(A) all right, title, and interest of the United States in and to the portion of the property commonly known as ''Ranch A'' in Crook County, Wyoming, other than the portion described in paragraph (2), consisting of approximately 600 acres of land (including all real property, buildings, and all other improvements to real property) and all personal property (including art, historic light fixtures, wildlife mounts, draperies, rugs, and furniture directly related to the site, including personal property on loan to museums and other entities at the time of transfer);

(B) all right, title, and interest of the United States in and to all buildings and related improvements and all personal property associated with the buildings on the portion of the property described in paragraph (2); and

(C) a permanent right of way across the portion of the property described in paragraph (2) to use the buildings conveyed under subparagraph (B).

(2) RANCH A.—Subject to the exceptions described in subparagraph (B) and (C) of paragraph (1), the United States shall retain all right, title, and interest in and to the portion of the property commonly known as ''Ranch A'' in Crook County, Wyoming, described as Township 52 North, Range 61 West, Section 24 N½ SE¼, consisting of approximately 80 acres of land.

(b) USE AND REVERSIONARY INTEREST.—

(1) USE.—The property conveyed to the State of Wyoming under this section shall be retained by the State and be used by the State for the purposes of—

(A) fish and wildlife management and educational activities; and

(B) using, maintaining, displaying, and restoring, through State or local agreements, or both, the museum-quality real and personal property and the historical interests and significance of the real and personal property, consistent with applicable Federal and State laws.

(2) ACCESS BY INSTITUTIONS OF HIGHER EDUCATION.—The State of Wyoming shall provide access to the property for institutions of higher education at a compensation level that is agreed to by the State and the institutions of higher education.

(3) REVERSION.—All right, title, and interest in and to the property described in subsection (a) shall revert to the United States if—

(A) the property is used by the State of Wyoming for any other purpose than the purposes set forth in paragraph (1);

(B) there is any development of the property (including commercial or recreational development, but not including the construction of small structures, to be used for the purposes set forth in subsection (b)(1), on lang conveyed to the State of Wyoming under subsection (a)(1)(A)); or

(C) the State does not make every reasonable effort to protect and maintain the quality and quantity of fish and wildlife habitat on the property.

(c) ADDITION TO THE BLACK HILLS NATIONAL FOREST.—

(1) TRANSFER.—Administrative jurisdiction of the property described in subsection (a)(2) is transferred to the Secretary of Agriculture, to be included in and managed as part of the Black Hills National Forest.

(2) NO HUNTING OR MINERAL DEVELOPMENT.—No hunting or mineral development shall be permitted on any of the land transferred to the administrative jurisdiction of the Secretary of Agriculture by paragraph (1).

## TENSAS RIVER WILDLIFE REFUGE

Mr. FRIST. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of Calendar No. 460, H.R. 2660.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

A bill (H.R. 2660) to increase the amount authorized to be appropriated to the Department of the Interior for the Tensas River National Wildlife Refuge.

The PRESIDING OFFICER. Is there objection to the immediate consideration of the bill?

There being no objection, the Senate proceeded to consider the bill.

AMENDMENT NO. 5400

(Purpose: To authorize an expansion of the Bayou Sauvage Urban National Wildlife Refuge)

Mr. FRIST. Senator JOHNSTON has an amendment at the desk. I ask for its consideration.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Tennessee [Mr. FRIST], for Mr. JOHNSTON, proposes an amendment numbered 5400.

The text of the amendment is as follows:

At the end of the bill, add the following:

**SEC. 3. BAYOU SAUVAGE URBAN NATIONAL WILDLIFE REFUGE.**

(a) REFUGE EXPANSION.—Section 502(b)(1) of the Emergency Wetlands Resources Act of 1986 (Public Law 99–645; 100 Stat. 3590), is amended by inserting after the first sentence the following: ''In addition, the Secretary may acquire, within such period as may be necessary, an area of approximately 4,228 acres, consisting of approximately 3,928 acres located north of Interstate 10 between Little Woods and Pointe-aux-Herbes and approximately 300 acres south of Interstate 10 between the Maxent Canal and Michoud Boulevard that contains the Big Oak Island archaeological site, as depicted on the map entitled ''Bayou Sauvage Urban National Wildlife Refuge Expansion'', dated August, 1996, on file with the United States Fish and Wildlife Service.''

Mr. FRIST. I ask unanimous consent the amendment be agreed to, the bill be deemed read a third time, passed, the motion to reconsider be laid upon the table, and any statements relating to the bill be printed at the appropriate place in the RECORD.

The PRESIDING OFFICER. Without objection, it is so ordered.

The amendment (No. 5400) was agreed to.

The bill (H.R. 2660), as amended, was deemed read for a third time and passed.

The title was amended so as to read:

To increase the amount authorized to be appropriated to the Department of the Interior for the Tensas River National Wildlife Refuge and for other purposes.

