renewal of the pilot broadband grant program at enhanced levels and an allocation of a portion of the authorized levels for broadband loans at reduced interest rates to accelerate deployment of this technology in rural areas.

Seeking language strengthening and improving the operation of the broadband loan program in the Committee Report accompanying the bill.

Supporting continued funding, as requested in the President's budget, in the amount of \$25 million in grant authority designated for distance learning and medical link purposes.

Mr. Chairman, Members of the Committee, my name is John F. O'Neal. I am General Counsel of the National Rural Telecom Association.

NRTA is comprised of commercial telephone companies that borrow their capital needs from the Rural Utilities Service of the U.S. Department of Agriculture (RUS) to furnish and improve telephone service in rural areas. Over 700 of the Nation's local, rural telephone systems borrow from RUS. About three-fourths of these are commercial telephone companies. RUS borrowers serve almost 6 million subscribers in 46 States and employ over 22,000 people. In accepting loan funds, borrowers assume an obligation under the act to serve the widest practical number of rural users within their service area.

Program Background

Rural telephone systems have an ongoing need for long-term, fixed rate capital at affordable interest rates. Since 1949, that capital has been provided through telecommunications lending programs administered by the Rural Utilities Service and its predecessor, the Rural Electrification Agency (REA).

RUS loans are made exclusively for capital improvements and loan funds are segregated from borrower operating revenues. Loans are not made to fund operating revenues or profits of the borrower system. There is a proscription in the Act against loans duplicating existing facilities that provide adequate service and State authority to regulate telephone service is expressly preserved under the Rural Electrification Act.

Rural telephone systems operate at a severe geographical handicap when compared with other telephone companies. While almost 6 million rural telephone subscribers receive telephone service from RUS borrower systems, they account for only 4 percent of total U.S. subscribers. On the other hand, borrower service territories total almost 40 percent of the land area—nearly 12 million squares miles. RUS borrowers average about six subscribers per mile of telephone line and have an average of more than 1,000 route miles of lines in their systems.

Because of low-density and the inherent high cost of serving these areas, Congress made long-term, fixed rate loans available at reasonable rates of interest to assure that rural telephone subscribers, the ultimate beneficiaries of these programs, have comparable telephone service with their urban counterparts at affordable subscriber rates. This principle is especially valid today as this administration endeavors to deploy broadband technology and as customers and regulators constantly demand improved and enhanced services. At the same time, the underlying statutory authority governing the current program has undergone significant change. In 1993, telecommunications lending was refocused toward facilities modernization. Much of the

subsidy cost has been eliminated from the program. The subsidy that remains has been targeted to the highest cost, lowest density systems in accordance with this administration's stated objectives.

We are proud to state once again for the record that there has never been a loan default by a rural telephone system. All of these loans have been repaid in accordance with their terms: almost \$13 billion in principal and interest at the end of the last fiscal year.

Need for RUS Telecommunications Lending Continues

The need for rural telecommunications lending is great today, possibly even greater than in the past. Technological advances make it imperative that rural telephone companies upgrade their systems to keep pace with improvements and provide the latest available technology to their subscribers. And 5 years ago, Congress established a national policy initiative mandating access to broadband for rural areas. But rapid technological changes and the inherently higher costs to serve rural areas have not abated, and targeted support remains essential.

Competition among telephone systems and other technological platforms have increased pressures to shift more costs onto rural ratepayers. These led to increases in both interstate subscriber line charges and universal service surcharges on end users to recover the costs of interstate providers' assessments to fund the Federal mechanisms. Pressures to recover more of the higher costs of rural service from rural customers to compete in urban markets continue to burden rural consumers. There is a growing funding crisis for the statutory safeguards adopted in 1996 to ensure that rates, services and network development in rural America will be reasonably comparable to urban telecommunications opportunities.

Ongoing Congressional Mandates for Rural Telecommunications

Considerable loan demand is being generated because of the mandates for enhanced rural telecommunications standards contained in the authorizing legislation. We are, therefore, recommending the following loan levels for fiscal year 2008 and the appropriation of the associated subsidy costs, as required, to support these levels:

5 percent Direct Loans	\$145,000,000
Cost-of-Money Loans	250,000,000
Guaranteed Loans	295,000,000
Broadband Loans	500,000,000
Total	1,190,000,000

These are the same levels for 5 percent direct, cost-of-money loans and guaranteed loans, as requested in the President's budget for fiscal year 2008 and the enacted amount for broadband loans in the fiscal year 2006 appropriations act. The authorized levels of loans in each of these programs were substantially obligated in fiscal year 2006 and current estimates are that authorized program levels will be met in fiscal year 2007.

We believe that the needs of this program balanced with the minimal cost to the taxpayer make the case for its continuation at the stated levels.

The Broadband Loan Program

The broadband loan program was funded in fiscal year 2006 at \$500 million. Very little subsidy cost is associated with this program since most of the loans are made at the government's cost-of-money. Despite that, the President's budget recommends reducing the loan levels for fiscal year 2008 by 40 percent to \$300 million. We are opposed to that reduced level and recommend to the committee that the fiscal year 2008 appropriations bill continue to fund the program at enacted levels. The demand for this program is still quite strong and if the Congress' stated objective of deploying this technology to all rural areas of this country is to be met, the \$500 million funding level should be maintained.

Renewal of Pilot Broadband Grants and Allocating Funds for Reduced Interest Rate Loans

Many of these un-served areas are in high cost, sparsely populated regions of the country making the feasibility of loans problematic. To facilitate the deployment of this technology to those areas, the Committee should consider reinstating the Pilot Broadband Grant program initiated by Congress in previous appropriations acts. We believe that supplementing loan funds with grant funds would make many of the projects feasible where they would not be otherwise. In fact, the government's security interest in the loan would be enhanced. If the Committee concurs in reinstating

the pilot grant program as a national priority, we believe it should be at enhanced levels to achieve the Committee's goals consistent with budgetary constraints.

We also believe that if a portion of the loan funds provided by Congress for fiscal year 2008 were made available at reduced interest rates many additional areas could be served as well. Currently, all broadband loans are made at the government's cost-of-money. However, both the 2002 Farm bill that authorized the broadband loan program as well as the President's fiscal year 2006 Budget envisioned reduced rate loans to accelerate deployment of this technology. Reduced rate loans could be made concurrently with cost-of-money loans producing a blended interest rate to achieve the desired loan feasibility. The agency has successfully accomplished this in the past.

Discretion could be left with the agency to allocate loan and grant funds according to program needs and the feasibility of specific applications.

Improving Program Implementation Through Committee Report Language

Distinct improvements can be made to the broadband loan program by providing the Rural Utilities Service (RUS) broader access to the legal expertise of the Department's Office of General Counsel (OGC). Over the years, due to cost and other considerations, the agency's access to counsel has been severely curtailed. This has resulted in an uneven application of the act's requirements in the loan approval process permitting unbridled agency discretion in administering the program. For example, in administering the broadband loan program enacted as Title VI of the Rural Electrification Act of 1936, as an amendment thereto, the agency has largely ignored the fundamental requirements and prohibitions of Title II of the act that originally authorized the telephone loan program as if they simply do not apply to the broadband loan program. First and foremost of the prohibitions is the principle contained in Title II that loans should not be made in areas that would result in a duplication of facilities.

Another example is that the agency is amending loan contract terms and publishing written policy standards without meeting the requirements of Title II that prohibits RUS from denying loans or taking adverse actions against applicants or borrowers for any reason not based upon a rule adopted in an informal rulemaking proceeding. Neither can applicants be required to increase their ratio of net income or margins before interest to obtain a loan nor can loans be rescinded without the consent of the borrower. In administering the broadband program the agency has not established a consistent definition of "broadband". The agency employs one standard for approving a loan and another for determining whether an area is "underserved". There should be a consistent definition for both to avoid duplicative service.

Better access to the advice and counsel of OGC could eliminate many of these issues and assure Congress and the public that the program is being administered in accordance with the act's requirements. This could be accomplished through language in the Committee Report requiring that OGC make available additional legal resources to the agency.

Grants for Medical Link and Distance Learning Purposes

We support the continuation in fiscal year 2008 of the \$25 million in grant authority provided in the President's budget for medical link and distance learning purposes and the decision to not request additional loan funds for these programs. The purpose of these grants is to accelerate deployment of medical link and distance learning technologies in rural areas through the use of telecommunications, computer networks, and related advanced technologies by students, teachers, medical professionals, and rural residents. We agree with the conclusion in the budget that these projects are more feasible when provided through grants to eligible recipients rather than loans.

Conclusion

Thank you for the opportunity to present the association's views concerning this vital program. The telecommunications lending programs of RUS continue to work effectively and accomplish the objectives established by Congress at a minimal cost to the taxpayer. They serve to assure that America's rural inhabitants will never become second-class citizens in this modern information age of telecommunications technology.

PREPARED STATEMENT OF THE NATIONAL TURFGRASS FEDERATION, INC.

Mr. Chairman and Members of the Subcommittee, on behalf of the National Turfgrass Federation (NTF), I appreciate the opportunity to present to you the

turfgrass industry's need and justification for continuation of the \$490,000 appropriated in the fiscal year 2007 budget for turfgrass research within the Agricultural Research Service (ARS) at Beltsville, MD. Secondly, we ask that the committee support the \$1,880,000 request for Drought Mitigation, either by supporting the President's budget request (we are unsure at this time if this funding was included in fiscal year 2008) or via a Congressional earmark. This funding will be used by ARS to conduct turfgrass water conservation and salinity research at Phoenix, AZ and Riverside, CA. Thirdly, we ask for your support of \$450,000 in separate continuing funding for ongoing research programs in Beaver, WV, and \$450,000 for Logan, UT. Finally, we request water quality research scientists at ARS stations in University Park, PA, (\$450,000) and Madison, WI (\$450,000). All funding provided by the Committee is requested to go directly to USDA-ARS, not the industry per se.

Restoration of Funding for the Existing ARS Scientist Position and Related Support Activities at Beltsville, MD (\$490,000)

NTF and the turfgrass industry are requesting the Subcommittee's support for \$490,000 to continue funding for the full-time scientist staff position within the USDA, ARS at Beltsville, MD, focusing on turfgrass research, that was provided by the Committee in the fiscal year 2007 budget, and in the five previous budget cycles. We consider this funding our Congressional 'baseline', i.e. that funding which is central to and critical for the mission of the National Turfgrass Research Initiative. We are very grateful for this support and hope the Committee will continue this funding.

Turfgrass is a 50,000,000 acre, \$40 billion per year industry in the United States, that is growing exponentially each year. Turfgrass provides multiple benefits to society including child safety on athletic fields, environmental protection of groundwater, reduction of silt and other contaminants in runoff, and green space in home lawns, parks and golf courses. Therefore, by cooperating with NTF, USDA has a unique opportunity to take positive action in support of the turfgrass industry. While the vast majority of the USDA's funds have been and will continue to be directed toward traditional "food and fiber" segments of U.S. agriculture, it is important to note that turfgrasses (e.g., sod production) are defined as agriculture in the Farm Bill and by many other departments and agencies. It should also be noted that the turfgrass industry is the fastest growing segment of U.S. agriculture, while it receives essentially no federal support. There are no subsidy programs for turfgrass, nor are any desired.

For the past 70 years, the USDA's support for the turfgrass industry has been modest at best. The turfgrass industry's rapid growth, importance to our urban environments, and impact on our daily lives warrant more commitment and support from USDA.

A new turfgrass research scientist position within USDA/ARS was created by Congress in the fiscal year 2001 budget. Additional funding was added in fiscal year 2002 with the total at \$490,000. A research scientist was hired, and is now working at the ARS, Beltsville, MD center. A research plan was developed and approved by ARS. This scientist has used the funding for a full-time technician, equipment and supplies to initiate the research plan and for collaborative research with universities. We have an excellent scientist in place, and he is making good progress in establishing a solid program. At this point, losing the funding for the position would be devastating to the turf industry, as significant research has begun.

Support the President's Budget Request for Drought Mitigation/Request a Congressional Earmark (\$1,880,000)

The turfgrass industry is excited that for the first time, the President's fiscal year 2007 budget contained funding for turfgrass research within ARS. Because the fiscal year 2007 was not passed before the President submitted his fiscal year 2008 request, we are unsure if this funding in the fiscal year 2008 President's budget. Therefore, if included in the fiscal year 2008 President's budget, we request support of this important drought mitigation research. If not included in the President's fiscal year 2008 budget, we request that this funding be supported and included by Congress as new projects. This funding will be used to hire scientists in two very important locations, Riverside, CA and Maricopa, AZ, focusing on water conservation, wastewater reuse and salinity research. These issues are the most critical research needs for the survival of the turf industry. Following is a brief description of the research that ARS will conduct with this funding:

ARS will:

Develop Technology and Management Systems to Use Non-Potable Water to Reduce Agriculture's Vulnerability to Drought (\$1,880,000 total). In the process, ARS will develop systems to safely reuse wastewater and low-quality water as a means

of irrigating agricultural, horticultural and turf-based enterprises in an environmentally and economically sustainable manner.

As noted in USDA's Explanatory Notes accompanying the fiscal year 2007 budget request, this funding will be directed to the following two critical locations:

Maricopa, AZ, (\$940,000).—The U.S. Water Conservation Lab in Maricopa will determine the on-site impacts and movement in the air, soil, plant, and ground water of biological and chemical substances contained in treated and untreated waste water used for irrigation of turfgrass. They will also develop irrigation technologies and management systems to mitigate the impact of elevated levels of these compounds and nutrients when wastewater is used in the production of turf and specialty crops.

Riverside, CA, (\$940,000).—This research will be conducted at the world-renowned U.S. Salinity Lab. The Riverside lab will focus on the development of new irrigation technologies and systems to either mitigate or manage the effect of saline irrigation on the production of turf and specialty crops.

Request Funding of Ongoing Programs and two ARS Scientist Positions at two ARS Installations @ \$450,000 Each (Total: \$900,000)

The turfgrass industry also requests that the Subcommittee appropriate an additional \$900,000 for funding first allocated in fiscal year 2005, and continued in fiscal year 2006 and fiscal year 2007 bills. As a part of the National Turfgrass Research Initiative, the research conducted at Logan, UT and Beaver, WV is vital to the turf industry. We are asking for \$450,000 at each location. Following is a brief description of the research that ARS will conduct with this funding:

Beaver, WV, (\$450,000).—The lab at Beaver has significant expertise in soils and by-products research. They have excellent staff and facilities already in place. For the turfgrass industry, they are working on improving soil conditions and management systems to make athletic fields softer and with improved turf cover, thereby increasing safety. They also are considering the use of local by-products to develop improved soil systems for parks, lawns, athletic fields and golf courses. Besides being vital to the turf industry, this research is very important to the regional economy and many industrial concerns.

Logan, UT, (\$450,000).—Logan, UT is an ideal location for research on drought tolerant grasses and how they function. The Logan lab is world renowned for its efforts in collecting and improving grasses and other native plants for forage and range purposes. With the funding that was initiated in fiscal year 2005, they have directed additional efforts research on breeding and genetics of turfgrass, with emphasis on identifying plant material with superior drought and salt tolerance. Reducing water use, through more drought tolerant plant material, is the number one priority of the turfgrass industry. This research needs to be continued and expanded because of the excellent ongoing research as well as the potential for the future.

Request new Funding of new Research on Water Quality Improvement at two ARS Installations @ \$450,000 Each (Total: \$900,000)

Finally, the turfgrass industry requests funding for water quality improvement research at University Park, PA and Madison, WI; \$450,000 for each location. Water quality improvement is very important to the turf industry. There is much speculation that fertilizers and pesticides applied to turf areas contribute to the contamination of streams, waterways and groundwater. Very little research has been conducted to date that proves or disproves this phenomenon. Therefore, answers are needed to make good production, management and regulatory decisions. In addition, the turf industry is concerned about our natural environment and wants to protect it. Therefore, research data is needed to understand the scope of the problem, as well as to develop practical solutions. To address the areas with the most critical needs, we propose funding for research at the following two locations:

University Park, PA, (\$450,000).—According to the EPA, runoff and groundwater contamination in the Chesapeake Bay Watershed is one of the critical contributors to the decline of Bay water quality. Although many industries have been implicated, fertilizer applications to lawns and golf courses are routinely mentioned as significant factors in this decline. Research to address this issue is virtually non-existent, yet is critical to the success of the turf industry in the Mid-Atlantic, as well as New England. The ARS lab at University Park is already researching these issues relating to pasture and forage. Therefore, they are uniquely positioned and they have expertise and facilities in place. We request that funding be allocated to hire a scientist dedicated to turf research.

Madison, WI, (\$450,000).—The other area of the United States with significant water quality concerns is the Upper Midwest. Phosphorus contamination in the region is the most pressing problem, with other nutrients also of concern. Several

states, including Minnesota and Wisconsin, have either already instituted turf fertilizer regulations or are considering them. ARS has facilities at Madison and Marshfield, WI, which have initiated research on dairy manure contamination and disposal. This is an excellent location to address the turf-related water quality issues in that region, issues that demand solutions to ensure the survival of the turf industry.

THE NATIONAL TURFGRASS RESEARCH INITIATIVE

This Initiative has been developed by USDA/ARS in partnership with the turfgrass industry. The USDA needs to initiate and maintain ongoing research on turfgrass development and improvement for the following reasons:

- The value of the turfgrass industry in the United States is \$40 billion annually. There are an estimated 50,000,000 acres of turfgrass in the U.S. Turfgrass is the number one or two agricultural crop in value and acreage in many states (e.g., MD, PA, FL, NJ, NC).

- As our society becomes more urbanized, the acreage of turfgrass will increase significantly. In addition, state and local municipalities are requiring the reduction of water, pesticides and fertilizers on turfgrass. However, demand on recreational facilities will increase while these facilities will still be required to provide safe turfgrass surfaces.

- Currently, the industry itself spends about \$10 million annually on applied and proprietary turfgrass research. However, private and university research programs do not have the time nor the resources to conduct basic research and to identify completely new sources of beneficial genes for stress tolerance. ARS turfgrass scientists will enhance the ongoing research currently underway in the public and private sectors. Because of its mission to conduct the nation's research for agricultural commodities, ARS is the proper delivery system for this research.

- Water management is a key component of healthy turf and has direct impact on nutrient and pesticide losses into the environment. Increasing demands and competition for potable water make it necessary to use water more efficiently. Also, drought situations in many regions have limited the water available and, therefore, have severely impacted the turf industry as well as homeowners and young athletes. Therefore, new and improved technologies are needed to monitor turf stresses and to schedule irrigation to achieve the desired quality. Technologies are also needed to more efficiently and uniformly irrigate turfgrasses. Drought tolerant grasses need to be developed. In addition, to increase water available for irrigation, waste water (treated and untreated) must be utilized. Some of these waste waters contain contaminants such as pathogens, heavy metals, and organic compounds. The movement and accumulation of these contaminants in the environment must be determined.

- USDA conducted significant turfgrass research from 1920–1988. However, since 1988, no full-time scientist has been employed by USDA, Agricultural Research Service (ARS) to conduct turfgrass research specifically, until the recently appropriated funds became available.

ARS and the turfgrass industry enjoy a special, collaborative relationship, and have even entered into a cooperative Memorandum of Understanding (MOU). The turfgrass industry has met on numerous occasions with USDA/ARS officials to discuss the new turfgrass scientist positions, necessary facilities, and future research opportunities. In January 2002, ARS held a customer workshop to gain valuable input from turfgrass researchers, golf course superintendents, sod producers, lawn care operators, athletic field managers and others on the research needs of the turfgrass industry. As a result of the workshop, ARS and the turfgrass industry have developed the National Turfgrass Research Initiative. The highlights of this strategy are as follows:

ARS, as the lead agency at USDA for this initiative, has graciously devoted a significant amount of time to the effort. Like the industry, ARS is in this research endeavor for the long-term. To ARS' credit, the agency has committed staff, planning and technical resources to this effort. Last year was the first time ARS has been able to include some funding in the President's budget for the Turfgrass Research Initiative. However, there are so many issues and needs, that the industry is desperate for answers. Thus, to address the critical research needs, the industry is left with no alternative but to come directly to Congress for assistance through the appropriations process.

The role and leadership of the federal government and USDA in this research are justifiable and grounded in solid public policy rationale. ARS is poised

and prepared to work with the turfgrass industry in this major research initiative. However, ARS needs additional resources to undertake this mission. The turfgrass industry is very excited about this new proposal and wholeheartedly supports the efforts of ARS. Since the customers at the workshop identified turfgrass genetics/germplasm and water quality/use as their top priority areas for ARS research, for fiscal year 2008, the turfgrass industry requests that the six positions above be established within USDA/ARS.

For this research we propose an ARS-University partnership, with funding allocated to ARS for in-house research as well as in cooperation with university partners. For each of the individual scientist positions, we are requesting \$300,000 for each ARS scientist position with an additional \$150,000 attached to each position to be distributed to university partners, for a total of \$450,000 per position. We are also asking that the funding be directed to ARS and then distributed by ARS to those university partners selected by ARS and industry representatives.

In addition, the Committee should be receiving Senators' requests for funding of each of the positions described above. We appreciate your strong consideration of each individual member request for the turfgrass research position in his or her respective state.