## ANIMAL DRUG AVAILABILITY ACT

Mr. FRIST. Mr. President, I ask unanimous consent the Labor Committee be discharged from further consideration of S. 773, and the Senate immediately proceed to its consideration.

The PRESIDING OFFICER. Without objection, it is so ordered. The clerk will report.

The assistant legislative clerk read as follows:

A bill (S. 773) to amend the Federal Food, Drug and Cosmetic Act to provide for improvements in the process of approving and using animal drugs, and for other purposes.

The PRESIDING OFFICER. Is there objection to the immediate consideration of the bill?

There being no objection, the Senate proceeded to consider the bill.

Amendment No. 5401

(Purpose: To provide for a substitute amendment)

Mr. FRIST. Mr. President, Senator KASSEBAUM has a substitute at the desk. I ask for its consideration.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Tennessee [Mr. FRIST], for Mrs. KASSEBAUM, proposes an amendment numbered 5401.

(The text of the amendment is printed in today's RECORD under ''Amendments Submitted.'')

Mrs. KASSEBAUM. Mr. President, I wish to thank my colleagues for agreeing to the passage of S. 773, the Animal Drug Availability Act. This legislation is designed to address the severe shortage of new drugs for the treatment of animals. The bill will modernize clinical testing requirements and make them more predictable and will improve the efficiency and timeliness of the Food and Drug Administration's [FDA] review of new animal drug applications, while at the same time ensuring that new animal drugs are safe for animals and humans and are effective.

The Senate's passage of this legislation is a testament to what can be accomplished when the FDA, the regulated industry, and Congress recognize a problem—in this case, the lack of new drugs for treating animals—and work together in good faith to craft and enact creative, reasonable solutions to that problem. Dr. Steve Sundlof, the director of the FDA's Center for Veterinary Medicine, and his staff deserve great credit for their dedication to meaningful animal drug law and regulation reform in this Congress.

I wish especially to thank each of the Members who has cosponsored and worked with me for the passage of this legislation. Without their effort and dedication to seeing this bill through the legislative process, we would not have succeeded in passing this bill today. Our former majority leader, Senator Dole, and Senators LUGAR, PRYOR, PRESSLER, GREGG, GORTON, COATS, JEFFORDS, FRIST, HARKIN, CRAIG, INHOFE, GRASSLEY, MCCONNELL, KYL, SANTORUM, HEFLIN, BOND, KERREY, BENNETT, HELMS, HUTCHISON, LOTT, BUMPERS, MACK, ASHCROFT, COCHRAN, ROTH, WARNER, FORD, KEMPTHORNE, ROBB, NICKLES, STEVENS, ABRAHAM, DASCHLE, GRAMS, CONRAD, BURNS, MOSELEY-BRAUN, DORGAN, BAUCUS, and HATCH each deserve great credit for their active support for this legislation.

I ask unanimous consent a summary of the bill be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

S. 773, THE ANIMAL DRUG AVAILABILITY ACT—SUMMARY

The Animal Drug Availability Act, S. 773, was introduced on May 5, 1995, by Senator Kassebaum. It was approved by the Senate Committee on Labor and Human Resources on March 28, 1996, as part of S. 1744, the FDA Performance and Accountability Act, and now has a total of 43 bipartisan Senate cosponsors. Subsequently, S. 773 was refined in close collaboration with the Food and Drug Administration (FDA), and the amendment in the nature to S. 773 reflects these refinements.

S. 773 is designed to address the serious lack of drugs for treating animals by modernizing and making more predictable the FDA's requirements for new animal drug testing and improving the efficiency and timeliness of FDA's review of new animal drug applications, without compromising either human or animal safety or product effectiveness.

These reforms include:

1. *Determination of effectiveness:* The legislation would clarify the discretionary authority of the FDA to rely on one adequate and well-controlled investigation for the determination of the effectiveness of an animal drug. The study or studies could, but would no longer automatically be presumed to, require field investigation(s).

2. *Combination drugs:* The legislation clarifies that when an already approved animal drugs are used in combination with one another, the FDA may approve the combination drug as long as none of the drugs in combination exceeds its established tolerance or none of the drugs interferes with the working of another of the drugs.

3. *Collaborative protocol design:* The legislation provides for a collaborative protocol design process. The FDA is required to meet with individuals intending to investigate or investigating new animal drugs to mutually decide on the appropriate protocol for the clinical investigation. If the FDA decides that more than one field investigation will be necessary, the FDA must set forth its scientific justification for that decision.

4. *Drugs for minor uses and species:* The legislation directs the Secretary to propose legislative or regulatory options for facilitating the approval of animal drugs for minor species and minor uses.