In conclusion, on behalf of the National Turfgrass Federation and the turfgrass industry across America, I respectfully request that the Subcommittee continue in fiscal year 2008 the funding appropriated in fiscal year 2007 for Beltsville, MD, (\$490,000) within the Agricultural Research Service. I also request that the committee support the President's budget request (or new funding) of \$1,880,000 for Drought Mitigation. Third, I request the Subcommittee's support of ongoing research programs at Beaver, WV and Logan, UT @ \$450,000 each. Finally, I request that the Subcommittee appropriate an additional \$900,000 for two new water quality research positions, at University Park, PA and Madison, WI, with \$450,000 provided for each location.

PREPARED STATEMENT OF THE NEW MEXICO INTERSTATE STREAM COMMISSION

SUMMARY

This Statement is submitted in support of appropriations for the U.S. Department of Agriculture's Environmental Quality Incentives Program (EQIP) and the Colorado River Basin Salinity Control Program. Prior to the enactment of the Farm Security and Rural Investment Act (FSRIA) in 2002, the salinity control program had not been funded at the level necessary to control salinity with respect to water quality standards since the enactment of the Federal Agriculture Improvement and Reform Act (FAIRA) of 1996. Inadequate funding of the salinity control program also negatively impacts the quality of water delivered to Mexico pursuant to Minute 242 of the International Boundary and Water Commission. Adequate funding for EQIP, from which the U.S. Department of Agriculture (USDA) funds the salinity program, is needed to implement salinity control measures. The President's budget for fiscal year 2008 requests an appropriation of \$1 billion for EQIP. I urge the Subcommittee to support an appropriation of at least \$1 billion to be appropriated for EQIP. I request that the Subcommittee designate 2.5 percent, but no less than \$20 million, of the EQIP appropriation for the Colorado River Basin salinity control program. I request that adequate funds be appropriated for technical assistance and education activities directed to salinity control program participants.

STATEMENT

The seven Colorado River Basin States, in response to the salinity issues addressed by Clean Water Act of 1972, formed the Colorado River Basin Salinity Control Forum (Forum). Comprised of gubernatorial appointees from the seven Basin States, the Forum was created to provide for interstate cooperation in response to the Clean Water Act, and to provide the States with information to comply with Sections 303(a) and (b) of the Act. The Forum has become the primary means for the seven Basin States to coordinate with federal agencies and Congress to support the implementation of the Salinity control program.

Congress authorized the Colorado River Basin salinity control program in the Colorado River Basin Salinity Control Act of 1974. Congress amended the Act in 1984 to give new responsibilities to the USDA. While retaining the Department of the Interior as the lead coordinator for the salinity control program, the amended Act recognized the importance of the USDA operating under its authorities to meet the objectives of the salinity control program. Many of the most cost-effective projects un-

dertaken by the salinity control program to date have occurred since implementation of the USDA's authorization for the program.

Bureau of Reclamation studies show that quantified damages from the Colorado River to United States water users are about \$330,000,000 per year. Unquantified damages are significantly greater. Damages are estimated at \$75,000,000 per year for every additional increase of 30 milligrams per liter in salinity of the Colorado River. It is essential to the cost-effectiveness of the salinity control program that USDA salinity control projects be funded for timely implementation to protect the quality of Colorado River Basin water delivered to the Lower Basin States and Mexico.

Congress concluded, with the enactment FAIRA in 1996, that the salinity control program could be most effectively implemented as a component of EQIP. However, until 2004, the salinity control program since the enactment of FAIRA was not funded at an adequate level to protect the Basin State-adopted and Environmental Protection Agency approved water quality standards for salinity in the Colorado River. Appropriations for EQIP prior to 2004 were insufficient to adequately control salinity impacts from water delivered to the downstream States, and hampered the required quality of water delivered to Mexico pursuant to Minute No. 242 of the International Boundary and Water Commission, United States and Mexico.

EQIP subsumed the salinity control program without giving adequate recognition to the responsibilities of the USDA to implement salinity control measures per Section 202(c) of the Colorado River Basin Salinity Control Act. The EQIP evaluation and project ranking criteria target small watershed improvements which do not recognize that water users hundreds of miles downstream are significant beneficiaries of the salinity control program. Proposals for EQIP funding are ranked in the States of Utah, Wyoming and Colorado under the direction of the respective State Conservationists without consideration of those downstream, particularly out-of-State, benefits.

Following recommendations of the Basin States to address the funding problem, the USDA's Natural Resources Conservation Service (NRCS) designated the Colorado River Basin an "area of special interest" including earmarked funds for the salinity control program. The NRCS concluded that the salinity control program is different from the small watershed approach of EQIP. The watershed for the salinity control program stretches almost 1,200 miles from the headwaters of the river through the salt-laden soils of the Upper Basin to the river's termination at the Gulf of California in Mexico. NRCS is to be commended for its efforts to comply with the USDA's responsibilities under the Colorado River Basin Salinity Control Act, as amended. Irrigated agriculture in the Upper Basin realizes significant local benefits of improved irrigation practices, and agricultural producers have succeeded in submitting cost-effective proposals to NRCS.

Years of inadequate Federal funding for EQIP since the 1996 enactment of FAIRA and prior to 2004 resulted in the Forum finding that the salinity control program needs acceleration to maintain the water quality criteria of the Colorado River Water Quality Standards for Salinity. Since the enactment of FSRIA in 2002, an opportunity to adequately fund the salinity control program now exists. The President's budget request of \$1 billion accomplishes the needed acceleration of the NRCS salinity control program if the USDA continues its practice of designating 2.5 percent of the EQIP funds appropriated. The requested funding of 2.5 percent, but no less than \$20 million, of the EQIP funding will continue to be needed each year for at least the next few fiscal years.

State and local cost-sharing is triggered by and indexed to the federal appropriation. Federal funding for the NRCS salinity control program of about \$19.5 million for fiscal year 2007 has generated about \$15.8 million in cost-sharing from the Colorado River Basin States and agricultural producers, or about an 80 percent match of the federal funds appropriated for the fiscal year.

USDA salinity control projects have proven to be a most cost-effective component of the salinity control program. USDA has indicated that a more adequately funded EQIP program would result in more funds being allocated to the salinity program. The Basin States have cost-sharing dollars available to participate in on-farm salinity control efforts. The agricultural producers in the Upper Basin are willing to cost-share their portion and are awaiting funding for their applications to be considered.

The Basin States expend 40 percent of the State funds allocated for the program for essential NRCS technical assistance and education activities. Previously, the Federal part of the salinity control program funded through EQIP failed to adequately fund NRCS for these activities, which has been shown to be a severe impediment to accomplishing successful implementation of the salinity control program. Recent acknowledgement by the Administration that technical assistance and education activities must be better funded has encouraged the Basin States and

local producers that cost-share with the EQIP funding for implementation of the essential salinity control work. I request that adequate funds be appropriated to NRCS technical assistance and education activities directed to the salinity control program participants (producers).

I urge the Congress to appropriate at least \$1 billion in fiscal year 2008 for EQIP. Also, I request that Congress designate 2.5 percent, but no less than \$20 million, of the EQIP appropriation for the Colorado River Basin salinity control program.

PREPARED STATEMENT OF THE ORGANIZATION FOR THE PROMOTION AND
ADVANCEMENT OF SMALL TELECOMMUNICATIONS COMPANIES

SUMMARY OF REQUEST

The Organization for the Promotion and Advancement of Small Telecommunications Companies (OPASTCO) seeks the Subcommittee's support for fiscal year 2008 loan levels for the telecommunications loans program administered by the Rural Utilities Service (RUS) in the following amounts:

5 percent hardship loans	\$145 million
Treasury rate loans	250 million
Guaranteed loans	300 million

In addition, OPASTCO requests that the distance learning, telemedicine, and broadband program be funded at sufficient levels.

OPASTCO is a national trade association of approximately 550 small telecommunications carriers serving primarily rural areas of the United States. Its members, which include both commercial companies and cooperatives, together serve over 3.5 million customers in 47 States.

Perhaps at no time since the inception of the RUS (formerly the REA) has the telecommunications loans program been so vital to the future of rural America. The telecommunications industry is at a crossroads, both in terms of technology and public policy. Rapid advances in telecommunications technology in recent years are delivering on the promise of a new "information age." Both Federal and state policymakers have made ubiquitous availability of advanced communications services a top priority. However, without continued support of RUS's telecommunications loans program, rural telecommunications companies will be hard pressed to continue deploying the infrastructure necessary to achieve policymakers' objectives.

Contrary to the belief of some critics, RUS's job is not finished. Actually, in a sense, it has just begun. We have entered a time when advanced services and technology—such as fiber-to-the-home, high-speed packet and digital switching equipment, and digital subscriber line technology—are expected by customers in all areas of the country, both urban and rural. Moreover, the ability of consumers to use increasingly popular Voice over Internet Protocol (VoIP) services requires that they first have a broadband connection from a facilities-based carrier. Unfortunately, the inherently higher costs of upgrading the rural wireline network, both for voice and data communications, has not abated.

Rural telecommunications continues to be more capital intensive and involves fewer paying customers per square mile than its urban counterpart. In the Federal Communication Commission's September 2004 report on the deployment of advanced telecommunications capability, the Commission correctly noted that "[r]ural areas are typically characterized by sparse and disperse populations, great distances between the customer and the service provider, and difficult terrain. These factors present a unique set of difficulties for providers attempting to deploy broadband services." More recently, the FCC's January 2007 release of statistics on high-speed connections in the United States illustrated that low population density has an inverse association with reports that high-speed subscribers are present in an area. Thus, in order for rural telecommunications companies to continue modernizing their networks and providing consumers with advanced services at reasonable rates, they must have access to reliable low-cost financing.

The relative isolation of rural areas increases the value of telecommunications for these citizens. Telecommunications enables applications such as high-speed Internet connectivity, distance learning, and telemedicine that can alleviate or eliminate some rural disadvantages. A modern telecommunications infrastructure can also make rural areas attractive for some businesses which results in revitalization of the rural economy. For example, businesses such as telemarketing and tourism can thrive in rural areas, and telecommuting can become a realistic employment option. Certainly, telecommunications plays a major role in any rural community's economic

development strategy, with the existence of modern and advanced telecommunications infrastructure being a major enabling factor in the development of small business and manufacturing enterprises in rural areas.

While it has been said many times before, it bears repeating that RUS's telecommunications loans program is not a grant program. The funds loaned by RUS are used to leverage substantial private capital, creating public/private partnerships. For a very small cost, the government is encouraging tremendous amounts of private investment in rural telecommunications infrastructure. Most importantly, the program is tremendously successful. Borrowers actually build the infrastructure and the government is reimbursed with interest.

In addition to RUS's telecommunications loans program, OPASTCO supports adequate funding of the distance learning, telemedicine, and broadband program. Through distance learning, rural students gain access to advanced classes which will help them prepare for college and jobs of the future. Telemedicine provides rural residents with access to quality health care services without traveling great distances to urban hospitals. Furthermore, funding that is targeted to finance the installation of broadband transmission capacity will allow more rural communities to gain high-speed access to the Internet and receive other advanced services. In light of the Telecommunications Act's purpose of encouraging deployment of advanced technologies and services to all Americans—including schools and health care providers—sufficient targeted funding for these purposes is essential in fiscal year 2008.

CONCLUSION

The transformation of the nationwide telecommunications network into an information superhighway, as envisioned by policymakers, will help rural America survive and prosper in any market—whether local, regional, national, or global. However, without the availability of low-cost RUS funds, building the information superhighway in communities that are isolated and thinly populated will be untenable. By supporting the RUS telecommunications programs at the requested levels, the Subcommittee will be making a significant contribution to the future of rural America.

PREPARED STATEMENT OF PICKLE PACKERS INTERNATIONAL, INC.

The pickled vegetable industry strongly supports and encourages your committee in its work of maintaining and guiding the Agricultural Research Service. To accomplish the goal of improved health and quality of life for the American people, the health action agencies of this country continue to encourage increased consumption of fruits and vegetables in our diets. Accumulating evidence from the epidemiology and biochemistry of heart disease, cancer and diabetes supports this policy. Vitamins (particularly A, C, and folic acid) and a variety of antioxidant phytochemicals in plant foods are thought to be the basis for correlation's between high fruit and vegetable consumption and reduced incidence of these debilitating and deadly diseases. The problem is that many Americans choose not to consume the variety and quantities of fruits and vegetables that are needed for better health.

As an association representing processors that produce over 85 percent of the tonnage of pickled vegetables in North America, it is our goal to produce new products that increase the competitiveness of U.S. agriculture as well as meet the demands of an increasingly diverse U.S. population. The profit margins of growers continue to be narrowed by foreign competition. Likewise, the people of this country represent an ever-broadening array of expectations, tastes and preferences derived from many cultural backgrounds. Everyone, however, faces the common dilemma that food costs should remain stable and preparation time continues to be squeezed by the other demands of life. This industry can grow by meeting these expectations and demands with reasonably priced products of good texture and flavor that are high in nutritional value, low in negative environmental impacts, and produced with assured safety from pathogenic microorganisms and from those who would use food as a vehicle for terror. With strong research to back us up, we believe our industry can make a greater contribution toward reducing product costs and improving human diets and health.

Many small to medium sized growers and processing operations are involved in the pickled vegetable industry. We grow and process a group of vegetable crops, including cucumbers, peppers, carrots, onions, garlic, cauliflower, cabbage (Sauerkraut) and Brussels sprouts, which are referred to as 'minor' crops. None of these crops is in any "commodity program" and as such, do not rely upon taxpayer subsidies. However, current farm value for just cucumbers, onions and garlic is \$2.3 bil-

lion with an estimated processed value of \$5.8 billion. These crops represent important sources of income to farmers, and the processing operations are important employers in rural communities around the United States. Growers, processing plant employees and employees of suppliers to this industry reside in all 50 States. To realize its potential in the rapidly changing American economy, this industry will rely upon a growing stream of appropriately directed basic and applied research from four important research programs within the Agricultural Research Service.

VEGETABLE CROPS RESEARCH LABORATORY, MADISON, WISCONSIN

The USDA/ARS Vegetable Crops Research Lab at the University of Wisconsin is the only USDA research unit dedicated to the genetic improvement of cucumbers, carrots, onions and garlic. Three scientists in this unit account for approximately half of the total U.S. public breeding and genetics research on these crops. Their past efforts have yielded cucumber, carrot and onion cultivars and breeding stocks that are widely used by the U.S. vegetable industry (i.e., growers, processors, and seed companies). These varieties account for over half of the farm yield produced by these crops today. All U.S. seed companies rely upon this program for developing new varieties, because ARS programs seek to introduce economically important traits (e.g., virus and nematode resistance) not available in commercial varieties using long-term high risk research efforts. The U.S. vegetable seed industry develops new varieties of cucumbers, carrots, onions, and garlic and over twenty other vegetables used by thousands of vegetable growers. The U.S. vegetable seed, grower, and processing industry, relies upon the USDA/ARS Vegetable Crops Research Lab for unique genetic stocks to improve varieties in the same way the U.S. health care and pharmaceutical industries depend on fundamental research from the National Institutes of Health. Their innovations meet long-term needs and bring innovations in these crops for the United States and export markets, for which the United States has successfully competed. Past accomplishments by this USDA group have been cornerstones for the U.S. vegetable industry that have resulted in increased profitability, and improved product nutrition and quality.

Both consumers and the vegetable production and processing industry would like to see fewer pesticides applied to food and into the environment in a cost-effective manner. Scientists in this unit have developed a genetic resistance for many major vegetable diseases that are perhaps the most important threat to sustained production of a marketable crop for all vegetables. Genetic resistance assures sustainable crop production for growers and reduces pesticide residues in our food and environment. Value of this genetic resistance developed by the vegetable crops unit is estimated at \$670 million per year in increased crop production, not to mention environmental benefits due to reduction in pesticide use. New research in Madison has resulted in cucumbers with improved disease resistance, pickling quality and suitability for machine harvesting. New sources of genetic resistance to viral and fungal diseases, environmental stress resistance like heat and cold, and higher yield have recently been mapped on cucumber chromosomes to provide a ready tool for our seed industry to significantly accelerate the development of resistant cultivars for U.S. growers. Nematodes in the soil deform carrot roots to reduce yield from 10 percent to over 70 percent in major production areas. A new genetic resistance to nematode attack was found to almost completely protect the carrot crop from one major nematode. This group improved both consumer quality and processing quality of vegetables with a resulting increase in production efficiency and consumer appeal. This product was founded on carrot germplasm developed in Madison, Wisconsin. Carrots provide approximately 30 percent of the U.S. dietary vitamin A. New carrots have been developed with tripled nutritional value, and nutrient-rich cucumbers have been developed with increased levels of provitamin A. Using new biotechnological methods, a system for rapidly and simply identifying seed production ability in onions has been developed that reduces the breeding process up to 6 years! A genetic map of onion flavor and nutrition will be used to develop onions that are more appealing and healthy for consumers.

There are still serious vegetable production problems which need attention. For example, losses of cucumbers, onions, and carrots in the field due to attack by pathogens and pests remains high, nutritional quality needs to be significantly improved and U.S. production value and export markets could certainly be enhanced. Genetic improvement of all the attributes of these valuable crops are at hand through the unique USDA lines and populations (i.e., germplasm) that are available and the new biotechnological methodologies that are being developed by the group. The achievement of these goals will involve the utilization of a wide range of biological diversity available in the germplasm collections for these crops. Classical plant breeding methods combined with bio-technological tools such as DNA marker-as-

sisted selection and genome maps of cucumber, carrot and onion will be the methods to implement these genetic improvements. With this, new high-value vegetable products based upon genetic improvements developed by our USDA laboratories can offer vegetable processors and growers expanded economic opportunities for United States and export markets.

U.S. FOOD FERMENTATION LABORATORY, RALEIGH, NORTH CAROLINA

The USDA/ARS Food Fermentation Laboratory in Raleigh, NC is the major public laboratory that this industry looks to as a source for new scientific information on the safety of our products and development of new processing technologies related to fermented and acidified vegetables. Over the years this laboratory has been a source for innovations, which have helped this industry remain competitive in the current global trade environment. We expect the research done in this laboratory to lead to new processing and product ideas that will increase the economic value of this industry and provide consumers with safe, high quality, healthful vegetable products.

To maintain the current level of research we request that Congress restore the funding increases provided in the fiscal year 2004 (\$270,000) and fiscal year 2005 (\$100,000) budgets. It is very important that Congress restore the full \$370,000 in the fiscal year 2008 budget, since the funds were not included in the budget sent to the Congress.

We seek additional funding to support two new research initiatives for this laboratory that have substantial economic potential for our industry and health benefits for the American public. These are: (1) Preservation of a variety of high nutrient/high antioxidant vegetables using fermentation or acidification techniques so as to maintain the natural levels of beneficial phytochemicals in convenient to use value-added products; (2) development of techniques to deliver living pro-biotic microorganisms to consumers in fermented or acidified vegetable products.

Certain vitamins (Vitamin C, folic acid) and beneficial phytochemicals in vegetables are stabilized by the low pH in acidified and fermented foods. In addition, low pH makes it possible to preserve vegetables with low heat or, ideally, no heat, which typically minimizes nutrient loss. While many high nutrient/high antioxidant vegetables are pickled to a very limited extent, traditional processes include steps, such as preserving in very high salt or acid followed by washing out the excess salt or acid, that result in loss many of the health-promoting components that diet authorities emphasize when they urge people to increase their consumption of fruits and vegetables. The objective will be develop new low acid/low salt preservation techniques for broccoli, Brussel sprouts, sweet potato, cauliflower, and peppers that will provide high levels of vitamin C, folic acid, carotenoids, glucosinolates, and phenolic compounds to maximize the health benefits of these vegetables in products that are convenient and attractive to consumers.

Most of what we hear about bacteria in foods concerns the pathogens that cause disease. However, lactic acid bacteria are intentionally grown in fermented foods because they are needed to give foods like sauerkraut, yoghurt, cheeses, and fermented salami the characteristic flavors and textures that we desire. There is a growing body of research to indicate that certain living lactic acid bacteria are 'pro-biotic' and can improve human health by remaining in the intestinal tract after they are consumed. Fermented or acidified vegetables may be a good way to deliver such pro-biotic bacteria to consumers. The objective will be to identify pro-biotic lactic acid bacteria that can survive in high numbers in selected vegetable products and investigate the potential for using vegetables as healthful delivery vehicles for probiotic organisms.

SUGAR BEET AND BEAN RESEARCH UNIT, EAST LANSING, MICHIGAN

The USDA/ARS East Lansing, Michigan location has the only federally funded research program that is devoted to developing new and/or improved engineering technologies and systems for assessing, retaining, and assuring postharvest quality, marketability, and wholesomeness of pickling cucumbers and other vegetable products. The vegetable postharvest engineering research is one component of the postharvest engineering research program within the Sugar Beet and Bean Research Unit in East Lansing, Michigan. The postharvest engineering research program currently has a full-time research agricultural engineer whose research is primarily focused on tree fruits. Over the past few years, the location has developed a number of innovative engineering technologies for rapid, nondestructive measurement and inspection of postharvest quality of tree fruits and vegetables. One is a novel laser-based multi-spectral scattering technology for assessing the texture and flavor of fruits. The technology may be used for inspecting a variety of vegetable

crops including cucumbers. The location did the pioneering work in applying hyperspectral imaging technology for quality assessment of fruits and vegetable. It recently developed an advanced hyperspectral imaging system for automated detection of quality/defect of pickling cucumbers.