5. *Drug tolerance setting:* The legislation clarifies that the FDA may approve animal drugs which will not exceed the tolerance set for that drug, as opposed to requiring the manufacturer to determine an optimal dose for the drug.

6. *Tolerance for unapproved drugs:* The legislation provides the Secretary new authority to set tolerances for new animal drugs that are not approved in the U.S. but are used in animals imported for consumption in this country.

7. *Veterainary feed directive drugs:* The legislation establishes a new category of animal drugs—''veterinary feed directive drugs.'' This is a category of drugs between prescription drugs and over-the-counter drugs. The bill establishes a number of requirements to ensure that these drugs can be tracked and that they are used appropriately.

8. *Feed mill licensing:* The legislation establishes a new requirement for the licensing of feed mills that are manufacturing feeds containing animal drugs to ensure conformity with good manufacturing practices and for other reasons.

Mr. LUGAR. Mr. President, I am pleased that the Animal Drug Availability Act (S. 773) is before the full Senate for consideration today.

As an original cosponsor of this legislation, I recognize the need for reform of the Food and Drug Administration [FDA] animal drug approval process. Producers and manufactures of animal drugs have been concerned with the lengthy time required to gain FDA approval of animal drugs as well as the lack of new drug options available to treat livestock and poultry.

The legislation before us today is a consensus bill that is acceptable to FDA, agricultural procedures, pharmaceutical and animal health organizations and has garnered bipartisan support in the Senate. I had written to Senator KASSEBAUM recently urging prompt action on this legislation and thank her for her efforts to move this bill forward.

The bill before us today will provide FDA with greater flexibility to determine when animal drugs are effective for intended uses; streamline approval of combination animal drugs when the drugs have been previously approved separately for the same species and conditions of use; provide FDA with greater flexibility in whether field investigations are necessary to prove efficacy; and require presubmission conferences to help FDA and drug manufacturers to reach agreement on testing requirements before a drug application is submitted to FDA. In addition, the bill streamlines the drug application licenses for feed mills, permits FDA to set import tolerances for drugs used in other countries, and includes a veterinary feed directive provision which will make new therapeutic animal drugs accessible in feed form.

I urge my colleagues to support this important bill.

Mr. GREGG. Mr. President, I rise today to talk about the demise of one very important piece of legislation—the 1996 FDA reform bill—and what I hope will be the success of another—the animal drug availability reform bill. These bills represent important Republican priorities: American patients and consumers, innovation in medicine and consumer products, and a smaller role for the Federal Government.

Republicans put forth an FDA reform bill, supported in the Labor Committee by three of our Democratic colleagues, that puts the needs of our citizens first. Our goal in developing this legislation was clearly to expedite the bureaucratic review process at the Food and Drug Administration, while still recognizing their role in ensuring the safety of products such as pharmaceuticals, medical devices, and food additives being introduced into domestic and international commerce.

In the Labor Committee, our discussions focused on the reprioritization of Agency resources and attitudes in order to achieve this goal. And while some have characterized these provisions as extreme, I believe that it is important to recognize that a number of provisions in the bill that our chairman, the senior Senator from Kansas [Mrs. KASSEBAUM] assembled simply recodify current law—albeit not current practice—by the FDA.

In addition, this legislation contained a number of incremental improvements to the Food, Drug and Cosmetic Act. While I will freely admit that many of these provisions do not go as far as the changes that I advocate, I recognize the balance that Senator KASSEBAUM was attempting to strike; that is why I voted in favor of this legislation in Committee. I also would like to mention the spirit of the negotiations that I observed Senator KASSEBAUM engaged in with our Democratic colleagues and the administration. I thought her approach to this important issue was eminently fair, balanced, and accommodating.

Mr. President, FDA reform is not a new idea. Like so many of the issues we take on, discussion and debate about FDA reform has been going on for many years. For example, the Edwards Commission was established by charter in 1989 and authorized by then Secretary of Health and Human Service Dr. Louis Sullivan. This task force was formed in response to a growing perception that FDA was in crisis. Serious questions had been raised about the agency's ability to do its job.

After a year of public testimony and study, they published a report in May, 1991—a detailed analysis of the FDA's inner workings. The report concluded that the FDA was an agency in crisis. A large part of the report focused on internal structure, organization and management; the report recommended individual center adopt mission statements and that paper work flow studies be conducted agencywide. As a result of the report, Congress gave FDA substantially more money and staff—but I think that we all now understand that simply providing the FDA more resources does not solve the problems they have at the Agency.

Mr. President, I originally had high hopes for FDA reform this Congress. On March 16, 1995, in a speech at an environmental facility in Virginia announcing phase II of the Reinventing Government initiative, the President even acknowledged that FDA reform was a vital issue. In RE–GO II, the administration issued specific recommendations for the reform of the FDA to be achieved through legislative and regulatory changes. However, I was concerned by the quotation used from the President's rhetoric on the first page of the follow up white paper: ''The Food and Drug Administration has made American drugs and medical devices the envy of the world and in demaind all over the world.''