Currently the location's cucumber postharvest engineering research is grossly under funded, and it has not been carried out at the full scope it would have been expected. Additional Federal funding for the location would enable the hiring of a full-time research agricultural engineer to focus on development of new and/or improved engineering technologies and equipment for postharvest handling of pickling vegetable products. Today, consumers have increasing choices of foods and they become more conscious of food quality and nutrition. An effective quality control and assurance system throughout the handling steps between harvest and retail is critical for providing consistent, superior products to the marketplace. Methods currently available for measuring and grading quality of cucumbers and other vegetables are either ineffective or time consuming. New and/or improved technologies are needed to assess, inspect and grade fresh cucumbers rapidly and accurately for various internal and external quality characteristics so that raw products can be directed to, or removed from, appropriate processing or marketing avenues. This will minimize postharvest losses of food that has already been produced and ensure high quality, consistent final product and end-user satisfaction. Research at East Lansing will lead to new inspection and grading technology that will help the pickling industry in delivering high-quality safe products to the marketplace.

U.S. VEGETABLE LABORATORY, CHARLESTON, SOUTH CAROLINA

The research program at the USDA/ARS Vegetable Laboratory in Charleston, South Carolina, addresses national problems in vegetable crop production and protection with emphasis on the southeastern United States. This research program is internationally recognized for its accomplishments, which have resulted in development of over 150 new vegetable varieties and lines along with the development of many new and improved disease and pest management practices. This laboratory's program currently addresses 14 vegetable crops including those in the cabbage, cucumber, and pepper families, which are of major importance to the pickling industry. The mission of the laboratory is to (a) develop disease and pest resistant vegetable crops and (b) develop new, reliable, environmentally sound disease and pest management programs that do not rely on conventional pesticides.

Continued expansion of the Charleston program is crucial. Vegetable growers depend heavily on synthetic pesticides to control diseases and pests. Cancellation and/or restrictions on the use of many effective pesticide compounds are having a considerable influence on the future of vegetable crop production. Without the use of certain pesticides, growers will experience crop failures unless other effective, non-pesticide control methods are found quickly. The research on improved, more efficient and environmentally compatible vegetable production practices and genetically resistant varieties at the U.S. Vegetable Laboratory continues to be absolutely essential. This gives U.S. growers the competitive edge they must have to sustain and keep this important industry and allow it to expand in the face of increasing foreign competition. Current cucumber varieties are highly susceptible to a new strain of the downy mildew pathogen; this new strain has caused considerable damage to commercial cucumber production in some South Atlantic and Midwestern states in 2005 and 2006, and a new plant pathologist position needs to be established to address this critical situation.

FUNDING NEEDS FOR THE FUTURE

It remains critical that funding continues the forward momentum in pickled vegetable research that the United States now enjoys and to increase funding levels as warranted by planned expansion of research projects to maintain U.S. competitiveness. We also understand that discretionary funds are now used to meet the rising fixed costs associated with each location. Additional funding is needed at the Wisconsin and South Carolina programs for genetic improvement of crops essential to the pickled vegetable industry, and at North Carolina and Michigan for development of environmentally-sensitive technologies for improved safety and value to the consumer of our products. The fermented and acidified vegetable industry is receptive to capital investment in order to remain competitive, but only if that investment is economically justified. The research needed to justify such capital investment involves both short term (6–24 months) and long term (2–10 years or longer) commitments. The diverse array of companies making up our industry assumes responsibility for short-term research, but the expense and risk are too great for individual companies to commit to the long-term research needed to insure future competitive-

ness. The pickled vegetable industry currently supports research efforts at Wisconsin and North Carolina and anticipates funding work at South Carolina and Michigan as scientists are put in place. Donations of supplies and processing equipment from processors and affiliated industries have continued for many years.

U.S. Vegetable Laboratory, Charleston, South Carolina

The newly constructed laboratory-office building at the U.S. Vegetable Laboratory was occupied in April 2003. Design of the accompanying greenhouse and head house using the funds appropriated for this purpose in fiscal year 2003 was completed in July 2004. In fiscal year 2004, construction of the head house component of this project was funded. The head house component of the project is now under construction with an expected completion in late spring 2006. In fiscal year 2005, \$2.976 million was appropriated for construction of greenhouses. In fiscal year 2006, an additional \$1.980 million was appropriated for construction of greenhouses, but \$7.794 million is still needed for the planned \$12.750 million greenhouse complex. This new facility replaces and consolidates outmoded laboratory areas that were housed in 1930s-era buildings and trailers. Completion of the total research complex will provide for the effective continuation and expansion of the excellent vegetable crops research program that has been conducted by the Agricultural Research Service at Charleston for over 70 years. It is most critical to the mission of the U.S. Vegetable Laboratory that the fiscal year 2002, fiscal year 2003, and fiscal year 2004 appropriated funds for expansion of the Charleston research staff is maintained in fiscal year 2008. In addition, new funds are needed to establish a plant pathology position to address cucumber diseases, especially the disease caused by a new strain of the downy mildew pathogen that has caused extensive damage to cucumber production in some South Atlantic and Midwestern states during the past 2 years. The plant pathologist is needed to characterize pathogen strains using molecular methodologies and to develop new management approaches and resistant cucumber lines. This new plant pathologist position will greatly contribute to the accomplishment of research that will provide for the effective protection of cucumbers from disease without the use of conventional pesticides. This position will require a funding level of \$450,000 for its establishment.

Appropriations to restore	Fiscal year	Gross funds impacted
Minor Use Pesticides (IR-4)	2002	\$5,398
U.S. Vegetable Laboratory	2003	489,868
U.S. Vegetable Laboratory	2004	266,260
Total Funds to Restore	761,526

New scientific staff needed	Current status	New funds needed
Plant Pathologist (cucumber disease)	Needed	\$450,000
New funds needed	450,000

Food Fermentation Laboratory, Raleigh, North Carolina

The current funding for the laboratory is \$1,274,000. This includes the new funds provided in fiscal year 2004 (\$270,000) and in fiscal year 2005 (\$100,000) that are not in the fiscal year 2008 budget proposal that was sent to the Congress. We request that the additional funding provided by the Congress in fiscal year 2004 and fiscal year 2005 be restored in the fiscal year 2008 budget.

To carry out the new research initiatives to maximize retention of beneficial components in high nutrient/high antioxidant vegetables and to develop systems to deliver pro-biotic lactic acid bacteria in acidified and fermented vegetable products, we request additional support for the Food Fermentation Laboratory of \$200,000 in fiscal year 2008. This will provide support for Post-Doctoral or Pre-Doctoral research associates along with necessary equipment and supplies to develop these new areas of research.

Scientific staff	Current status	Funds needed
Microbiologist	Active	\$318,500
Chemist	Active	318,500
Food Technologist/Biochemist	Active	318,500

Scientific staff	Current status	Funds needed
Microbial Physiologist	Active	318,500
Fiscal year 2008 Post-doctoral or Predoctoral Research Associates	Needed	200,000
Total funding required	1,474,000
Presidential Budget (fiscal year 2008)	912,195
Appropriations to restore	361,805
New funds needed	200,000

Vegetable Crops Research Laboratory Unit, Madison, Wisconsin

Current base funding for three scientists is \$849,172, of which \$200,000 was added in fiscal year 2002. An additional \$50,828 is needed to fully fund the scientists and support staff, including graduate students and post-doctorates.

Scientific staff in place	Current status	Funds needed
Geneticist	Active	\$300,000
Horticulturist	Active	300,000
Geneticist	Active	300,000
Total funding required	900,000
Presidential Budget (fiscal year 2008)	798,222
Appropriations to restore	50,950
New funds needed	50,828

A temporary addition of \$200,000 was provided to enhance the research effort of this program in fiscal year 2002, and we greatly appreciate that additional support, but that addition is being proposed for reduction in fiscal year 2008. Thus, the restoration of the funds proposed for reduction, is urgently requested. We request a \$101,778 permanent addition this year to sustain the long-term research of this group.

Sugar Beet and Bean Research Unit, East Lansing, Michigan

The location urgently needs to hire a full-time research engineer to develop a comprehensive research program on nondestructive inspection, sorting and grading of pickling cucumbers and other vegetable crops to assure the processing and keeping quality of pickled products. The current base funding for the cucumber engineering research is \$200,000. An increase of \$150,000 in the current base funding level would be needed to fund the research engineer position.

Scientific staff in place	Current status	Funds needed
Postdoctoral Research Associate	Active	\$200,000
Research Engineer	Needed	150,000
Total funding required	350,000
Current Funding	200,000
New funds needed	150,000

Thank you for your consideration and expression of support for the USDA/ARS.

PREPARED STATEMENT OF THE RED RIVER VALLEY ASSOCIATION

Mr. Chairman and members of the Committee, I am Wayne Dowd, and I am pleased to represent the Red River Valley Association as its President. Our organization was founded in 1925 with the express purpose of uniting the citizens of Arkansas, Louisiana, Oklahoma and Texas to develop the land and water resources of the Red River Basin. (Enclosure 1)

The Resolutions contained herein were adopted by the Association during its 82nd Annual Meeting in Shreveport, Louisiana on February 22, 2007, and represent the combined concerns of the citizens of the Red River Basin Area as they pertain to the goals of the Association. (Enclosure 2)

As an organization that knows the value of our precious water resources we support the most beneficial water and land conservation programs administered through the Natural Resources Conservation Service (NRCS). We understand that attention and resources must be given to our national security and the war in Iraq; however, we cannot sacrifice what has been accomplished on our Nation's lands. NRCS programs are a model of how conservation programs should be administered and our testimony will address the needs of the Nation as well as our region.

The President's fiscal year 2008 budget for NRCS indicates a decrease of \$131,740,000 (16 percent decrease) from what Congress appropriated in fiscal year 2007, \$841,340,000. In addition, the Administration eliminated two crucial watershed programs: Watershed & Flood Prevention Operations and Watershed Survey & Planning. Along with drastic reductions in the other programs, NRCS manpower for fiscal year 2008 would have to decrease by over 1,500 staff years, if the President's budget is implemented. This is unacceptable.

This means that NRCS assistance to landowners will not be adequately funded, to the detriment of the Nation and our natural resources. We would like to address several of the programs administered by NRCS. Failure to adequately fund these initiatives would reduce assistance to those who want it and the resources that need protection.

Conservation Operations.—This account has been in steady decline, in real dollars, over the past several years. The President's budget included \$689 million, which is a decrease of \$70 million from what Congress appropriated in fiscal year 2007. Mandated increases in pay and benefits, continuing increases in the cost of doing business' and budget reductions greatly reduces the effective work that can be accomplished in this account. Allocations should be increased not decreased.

We request a total of \$930 million be appropriated for Conservation Operations for NRCS to meet the demands it faces today.

Conservation Technical Assistance is the foundation of technical support and a sound, scientific delivery system for voluntary conservation to the private users and owners of lands in the United States. It is imperative that we provide assistance to all "working lands" not just those fortunate few who are able to enroll in a Federal program. Working lands are not just crops and pasture (commodity staples) but includes forests, wildlife habitat and coastal marshes. The problem is that NRCS personnel funded from "mandatory programs" can only provide technical assistance to those enrolled in these programs, leaving the majority of the agricultural community without technical assistance. We recommend that adequate funding be placed in "Conservation Technical Assistance", and allow NRCS to provide assistance to all who are in need of assistance.

It is our understanding that the Technical Service Providers (TSP) program has not lived up to its expectations. Experience indicates landowners are hesitant to use the program. This program funds projects at a level estimated if NRCS conducted the work. Usually the TSP cost exceeds this estimate and the landowner is responsible for the difference, effectively making the landowner cost share. We believe that TSPs should be used only after NRCS staffing is brought up to levels commensurate with the increase in workload caused by the Farm Bill, not to replace NRCS staffing.

Watershed and Flood Prevention Operations (Public Law 566 & 534).—We are greatly disappointed that the President's Budget provided no funding for watershed operations in the last two fiscal years. There is no doubt that this is a Federal responsibility, in conjunction with a local sponsor. This program addresses all watershed needs to include: flood protection, water quality, water supply and the ecosystem. There is no Corps of Engineer, Bureau of Reclamation or FEMA program to address small watershed needs, before disaster strikes. We recommend that Congress continue to hold oversight hearings to understand the importance and hear how popular this program is to our communities.

Over the past 50 years these projects have developed a \$15 billion infrastructure that is providing \$1.5 billion in annual benefits to over 47 million people. It is not a Federal program, but a federally assisted program. This partnership between local communities, State agencies and NRCS has been successful for over 50 years. It would take \$1.6 billion to fund the existing Federal commitment to local project sponsors. This cost only increases every year if adequate funding is not provided.

All ongoing contracts will be terminated, if you allow this program to end. This will ultimately lead to lawsuits and tort claims filed by both sponsors and contractors, due to the Federal Government not fulfilling its contractual obligation.

We are very appreciative for the funding level of \$75 million enacted in fiscal year 2006, but that was the last year funding was provided. No funding was provided in fiscal year 2007. For every \$1 spent, the Nation realizes \$2 in benefits. Congress must take back responsibility for this program.

There are many new projects, which are awaiting funds for construction under this program. We strongly recommend that a funding level of \$190 million be appropriated for Watershed Operations Programs, Public Law 534 (\$20 million) and Public Law 566 (\$170 million).

The Red River has proven, through studies and existing irrigation, to be a great water source for "supplemental" irrigation. The two projects mentioned below, will use existing, natural bayous to deliver water for landowners to draw from. The majority of expense will be for the pump system to take water from the Red River to the bayous. These projects will provide the ability to move from ground water dependency to surface water, an effort encouraged throughout the Nation. Both will enhance the environmental quality and economic vitality of the small communities adjacent to the projects.

—*Walnut Bayou Irrigation Project, AR.*—Plans and specifications have been completed and it is ready to proceed into the construction phase. An irrigation district has been formed and they are prepared to take on the responsibility to generate the income for the O&M required to support this project. We request that \$4,000,000 be appropriated for these projects in fiscal year 2008.

—*Red Bayou Irrigation Project, LA.*—The plans and specifications have been completed, making this project ready for construction in fiscal year 2007. An irrigation district has been formed and is prepared to collect funds to support the O&M for this proposed system.

We request that \$2,500,000 be specifically appropriated to begin construction in fiscal year 2008.

Watershed Rehabilitation.—More than 10,400 individual watershed structures have been installed nationally, with approximately one-third in the Red River Valley. They have contributed greatly to conservation, environmental protection and enhancement, economic development and the social well being of our communities. More than half of these structures are over 30 years old and several hundred are approaching their 50-year life expectancy. Today you hear a lot about the watershed approach to resource management. They protect more people and communities from flooding now than when they were first constructed. The benefit to cost ratio for this program has been evaluated to be 2.2:1. What other Federal program can claim such success?

In the next 5 years over 900 watershed structures will require over \$570 million for rehabilitation. Each year this number increases as more dams reach their 50-year life. There is no questioning the value of this program. The cost of losing this infrastructure exceeds the cost to reinvest in our existing watersheds. Without repairing and upgrading the safety of existing structures, we miss the opportunity to keep our communities alive and prosperous. It would be irresponsible to dismantle a program that has demonstrated such great return and is supported by our citizens. We cannot wait for a catastrophe to occur, where life is lost, to decide to take on this important work.

The President's budget neglects the safety and well being of our community needs and only recommends \$6 million for this program. This is drastically lower than the levels authorized in the 2002 Farm Bill, which authorized \$600 million for rehabilitation for 2003–2007.

We request that \$75 million be appropriated to provide financial and technical assistance to those watershed projects where sponsors are prepared (35 percent cost share) to commence rehabilitation.

Watershed Survey and Planning.—In fiscal year 2006, \$6.1 million was appropriated to support this extremely important community program. Again, no funding was provided in fiscal year 2007. NRCS has become a facilitator for the different community interest groups, State and Federal agencies. In our States such studies are helping identify resource needs and solutions where populations are encroaching into rural areas. The Administration decided to eliminate this program. We disagree with this and ask Congress to fund this program at the appropriate level.

Proper planning and cooperative efforts can prevent problems and insure that water resource issues are addressed. Zeroing out the planning process assumes the economy will not grow and there is no need for future projects. We do not believe anyone supports or believes this. Another serious outcome is that NRCS will lose its planning expertise, which is invaluable.

We request this program be funded at a level of \$35 million.

We request that the following two studies be specifically identified and funded in the fiscal year 2008 appropriation bill.

—*Maniece Bayou Irrigation Project, AR.*—This is a project in its initial stage of planning. An irrigation district is being formed to be the local sponsor. This project transfers water from the Red River into Maniece Bayou where landowners would draw water for supplemental irrigation. We request that \$200,000 be appropriated to initiate the plans and specifications.

—*Lower Cane River Irrigation Project, LA.*—The transfer of water from the Red River to the Lower Cane River will provide opportunities for irrigation and economic development. Funds are needed to initiate a Cooperative River Basin Study. We request that \$250,000 be appropriated for this study.

Resource Conservation and Development (RC&D).—This has traditionally been a well-received program by the Administration, not this year. Their budget proposal only had \$14.6 million, far short of national needs. This program leverages its resources at 4 to 1, with communities, local sponsors and non-government organizations. The benefits are realized at over 14 to 1, average per project. This drastic cut is proposed by eliminating 325 of 375 coordinator positions. The remaining 50 positions are supposed to serve all councils in all the 50 States.

We request that \$56 million be appropriated for this program, at the same level as in fiscal year 2006.

Mandatory Accounts (CCC) Technical Assistance (TA).—Request for assistance through the CCC programs has been overwhelming. Requests far exceed the available funds and place an additional workload on NRCS's delivery system. Adequate funding for TA must be provided at the full cost for program delivery. This includes program administration, conservation planning and contracting with each applicant. Congress, in the 2002 Farm Bill, wisely increased conservation programs each year. This increased investment, will increase the NRCS workload. It is imperative that NRCS receive the TA funding levels required to administer these programs. If they do not receive full funding these programs will not realize their full capability.

It has been mandated that a set percent of TA, from the CCC Program, must be used for TSPs, approximately \$40 million. This is equivalent to losing 600 staff years from NRCS manpower. This is another unacceptable policy, which will reduce the effectiveness of NRCS. This mandate must be eliminated.

Over 70 percent of our land is privately owned. This is important in order to understand the need for NRCS programs and technical assistance. Their presence is vital to ensuring sound technical standards are met in conservation. These programs not only address agricultural production, but sound natural resource management. Without these programs and NRCS properly staffed to implement them, many private landowners will not be served adequately to apply conservation measures needed to sustain our natural resources for future generations. Technical Assistance cannot be contracted out to private companies.

We are all aware of the issue with TMDL levels in our waterways. If our Nation is to seriously address this we must look at the impacts from our farmlands. Assistance for land treatment plans and plan implementation is exactly what the NRCS Watershed programs are intended to address. Watershed programs should be receiving an increase in funds, not zeroed out!

With these new clean water initiatives why do we ignore the agency that has a proven record for implementing watershed conservation programs? Congress must decide; will NRCS continue to provide the leadership within our communities to build upon the partnerships already established? It is up to Congress to insure NRCS is properly funded and staffed to provide the needed assistance to our taxpayers for conservation programs.

These NRCS studies and watershed projects are an example of true "cooperative conservation" initiatives. There is an interface with communities and local sponsors at each step of the process and local sponsors do cost share at the levels expected of them.

All these programs apply to the citizens in the Red River Valley and their future is our concern. The RRVA is dedicated to work toward the programs that will benefit our citizens and provide for high quality of life standards. We therefore request that you appropriate the requested funding within these individual programs, to insure our Nation's conservation needs are met.

I thank you for the opportunity to present this testimony on behalf of the members of the Red River Valley Association and we pledge our support to assist you in the appropriation process. Please direct your comments and questions to our Executive Director, Richard Brontoli, P.O. Box 709, Shreveport, LA 71162, (318) 221-5233, E-mail: redriverva@hotmail.com.

Grant Disclosure.—The Red River Valley Association has not received any Federal grant, sub-grant or contract during the current fiscal year or either of the 2 previous fiscal years.

ENCLOSURE 1.—RED RIVER VALLEY ASSOCIATION

The Red River Valley Association is a voluntary group of citizens bonded together to advance the economic development and future well being of the citizens of the four State Red River Basin area in Arkansas, Louisiana, Oklahoma and Texas.

For the past 80 years, the Association has done notable work in the support and advancement of programs to develop the land and water resources of the Valley to the beneficial use of all the people. To this end, the Red River Valley Association offers its full support and assistance to the various Port Authorities, Chambers of Commerce, Economic Development Districts, Municipalities and other local governmental entities in developing the area along the Red River.

The Resolutions contained herein were adopted by the Association during its 82nd Annual Meeting in Shreveport, Louisiana on February 22, 2007, and represent the combined concerns of the citizens of the Red River Basin area as they pertain to the goals of the Association, specifically:

- Economic and Community Development
- Environmental Restoration
- Flood Control
- Irrigation
- Bank Stabilization
- A Clean Water Supply for Municipal, Industrial and Agricultural Uses
- Hydroelectric Power Generation
- Recreation
- Navigation

The Red River Valley Association is aware of the constraints on the Federal budget, and has kept those constraints in mind as these Resolutions were adopted. Therefore, and because of the far-reaching regional and national benefits addressed by the various projects covered in the Resolutions, we urge the members of Congress to review the materials contained herein and give serious consideration to funding the projects at the levels requested. We can be contacted at (318) 221-5233 or redriverva@hotmail.com.

ENCLOSURE 2

RED RIVER VALLEY ASSOCIATION FISCAL YEAR 2008 APPROPRIATIONS—NATURAL RESOURCES CONSERVATION SERVICE (NRCS)

[In thousands of dollars]

Discretionary Accounts	Fiscal year 2006 Approp	Fiscal year 2007 Approp	Pres. 2008 Budget	RRVA 2008 Request
Conservation Operations	839,519	759,124	689,000	930,000
Watershed & Flood Prevention Operations	75,000	190,000
Walnut Bayou Irrigation Project, AR	4,000
Red Bayou Irrigation Project, LA	1,600
Watershed Rehabilitation	31,516	31,516	6,000	75,000
Watershed Survey & Planning	6,083	35,000
Maniece Bayou Irrigation Project, AR	200
North Wallace Lake Watershed, LA	250
Resource Conservation & Development(RC&D)	51,300	50,700	14,600	56,000

NOTE: The President's fiscal year 2008 budget is 16 percent less than Congress appropriated in fiscal year 2007.

PREPARED STATEMENT OF THE SOCIETY FOR ANIMAL PROTECTIVE LEGISLATION

\$1.8 Million Line Item for the Animal Welfare Information Center at the National Agricultural Library

The Animal Welfare Information Center (AWIC) was established by the Improved Standards for Laboratory Animals Act (the 1985 amendment to the Animal Welfare Act) to serve as a clearing-house, training center, and educational resource for institutions using animals in research, testing and teaching. The Center is the single most important resource for helping personnel at more than 1,200, U.S. research facilities meet their responsibilities under the AWA. Supported by a modest funding level, its services are available to all individuals at these institutions, including cage washers, animal technicians, research investigators, attending veterinarians, IACUC representatives and the Institutional Official.

AWIC provides data on alleviating or reducing pain and distress in experimental animals (including anesthetic and analgesic procedures), reducing the number of

animals used for research where possible, identifying alternatives to the use of animals for specific research projects, and preventing the unintended duplication of animal experiments. The Center collects, updates, and disseminates material on humane housing and husbandry, the functions and responsibilities of Institutional Animal Care and Use Committees (IACUCs), animal behavior, improved methodologies, psychological well-being of primates, and exercise for dogs.

There is general consensus between the biomedical research industry (including the National Association for Biomedical Research) and the animal welfare community about the need for increased funding. A number of individuals representing these disparate interests have endorsed the request for \$1.8 million in funding for AWIC. The AWIC helps to improve the conduct of research, including the care provided to the animals who are used, thereby ensuring a reduction in variables that might skew the research. Better science is the end result.

The AWIC website (<http://www.nal.usda.gov/awic>) is one of the most accessed sites at the NAL, receiving millions of hits each year. It provides valuable information on issues of importance not only to the science community but also to the agriculture and public health communities, including BSE and avian influenza, two of the top areas of inquiry for visitors to its website. In fiscal year 2006, nearly 440 million kbytes of information were distributed via the web, and more than 77,000 hard copies were distributed as well. AWIC staff provided over 3,000 personal reference services. Exhibitions and/or presentations have been conducted at such venues as the American Association for Laboratory Animal Science (AALAS) annual meeting, Society of Neuroscience, New Jersey Association for Biomedical Research, American Veterinary Medical Association, International Conference on Environmental Enrichment, American Association for the Advancement of Science and the 5th World Congress on the Use of Animals in the Life Sciences, Scientists Center for Animal Welfare meetings, and the Public Responsibility in Medicine and Research annual meeting.

We greatly appreciate Congress' past support for AWIC to carry out its programs. Given its indispensability not only in assisting with compliance with the AWA but also in providing up-to-date information on a range of issues, from BSE to primate enrichment, that are critical to the scientific and agricultural communities, we recommend that AWIC be listed as a separate line item. We urge Congress to resist any effort by ARS to eliminate AWIC; rather, it is essential to maintain a minimum base of \$1.15 million. Moreover, we respectfully request an additional \$650,000 in fiscal year 2008 for desperately needed expansion to meet growing demand for AWIC's expertise on two fronts.

First, as evidenced by the findings of an Office of Inspector General (OIG) audit, "APHIS Animal Care Program Inspection and Enforcement Activities," there has been an increase in apparent violations of the AWA by research facilities over the past few years. There appears to be a significant problem with the oversight of IACUCs and the audit recommends training for IACUC members. In response to this need, we are requesting funds to allow AWIC to do the following:

- Continue to conduct workshops at locations around the country rather than being limited to conducting them only from the Center's base in Maryland.
- Hold a symposium on AWA requirements for IACUC nonaffiliated members (i.e., members from the community charged with representing the communities' concerns for the animals).
- Work with Animal Care more closely to identify and assist those licensees and registrants that are cited for AWA violations most frequently.

Second, increased funding is also necessitated by the expansion of AWIC's mandate to include the broader industry regulated under the Animal Welfare Act: animal dealers, carriers and handlers, zoos and other exhibitors. Other topics covered by the Center include animal diseases, animal models, animal training, and environmental enrichment for all species. Animal Care's veterinary medical officers and animal care inspectors are able to utilize the full range of services provided by the AWIC to better fulfill their responsibilities. The AWIC also works closely with both Animal Care and with Emergency Veterinary Services on emerging crises such as the highly pathogenic Avian Influenza. The Center is focused on transmissible spongiform encephalopathy, exotic Avian Newcastle disease, tuberculosis, West Nile Virus and microbacterial diseases.

The \$1.8 million would be used as follows: Staff salary and benefits (\$1,273,000), including the addition of two much-needed positions: a Technical Information Specialist and an Information Technology Specialist, whose jobs would be to expand the content of the Center's database and make it more user-friendly and searchable; exhibitions at major scientific conferences, including underserved areas of the country (\$61,400); workshops, in conjunction with Animal Care, to assist licensees and registrants frequently cited for AWA violations (\$36,000); informational workshops at

research institutions across the country (\$28,000) and locally at the Center (\$4,100); printing and reproduction of paper and electronic material (\$29,200); training for the NAL staff (\$13,900); acquisition of, including electronic access to, data (\$38,000); internet services (\$20,400); office supplies, including hardware and software (\$26,000); and the overhead that must be provided to the Agricultural Research Service and the National Agricultural Library (at least \$270,000).

\$750,000, Plus a One-Time Infusion of \$1 Million, for APHIS/Animal Care's Enforcement of the Horse Protection Act

More than 30 years ago Congress adopted the Horse Protection Act, yet soring of Tennessee Walking Horses continues to be a widespread problem. Soring is defined by APHIS as "the application of any chemical or mechanical agent used on any limb of a horse or any practice inflicted upon the horse that can be expected to cause it physical pain or distress when moving." Horses are sored to produce an exaggerated gait. (<http://www.saplonline.org/pdf/EquusSoring.pdf>)

The most effective method to reduce the showing of sored horses is to have Animal Care (AC) inspectors present at the shows. Oftentimes, as soon as an AC inspector arrives at a show, there is a rush to put horses back into trailers and haul them away. If the likelihood that an AC inspector will show up increases significantly, this will have a huge deterrent effect on those who routinely sore their horses.

AC was able to attend only 32 events in fiscal year 2004 out of a total of approximately 865 shows. Funding of \$750,000 (\$500,000 plus a \$250,000 add-on) is needed to enable AC to attend even a modest number of events.

Unfortunately, the amount of penalties assessed for violations of the law has dropped to a negligible amount. In addition to increasing the presence of inspectors, USDA must increase the penalties that it assesses or the industry will continue to defy the law with impunity. Congress should direct USDA to take this step.

Lack of financial support has made it necessary for Animal Care to rely heavily on the industry to assume responsibility for enforcement of the law. This is the same industry that has turned a blind eye to compliance with the law since 1970! "Designated Qualified Persons" (DQPs) are the "inspectors" from industry who are supposed to assist AC in identifying sore horses and pursuing action against the individuals who are responsible. The history of the DQPs reveals their failure to achieve the level of enforcement of the unbiased, well-trained, professional inspectors who work for AC, as illustrated by radically different enforcement rates: In 2004 and 2005, the rate of violations cited at a variety of horse shows was as much as 23 times higher under USDA inspections versus HIO inspections. Oftentimes, owners withdraw their horses completely from a show rather than risk an inspection by USDA.

We have few current figures on enforcement; however, we recently learned from USDA that in 2005, of the samples taken by a gas chromatography machine (used to test for use of illegal substances to sore horses) at the Kentucky Celebration horse show, 100 percent indicated the presence of diesel fuel or another similar fuel plus numbing agents. Clearly the law is not being taken seriously by the industry. In September 2006, having ignored repeated warnings from USDA that too many horses were showing signs of soring, organizers canceled the Shelbyville (TN) Celebration, the prestige event in the walking horse industry, after USDA inspectors disqualified most of the horses because of soring. This was an unprecedented action on the part of the industry and is a testament to USDA's commitment to vigorous enforcement of the HPA, even in the face of threats to its inspectors.

An appropriation of at least \$750,000 is essential to permit AC to maintain a modest level of compliance with the Horse Protection Act by trained AC professionals. USDA also needs a one-time allocation of \$1 million to purchase additional equipment, such as digital radiography machines to take radiographs of the hoof to detect changes indicative of pressure-shoeing; and algometers, which apply consistent pressure during the examination process. Adding these machines to the inspectors' tools for verifying the use of soring techniques further enhances the objectivity and consistency of the evidence obtained.

\$21.126 Million for APHIS/Animal Care's Enforcement of the Animal Welfare Act

The Animal Welfare Act (AWA) is the chief Federal law for the protection of animals. The USDA seeks compliance with its minimum standards for the care and treatment of animals during transportation and at the nearly 13,000 sites of dealers, research, testing and teaching facilities, zoos, aquariums, circuses, carriers (airlines, motor freight lines and other shipping businesses) and handlers (ground freight handlers). There are a mere 101 Veterinary Medical Officers (VMOs) and

Animal Care Inspectors (ACIs) conducting searches, preclicensing inspections and enforcement inspections across the country.

In fiscal year 2005, IES resolved 169 cases involving violations of the AWA; in fiscal year 2006, 191 cases were resolved through stipulations or ALJ decisions. These enforcement actions help ensure the protection of both animals and people as evidenced by the OIG Audit.

We support the President's request for \$21.126 million for enforcement of the AWA. We hope the additional funds will permit USDA to hire additional inspectors and to conduct a national meeting, with all inspectors in attendance. A national meeting is indispensable to providing proper training of inspectors and ensuring that field inspectors nationwide apply a high and equal standard of enforcement. The cost for a national meeting is expected to be \$150,000.

We also support the President's budget request for funds under the emergency management systems line item, which will enable Animal Care to execute its new responsibilities for pet evacuation during disasters. However, an additional \$1 million is needed (for a total of \$2 million) to ensure that AC does not have to meet these new obligations at the expense of ongoing services.

Strengthened Enforcement of Humane Slaughter Act by FSIS

When President Eisenhower signed the Humane Methods of Slaughter Act (HMSA) into law, he noted that if he went by his mail he would think Americans were interested in no other issue. That concern is as strong today as it was then. Over the past few years, Congress has generously provided additional appropriations to the Food Safety and Inspection Service (FSIS) to improve enforcement of the HMSA; nonetheless, problems persist. A big part of the problem is that the vast majority of animals currently slaughtered at the approximately 900 federally inspected plants are already dead by the time FSIS observes them.

In addition, FSIS inspectors are discouraged from enforcing the law. Inspectors are supposed to be able to stop the slaughter line if violations are seen. However, stopping the line will markedly reduce the plant's profits, so there is intense pressure for the inspector not to take action. The situation at plants appears to be cozy for people; meanwhile, animals are suffering. For example, the Office of the Inspector General conducted an investigation of a large plant in Iowa, issuing a report on April 25, 2005, that concluded that—employees of AGRI had engaged in acts of inhumane slaughter. It was also determined that FSIS employees observed the acts of inhumane slaughter and did nothing to stop the practice. Additionally, the investigation revealed that FSIS inspectors accepted meat products from AGRI employees and that FSIS employees engaged in other acts of misconduct.”

FSIS has attempted a variety of machinations in an effort to dupe Congress into believing that enforcement efforts have increased dramatically. This is mere window dressing, and inspectors in the plants have confirmed that little has changed—and abuses are rife. The situation at AGRI, described above is but one example (http://awionline.org/pubs/Quarterly/05_54_1/541p7a.htm). We vehemently oppose increased resources for FSIS because the agency hasn't demonstrated resolve to strongly enforce the law.

Bill language should direct FSIS to fill the many current vacancies in its inspector force and to re-assign and/or hire no fewer than 50 individual inspectors (as opposed to FTE's or staff years) to serve as full-time, permanent fixtures in each of the largest slaughter plants to observe the handling, stunning and slaughter of animals for compliance with the law. When inspectors are not present, line speeds are increased and the operations are conducted in a completely different (and horrific) manner. A full-time presence is the only way to ensure compliance. Congress' previous effort to achieve this goal has resulted in the hiring of more upper-level personnel who are involved in many supervisory tasks and are not present on a full-time basis in these slaughter plants. FSIS should report the results of this effort to the Committee and evaluate the effectiveness of having full-time (not full time equivalent) enforcement of the humane slaughter requirements following a year of diligence.

All inspectors who engage in HSA enforcement must receive adequate training about the law and, more importantly, must receive a strict mandate from the Secretary of Agriculture to take strong, immediate action against any violators of the HSA. This would be a modest step toward protecting the millions of animals who are killed for food from unnecessary suffering. While the Humane Activities Tracking system was intended to promote accountability regarding enforcement of the Humane Slaughter Act, and to provide data to guide the risk-based inspection system, it has failed to meet these goals. Instead it yields skewed data that actually result in needed attention being diverted from problem plants. We suggest that real progress in ensuring compliance with the HMSA rests with redirecting HAT funds

towards securing the many needed inspectors and improving training in HMSA enforcement.

Congress Needs to Provide Increased Oversight of Wildlife Services Operations and Research

Wildlife Services (WS) needs to ensure that the variety of tools it uses for management of wildlife under its purview are both effective and publicly acceptable. As improved tools are developed through research, operations must make use of this data and shift methods accordingly.

WS needs to phase out use of steel jaw leghold traps. WS' own research demonstrates the archaic nature of certain leghold traps; these should be prohibited immediately. Leghold traps slam shut with bone-crushing force on the limbs of their victims, tearing ligaments and tendons, severing toes and causing excruciating pain. These traps, opposed by the vast majority of Americans, have been condemned as "inhumane" by the American Veterinary Medical Association, American Animal Hospital Association, World Veterinary Association and National Animal Control Association.

WS should pursue no further testing of leghold traps as this would be an extremely wasteful and cruel use of taxpayer money. Previously, funds designated for trap research were merely passed through to a nongovernmental organization to utilize as it saw fit, without involvement from WS. If funds are allocated for trap testing, WS should conduct the research (on the myriad devices other than steel jaw traps) since the agency has the appropriate technical expertise.

Further, WS should adopt a policy of checking all restraining traps within a 24-hour period. WS has developed a device that can be attached to a trap, and the device emits a signal when the trap is triggered; this wonderful new technology permits trappers to focus their energies on prompt checking of those traps that have actually been triggered. A wealth of scientific studies documents the fact that the longer an animal is in a restraining trap, the greater the injury. For this reason, the majority of States have a daily trap check requirement. Animals should not be subjected to long-drawn out pain because of a failure to assume the responsibility of carefully checking traps every day. This policy will help reduce the trauma experienced by non-target animals, too, ensuring that more of these animals will be able to be released alive.

Thank you very much for the opportunity to submit testimony. We would be happy to provide any additional information that might be of interest.

PREPARED STATEMENT OF THE HUMANE SOCIETY

As the largest animal protection organization in the country, we appreciate the opportunity to provide testimony to the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Subcommittee on fiscal year 2008 funding items of great importance to The Humane Society of the United States (HSUS) and its nearly 10 million supporters nationwide.

ENFORCEMENT OF ANIMAL WELFARE LAWS

We thank you for your outstanding support during recent years for improved enforcement by the U.S. Department of Agriculture (USDA) of key animal welfare laws and we urge you to sustain this effort in fiscal year 2008. Your leadership is making a great difference in helping to protect the welfare of millions of animals across the country. As you know, better enforcement will also benefit people by helping to prevent: (1) orchestrated dogfights and cockfights that often involve illegal gambling, drug trafficking, and human violence, and can contribute to the spread of costly illnesses such as Exotic Newcastle Disease and bird flu; (2) injuries to slaughterhouse workers from animals that are still conscious; (3) the sale of unhealthy pets by commercial breeders, commonly referred to as "puppy mills"; (4) laboratory conditions that may impair the scientific integrity of animal based research; (5) risks of disease transmission from, and dangerous encounters with, wild animals in or during public exhibition; and (6) injuries and deaths of pets on commercial airline flights due to mishandling and exposure to adverse environmental conditions. In order to continue the important work made possible by the Committee's prior support, we request the following for fiscal year 2008:

APHIS/ANIMAL WELFARE ACT (AWA) ENFORCEMENT

We request that you support the President's request of \$21,126,000 for AWA enforcement under APHIS. We commend the Committee for responding in recent years to the urgent need for increased funding for the Animal Care division to improve

its inspections of more than 13,000 sites, including commercial breeding facilities, laboratories, zoos, circuses, and airlines, to ensure compliance with AWA standards. Animal Care now has 100 inspectors (with eight vacancies that the agency is in the process of filling), compared to 64 inspectors at the end of the 1990s. We are pleased that the President's budget recommends an increase of \$3,340,000 (plus allowance for pay costs) to cover hiring 21 new staff to further improve AWA enforcement in fiscal year 2008. This increase will enable the agency to handle additional responsibilities as the number of licensed/registered facilities has grown by 13 percent from fiscal year 2005 to fiscal year 2006.

APHIS /INVESTIGATIVE AND ENFORCEMENT SERVICES

We request that you support the President's request of \$12,728,000 for APHIS Investigative and Enforcement Services. We appreciate the Committee's consistent support for this division, which handles many important responsibilities including animal welfare. The President's budget recommends an increase of \$2,143,000 (plus allowance for pay costs) and 18 staff years for IES in fiscal year 2008, of which \$291,000 and 3 staff years will be used to improve enforcement of Federal animal welfare laws. In fiscal year 2006, IES resolved 191 cases through either civil penalty stipulations or Administrative Law Judge decisions (compared to 169 cases resolved during fiscal year 2005).

OFFICE OF INSPECTOR GENERAL/ANIMAL FIGHTING ENFORCEMENT

We request sustained funding of \$800,000 for the Office of Inspector General to focus on enforcement of animal fighting laws (this amount is incorporated in the President's request for OIG base funding). We appreciate the inclusion of \$800,000 in recent years for USDA's Office of Inspector General to focus on animal fighting cases. Congress first prohibited most interstate and foreign commerce of animals for fighting in 1976 and tightened loopholes in the law in 2002. Dogfighting and cockfighting are barbaric practices in which animals are drugged to heighten their aggression and forced to keep fighting even after they've suffered grievous injuries. Animal fighting is almost always associated with illegal gambling, and also often involves illegal drug trafficking and violence toward people. Dogs bred and trained to fight endanger public safety, and some dogfighters steal pets to use as bait for training their dogs. Cockfighting was linked to an outbreak of Exotic Newcastle Disease in 2002–2003 that cost taxpayers more than \$200 million to contain. It's also been linked to the death of at least nine people in Asia reportedly exposed through cockfighting activity to bird flu. Given the potential for further costly disease transmission, as well as the animal cruelty involved, we believe it would be a sound investment for the Federal Government to continue its efforts to combat illegal animal fighting activity. We also hope language can be included directing the agency to report back to the Committee on specific Federal animal fighting enforcement efforts undertaken during fiscal year 2008.

FOOD SAFETY AND INSPECTION SERVICE/HUMANE METHODS OF SLAUGHTER ACT (HMSA) ENFORCEMENT

We request sustained funding of no less than \$5,000,000 and no fewer than 63 staff years for HMSA enforcement (this amount is incorporated in the President's request for FSIS base funding) and continued funding of \$3,000,000 as provided in fiscal year 2007 to maintain the new Humane Animal Tracking system. We are grateful that Congress provided \$5 million in fiscal year 2007 to sustain at least 63 full time equivalent positions dedicated solely to inspections and enforcement related to the HMSA, plus \$4 million in fiscal year 2006 and \$3 million in fiscal year 2007 to incorporate a new tracking system to ensure compliance with this law. The HMSA is designed to ensure that livestock are treated humanely and rendered unconscious before they are killed. The effort to target funds for this purpose was undertaken following reports of lax enforcement of the HMSA and animals being skinned, dismembered, and scalded while still alive and conscious.