I believe that it is this sort of perception that has gotten us to the point where we are today: a regulatory system that no longer has clear boundaries or delineated goals, is anticompetitive, and has an attitude that we must function as ''the FDA to the

world.'' Former Commissioner Dr. Charles Edwards put it more appropriately when he said that, ''The mission of the FDA is consumer protection. Unfortunately, the FDA has tended to confuse its mission with the power to promote what it deems to be appropriate personal and professional behavior.'' No matter—the administration's white paper of reforms proved to be more of a red herring than anything else.

The FDA has demonstrated a lack of investment on their part in the private sectors' efforts to bring cutting edge medicine to American patients. Businesses do not engage in activities lightly, especially small business making substantial investments in their own future. The FDA has also indicated an unwillingness to let scientists determine the standard of science, to let doctors freely practice medicine, and to allow patients to be informed about their range of options.

To the FDA, it all seems to be about money. The authorized user fees—or taxes placed on the backs of companies working to provide innovative health care solutions—in the Administration's budget request continue to grow. The Administration also continues to annually request two unauthorized user fees: one would levy a new tax on medical device manufacturers and another would be an important inspection fee. Increasing taxes will not solve the problems that persist at the Food and Drug Administration.

Peter Barton Hutt, former FDA General Counsel, summed this up well in a speech before the Utah International Medical Device Congress in 1993. He stated, ''User fees is a false issue. If we do not change the philosophy of the FDA reviewers about the criteria for approving either Section 510(k) notifications or PMA applications, we can triple the number of people in the FDA and not get one additional application approved.'' It is these sort of changes in philosophy, as well as corrections to the fiscal priorities, that we are seeking at the FDA through our reform efforts. But, unfortunately, Congress cannot legislate attitude.

I also remain unconvinced that new user fees would ever be sunset, even if the application backlog is cleared. I think the discussion we will soon begin in regard to the renegotiation of PDUFA will be revealing on this count. I also have yet to see any proposal that would refund user fees to any company if the product review was not completed within the statutory timeline—this is an agency that wants to function like a business without regard to the rules of business—''Get what you pay for.'' I don't see why businesses should be expected to tolerate this.

In recent years, there also seems to have been a marked shift from product approval to enforcement at FDA. While there is no clear cut cause for this sea change, the intimidation that has resulted from these actions is great. There is, of course, no way to accurately measure the chilling effect this may be having on relevant industries. But this police state mentality has spilled over into the appropriate regulation of product safety.

Companies are terrified that they will be made the victim of a public campaign in the media. The FDA is reputed for its role in propagating widespread fear of retaliation against any company that would cooperate with Congress in its examination of the FDA's mission and regulatory practices. We have found that a number of individuals and companies fear retribution in the form of delayed FDA product reviews and regulatory discrimination if they should criticize the agency. This fear has led to hesitancy on the part of potential witnesses to provide committees with the testimony that they need in order to make an informed judgment on the policies and practices of the agency.

Commissioner Kessler has argued that the industry perceives issues to be something other than what they actually are, such as the Reference List being viewed as a ''black list.'' While we appreciated the assurances made to the Labor Committee by the Commissioner that such fears are unfounded, I have yet to learn what affirmative steps the FDA has taken to reassure those regulated by the agency that they may feel completely comfortable exercising their right to speak freely to the Congress, without threat of retribution or retaliation from the agency. I have to wonder how many stories continue to go untold, how many problems go unexplored, how many questions remain unanswered.

However, Mr. President, I am pleased to note that a couple of FDA-related problems have been resolved this Congress. One dealt with the untenable restrictions placed on U.S. manufacturers regarding their ability to export products approved for use in other countries, but not yet approved for domestic commerce. Working closely with my colleague from Utah, Senator HATCH, we engaged in a lengthy dialog with ranking minority member of the Labor Committee, Mr. KENNEDY. The result was passage of reform of sections 801 and 802 of the Federal Food, Drug and Cosmetic Act, provisions which govern the import and export of FDA-regulated products. Subsequently, these provisions were signed into law, a major victory for U.S. manufacturers who are no longer obligated to build factories and send jobs and investment capital overseas.

A second major issue that was partially resolved dealt with the ridiculously unscientific Delaney Clause. Countless experts and virtually every former Commissioner have stated the fact that a ''zero risk'' standard is not only unscientific, but virtually immeasurable. As analytical examinations have improved, science has been able to detect ever-shrinking amounts of trace chemicals in our food supply—excellent science means that minute, formerly undetectable amounts of pesticides and chemicals can be detected, and even though they pose no threat over a human lifetime, would be banned under the unrealistic Delaney scheme. Fortunately, this Congress had the bipartisan wisdom to institute a realistic, scientifically based standard in place of the Delaney Clause as it related to the regulation of pesticides. Congress recognized that in this day and age ''zero risk'' would come close to meaning ''zero food.'' The Delaney reform signed into law takes us out of the realm of the theory of a health treat, and into a food safety realm that balances health considerations with an abundant, affordable food supply.