COOPERATIVE STATE RESEARCH, EDUCATION, AND EXTENSION SERVICE/VETERINARY STUDENT LOAN FORGIVENESS

We request \$1,000,000 to begin to fully implement the National Veterinary Medical Service Act (Public Law 108–161), specifically authorized in 2003, that received initial funding of \$500,000 in fiscal year 2006 and an additional \$500,000 in fiscal year 2007. We appreciate that Congress has begun to address the critical shortage of veterinarians practicing in rural and inner-city areas, as well as in government positions such as at FSIS and APHIS. Having adequate veterinary care is a core

animal welfare concern. A study released in June 2006 demonstrated the acute and worsening shortage of veterinarians working in rural farm animal practice, while domestic pets in both rural and urban areas are often left without necessary medical care. Veterinarians support our Nation's defense against bioterrorism (the Centers for Disease Control estimate that 80 percent of potential bioterrorism agents are zoonotic—transmitted from animals to human). They are also on the front lines addressing public health problems associated with pet overpopulation, parasites, rabies, chronic wasting disease, bovine spongiform encephalopathy ("mad cow" disease), and a host of other concerns. Veterinary school graduates face a debt burden of over \$100,000 on average, and the lowest pay of any of the medical professions, with an average starting salary of \$43,000. For those who choose employment in underserved rural or inner-city areas or public health practice, the National Veterinary Medical Service Act authorizes the Secretary of Agriculture to forgive student debt. It also authorizes financial assistance for those who provide services during Federal emergency situations such as disease outbreaks or disasters. We hope you will build on the initial funding provided last year to expand this needed program under CSREES or such other account as the Committee deems appropriate.

APHIS/EMERGENCY MANAGEMENT SYSTEMS/DISASTER PLANNING FOR ANIMALS

We request that you support the President's request of \$1 million for Animal Care under APHIS' Emergency Management Systems line item. Hurricanes Katrina and Rita demonstrated that many people refuse to evacuate if they are forced to leave their pets behind. The Animal Care division has been asked to develop an infrastructure to help prepare for and respond to animal issues in a disaster and incorporate lessons learned from previous disasters. These funds will be used for staff time and resources to support State and local governments' and humane organizations' efforts to plan for protection of people with animals. The additional resources will enable the agency to participate, in partnership with FEMA, in the newly revised National Response Plan without jeopardizing other Animal Care programs.

APHIS/HORSE PROTECTION ACT ENFORCEMENT

We hope you will provide \$750,000 (an add-on of \$254,000 above the amount requested by the President for fiscal year 2008) plus a one-time appropriation of \$1 million for specialized equipment, and we urge the Committee to oppose any effort to restrict USDA from enforcing this law to the maximum extent possible. Congress enacted the Horse Protection Act in 1970 to end the obvious cruelty of physically soring the feet and legs of show horses. In an effort to exaggerate the high-stepping gait of Tennessee Walking Horses, unscrupulous trainers use a variety of methods to inflict pain on sensitive areas of the feet and legs for the effect of the leg-jerk reaction that is popular among many in the show-horse industry. This cruel practice continues unabated by the well-intentioned but seriously understaffed APHIS inspection program. The most effective way to meet the goal of the Horse Protection Act—to reduce the showing of sore horses—is to have Animal Care inspectors present at the shows. Owners who sore their horses go to great lengths to avoid detection, including leaving a show when USDA inspectors show up. The greater the likelihood of a USDA inspection, the greater the deterrent effect on those who routinely sore their horses. Unfortunately, Animal Care is able to attend fewer than 10 of the 500-plus shows held annually. Funding of \$750,000 is needed to maintain a modest level of compliance with the Horse Protection Act by trained Animal Care professionals. Moreover, a one-time infusion of \$1 million is needed to enable Animal Care to buy specialized equipment, such as digital radiography machines, that would enhance the ability of USDA inspectors to detect evidence of soring.

DOWNED ANIMALS AND BSE

We are pleased that the Bush Administration proposed an interim final rule in January 2004 to ban the use of downed cattle for human food, in the wake of the discovery of a cow in Washington State that was infected with Bovine Spongiform Encephalopathy (BSE). We hope the Committee will codify this ban—and extend it to other livestock besides cattle. While transmission of BSE from infected cows to people is most well understood, there is some science indicating that pigs may also harbor a form of this disease and downer pigs and other downer livestock are at a significantly higher risk of transmitting other serious and sometimes fatal illnesses through their meat, such as *E. coli* and *Salmonella*. Moreover, these animals suffer just as downed cattle do when they are moved en route to slaughter.

As the Committee is aware, some segments of industry and members of Congress have recommended weakening the USDA downed cattle ban. They claim that animals unable to walk because of injury pose no health risk. But injury and illness

are often interrelated—an animal may stumble and break a leg because of disease that causes weakness and disorientation. And USDA inspectors would have a difficult—if not impossible—task trying to sort out the reason an animal became non-ambulatory. Major consumer groups including Consumers Union and Consumer Federation of America, support groups for victims of food-borne illness such as Safe Tables Our Priority (S.T.O.P.), Creutzfeldt-Jakob Disease Foundation, and CJD Voice, food safety organizations, companies such as McDonald's and Wendy's, and many others have all pointed out how reckless such a system would be. Of the BSE cases identified in Canada and the United States to date, 10 out of 11 have involved downers, and at least 3 of these were identified as downed due to injuries, including the Washington State case ("calving injuries") and a January 2005 case in Canada ("slipped on ice/broken leg"). The sole BSE-positive animal not identified as a downer was a Canadian cow exhibiting "abnormal locomotion and posture" who was euthanized in January 2006.

From an animal welfare perspective, a comprehensive ban is needed because a downed animal with a broken leg would suffer just as much as a sick one if it's dragged through a slaughterplant—maybe even more. A ban on use of all downers for human food also provides an incentive for producers to treat animals humanely and prevent livestock from going down. Even before the administrative ban, USDA estimated that only 0.4 percent to 0.8 percent of all cows processed annually were non-ambulatory. The downer ban encourages producers and transporters to engage in responsible husbandry and handling practices, so that this percentage may be reduced to levels approaching zero. Temple Grandin—advisor to the American Meat Institute and others in the meat industry—has noted that as many as ninety percent of all downers are preventable. Cases that involve broken bones and other injuries are perhaps the most preventable with improved husbandry.

Most Americans had no idea that animals too sick or injured to walk were being dragged with chains or hauled by bulldozer en route to the food supply. When that fact came to light in December 2003, USDA's prompt decision to ban all downer cattle from human food calmed consumers. Unraveling the ban would undermine consumer confidence. More than 99 percent of the 22,000+ public comments USDA received on its downer ban called on the agency to maintain and strengthen its downer ban, with most asking that other species be included. For a report on the comments received by the agency, please go to: http://files.hsus.org/web-files/PDF/2004_06_16_rept_USDA_comments.pdf.

USDA testimony before various congressional committees has made clear that the agency need not rely on slaughterplant testing of downers for BSE surveillance purposes. Surveillance of downers can and should be conducted at rendering plants and on farms.

In addition to the downer issue, we urge the Committee to provide adequate funding to ensure meaningful enforcement by the Food and Drug Administration of its "feed ban," designed to prevent BSE-contaminated animal products from being fed to other animals. We are concerned that inspectors visit facilities infrequently and rely on self-reporting by those facilities and paperwork checking rather than first-hand evaluation of feed content and dedicated production lines. We are also concerned that FDA relies a great deal on State agencies to conduct this oversight, when most States face severe budget constraints that may compromise their ability to handle this job. Preventing the spread of BSE is vital to the Nation as a whole, for public health, the agricultural industry, and animal welfare. Vigorous enforcement of the feed ban is an essential component of this effort. We hope adequate Federal funds will be provided in fiscal year 2008 to meet this challenge.

ANIMAL WELFARE INFORMATION CENTER (AWIC)

AWIC was established by the 1985 amendment to the Animal Welfare Act (the Improved Standards for Laboratory Animals Act) to serve as a clearinghouse, training center, and educational resource for institutions using animals in research, testing and teaching. This Center is the single most important resource for helping personnel at more than 1,200 U.S. research facilities meet their responsibilities under the AWA. Supported by a modest funding level, its services are available to all individuals at these institutions, from cage washers to Institutional Animal Care and Use Committee (IACUC) representatives and the Institutional Official. Given its indispensability not only in assisting with compliance with the AWA but also in providing up-to-date information on issues ranging from BSE to primate enrichment that are critical to the scientific and agricultural communities, we recommend that AWIC be listed as a separate line item. We urge Congress to resist any effort by ARS to eliminate AWIC; rather, it is essential to maintain a minimum base of \$1.15 million. Moreover, we respectfully request an additional \$650,000 (for a total of \$1.8

million) in fiscal year 2008 for critically needed expansion and other improvements to meet growing demand for AWIC's expertise.

Again, we appreciate the opportunity to share our views and priorities for the Agriculture, Rural Development, FDA, and Related Agencies Appropriation Act of Fiscal Year 2008. We appreciate the Committee's past support, and hope you will be able to accommodate these modest requests to address some very pressing problems affecting millions of animals in the United States. Thank you for your consideration.

PREPARED STATEMENT OF THE WILDLIFE SOCIETY

The Wildlife Society appreciates the opportunity to submit testimony concerning the fiscal year 2008 budgets for the Natural Resources Conservation Service (NRCS), Animal Plant Health Inspection Service (APHIS), and Cooperative State Research, Education and Extension Services (CSREES). The Wildlife Society represents over 7,500 professional wildlife biologists and managers dedicated to sound wildlife stewardship through science and education. The Wildlife Society is committed to strengthening all Federal programs that benefit wildlife and their habitats on agricultural and other private land.

Natural Resources Conservation Service

The Wildlife Habitat Incentives Program (WHIP) is a voluntary program that provides technical and financial support to farmers and ranchers to create high quality wildlife habitat. Since 1998, nearly \$150 million has been dedicated to the program and over 2.8 million acres involving over 18,000 contracts have been enrolled. The Wildlife Society recommends funding WHIP at \$100 million in fiscal year 2008 so that the program can continue to provide for fish and wildlife benefits.

The Wetland Reserve Program (WRP) is a valuable program designed to assist farmers and ranchers in protecting and restoring wetland habitat. The Wildlife Society supports the President's enrollment target of 250,000 acres in fiscal year 2008. Full WRP enrollment is needed if the Administration intends to achieve the President's stated goal of no-net-loss of wetlands.

Animal and Plant Health Inspection Service

Wildlife Services (WS), a unit of APHIS, is responsible for controlling wildlife damage to agriculture, aquaculture, forest, range, and other natural resources, for controlling wildlife-borne diseases, and for controlling wildlife at airports. Its activities are based on the principles of wildlife management and integrated damage management, and are carried out cooperatively with State fish and wildlife agencies. The Wildlife Society is concerned by the Administration's proposal to decrease funding in key activity areas for WS. The President's fiscal year 2008 proposed budget includes increases for wildlife monitoring and surveillance (\$5.016 million) and the oral rabies vaccination program (\$2 million), but proposes an overall decrease of \$1.684 million in the WS Operations line item, requiring a redirection of \$8.7 million. While we are pleased that these activities have gained presidential support, the net decrease to the WS operational budget will effectively result in an overall reduction in key activity areas. The Wildlife Society strongly recommends that Congress restore the proposed decrease of \$1.684 million.

We understand the importance of safeguarding our Nation against highly pathogenic avian influenza and applaud the added fiscal resources to address this critical issue. The President's fiscal year 2008 budget proposal redirects \$3.2 million for avian influenza research. The Wildlife Society recommends that Congress provide additional money to adequately fund this and other important and associated research. Redirection of funds for this program would have serious and, in many cases, terminal effects on important existing projects, including the Jack Berryman Institute for Wildlife Damage Management at Utah and Mississippi State Universities; the Logan, Utah Predator Research Station; the newly-established Texas A&M University-Kingsville Research Field Station; and the Starkville, Mississippi Research Field Station.

The Wildlife Society is very concerned about the proposed \$1.39 million reduction in the Brucellosis Program budget. Because of its presence in wild elk and bison, brucellosis in the Greater Yellowstone Area will be especially difficult to eliminate and will require more, not less, fiscal resources to accomplish. We recommend Congress restore brucellosis funding to \$11 million in fiscal year 2008 and that USDA-APHIS-Veterinary Services continue to utilize the authorities and expertise of the Greater Yellowstone Interagency Brucellosis Committee to address domestic livestock interactions with wild elk and bison in the region.

The Wildlife Society commends APHIS-Veterinary Services for providing funding to State wildlife management agencies for Chronic Wasting Disease (CWD) surveil-

lance and management in free-ranging deer and elk. Additionally, The Wildlife Society strongly supports APHIS' efforts to eliminate CWD from captive cervids in order to eliminate the risk of spread of the disease from these animals to free-ranging deer and elk. The surveillance and monitoring efforts conducted by all 50 States during 2004 and 2005 would not have been possible without this cooperative funding. Additionally, knowledge of the presence and prevalence of CWD has been enhanced by this program. Without continued funding, States will be unable to maintain the level of CWD surveillance necessary to track the disease. The Wildlife Society recommends restoring the \$6.3 million decrease to return funding to fiscal year 2007 levels.

Cooperative State Research, Education, and Extension Service

The Renewable Resources Extension Act (RREA) provides an expanded, comprehensive extension program for forest and rangeland renewable resources. The RREA funds, which are apportioned to State Extension Services, effectively leverage cooperative partnerships at an average of four to one, with a focus on private landowners. The need for RREA educational programs is greater today than ever because of continuing fragmentation of ownership, urbanization, the diversity of landowners needing assistance and increasing societal concerns about land use and the impact on natural resources including soil, water, air, wildlife and other environmental factors. The Wildlife Society recommends that the Renewable Resources Extension Act be funded at \$30 million, as authorized in the 2002 Farm Bill.

The proposed budget for fiscal year 2008 reflects a slight decrease for the McIntire-Stennis Cooperative Forestry program. The proposal would modify the McIntire-Stennis formula program by creating a multi-State research program supported by about 62 percent of the total funding. All McIntire-Stennis multi-State funds will be distributed through competitively awarded grants in 2008. This represents a significant departure from prior years. These funds are essential to the future of resource management on non-industrial private forestlands, as forest products are produced while conserving natural resources, including fish and wildlife. As demand for forest products grow, private-land forests will increasingly be needed to supplement supplies, but trees suitable for harvest take decades to produce (versus the single year in which crops such as corn and soybeans can be harvested). In the absence of long-term and on-going research, such as provided through McIntire-Stennis, the Nation could easily become ill-suited to meet future forest-product needs. Replacement of McIntire-Stennis funding with competitive grants will leave long-term and stable forest research to chance. The Wildlife Society strongly believes that the reasons for continuing the McIntire-Stennis Cooperative Forestry program into the future are compelling and urges Congress to increase the fiscal year 2008 budget to \$25 million, an amount more consistent with historic levels.

National Research Initiative (NRI) Competitive Grants are open to academic institutions, Federal agencies, and private organizations to fund research on improving agricultural practices, particularly production systems that are sustainable both environmentally and economically, and to develop methods for protecting natural resources and wildlife. Innovative grant programs such as NRI help broaden approaches to land management, such as integrating timber and wildlife management on private lands. The Wildlife Society supports the Administration's request of \$256.5 million for National Research Initiative Competitive Grants. Included within that total, however, is approximately \$36 million for programs authorized under Section 406 of the Research, Extension and Education Act of 1998 and previously funded under the "Integrated Activities" line in the CSREES budget. While The Wildlife Society does not oppose this consolidation, Congress should ensure that sufficient funding is available to support all of these efforts at no less than their fiscal year 2007 levels.

Thank you for considering the views of wildlife professionals. We look forward to working with you and your staff to ensure adequate funding for wildlife conservation.

PREPARED STATEMENT OF THE UNITED STATES TELECOM ASSOCIATION

SUMMARY OF REQUEST

Project Involved

Telecommunications Loan and Grant Programs Administered by the Rural Utilities Service of the U.S. Department of Agriculture.

Actions Proposed

Supporting RUS loan levels and the associated funding subsidy, as required, for the 5 percent direct loan program (\$145 million) and cost of money program (\$250 million) in fiscal year 2008 in the amounts requested in the President's budget.

Supporting Section 306 guaranteed loans in the amount (\$295 million) requested in the President's budget.

Opposing the budget request that would cut direct loans for broadband facilities and internet service access by 40 percent from the fiscal year 2006 enacted level of \$500 million.

Supporting renewal of the pilot broadband grant program and an allocation of a portion of the authorized levels for broadband loans at reduced interest rates to accelerate deployment of this technology in rural areas.

Continuation of the general provision contained in previous appropriations acts that would prohibit RUS from drafting or implementing any regulation or rule requiring recertification of rural status for telephone borrowers.

Supporting the continued elimination of the 7 percent cap on cost of money loans Supporting continued funding, as requested in the President's budget, in the amount of \$25 million for telemedicine and distance learning grants in rural areas.

Seeking language strengthening and improving the operation of the broadband loan program in the Committee Report accompanying the bill.

Supporting provision of sufficient funds for staff, including legal staff, to properly administer the telecommunications and broadband programs.

I am Walter B. McCormick, Jr., President and CEO of the United States Telecom Association (USTelecom). I submit this testimony in the interests of the members of USTelecom and the customers they serve. USTelecom represents innovative companies ranging from the smallest rural telecoms in the Nation to some of the largest corporations in the U.S. economy. Our member companies offer a wide range of services across the communications landscape, including voice, video and data over local exchange, long distance, Internet and cable networks.

USTelecom members firmly believe that the targeted assistance offered by a strong RUS telecommunications loan and grant program remains essential to a healthy and growing rural telecommunications industry that contributes to the provision of universal telecom service. We appreciate the strong support this Committee has provided for the RUS telecom program since its inception in 1949 and look forward to a vigorous program for the future.

Rural Areas Need Access to Broadband Service

Access to a reliable source of capital such as the RUS loan programs is key to the system upgrades which will enable rural areas to experience the economic growth and job creation that a freely competitive market with ready access to fairly priced capital can provide.

It is critically important that rural areas be included in the nationwide drive for greater bandwidth capacity. In order to provide higher speed data services, such as Digital Subscriber Line (DSL) or even fiber optic connections to the Internet, outside plant must be modernized and switching must be migrated to new platforms. These investments may not be justified by market conditions in low density high cost rural areas, so the RUS program provides important financial incentives for additional investment which encourages rural telecommunications companies to build facilities which allow advanced services, including distance learning and telemedicine, to be provided. The externalities measured in terms of economic development and human development more than justify this investment in the future by the federal government.

Greater bandwidth and packet switching capabilities are crucial infrastructure elements which will allow rural businesses, schools and health care facilities to take advantage of the other programs available to them as end users. The money spent on having the most modern and sophisticated equipment available at the premises of businesses, schools or clinics is wasted if the local telecommunications company cannot afford to build facilities that quickly transport and switch the large amounts of voice, video and data that these entities generate. RUS funding enhances the synergies among the FCC and RUS programs targeted at improving rural education and health care through telecommunications.

RUS endures because it is a brilliantly conceived public-private partnership in which the borrowers are the conduits for the federal government benefits that flow to rural telephone customers, the true beneficiaries of the RUS program. The government's contribution is leveraged by the equity, technical expertise and dedication of local telecom companies. The small amount of government capital involved is more than paid back through a historically perfect repayment record by telecom borrowers, as well as the additional tax revenues generated by the jobs and economic

development resulting from the provision and upgrading of telecommunications infrastructure. RUS is the ideal government program—it provides incentives where the market does not for private companies to invest in infrastructure promoting needed rural economic development, it allows citizens to have access to services which can mean the difference between life and death, and it has never lost a nickel of taxpayer money because of a telecom carrier default.

Recommendations

For fiscal year 2008, this Committee should set the loan levels and necessary associated subsidy amounts for the 5 percent direct loan program and cost of money loan programs consistent with the levels recommended in the President's budget. The guaranteed telecommunications loan program should also be funded at the level requested in the budget.

Congress and the President have recognized the tremendous potential of broadband technology to enhance human and economic development in rural areas by establishing as a priority loans for the deployment of such technology in rural areas. USTelecom urges the provision of funding for these loans sufficient to support \$500,000,000, the same amount adopted in the 2006 appropriations act. The capital intensive nature of the telecommunications industry, particularly with respect to implementation of broadband, requires a stable and predictable source of funds. Congress should be lauded for its recognition of the importance of broadband deployment to our Nation's economy and particularly for the recognition, through support of the RUS program, of the tremendous impact broadband telecommunications can have on economic growth and development in rural America. The pilot broadband grant program, initiated by Congress in previous appropriations acts, should be renewed at a higher level and increased funding should be provided so that a portion of the authorized levels for broadband loans can be allocated to reduced interest rate loans.

Improving the Effectiveness of the RUS Broadband Program

Redirecting Broadband Program Funding to Unserved Areas.—Since the inception of the broadband program, RUS has used a substantial portion of the available funds to make loans to areas that already have broadband service. RUS justifies these loans for duplicative facilities with the contention that service in these areas is inadequate and so the areas are “underserved”, thereby permitting such duplication. For purposes of making broadband loans, RUS defines broadband service as 200 kbps. Yet when determining whether an area is underserved, RUS will make a loan to any entity which promises a faster speed than is provided by the incumbent, even if the incumbent is providing service far in excess of the 200kbps standard RUS has set for new loans. RUS should be directed to use the same standard for new broadband loans as for the determination that an area is “underserved”.

RUS also has determined that an area is underserved if the applicant seeking to provide duplicative service will offer a substantial price differential relative to the incumbent. RUS has no objective standard for determining what constitutes a “substantial price differential”. RUS should be directed to establish an objective standard through report language.

The RUS broadband program should exclusively focus on extending the reach of broadband in rural America with a goal of ubiquitous deployment. Making loans for duplicative facilities and service, when other citizens in rural America reside in areas with no service at all, is a waste of scarce government resources. To properly redirect government funds to areas unserved by broadband, Congress should clarify that loans funds not be used for duplicative facilities, and should reaffirm that the non-duplication requirements of Title II of the Rural Electrification Act are equally applicable to the Title VI broadband program. The Undersecretary for Rural Development should be required to make a legal finding that any loan for broadband will not result in a duplication of facilities. To assist the Undersecretary in making this finding, RUS broadband applications should include the identity, list of services and charges as well as the service areas of the incumbent provider. Also, to the extent that they do not conflict, Congress should reaffirm that all the provisions of Title II, such as those relating to area coverage and loan feasibility, are equally applicable to the Title VI broadband program.

Congress Should Amend the Farm Bill to Improve the Efficiency of the Broadband Program.—The statutory exclusion of companies with more than 2 percent of that Nation's access lines from the broadband program is an unfortunate policy decision that limits the effectiveness of RUS in targeting funds to unserved areas. The RUS telephone program contains no such exclusion. Rural customers, the true beneficiaries of the RUS program, should not be denied its benefits because of the identity of the carrier from which they receive service. Similarly, the statutory require-

ment that the term of broadband loans cannot exceed the expected useful life of the facilities being financed increases the size of periodic loan repayments and diminishes loan feasibility. Since RUS has a lien on all the property of the borrower, not just the new facilities, in most instances there is more than sufficient security for the loan for the broadband equipment. As long as the security of the government's loan is sufficient, the term of the loan in relation to the life of the facilities financed is irrelevant.

Congress Should Take Action to Improve the Feasibility of Loans in Unserved Areas by Renewing the Pilot Broadband Grant Program at a Higher Level and Increasing Funding to Permit Reduced Interest Rate Loans.—The RUS program is a public/private partnership. The government provides funds to fulfill a social goal and the borrowers use those funds to implement that goal in a way that makes sense for their business. Both goals are met when the revenues from the financed facilities generate sufficient revenue to repay the loan according to its terms. Providing broadband service in rural and remote areas currently unserved is a financially challenging proposition. While cost of money loans may provide a cost savings sufficient to make a project financially doable in some areas, other areas may need below cost loans or a combination of loans and grants in order to ensure feasibility. The pilot broadband grant program should be renewed at a higher level and increased funding should be provided so that a portion of the authorized levels for broadband loans can be allocated at reduced interest rates to accelerate deployment of broadband facilities in rural areas.

Elimination of the Seven Percent cap on the Interest Rate for the “Cost of Money” Program

For a number of years, through the appropriations process, Congress has eliminated the seven percent “cap” placed on the insured cost-of-money loan program. The elimination of the cap should continue. If long term Treasury interest rates exceeded the 7 percent ceiling contained in the authorizing act, the subsidy would not be adequate to support the program at the authorized level. This would be extremely disruptive and hinder the program from accomplishing its statutory goals. Accordingly, USTelecom supports continuation of the elimination of the seven percent cap on cost-of-money insured loans in fiscal year 2008.

Recommended Loan Levels

USTelecom recommends that the telephone program loan levels for fiscal year 2008 be set as follows:

Insured 5 percent Direct Loans	\$145,000,000
Insured Cost-of-Money Loans	250,000,000
Loan Guarantees	295,000,000
Broadband Telecommunications Loans	500,000,000
Total	1,190,000,000

Loans and Grants for Telemedicine and Distance Learning

USTelecom supports the continuation of \$25 million in grants for distance learning and telemedicine, as provided in the President's budget. As we move into the Information Age with the tremendous potential of the Internet to increase productivity, economic development, education and medicine, such funds can help continue the historic mission of RUS to support the extension of vital new services to rural America.

Recertification of Rural Status Would Be Disruptive and Chill Rural Telecom Investment

The Administration's budget notes that USDA will propose rule changes to require recertification of rural status for each electric and telecommunications borrower on the first loan request received in or after 2008 and on the first loan request received after each subsequent Census. Telecom construction and investment is a long term continuous process, not a project by project proposition. The uncertainty created by the possibility of decertifying a borrower as rural after it has established a relationship with RUS and begun borrowing funds for expansion and upgrading according to a long term plan would be disruptive and discourage borrowers from participating in the RUS program, thereby denying its benefits to subscribers. The “once rural always rural” practice of RUS has been extraordinarily successful at providing needed long term capital, at a careful and measured pace, to telecom carriers intent on expanding and upgrading service to promote rural economic development. Congress should deny funding in fiscal year 2008 for such a rule change.

Conclusion

Our members take pleasure and pride in reminding the Committee that the RUS telecommunications program continues its perfect record of no defaults by telecommunications carriers in over a half century of existence. RUS telecom borrowers take seriously their obligations to their government, their Nation and their subscribers. They will continue to invest in our rural communities, use government loan funds carefully and judiciously, and do their best to assure the continued affordability of telecommunications services in rural America. Our members have confidence that the Committee will continue to recognize the importance of assuring a strong and effective RUS Telecommunications and Broadband Program through authorization of sufficient funding and loan levels.

PREPARED STATEMENT OF THE UNIVERSITY OF SOUTHERN MISSISSIPPI AND THE MISSISSIPPI POLYMER INSTITUTE

Mr. Chairman, distinguished Members of the Subcommittee, I thank you for this opportunity to provide testimony describing ongoing research and commercializing efforts of The University of Southern Mississippi (USM) and the Mississippi Polymer Institute. I am very grateful to the Subcommittee for its leadership and the continued support of the Institute and its work. This testimony will include an update on the progress of the Institute since my testimony of approximately one year ago. During the past year, our efforts have focused principally on two research and commercialization areas. One effort involves our novel, agricultural-based inventions in emulsion polymerizations, and the other is to produce a commercial quality, formaldehyde-free, soybean based adhesive for composite board materials, specifically, particleboard. During the past year, we have advanced emulsion polymerization technology, and continued to refine the soy adhesive while preparing lab scale particleboards that now exceed all levels of commercial specifications for particleboard. It is my strong belief that additional research can expand the commercial use of the products and technology produced in these projects. However, more work must be accomplished to capitalize upon the variety of current and potential uses for these novel agricultural derived technology developments. I will discuss the progress for each of these research and development thrusts to provide maximum clarity.

Seven patents, patent applications, and memorandums of invention were generated in 2006. Additionally in 2006, seven manuscripts were published, seven presentations to technical societies were given, and students who have performed laboratory research have won three awards. We remain energized, active, and successful at utilizing funding to increase the value of agricultural products and co-products, and discovering viable methods for utilizing agricultural-based products as alternatives or supplements to petroleum-derived materials. The success of our technology depends upon the use of agricultural materials as the primary building blocks for emulsion-derived polymers, and thus clearly offers opportunities for using ag-derived materials as a basic feedstock in the polymer industry. The same is true for the use of soybeans as an alternative to formaldehyde, a known carcinogen.

The 2006–2007 research and development year was quite successful resulting in several pilot plant trials and planned commercial scale production for vegetable oil-based monomers and polymers. Vegetable oil macromonomers (VOMMs) have proved valuable in the synthesis of zero volatile organic content (VOC) architectural latexes, associative thickeners in coatings, as well as serving as the polymer infrastructure for Navy Haze Gray paint. The DOD is desirable of a replacement technology that excludes flammable organic solvents, contains zero VOCs, and matches or exceeds current performance requirements. We are happy to report that these requirements have been realized by use of unique agricultural-derived monomer technology invented in these laboratories. Vegetable oil-based monomers and latexes derived from this technology are being evaluated for use in adhesives, foams, wood composites, and several different coatings applications. Our VOMM synthesis techniques have been optimized to achieve greater than 90 percent conversion, producing only glycerol as a byproduct. The revised and now accepted synthetic procedure affords a useful, polymerizable VOMM without extraordinary methods or processes, thus reducing the cost of manufacture. During 2005 and 2006, our successful and novel synthetic techniques have allowed the synthesis of new emulsion polymers whose composition contains up to 70 percent VOMM by weight (based upon polymer solids). Moreover, this technology provides chemically and physically stable polymers suitable for a variety of end uses, particularly in coatings formulations. A significant advancement this year is attributed to our new level of control and understanding between monomer design and partitioning during the emulsion po-

lymerization process. The novel derivatives provide VOMMs that are more readily copolymerizable with common commercial monomers.

As an example of the potential impact of monomers and polymers derived from this technology, the following statistics are cited. In 2004, sales of low gloss water thinned paints (including tinting bases) were 181 million gallons, with a value of \$1,551 million (www.census.gov/mcd). A 1 percent share of this market within two years would amount to 1.81 million gallons of low gloss paint. A typical flat latex paint contains 1,200 g of latex per gallon. With latexes containing 20 percent soybean oil derivatives, this market share would consume 950,000 lbs of soybean oil or 89,540 bushels (up to 70 percent soy oil derivatives have already been achieved in 2005–2006). It would not be unrealistic to expect that in five years, a market share of 5 percent resulting in the annual consumption of 447,700 bushels of soybeans for high value-added monomers and high performance decorative and protective coatings. The environmental impact has potential to reduce volatile organic emissions by 3.6 million lbs per year at only 1 percent market share (data 250 g/L VOC 3.78L/gal, 1.81 million gallons and 1 percent market share).

Vernonia oil, a naturally occurring epoxidized oil, was reacted with supercritical carbon dioxide to yield carbonated vernonia oil. This derivative has much lower viscosity than its synthetic analogs and can serve as a precursor for synthesizing isocyanate-free polyurethanes. The synthesis is an attractive option for reducing global levels of carbon dioxide while utilizing mainly natural products. Additionally, vernonia oil was modified to yield a novel polyol that resulted in lower viscosity than commercial, petrochemical-based polyol at the same hydroxyl value. This polyol was the key component in the synthesis of rigid foams that meet or exceed the mechanical performance of commercial foams based on petrochemical derivatives.

A soybean oil-based VOMM was employed in the synthesis of associative thickeners for use with commercial latexes. The biobased thickener provided improved thickening efficiency when compared to commercial petrochemical-based thickeners at equal concentrations. The soybean oil-based VOMM was also used in the synthesis of a biobased ultraviolet absorber (UVA). The UVA displayed good gloss retention properties and its synthesis is being optimized to improve its effect on color retention.

Commercial nail polishes contain very high amounts of organic solvents which constitute volatile organic compounds (VOCs) and negatively impact the environment. VOMM-based latexes, without the organic solvents, were formulated into environmentally-responsible, glossy nail polishes with acceptable dry times and water resistance properties.

In summary, commercialization efforts have continued over the past year with waterborne architectural coatings, new technology to meet DOD needs for Navy Haze Gray waterborne paint, environmentally-responsible nail polish formulations, associative thickeners, and UV absorbers. Patents have been approved; new patent applications have been submitted; high performance monomers have been created and scaled-up for manufacture at toll production levels; new higher performing coatings have been designed, manufactured, formulated, and tested; and formulation efforts have been directed toward the generation of high performance, low odor, and low VOC coatings. We are optimistic that commercialization and sales of one or more of these ag-derived products will be realized in the year ahead.

In yet another of our novel ag-based technologies, we have developed formaldehyde-free adhesives for use in particleboard composites. The developmental adhesive is composed of soy protein isolate (SPI), and lab produced particleboards made with this formaldehyde-free adhesive meet or exceed industry performance requirements as defined by ANSI standards for M1, M2, M3, and M-S grade boards. Processing and board production are compatible with current equipment and methodologies. Sustained research efforts have resulted in higher adhesive solids resulting in faster line speeds. Plant trials conducted with this novel soy-derived adhesive at a commercial particleboard manufacturing plant generated boards that were consistent with boards made in our laboratories under similar processing conditions. Particleboards typically employ wood chips as the discontinuous phase. Alternate sources of wood furnish are of interest in expanding the utility of soybean protein adhesive in composite applications. We have developed biobased composites using our soybean protein-based adhesive in conjunction with alternative materials such as cork, vermiculite, kenaf, and recycled paper, while polycaprolactone, defatted soy flour, lignin, and cellulose were evaluated as additives.

In 1983, the Mississippi Legislature authorized the Mississippi Polymer Institute at USM to work closely with emerging industries and other existing polymer-related industries to assist with research, problem solving, commercializing efforts, and workforce development. The Institute has maintained that thrust during the past year with much success. In fact, while manufacturing jobs alone in Mississippi have

declined over the past 10 years, manufacturing jobs in the plastics sector have continued to increase (45 percent growth in 2004). The Institute provides industry and government with applied or focused research, development support, commercializing assistance, and workforce development. This effort complements existing strong ties with industry and government involving exchange of information and improved employment opportunities for USM graduates. Most importantly, through basic and applied research coupled with developmental and commercializing efforts of the Institute, the School of Polymers and High Performance Materials continues to address national needs of high priority.

Our research remains focused on the study and development of technology platforms that facilitate further commercialization of alternative agricultural crops for use in the polymer industry. The polymer industry maintains its position as the single largest consumer of petroleum chemical intermediates in the world. The finite supply of petroleum resources has resulted in extreme price pressures as worldwide demand continues to increase. Unfortunately, this feedstock normally generates non-biodegradable raw materials that are not carbon neutral, and therefore do not represent a sustainable alternative for economic development in the polymer industry. The theme of our work is to develop high performance, and environmentally responsible technology utilizing agricultural intermediates. In this way, we as a Nation can improve our environment, reduce our dependence on imported petroleum, and keep America's farmlands in production. As farm products meet the industrial needs of the American society, rural America is the benefactor. Heretofore, these successful efforts to utilize alternative agricultural products as an industrial feedstock continue to receive more and more attention but drastically less than these high tech innovations and opportunities warrant. Your decisions are crucial to the accomplishment of these goals as funding from this Subcommittee has enabled us to implement and maintain an active group of university-based polymer scientists whose energies are devoted to commercializing alternative crops. We are most grateful to you for this support, and ask for your continued commitment.

Polymers, which include fibers, plastics, composites, coatings, adhesives, inks, and elastomers, play a key role in the materials industry. They are used in a wide range of industries including textiles, aerospace, automotive, packaging, construction, medical prosthesis, and health care. In the aerospace and automotive applications, reduced weight and high strength make them increasingly important as fuel savers. Their non-metallic character and almost unlimited design potential support their use for many national defense purposes. Moreover, select polymers are possible substitutes for so-called strategic materials, some of which come from potentially unreliable sources.

As a polymer scientist, I am intrigued by the vast opportunities offered by American agriculture. As a professor, however, I continue to be disappointed that few of our science and business students receive training in the polymer-agricultural discipline despite its enormous potential. At USM, we are attempting to make a difference by showing others what can be accomplished if appropriate time, energy, and resources are devoted to the understanding of ag-based products. For more than 40 years, I have watched the evolution of polymers where almost each new product offered the opportunity for many more. Although polymer science as a discipline has experienced expansion and a degree of public acceptance, alternative agricultural materials in the polymer industry continue to be an underutilized national treasure. Now is the ideal time for agricultural materials to make significant inroads as environmentally-responsible, biodegradable, and renewable raw materials.

U.S. agriculture has made the transition from the farm fields to the kitchen tables, but America's industrial community continues to be frightfully slow in adopting ag-based industrial materials. The prior sentence was included in my last four testimonies but continues to ring true, even as I write this report. We are making progress and we must persist. We must aggressively pursue this opportunity and in doing so:

- Intensify United States efforts to commercialize alternative crops and dramatically reduce atmospheric VOC emissions and odor for a much cleaner and less noxious air for all Americans.
- Reduce United States reliance on imported petroleum.
- Maintain a healthy and prosperous farm economy.
- Foster new cooperative opportunities between American farmers and American industry.
- Create advanced polymer technology-based manufacturing jobs that cannot be easily exported to other countries.
- Maintain our innovative and developmental competitive edge over other less environmentally-responsible countries and less competitive economies.

Mr. Chairman, your leadership and support are deeply appreciated by the entire University of Southern Mississippi community. While I can greatly appreciate the financial restraints facing your Subcommittee, I feel confident that further support of the Mississippi Polymer Institute will continue to pay dividends by way of increasing commercialization opportunities for agricultural materials in the American industry. Advances in polymer research are crucial to food, transportation, housing, and defense industries. Our work has clearly established the value of ag products as industrial raw materials, and we must move it from the laboratories to the industrial manufacturing sector. Only then can the United States enjoy the cleaner and safer environment that these technologies offer, as well as new jobs, and expanded opportunities for the U.S. farmer. We are most grateful for the support provided by you in the past. The funding you provided has facilitated laboratory work to be conducted, manufacturing scale-up to be accomplished, and ensured sales (although limited) of products based on this technology. However, additional funds are needed to make these technologies cost effective while maintaining the high performance standards to which we are accustomed. Pilot scale processes are necessary to move this technology into the market place, and will be the principal focus of our upcoming work. Of course, while working to achieve commercialization, we are committed to continue technology advancement, as will basic research on those topic areas where knowledge is required.

Since our testimony last year, our research and development efforts have effectively shown that sustained research has expanded the viability of agricultural derivatives. Indeed, the technology is maturing, which must be followed by marketing and sales to realize full potential. Thus, we are asking for your support to advance these technologies to the market place, and to continue our development of other useful ag-derived technologies. We therefore respectfully request \$1.5 million in Federal funding to more fully exploit the potential of commercializing the technologies described herein. We have shown that we can be successful, yet we need additional resources to optimize the potential of the knowledge creation described herein. Our efforts will be recognized as instrumental in developing a "process" for the commercialization of new ag-based products. We have proven that we are successful in developing technologies from the "idea" stage to scale-up for commercialization in several market areas. Thank you, Mr. Chairman and Members of the Subcommittee, for your support and consideration.

PREPARED STATEMENT OF THE UPPER MISSISSIPPI RIVER BASIN ASSOCIATION

The Upper Mississippi River Basin Association (UMRBA) is the organization created in 1981 by the Governors of Illinois, Iowa, Minnesota, Missouri, and Wisconsin to serve as a forum for coordinating the five States' river-related programs and policies and for collaborating with Federal agencies on regional water resource issues. As such, the UMRBA has an interest in the budget for the U.S. Department of Agriculture's conservation programs and technical assistance.

Of particular importance to the UMRBA is funding for the Conservation Reserve Program (CRP), Wetlands Reserve Program (WRP), Environmental Quality Incentives Program (EQIP), and Conservation Security Program (CSP). Taken together, these four programs provide an invaluable means for the USDA to work with landowners, local conservation districts, and the States to maintain agricultural productivity while protecting the nation's soil and water resources. CRP, WRP, EQIP, and CSP are key non-regulatory elements in the States' efforts to address agricultural sources of water quality impairment through the Total Maximum Daily Load program and can help address the national concern with hypoxia in the Gulf of Mexico.

Conservation Reserve Program

The UMRBA supports President Bush's fiscal year 2008 budget request of \$2 billion for the Conservation Reserve Program, a slight increase over fiscal year 2007. Through CRP, farmers and ranchers can voluntarily establish long term conservation practices, such as filter strips and riparian buffers, on highly erodible and environmentally sensitive cropland.

In the UMRBA States (Illinois, Iowa, Minnesota, Missouri, and Wisconsin), total CRP enrollment is currently 7.1 million acres, or approximately 19 percent of the national CRP acreage. Yet the five States' CRP enrollment represents 41 percent of the total number of CRP contracts, 40 percent of the total number of farms enrolled nationwide in the CRP, and 32 percent of the total annual CRP rental payments. CRP contracts expiring in 2007 cover 2 million acres in the five UMRBA States. Preliminary data indicate that 77 percent of those expiring acres will be re-enrolled or extended.

All five UMRBA States also have active Conservation Reserve Enhancement Programs (CREP) tailored to meet their priority conservation needs. Current CREP enrollment in the five States is over 261,000 acres, or 28 percent of the national total. These rates of participation clearly demonstrate the importance of the CRP and CREP in the nation's agricultural heartland and reflect the compatibility of these programs with agricultural productivity.

Wetlands Reserve Program

The President's fiscal year 2008 budget proposes \$455 million for the Wetlands Reserve Program, an increase of 72 percent over fiscal year 2007 spending estimates. UMRBA applauds this substantial increase and the Administration's goal of enrolling 250,000 acres, bringing the total acres to WRP's authorized program cap.