And, Mr. President, I am hopeful that we will add this animal drug reform compromise to the list of items we have accomplished this Congress. I understand from my colleague from Kansas that this legislation is the result of a real effort on the part of the FDA, the relevant industry, and her staff. I also understand that the House has taken action on this matter, so there is a realistic chance for these provisions to become law—the type of all that we can all feel good about, a law that balances consumer safety with an appropriate level of Federal regulation.

I also hope that we will have an opportunity to clear the way for one other related measure before Congress adjourns—the biomaterials bill that Senators GORTON, LIEBERMAN, and MCCAIN have been championing for many months. This legislation, which provides reasonable relief to the suppliers of critical raw materials. This relief is necessary to ensure that life-sustaining and life-enhancing devices will remain readily available to American patients.

Mr. President, let me just conclude by saying that the discussion of FDA reform will continue into the next Congress. This is a high priority for many of us, as it is such a high priority for American patients and consumers on a daily basis. We will continue to work hard to define an appropriate role for the Federal Government—for the FDA—in the lives of our citizens.

Mr. HARKIN. Mr. President, I am pleased to that we are today seeing Senate passage of this important legislation. I especially want to thank Senator KASSEBAUM for her efforts in working out the details of this consensus bill and in arranging for its passage as a freestanding measure. I also want to thank Senator KENNEDY for his cooperation and efforts in clearing the bill for passage.

I am proud to be an original cosponsor of the legislation. It has been very gratifying to have been a part of the process of reaching agreement on the provisions of this bill among representatives of the animal drug industry, livestock and poultry producer organizations, consumers and the Food and Drug Administration. In particular, I would like to commend Dr. Stephen Sundlof, Director of the Center for Veterinary Medicine at FDA for his hard

work and cooperation in reaching consensus on this bill. This has been an exemplary effort in reaching a commonsense balance between the need for adequate regulation and the practical realities of livestock and poultry production.

The bill does not in any way weaken the protections for human health contained in current law pertaining to animal drugs. The bill does, however, streamline the animal drug approval process, primarily by removing unnecessary and duplicative testing and investigation requirements found in current law. By reducing unnecessary requirements in the approval process, the approval of new animal drugs will become less costly and time consuming. That is very important, since the livestock and poultry industries are facing a near crisis caused by the lack of approved new drugs. For example, there has been only one new drug approved for use in swine since 1990, and that drug cannot be marketed as a practical matter until this legislation passes.

The bill also contains a much needed resolution of the problems associated with veterinary oversight in dispensing of drugs for use in livestock and poultry feeds.

This legislation is a huge step forward in improving FDA's animal drug approval process and a real victory for livestock and poultry producers, consumers and producers of animal drugs.

Mr. FRIST. Mr. President, I ask unanimous consent the amendment be agreed to, the bill be deemed read a third time and passed, the motion to reconsider be laid upon the table, and that any statement relating to the bill appear at this point in the RECORD.

The PRESIDING OFFICER. Without objection, it is so ordered.

The amendment (No. 5401) was agreed to.

The bill (S. 773), as amended, was deemed read for a third time and passed, as follows:

S. 773

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE; REFERENCE.**

(a) SHORT TITLE.—This Act may be cited as the ''Animal Drug Availability Act of 1996''.

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

**SEC. 2. EVIDENCE OF EFFECTIVENESS.**

(a) ORIGINAL APPLICATIONS.—Paragraph (3) of section 512(d) (21 U.S.C. 360b(d)) is amended to read as follows:

''(3) As used in this section, the term 'substantial evidence' means evidence consisting of one or more adequate and well controlled investigations, such as—

''(A) a study in a target species;

''(B) a study in laboratory animals;

''(C) any field investigation that may be required under this section and that meets the requirements of subsection (b)(3) if a presubmission conference is requested by the applicant;

''(D) a bioequivalence study; or

''(E) an in vitro study;

by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.''.

(b) CONFORMING AMENDMENTS.—

(1) Clauses (ii) and (iii) of section 512(c)(2)(F) (21 U.S.C. 360b(c)(2)(F)) are each amended—

(A) by striking ''reports of new clinical or field investigations (other than bioequivalence or residue studies) and,'' and inserting ''substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or,''; and

(B) by striking ''essential to'' and inserting ''required for''.