WRP easements have proven to be important tools for restoring and protecting wetlands in agricultural areas. This is clearly evident from the overwhelming landowner response and the resulting improvements to water quality and habitat. From fiscal year 1992 through fiscal year 2006, NRCS has enrolled 2,680 contracts in Illinois, Iowa, Minnesota, Missouri, and Wisconsin totaling more than 352,000 acres, or 19 percent of the national total. In fiscal year 2006, \$56.3 million of WRP funding was allocated to the five Upper Mississippi River States, representing a quarter of all WRP investment that year. Yet the future viability of WRP is in question as a result of the 2006 change in the way USDA appraises property for WRP easements. The new "Yellow Book" appraisal system has resulted in lower price-per-acre offers, making enrollment in WRP less attractive for many landowners and potentially leading to enrollment of less environmentally valuable lands. UMRBA is concerned that WRP target the most ecologically valuable wetland areas and thus urges Congress and USDA to evaluate the impacts of the new WRP appraisal system and take action to maintain the program's future effectiveness.

Environmental Quality Incentives Program

In contrast to conservation programs that protect land and water resources by curtailing production on sensitive lands, the Environmental Quality Incentives Program (EQIP) supports conservation on working lands. Promoting agricultural production and environmental quality as compatible goals is particularly important in the Midwest agricultural heartland.

The President is proposing to fund EQIP at \$1.0 billion in fiscal year 2008, essentially unchanged from the fiscal year 2007 funding level. The UMRBA supports this investment, noting that EQIP is a tremendously popular conservation program in the 5 States of the Upper Mississippi River Basin. In fiscal year 2006, \$75.7 million was paid for conservation practices completed in UMR States under 1997–2006 EQIP contracts. In addition, 5700 new EQIP contracts were approved in fiscal year 2006 in the UMR States, obligating \$97 million in future financial assistance. Yet that same year, an additional 6700 applications, totaling \$125 million, were left unfunded.

Conservation Security Program

The President's fiscal year 2008 budget request of \$316 million for the Conservation Security Program (CSP) reflects a 22 percent increase over fiscal year 2007 for this popular voluntary program, which provides financial and technical assistance to agricultural producers who implement conservation measures on working lands. However, the President's proposed funding level will only be sufficient to continue to support CSP contracts signed in prior years. No new enrollments would be offered in 2008. Given the popularity and effectiveness of the CSP, the UMRBA urges Congress to consider increasing CSP funding beyond what the Administration has proposed to enable additional eligible acreages to benefit.

In the first 3 years of CSP (2004–2006), 28 of the 280 eligible watersheds in the nation were in the 5 States of the Upper Mississippi River Basin. Within those 28 watersheds, there are 6,139 approved CSP contracts, which constitute nearly one-third of all CSP contracts, and total \$56 million in approved payments.

In fiscal year 2007, there are 51 additional watersheds eligible for CSP nationwide, including one in each of the 5 UMRBA States.

Conservation Technical Assistance

Through the Conservation Technical Assistance (CTA) program, NRCS provides the technical capability that helps people plan and apply conservation on the land. NRCS works through and in partnership with conservation districts to assist individuals and groups in assessing conservation needs and planning, designing, and installing conservation practices. In addition, the CTA program assists in preparing landowners to participate in USDA conservation financial assistance and easement programs, provides emergency disaster technical assistance, and enables NRCS to

coordinate with other programs such as U.S. EPA's nonpoint source management program and U.S. Fish and Wildlife Service's Partners for Wildlife. Approximately \$91 million in CTA funding was allocated to the five UMRBA States (Illinois, Iowa, Minnesota, Missouri, and Wisconsin) in fiscal year 2006.

Given that CTA is the foundation for much of the nation's private lands conservation assistance, UMRBA supports the President's fiscal year 2008 funding request of \$679 million for CTA, a 3 percent increase over the fiscal year 2007 estimated spending level.

Watershed Programs

The UMRBA is concerned that the President is proposing deep cuts to NRCS's watershed programs, including total elimination of the Watershed and Flood Prevention Operations program, which funds Public Law 566 and Public Law 534 projects. Funding for Watershed Operations has declined substantially over the past 20 years, from an historical high of \$199 million in fiscal year 1994 to only \$74 million in fiscal year 2006. And yet this program provides significant local, regional, and national benefits, by addressing watershed protection, flood prevention, erosion and sediment control, water supply, water quality, water conservation, agricultural drought problems, rural development, municipal and industrial water needs, upstream flood damages, fish and wildlife habitat enhancement, and wetland creation and restoration. In September 2005 there were \$1.85 billion of unfunded Federal commitments to Public Law 566 and Public Law 534 projects nationwide, with \$208 million of that in the States of Illinois, Iowa, Minnesota, and Missouri. Despite the fact that Public Law 566 and Public Law 534 projects in these 4 States were allocated 31 percent of the total national funding in fiscal year 2006, that amount (\$21.7 million) was far less than the \$208 million backlog. In fiscal year 2006, although there was only \$69 million allocated for watershed protection and flood prevention operations nationwide, there were funding requests totaling over \$174 million, \$44 million of which were in the five UMRBA States. Rather than eliminating this important program, UMRBA urges that it be funded at least equal to the fiscal year 2006 level.

The rehabilitation of aging flood control dams must also be addressed. Of the 11,000 Public Law 534 and Public Law 566 dams nationwide, more than 3,000 will reach the end of their design life by 2013. Recognizing this fact, Congress authorized the Watershed Rehabilitation Program in 2000 and authorized significant new funding for the program in the 2002 Farm Bill. However, that authorization expires at the end of fiscal year 2007. Nevertheless, the President has proposed \$6 million for the Watershed Rehabilitation program in fiscal year 2008, targeting it exclusively on technical assistance. That amount is well below the recent funding levels of \$30 million and only a small fraction of the \$150 million authorized for fiscal year 2007. Repair, upgrade, or removal of aging dams, which could become a threat to public health and safety, is extremely important and UMRBA thus urges Congress to reauthorize and increase funding for the Watershed Rehabilitation Program.

PREPARED STATEMENT OF THE USA RICE FEDERATION

This is to convey the rice industry's request for fiscal year 2008 funding for selected programs under the jurisdiction of your respective subcommittees. The USA Rice Federation appreciates your assistance in making this letter a part of the hearing record.

The USA Rice Federation is the national advocate for all segments of the rice industry, conducting activities to influence government programs, developing and initiating programs to increase worldwide demand for U.S. rice, and providing other services to increase profitability for all industry segments. USA Rice members are active in all major rice-producing states: Arkansas, California, Florida, Louisiana, Mississippi, Missouri, and Texas. The USA Rice Producers' Group, the USA Rice Council, the USA Rice Millers' Association, and the USA Rice Merchants' Association are members of the USA Rice Federation.

USA Rice understands the budget constraints the subcommittees face when developing the fiscal year 2008 appropriations bill. We appreciate your past support for initiatives that are critical to the rice industry and look forward to working with you to meet the continued needs of research, food aid and market development in the future.

A healthy U.S. rice industry is also dependent on the program benefits offered by the Farm Security and Rural Investment Act of 2002. Therefore, we oppose any attempts to modify the support levels provided by this vital legislation through more restrictive payment limitations or other means and encourage the subcommittees

and committees to resist such efforts during the appropriations process, in particular with the 2002 farm bill up for reauthorization this year.

A list of the programs the USA Rice Federation supports for appropriations in fiscal year 2008 are as follows:

FUNDING PRIORITIES

Research and APHIS

The Dale Bumpers National Rice Research Center should receive continued funding at the fiscal year 2007 approved level, which was approximately \$3.9 million, and appropriate additional funding to reflect any increased administrative and operations costs. This center conducts research to help keep the U.S. rice industry competitive in the global marketplace by assuring high yields, superior grain quality, pest resistance, and stress tolerance. We urge you to provide full funding to the Dale Bumpers National Rice Research Center.

In addition, we have attached information outlining the top priority research request from the USA Rice Federation: funding for aromatic rice variety research at the Dale Bumpers Center. The request is for \$250,000 for fiscal year 2008 for research to develop high-yielding, high-quality domestic aromatic rice varieties for the U.S. rice industry. Further details and specifics of this request are attached in a separate document.

For the Western Regional Research Center, in Albany, California, we support the Administration's budget proposal for the Renewable Energy Resources within the Agricultural Research Service (ARS) account. The total budget request for the Renewable Energy Resources project is \$10,954,000, of which, we understand, approximately \$5,399,000 is to be directed to the Albany, CA facility for research on modification of plant cell walls in energy crops and crop residues for efficient conversion to biofuels.

This research will play a key role in the ability to utilize rice straw and other rice crop residues for the production of biofuels. Rice straw represents a current and ready-made feedstock that could meet a substantial portion of the demand for biofuels production in the regions of the country where rice is produced, including the Sacramento Valley of California. We urge you to fully fund this request as our researchers work to develop the technologies necessary to meet the ambitious goals for biofuels production set before us.

For APHIS-Wildlife Services, we encourage the subcommittees to fund the Louisiana blackbird control project at \$150,000. This program annually saves rice farmers in Southwest Louisiana over \$4,000 per farm, or \$2.9 million total.

Market Access

Exports are critical to the U.S. rice industry. Historically, 40–50 percent of annual U.S. rice production has been shipped overseas. Thus, building healthy export demand for U.S. rice is a high priority.

The Foreign Market Development Program (FMD) allows USA Rice to focus on importer, foodservice, and other non-retail promotion activities around the world. For fiscal year 2008, FMD should be fully funded at no less than \$34.5 million.

The Market Access Program (MAP) allows USA Rice to concentrate on consumer promotion and other activities for market expansion around the world. For fiscal year 2008, MAP should be funded at no less than \$200 million.

In addition, the Foreign Agricultural Service should be funded to the fullest degree possible to ensure adequate support for trade policy initiatives and oversight of export programs. These programs are critical for the economic health of the U.S. rice industry.

Food Aid

We urge the subcommittees to fund Public Law 480 Title I. No Title I funding was provided in fiscal year 2007. At a minimum, fiscal year 2008 funding should be the same as 2006, the last year in which the program was funded. Public Law 480 Title I is our top food-aid priority and we support continued funding in order to meet international demand. Food-aid sales historically account for an important portion of U.S. rice exports.

For Public Law 480 Title II, we support funding for fiscal year 2008 at \$1.632 billion, which is its fiscal year 2006 level. We encourage the subcommittees to fund Title II at a level to ensure consistent tonnage amounts for the rice industry. We oppose any shifting of funds, as all Title II funds have traditionally been contained within USDA's budget. We believe all food-aid funds should continue to be used for food-aid purchases of rice and other commodities from only U.S. origin.

USA Rice supports continued funding at fiscal year 2006 levels, at a minimum, for the Food for Progress Program's Public Law 480 Title I-sourced funding and at

fiscal year 2007 levels, at a minimum, for the program's Commodity Credit Corporation funding component. Funding for this program is important to improve food security for food-deficit nations.

The McGovern-Dole International Food for Education and Child Nutrition Program is a proven success and it is important to provide steady, reliable funding for multi-year programming. USA Rice supports funding at the \$140 million level for this education initiative because it efficiently delivers food to its targeted group, children, while also encouraging education, a primary stepping-stone for populations to improve economic conditions.

Other

Farm Service Agency.—We encourage the subcommittees to provide adequate funding so the agency can deliver essential programs and services. The Agency has been hard hit by staff reductions and our members fear a reduction in service if sufficient funds are not allocated.

Please feel free to contact us if you would like further information about the programs we have listed. Additional background information is available for all of the programs we have referenced; however, we understand the volume of requests the subcommittees receive and have restricted our comments accordingly.

Thank you for your consideration of our recommendations.

PREPARED STATEMENT OF THE WESTERN COALITION OF ARID STATES (WESTCAS)

The Western Coalition of Arid States (WESTCAS) is submitting this testimony to the Senate Appropriations Subcommittee on Agriculture regarding their hearing on the fiscal year 2008 U.S. Department of Agriculture budget, with specific reference to the 2007 Farm Bill proposals. My name is Charlie Nylander, and I represent the interests of WESTCAS and serve on the Board of Directors (representing the State of New Mexico) and as Treasurer.

WESTCAS is a coalition of approximately 125 water and wastewater districts, municipalities, and professional organizations focused on water quality and quantity issues in eight western States, including: Arizona, California, Colorado, Idaho, Nevada, New Mexico, Oregon, and Texas. WESTCAS advocates wise use of water resources by promoting scientifically-sound laws, regulations, appropriations, and policies that protect public health and the environment in the arid West. My testimony today focuses on those aspects of the fiscal year 2008 USDA budget and the 2007 Farm Bill proposals that impact water quality and quantity in the arid West.

This WESTCAS testimony will focus on two areas of importance to our membership, i.e. the conservation programs and the rural development programs. First, the Administration proposes to provide approximately 547,000 rural households with new and improved water and wastewater disposal facilities. The proposed \$1.5 billion funding level includes \$1.2 billion in loans and \$349 million in grants. This combination of funding represents a higher loan to grant ratio than exists in 2007, according to the budget proposal. However, USDA is proposing to reduce the interest rate on loans, and state that most rural communities would have lower repayment costs as a result of the combination of these changes. Although WESTCAS would like to see a significant increase in the proposed funding for this program, given the current national budget demands, we support the proposed funding level and the approach taken with respect to loans and grants.

The water and wastewater disposal program provides financing for rural communities to establish, expand or modernize water treatment and waste disposal facilities. Eligibility is limited to communities of 10,000 or less in population which are unable to obtain credit elsewhere. In addition, they are available only to those communities with low median household income levels. The eight WESTCAS member western states contain hundreds of communities that meet these criteria. Moreover, due to the evolving demographics of the western United States, many of our rural communities are either seeing an influx of new residents who are moving to the area in their retirement, or are seeing a reduction in population due to a weakened economic picture and the lack of reasonable employment opportunities. In either case, the physical and financial impact on existing, aged, or needed water and wastewater infrastructure is demonstrable. These rural communities cannot cope with the maintenance or new development of adequate water and wastewater infrastructure without programs such as proposed in this fiscal year 2008 USDA budget request.

I would like to provide an example in my own State of New Mexico. I currently facilitate the Española Basin Regional Planning Issues Forum (EBRPIF). This forum represents a government-to-government ad hoc group of 14 members rep-

representing city, county, and tribal jurisdictions in Northern New Mexico. For the past three years, this forum has met monthly to candidly discuss planning issues of regional concern, with a focus on water and wastewater. The three county governments represented among the 14 members contain rural communities that have populations of less than 10,000 people. Many of those communities are increasingly financially-burdened by water and wastewater infrastructure needs that result from: aged, existing infrastructure; population growth that demands new utility services; local groundwater contamination issues resulting from the existing use of on-site individual liquid waste systems and historic use of cesspools (that are now illegal); inadequate operation and maintenance; declining groundwater levels in over-drafted aquifers; the effects of a 7+ year drought; naturally-occurring groundwater contaminants that exceed new, and increasingly stringent drinking water standards, e.g. the U.S. Environmental Protection Agency's standard for arsenic; and challenging new concerns for utility safeguards and security measures. All of these very typical factors exacerbate the financial, planning, maintenance, and development demands affecting these small, rural communities, who without the availability of government program support, like the USDA Rural Development Program, would have no place to turn.

According to the Administrations proposal, these grants are limited to a maximum of 75 percent of project costs, but have typically averaged 35 to 45 percent of project costs. Program regulations stipulate that the grant amount should only be as much as necessary to bring the user rates down to a reasonable level for the area. Water and wastewater grant and loan funds are usually combined, based on the income levels of users and user costs. Throughout the WESTCAS western states, when it comes to financing water and wastewater infrastructure, all of the rural communities are increasing user rates, while still needing to augment funding through federal and state financing programs. Thus, WESTCAS strongly supports the continuation the USDA Rural Development Program.

The second area of concern to WESTCAS, funding and technical assistance to support the Farm Bill conservation programs is vital to the management of water resources in the arid West. The Administration's proposal includes about \$4 billion for these programs, an increase of \$242 million over the 2007 level. This includes funding for the Conservation Security Program at a level of \$316 million, and increase of \$57 million over 2007, in order to support prior year contracts. The budget also includes \$455 million to enroll up to 250,000 acres in the Wetlands Reserve Program in 2008 to reach the program cap of 2,275,000 acres. In addition, the proposed budget includes \$1 billion for the Environmental Quality Incentives Program (EQIP), enabling nearly 39,700 producers to participate in the program, covering nearly 21 million acres of land. The EQIP program will continue to emphasize land management practices.

WESTCAS strongly supports the proposed conservation programs, however we have the following comments.

- The Conservation Security Program pays farmers for improving soil and water quality or enhancing wildlife habitat. Some voices in Congress have recently advocated also using these funds to promote the planting of energy crops. WESTCAS supports this program because it has a fundamental connection to water quality and quantity. By wisely managing the land, this USDA program has a very positive affect on non-point sources of water pollution. Sediment and nutrients are less likely to runoff and end up in the surface waters where they contribute to water pollution. In addition, this program can enhance the ability of soils to hold moisture and reduce the demands for irrigation water from surface or groundwater sources. Enhancing wildlife habitat is also a vital benefit, especially in those areas of the country, like the western states, where growth and development are increasingly marginalizing wildlife habitat. Additionally, if one examines other federal agency budgets, (like the Fish and Wildlife Service's fiscal year 2008 proposed budget where grants are being eliminated that help landowners restore habitat for species on their land), there are proposed cuts in funding for wildlife habitat. Thus, the USDA program funding is of vital importance.

WESTCAS supports increased appropriations for the Conservation Security Program, but does not want it be closed to new subscribers, as Secretary Johanns has recently proposed. Across the western states, many new opportunities exist to improve soil and water quality and enhance wildlife habitat. Rather than cap the program to allow funding to present subscribers, WESTCAS believes that it should be expanded, and that USDA should implement a monitoring and reporting program to quantify, to the best of their ability, the benefits derived from the program's implementation. A comprehensive monitoring program could be networked with other agencies such as the U.S. Geological

Survey, Bureau of Land Management, and Environmental Protection Agency, so as to more efficiently collect and quantify the data. Such monitoring and reporting would greatly impact the continuation and expansion of this important program, and help assess the positive benefits being derived for water quality.

Regarding the proposal to use these funds for the planting of energy crops, WESTCAS offers one caution. That caution concerns the impact of extensive new energy crop plantings on both water quantity and quality. By promoting the planting of energy crops, the USDA (or Congress) may be exacerbating the problems associated with nutrient-caused eutrophication of water resources due to seepage and/or runoff of applied crop nutrients that affect water quality. But more importantly, promotion of such planting may negatively impact the increasing strain on scarce water resources in the arid western states through the promotion of irrigated agriculture to produce energy. By promoting planting of energy crops, there is a promotion of irrigation which may have deleterious affects on both surface and groundwater resources in the arid West. Historically, USDA price supports for cotton, resulted in increased planting that resulted in excessive water level declines in important aquifers, such as the Ogallala aquifer. Thus, prudent caution should be given when including such proposals in the program due to inadvertent consequences.

- The Wetlands Reserve Program proposal for increased funding and maximizing the subscription acreage is heartily supported by WESTCAS. Although the arid West has minimal acres of wetlands, as a water quality organization WESTCAS recognizes the natural benefits of increased wetlands promoting water quality and wildlife. Wetlands are natural systems that greatly contribute to the promotion of water quality, and aid in providing buffer zones for riparian vegetation that mitigate the affects of runoff events and flood flows. In the arid West, the use of artificial wetlands is utilized more and more in the treatment and reclamation of wastewater effluent. The natural purification processes that take place in a wetland environment greatly benefit water quality, and this USDA program is of great national import regarding the protection of water quality and provision of wildlife habitat.
- WESTCAS strongly supports the Environmental Quality Incentive Program (EQIP). This program is very important in providing assistance to landowners that face serious natural resource challenges that impact soil, water, and related natural resources. As was mentioned above regarding the Conservation Security Program, EQIP provides resources for those stewards of the land that are in need so as to enhance the natural resources. The EQIP financial resources improve water quality and quantity through the subscriber application of sound remedial projects that improve both land and water.
- Lastly, WESTCAS supports the premise of the Healthy Forest Initiative in reducing the risk of catastrophic wildfires. It is very important that the USDA continue to implement this initiative, and reduce the risk of wildfire. Through hazardous fuel treatment, provision of adequate fire preparedness, and providing technical assistance, the USDA is assisting the arid West in safeguarding our vulnerable forested watersheds that provide the source of water for our cities, towns, industries, ranches and farms. During the past 7 years of sustained drought conditions, the arid West has felt the impact of catastrophic wildfire from California, across Arizona, through New Mexico and Colorado. Wildfires can destroy the vital watersheds upon which our populations depend for their annual and long-term supply of water. WESTCAS urges your support for the proposed budget for this important program.

On behalf of WESTCAS, thank you for this opportunity to provide this testimony.

PREPARED STATEMENT OF THE SOCIETY FOR WOMEN'S HEALTH RESEARCH AND THE
WOMEN'S HEALTH RESEARCH COALITION

On the behalf of the Society for Women's Health Research and the Women's Health Research Coalition, we are pleased to submit testimony in support of increased funding for the Food and Drug Administration, and more specifically for the Office of Women's Health, a critical focal point within the Agency on women's health.

The Society is the only national non-profit women's health organization whose mission is to improve the health of women through research, education, and advocacy. Founded in 1990, the Society brought to national attention the need for the appropriate inclusion of women in major medical research studies and the need for more information about conditions affecting women disproportionately, predominately, or differently than men.