(2) Section 512(c)(2)(F)(v) (21 U.S.C. 360b(c)(2)(F)(v)) is amended—

(A) by striking ''subparagraph (B)(iv)'' each place it appears and inserting ''clause (iv)'';

(B) by striking ''reports of clinical or field investigations'' and inserting ''substantial evidence of the effectiveness of the drug involved, any studies of animal safety,''; and

(C) by striking ''essential to'' and inserting ''required for''.

(c) COMBINATION DRUGS.—Section 512(d) (21 U.S.C. 360b(d)) , as amended by subsection (a) is amended by adding at the end the following:

''(4) In a case in which an animal drug contains more than one active ingredient, or the labeling of the drug prescribes, recommends, or suggests use of the drug in combination with one or more other animal drugs, and the active ingredients or drugs intended for use in the combination have previously been separately approved for particular uses and conditions of use for which they are intended for use in the combination—

''(A) the Secretary shall not issue an order under paragraph (1)(A), (1)(B), or (1)(D) refusing to approve the application for such combination on human food safety grounds unless the Secretary finds that the application fails to establish that—

''(i) none of the active ingredients or drugs intended for use in the combination, respectively, at the longest withdrawal time of any of the active ingredients or drugs in the combination, respectively, exceeds its established tolerance; or

''(ii) none of the active ingredients or drugs in the combination interferes with the methods of analysis for another of the active ingredients or drugs in the combination, respectively;

''(B) the Secretary shall not issue an order under paragraph (1)(A), (1)(B), or (1)(D) refusing to approve the application for such combination on target animal safety grounds unless the Secretary finds that—

''(i)(I) there is a substantiated scientific issue, specific to one or more of the active ingredients or animal drugs in the combination, that cannot adequately be evaluated based on information contained in the application for the combination (including any investigations, studies, or tests for which the applicant has a right of reference or use from the person by or for whom the investigations, studies, or tests were conducted); or

''(II) there is a scientific issue raised by target animal observations contained in studies submitted to the Secretary as part of the application; and

''(ii) based on the Secretary's evaluation of the information contained in the application with respect to the issues identified in clauses (i)(I) and (II), paragraph (1)(A), (B), or (D) apply;

''(C) except in the case of a combination that contains a nontopical antibacterial ingredient or animal drug, the Secretary shall not issue an order under paragraph (1)(E) refusing to approve an application for a combination animal drug intended for use other than in animal feed or drinking water unless the Secretary finds that the application fails to demonstrate that—

''(i) there is substantial evidence that any active ingredient or animal drug intended only for the same use as another active ingredient or animal drug in the combination makes a contribution to labeled effectiveness;

''(ii) each active ingredient or animal drug intended for at least one use that is different from all other active ingredients or animal drugs used in the combination provides appropriate concurrent use for the intended target population; or

''(iii) where based on scientific information the Secretary has reason to believe the active ingredients or animal drugs may be physically incompatible or have disparate dosing regimens, such active ingredients or animal drugs are physically compatible or do not have disparate dosing regimens; and

''(D) the Secretary shall not issue an order under paragraph (1)(E) refusing to approve an application for a combination animal drug intended for use in animal feed or drinking water unless the Secretary finds that the application fails to demonstrate that—

''(i) there is substantial evidence that any active ingredient or animal drug intended only for the same use as another active ingredient or animal drug in the combination makes a contribution to the labeled effectiveness;

''(ii) each of the active ingredients or animal drugs intended for at least one use that is different from all other active ingredients or animal drugs used in the combination provides appropriate concurrent use for the intended target population;

''(iii) where a combination contains more than one nontopical antibacterial ingredient or animal drug, there is substantial evidence that each of the nontopical antibacterial ingredients or animal drugs makes a contribution to the labeled effectiveness; or

''(iv) where based on scientific information the Secretary has reason to believe the active ingredients or animal drugs intended for use in drinking water may be physically incompatible, such active ingredients or animal drugs intended for use in drinking water are physically compatible.''.

(d) PRESUBMISSION CONFERENCE.—Section 512(b) (21 U.S.C. 360b(b)) is amended by adding at the end the following:

''(3) Any person intending to file an application under paragraph (1) or a request for an investigational exemption under subsection (j) shall be entitled to one or more conferences prior to such submission to reach an agreement acceptable to the Secretary establishing a submission or an investigational requirement, which may include a requirement for a field investigation. A decision establishing a submission or an investigational requirement shall bind the Secretary and the applicant or requestor unless (A) the Secretary and the applicant or requestor mutually agree to modify the requirement, or (B) the Secretary by written order determines that a substantiated scientific requirement essential to the determination of safety or effectiveness of the animal drug involved has appeared after the conference. No later than 25 calendar days after each such conference, the Secretary shall provide a written order setting forth a scientific justification specific to the animal

drug and intended uses under consideration if the agreement referred to in the first sentence requires more than one field investigation as being essential to provide substantial evidence of effectiveness for the intended uses of the drug. Nothing in this paragraph shall be construed as compelling the Secretary to require a field investigation.''.