The Coalition was created by the Society in 1999 to give a voice to scientists and researchers from across the country that are concerned and committed to improving women's health research. The Coalition now has more than 650 members, including leaders within the scientific community and medical researchers from many of the country's leading universities and medical centers, directors from various Centers of Excellence on Women's Health as well as leading voluntary health associations, and pharmaceutical and biotechnology companies.

The Society and the Coalition are committed to advancing the health status of women through the discovery of new and useful scientific knowledge. We strongly believe that appropriate funding of the FDA by Congress is absolutely critical for the Agency to be able to maintain basic functions and to assure the American public of the safety of our food and drugs. More specifically, we recommend that Congress not only sustain but should increase funding for the Office of Women's Health and its women's health research programs. These programs, often conducted with the Agency centers, are necessary if we are to maintain any focus on women's health within the Agency. Furthermore, these programs are critical to improve care and increase awareness of disease specific impacts to women such as those associated with differences in the efficacy of drugs, devices and diagnostics, as a function of sex. Therefore, we strongly urge Congress to support a robust increase for fiscal year 2008 budget for the FDA, and within that budget to provide the Office of Women's Health funding of \$5 million such that it may meet and exceed its program goals.

OFFICE OF WOMEN'S HEALTH

The Office of Women's Health (OWH) at the FDA, established in 1994, plays a critical role in women's health, both within and outside the Agency, supporting sex- and gender-based research, areas in which the Society has long been a proponent. OWH aims to provide scientific and policy expertise on sex and gender sensitive regulatory and oversight issues; to correct gender disparities in the areas for which the FDA is responsible—drugs, devices, and biologics; and to monitor women's health priorities, providing both leadership and an integrated approach across the agency. Despite inadequate funding, OWH provides all women with invaluable tools for their health.

With little difficulty, OWH exhausts its tiny budget each year. For the past five years, OWH has been provided a flat budget of \$4 million, which is, in essence, a decrease due to required Federal cost of living adjustments, benefit cost increases and other related issues. Despite this squeeze, the office has managed to advance its mission both within the Agency and externally through its research grants, drug and disease pamphlets and outreach programs. OWH's pamphlets are the most requested of any documents at the government printing facility in New Mexico. (More than 3.5 million pieces are distributed to women across the Nation including target populations such as Hispanic communities, seniors and low income citizens.) Yet despite these successes, the OWH was targeted to have its fiscal year 2007 programs budget raided by \$1.2 million, virtually shutting down the ability of this office to function for the rest of the year. Thankfully, this decision was reversed at the very last minute.

Despite clear funding intentions within the Administration's proposal for fiscal year 2008 for OWH to receive \$4million, the FDA has indicated that it will be cutting the budget of OWH by \$350,000 from the OMB designated amount of \$4 million. These two actions (fiscal year 2007 and fiscal year 2008) taken together cause us great concern and set a precedent that leads us to believe the office's functionality is in serious jeopardy.

IT IS ABSOLUTELY CRITICAL FOR CONGRESS TO TAKE ACTION NOW TO HELP PRESERVE THE VITAL FUNCTIONS OF OWH

Since its beginning, OWH has funded high quality scientific research to serve as the foundation for Agency activities that improve women's health. To date, OWH has funded over 100 research projects with approximately \$15.2 million. Intramural grants support projects within the FDA that address knowledge gaps or set new directions for sex and gender research. Extramural contracts leverage a wealth of expertise and other resources outside the Agency to provide insight on regulatory questions pertinent to women's health. All contracts and grants are awarded through a competitive process. A large number of these studies are published, many of which appear in peer reviewed journals.

OWH has recently funded research to more fully understand heart disease in women. Despite being the number one cause of death, women with heart disease face misdiagnosis, delayed diagnosis, under-treatment, and mistreatment due to their under-representation in heart-related research studies. Extramural research

funded by OWH is looking into the use of coronary stents in women and problems associated with breast interference in interpretation of heart catheterization studies.

As part of its educational outreach efforts to consumers, OWH continues to work closely with women's advocacy and health professional organizations to provide clarity on the results of the Women's Health Initiative. Due to OWH efforts, an informational fact sheet about menopause and hormones and a purse-sized questionnaire to review with the doctor were distributed to national and local print, radio, and Internet advertisements. OWH's website received over three million hits to download campaign materials. This website provides free, downloadable fact sheets on over 40 different illnesses, diseases, and health related issues.

In addition, OWH has recently completed medication chart brochures on seven chronic diseases. These are unique within the Agency. These charts list, in one place, all the medications that are prescribed and available for each disease. Again, the information is available on the website and is ideal for women to use in talking to their doctors, pharmacists or nurses about their treatment options.

As a result of FDA information system aging, combined with the inability to keep pace with information technology needs due to budget constraints, the OWH has been unable to conduct much needed data analysis on women's health and sex-related differences. This effort originally started in 2001, when the Society submitted testimony on behalf of the OWH in support of a centralized FDA database to coordinate clinical trial oversight, monitor the inclusion of women in clinical trials, oversee the parameters of informed consent, and identify health provider training needs. As a result of Society efforts and this Committee's commitment, in 2002 Congress provided the OWH with funds to develop an agency-wide database focused on women's health activities to include demographic data on clinical trials. OWH did begin developing this database, now known as the "Demographic Information and Data Repository", to review clinical studies, enhance product labeling, identify knowledge gaps, and coordinate data collection. However, without the ability to match this capability to the rest of the Agency efforts developing this important Repository have been halted at the present time.

While progress has been made, the database is far from up and running due to the aging and outdated information technology systems of the Agency. Currently, the FDA receives large volumes of information in applications from drug manufacturers for review and evaluation. The FDA reviewers must manually comb through the submitted drug trial reports and digital data in as many as twelve formats to evaluate a new drug's safety and effectiveness. With no uniform system or database, reviewers must handpick sex, age, and ethnicity information manually from stacks of paper reports and craft their own data comparisons. This is time consuming, makes the review process less efficient, is error-prone and delays access to important information. Scientific and medical advances are occurring rapidly and the public needs and deserves access to the most recent and accurate information regarding their health. Therefore, in order to fully capitalize on the potential of the data warehouse and the resulting wealth of information, we urge Congress to commit \$1 million to OWH for the Demographic Information and Data Repository. It is time for us all to recognize that the Agency must utilize up to date information technology and sorely needs the resources to maintain them.

Scientists have long known of the anatomical differences between men and women, but only within the past decade have they begun to uncover significant biological and physiological differences. Sex differences have been found everywhere from the composition of bone matter and the experience of pain, to the metabolism of certain drugs and the rate of neurotransmitter synthesis in the brain. Sex-based biology, the study of biological and physiological differences between men and women, has revolutionized the way that the scientific community views the sexes, with even more information forthcoming as a result of the sequencing of the X chromosome. The evidence is overwhelming, and as researchers continue to find more and complex biological differences, they are gaining a greater understanding of the biological and physiological composition of both sexes.

Much of what is known about sex differences is the result of observational studies, or is descriptive evidence from studies that were not designed to obtain a careful comparison between females and males. The Society has long recognized that the inclusion of women in study populations by itself was insufficient to address the inequities in our knowledge of human biology and medicine, and that only by the careful study of sex differences at all levels, from genes to behavior, would science achieve the goal of optimal health care for both men and women. Many sex differences are already present at birth, whereas others develop later in life. These differences play an important role in disease susceptibility, prevalence, time of onset and severity and are evident in cancer, obesity, coronary heart disease, immune dysfunction, mental health disorders, and other illnesses. Physiological and hormonal

fluctuations may also play a role in the rate of drug metabolism and effectiveness of response in females and males. This research must be supported and encouraged.

Building upon sex differences research, the Society encourages the establishment of drug-labeling requirements that ensure labels include language about differences experienced by women and men. Further, we advocate for research on the comparative effectiveness of drugs with specific emphasis on data analysis by sex. When available, this information should be on labels.

Our country's drug development process has succeeded in developing new and better medications to ensure the health of both women and men. However, there is no requirement that the data acquired during research of a new drug's safety and effectiveness be analyzed as a function of sex or that information about the ways drugs may differ in various populations (e.g., women requiring a lower dosage because of different rates of absorption or chemical breakdown) be included in prescription drug labels and other patient educational and instructional materials.

Proper drug labeling is not always the complete solution. If the drug is not one newly approved or if the sex-specific information is detected only in post-marketing studies, the drug label will not reflect sex specific information discovered to the prescribing physician, and it may be difficult to get new information incorporated into physicians' prescribing habits.

The Society believes the opportunity is now before us to communicate sex differences data discovered from clinical trials to the medical community and to consumers through drug labeling and packaging inserts and other forms of alerts. As part of advancing the need to analyze and report sex differences, the Society encourages the FDA to continue adequately addressing the need for accurate drug labeling to identify important sex and gender differences, as well as to ensure that appropriate data analysis of post-market surveillance reporting for these differences is placed in the hands of physicians and ultimately the patient.

In conclusion, Mr. Chairman, we thank you and this Committee for its strong record of support for women's health and your commitment to OWH. We encourage you to provide it with funding of \$5 million for fiscal year 2008 and to provide the FDA with a significant increase over the fiscal year 2007 budget to address its urgent needs and chronic shortfalls. We look forward to continuing to work with you to build a healthier future for all Americans.

LIST OF WITNESSES, COMMUNICATIONS, AND PREPARED STATEMENTS

	Page
Ad Hoc Coalition, Prepared Statement of	721
Advanced Medical Technology Association, Prepared Statement of	724
American:	
Forest & Paper Association, Prepared Statement of	726
Honey Producers Association, Inc., Prepared Statement of	727
Sheep Industry Association, Prepared Statement of	733
Society for Microbiology, Prepared Statements of.....	738, 741
Animal:	
Health Institute, Prepared Statement of	745
Welfare Institute, Prepared Statement of	745
Bennett, Senator Robert F., U.S. Senator From Utah:	
Questions Submitted by.....	136, 708
Statement of	2
Bond, Senator Christopher S., U.S. Senator From Missouri, Questions Submitted by	156
Brownback, Senator Sam, U.S. Senator From Kansas, Questions Submitted by	476
Byrd, Senator Robert C., U.S. Senator From West Virginia, Questions Submitted by	153
California Industry and Government Central California Ozone Study Coalition, Prepared Statement of	746
Christopherson, Charles R., Jr., Chief Financial Officer, Office of the Chief Financial Officer, Department of Agriculture, Prepared Statement of	24
Coalition on Funding Agricultural Research Missions, Prepared Statement of	747
Cochran, Senator Thad, U.S. Senator From Mississippi, Prepared Statement of	6
Colorado River:	
Basin Salinity Control Forum, Prepared Statement of	749
Board of California, Prepared Statement of	752
Collins, Dr. Keith, Chief Economist, Office of the Secretary, Department of Agriculture	1
Prepared Statement of	31
Combs, David M., Chief Information Officer, Department of Agriculture, Prepared Statement of	20
Conner, Charles, Deputy Secretary, Office of the Secretary, Department of Agriculture	1
Dorgan, Senator Byron L., U.S. Senator From North Dakota:	
Questions Submitted by.....	123, 701
Statement of	3
Durbin, Senator Richard J., U.S. Senator From Illinois, Questions Submitted by.....	123, 705
Dyer, John, Deputy Commissioner for Operations, Food and Drug Administration, Department of Health and Human Services	479
Feinstein, Senator Dianne, U.S. Senator From California, Statement of	5
Florida State University, Prepared Statement of	753
Fong, Phyllis K., Inspector General, Office of the Inspector General, Department of Agriculture, Prepared Statement of	45
Food and Water Watch, Prepared Statement of	754

	Page
Friends of Agricultural Research—Beltsville, Prepared Statement of	757
Hardwood Federation, Prepared Statement of	760
Harkin, Senator Tom, U.S. Senator From Iowa, Questions Submitted by	694
Heart Rhythm Society, Prepared Statement of	761
Imperial Valley Conservation Research Center Committee, Prepared Statement of	763
Johanns, Hon. Mike, Secretary, Office of the Secretary, Department of Agriculture	1
Prepared Statement of	10
Statement of	7
Kohl, Senator Herb, U.S. Senator From Wisconsin:	
Opening Statement of	1
Questions Submitted by.....	84, 492
McKay, Margo M., Assistant Secretary for Civil Rights, Office of the Assistant Secretary for Civil Rights, Department of Agriculture, Prepared Statement of	28
Multi-Crop Aflatoxin Working Group, Prepared Statement of	765
National:	
Association of State:	
Departments of Agriculture, Prepared Statement of	760
Foresters, Prepared Statement of	760
Coalition for Food and Agricultural Research, Prepared Statement of	766
Commodity Supplemental Food Program Association, Prepared Statement of	772
Corn Growers Association, Prepared Statement of	770
Environmental Services Center (NESC), Prepared Statement of	778
Fish and Wildlife Foundation, Prepared Statement of	779
Potato Council, Prepared Statement of	782
Rural Telecom Association, Prepared Statement of	784
Turfgrass Federation, Inc., Prepared Statement of	786
Nelson, Senator Ben, U.S. Senator From Tennessee:	
Questions Submitted by	126
Statement of	5
New Mexico Interstate Stream Commission, Prepared Statement of	790
Organization for the Promotion and Advancement of Small Telecommunications Companies, Prepared Statement of	792
Pellett, Nancy C., Chairman and Chief Executive Officer, Farm Credit Administration, Prepared Statement of	59
Pickle Packers International, Inc., Prepared Statement of	793
Red River Valley Association, Prepared Statement of	798
Reed, Senator Jack, U.S. Senator From Rhode Island:	
Questions Submitted by.....	135, 707
Statement of	5
Rutherford, Boyd K., Assistant Secretary for Administration, Department of Administration, Department of Agriculture, Prepared Statement of	18
Society:	
For:	
Animal Protective Legislation, Prepared Statement of	802
Women's Health Research and the Women's Health Research Coalition, Prepared Statement of	824
Of American Foresters, Prepared Statement of	760
Specter, Senator Arlen, U.S. Senator From Pennsylvania, Questions Submitted by	154, 718
Steele, W. Scott, Budget Officer, Office of the Secretary, Department of Agriculture	1
Teuber, Terri, Director, Office of Communications, Department of Agriculture, Prepared Statement of	30
The Humane Society, Prepared Statement of	806
The Nature Conservancy, Prepared Statement of	760

	Page
The Wildlife Society, Prepared Statement of	810
Turman, Richard, Deputy Assistant Secretary for Budget, Food and Drug Administration, Department of Health and Human Services	479
United States Telecom Association, Prepared Statement of	811
University of Southern Mississippi and the Mississippi Polymer Institute, Prepared Statement of	815
Upper Mississippi River Basin Association, Prepared Statement of	818
USA Rice Federation, Prepared Statement of	820
Western Coalition of Arid States (WESTCAS), Prepared Statement of	822
von Eschenbach, Hon. Andrew, Commissioner, Food and Drug Administra- tion, Department of Health and Human Services	479
Prepared Statement of	481

SUBJECT INDEX

DEPARTMENT OF AGRICULTURE

	Page
Additional Committee Questions	83
Administrative:	
Costs for Earmarks	73
Expenses for Earmarks	71
Afghanistan/Iraq Provincial Reconstruction Activities	85
Agricultural:	
Credit Insurance Fund	475
Disaster Assistance	138
Marketing Service	105, 120
Quarantine Inspection:	
Fees	77
Positions Transferred to DHS	77
Reconstruction Activities	103
Research	87
Service, Buildings and Facilities	149
Agriculture:	
Buildings and Facilities and Rental Payments	19
Quarantine and Inspection	121
APHIS:	
Cooperative Agreements	107
Program Cost Share	147
Appropriate Technology Transfer for Rural Areas	122
ARS Research Funding	123
Avian Flu	63, 88
Broadband and Distance Learning and Telemedicine Funding	124
BSE Surveillance	126
Capital Security Cost Sharing Program	102
Center for Nutrition Policy and Promotion	110
Chronic Wasting Disease/State Match	90
Commodity Supplemental Food Program	79, 109, 129, 154
Elimination	144
Common Computing Environment	108
And Information Technology	86
Community Facilities Grants	96
Conservation:	
Contingency Funding	82
Operations	104
Program	125
Security Program	122
Corporate Activities	61
Country of Origin Labeling	69, 93
Crop:	
Insurance	122
Gap Coverage	82
Cross-Cutting Trade Negotiations and Biotechnology Resources	148
DA Direct	19
DHS:	
Agricultural Inspections at U.S. Borders	75
AQI Inspectors	81
Disaster:	
Aid	67
Assistance	126

	Page
E. Coli in Specialty Crops	78
Electronic Government	23
Emerald Ash Borer	64
Emerging Pests.....	88, 106
Enterprise Architecture (EA) and IT Management Programs	23
Eradication Versus Management	89
Examination Programs for FCS Banks and Associations	60
Farm Program Staffing	475
Farm Service Agency (FSA)	154
Computer System	65
Field Staff and Office Structure	102
Financial Management System.....	102, 141
Financing New Electric Generation Facilities	99
Fiscal Year 2008:	
Budget Request	29, 31, 36
Key Outcomes	29
Objectives.....	18, 29
Request	19
Food:	
Aid	81
Stamp Program Legislative Proposals	110
Food Safety and Inspection Service	111
Food Inspectors	116
Funding	142
Level	62
IT Infrastructure	155
Research	152
Risk Based Inspection	113
Fresh Fruit and Vegetable Program in Schools	123
Genetically Modified Materials in Commercial Crops	93, 120
Global Warming	94
Greenbook Charges	140
Hazardous Materials Management	20
Information:	
Security	22
Technology (IT) Issues	101
International Trade	66
Invasive Species.....	89, 119
Johne's Disease	90
Loan Program Delinquency Rates	156
Locally Produced Food to Schools	74
Multi-Family Housing:	
Revitalization	98
Vouchers	98
Mutual and Self-Help Housing	97
National:	
Animal:	
Health Laboratory Network Funding	123
Identification System.....	67, 91, 118 143
Information Technology Data Center (NITC) Hosting	22
Organic Certification Cost Share Program	106
Veterinarian Medical Service Act	70, 87, 122, 476
Natural Resources Conservation Service	153
Technical Assistance Funding	126
Number of AQI Inspectors	77
Office:	
Consolidations	96
Of the Secretary, Provincial Reconstruction Teams	149
OIG's Fiscal Year 2008 Budget Request	58
Organic Farming	80
Progress Implementing Local Food Purchase Provision	135
Proposed Limit on WIC Administrative Funding	109
Protecting and Improving the Integrity of USDA Programs	49
Provincial Reconstruction Teams (PRTs)	73
Public Law 480 Titles I and II and Food for Progress	103
Regulatory Activity	61
Renewable Energy—Commodity Prices	138
Rental Assistance	136

	Page
Research, Education, and Economics Reorganization	146
Resource Conservation and Development	105
Risk:	
Based Inspection	142
Management Agency.....	94, 118
Crop Insurance User Fee	137
Rural:	
Business Development Grants	99
Development	154
Direct Loans	137
Guaranteed Lending	128
Housing Programs	125
Rental Housing	97
Safety, Security, and Public Health	45
Service Center Modernization Initiative—(SCMI)	21
Single Family Housing Loan Programs	95
Small Farm/Organics/AMS Seed Mislabeling	91
Telecommunications	22
The Management of USDA's Public Resources	55
2008 Budget Request for Public Law 480 Title II Donations	82
U.S.:	
Agricultural Trade	130
Foreign Food Assistance	121
USDA:	
Fiscal Year 2008 Information Technology Investment Summary	20
Loan Guarantee Authority	69
Overseas Activities	150
Renewable Energy and Biofuels Investment	127
User Fee Proposals	140
Value-Added Grants.....	95, 120
Veal	84
Water and Waste Program	100
WIC:	
Food Package	146
Legislative Proposals	144
Management Information System Funding	145
\$200 Million Contingency Fund	145

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

Additional Committee Questions	492
Adverse Event Reporting on Dietary Supplements	694
Advisory Committees	706
AERS II	497
Biologic License Application Approvals	717
Carbon Monoxide	692
Color Certification Fees	694
Counterfeit Drugs	708
Department of Health and Human Services	492
Dietary Supplements	705
Direct to Consumer Advertising.....	691, 701
Drug Importation	702
FDA:	
Alliance Request for FDA Funding	710
Pay Costs	709
Follow-on Biologics	718
Food Safety	493, 706
Inspections	485, 696
Generic Drugs	494
Review Fiscal 2007 Funding	710
Good Manufacturing Practices of Dietary Supplements	695
Import Inspection	495
Medical Device User Fee and Modernization Act (MDUFMA)	713
Office of:	
Cosmetics and Colors	693
The Commissioner	693

	Page
Office of—Continued	
Women's Health	689
ORA Consolidation	718
Overall Funding	492
Pandemic Flu.....	486, 711
Pay Costs	687
Pending Approval of Cefquinome	703
Probiotics in Yogurt	692
Proposed:	
Generic Drug User Fee	710
Re-Inspection User Fee	710
User Fees	686
Pseudoephedrine	694
Rent	687
Research Reduction.....	688, 713
Salt	698
Sunscreen Monographs	489, 707
Tobacco	489
Trans Fat	700
User Fees	490
Reauthorization	711
White Oak	688
Women's Health.....	487, 488