(e) IMPLEMENTATION.—

(1) IN GENERAL.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue proposed regulations implementing the amendments made by this Act as described in paragraph (2)(A) of this subsection, and not later than 18 months after the date of enactment of this Act, the Secretary shall issue final regulations implementing such amendments. Not later than 12 months after the date of enactment of this Act, the Secretary shall issue proposed regulations implementing the other amendments made by this Act as described in paragraphs (2)(B) and (2)(C) of this subsection, and not later than 24 months after the date of enactment of this Act, the Secretary shall issue final regulations implementing such amendments.

(2) CONTENTS.—In issuing regulations implementing the amendments made by this Act, and in taking an action to review an application for approval of a new animal drug under section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b), or a request for an investigational exemption for a new animal drug under subsection (j) of such section, that is pending or has been submitted prior to the effective date of the regulations, the Secretary shall—

(A) further define the term ''adequate and well controlled'', as used in subsection (d)(3) of section 512 of such Act, to require that field investigations be designed and conducted in a scientifically sound manner, taking into account practical conditions in the field and differences between field conditions and laboratory conditions;

(B) further define the term ''substantial evidence'', as defined in subsection (d)(3) of such section, in a manner that encourages the submission of applications and supplemental applications; and

(C) take into account the proposals contained in the citizen petition (FDA Docket No. 91P–0434/CP) jointly submitted by the American Veterinary Medical Association and the Animal Health Institute, dated October 21, 1991.

Until the regulations required by subparagraph (A) are issued, nothing in the regulations published at 21 C.F.R. 514.111(a)(5) (April 1, 1996) shall be construed to compel the Secretary of Health and Human Services to require a field investigation under section 512(d)(1)(E) of the Federal Food, Drug, and Cosmetic Act (21 US.C. 360b(d)(1)(E)) or to apply any of its provisions in a manner inconsistent with the considerations for scientifically sound field investigations set forth in subparagraph (A).

(f) MINOR SPECIES AND USES.—The Secretary of Health and Human Services shall consider legislative and regulatory options for facilitating the approval under section 512 of the Federal Food, Drug, and Cosmetic Act of animal drugs intended for minor species and for minor uses and, within 18 months after the date of enactment of this Act, announce proposals for legislative or regulatory change to the approval process under such section for animal drugs intended for use in minor species or for minor uses.

**SEC. 3. LIMITATION ON RESIDUES.**

Section 512(d)(1)(F) (21 U.S.C. 360b(d)(1)(F)) is amended to read as follows:

''(F) Upon the basis of information submitted to the Secretary as part of the application or any other information before the Secretary with respect to such drug, any use prescribed, recommended, or suggested in labeling proposed for such drug will result in a residue of such drug in excess of a tolerance found by the Secretary to be safe for such drug.''.

**SEC. 4. IMPORT TOLERANCES.**

Section 512(a) (21 U.S.C. 360b(a)) is amended by adding the following new paragraph at the end:

''(6) For purposes of section 402(a)(2)(D), a use or intended use of a new animal drug shall not be deemed unsafe under this section if the Secretary establishes a tolerance for such drug and any edible portion of any animal imported into the United States does not contain residues exceeding such tolerance. In establishing such tolerance, the Secretary shall rely on data sufficient to demonstrate that a proposed tolerance is safe based on similar food safety criteria used by the Secretary to establish tolerances for applications for new animal drugs filed under subsection (b)(1). The Secretary may consider and rely on data submitted by the drug manufacturer, including data submitted to appropriate regulatory authorities in any country where the new animal drug is lawfully used or data available from a relevant international organization, to the extent such data are not inconsistent with the criteria used by the Secretary to establish a tolerance for applications for new animal drugs filed under subsection (b)(1). For purposes of this paragraph, 'relevant international organization' means the Codex Alimenterius Commission or other international organization deemed appropriate by the Secretary. The Secretary may, under procedures specified by regulation, revoke a tolerance established under this paragraph if information demonstrates that the use of the new animal drug under actual use conditions results in food being imported into the United States with residues exceeding the tolerance or if scientific evidence shows the tolerance to be unsafe.''.

**SEC. 5. VETERINARY FEED DIRECTIVES.**

(a) SECTION 503.—Section 503(f)(1)(A) (21 U.S.C. 353(f)(1)(A)) is amended by inserting after ''other than man'' the following: '', other than a veterinary feed directive drug intended for use in animal feed or an animal feed bearing or containing a veterinary feed directive drug,''.

(b) SECTION 504.—The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 503 the following:

''VETERINARY FEED DIRECTIVE DRUGS

''SEC. 504. (a)(1) A drug intended for use in or on animal feed which is limited by an approved application filed pursuant to section 512(b) to use under the professional supervision of a licensed veterinarian is a veterinary feed directive drug. Any animal feed bearing or containing a veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice. When labeled, distributed, held, and used in accordance with this section, a veterinary feed directive drug and any animal feed bearing or containing a veterinary feed directive drug shall be exempt from section 502(f).

''(2) A veterinary feed directive is lawful if it—

''(A) contains such information as the Secretary may by general regulation or by order require; and

''(B) is in compliance with the conditions and indications for use of the drug set forth in the notice published pursuant to section 512(i).

''(3)(A) Any persons involved in the distribution or use of animal feed bearing or containing a veterinary feed directive drug and the licensed veterinarian issuing the veterinary feed directive shall maintain a copy of the veterinary feed directive applicable to each such feed, except in the case of a person distributing such feed to another person for further distribution. Such person distributing the feed shall maintain a written acknowledgment from the person to whom the feed is shipped stating that that person shall not ship or move such feed to an animal production facility without a veterinary feed directive or ship such feed to another person for further distribution unless that person has provided the same written acknowledgment to its immediate supplier.

''(B) Every person required under subparagraph (A) to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

''(C) Any person who distributes animal feed bearing or containing a veterinary feed directive drug shall upon first engaging in such distribution notify the Secretary of that person's name and place of business. The failure to provide such notification shall be deemed to be an act which results in the drug being misbranded.

''(b) A veterinary feed directive drug and any feed bearing or containing a veterinary feed directive drug shall be deemed to be misbranded if their labeling fails to bear such cautionary statement and such other information as the Secretary may by general regulation or by order prescribe, or their advertising fails to conform to the conditions and indications for use published pursuant to section 512(i) or fails to contain the general cautionary statement prescribed by the Secretary.

''(c) Neither a drug subject to this section, nor animal feed bearing or containing such a drug, shall be deemed to be a prescription article under any Federal or State law.''.

(c) CONFORMING AMENDMENT.—Section 512 (21 U.S.C. 360b) is amended in subsection (i) by inserting after ''(including special labeling requirements'' the following: ''and any requirement that an animal feed bearing or containing the new animal drug be limited to use under the professional supervision of a licensed veterinarian''.

(d) SECTION 301(e).—Section 301(e) (21 U.S.C. 331(e)) is amended by inserting after ''by section 412'' the following: '', 504,''; and by inserting after ''under section 412,'' the following: ''504,''.

**SEC. 6. FEED MILL LICENSES.**

(a) SECTION 512(a).—Paragraphs (1) and (2) of section 512(a) (21 U.S.C. 360b(a)) are amended to read as follows:

''(a)(1) A new animal drug shall, with respect to any particular use or intended use of such drug, be deemed unsafe for the purposes of section 501(a)(5) and section 402(a)(2)(D) unless —

''(A) there is in effect an approval of an application filed pursuant to subsection (b) with respect to such use or intended use of such drug, and

''(B) such drug, its labeling, and such use conform to such approved application.

A new animal drug shall also be deemed unsafe for such purposes in the event of removal from the establishment of a manufacturer, packer, or distributor of such drug for use in the manufacture of animal feed in any State unless at the time of such removal such manufacturer, packer, or distributor has an unrevoked written statement from the consignee of such drug, or notice from the Secretary, to the effect that, with respect to the use of such drug in animal feed, such consignee (i) holds a license issued

under subsection (m) and has in its possession current approved labeling for such drug in animal feed; or (ii) will, if the consignee is not a user of the drug, ship such drug only to a holder of a license issued under subsection (m).

''(2) An animal feed bearing or containing a new animal drug shall, with respect to any particular use or intended use of such animal feed be deemed unsafe for the purposes of section 501(a)(6) unless—

''(A) there is in effect an approval of an application filed pursuant to subsection (b) with respect to such drug, as used in such animal feed,

''(B) such animal feed is manufactured at a site for which there is in effect a license issued pursuant to subsection (m)(1) to manufacture such animal feed, and

''(C) such animal feed and its labeling, distribution, holding, and use conform to the conditions and indications of use published pursuant to subsection (i).''.

(b) SECTION 512(m).—Section 512(m) (21 U.S.C. 360b(m)) is amended to read as follows:

''(m)(1) Any person may file with the Secretary an application for a license to manufacture animal feeds bearing or containing new animal drugs. Such person shall submit to the Secretary as part of the application (A) a full statement of the business name and address of the specific facility at which the manufacturing is to take place and the facility's registration number, (B) the name and signature of the responsible individual or individuals for that facility, (C) a certification that the animal feeds bearing or containing new animal drugs are manufactured and labeled in accordance with the applicable regulations published pursuant to subsection (i), and (D) a certification that the methods used in, and the facilities and controls used for, manufacturing, processing, packaging, and holding such animal feeds are in conformity with current good manufacturing practice as described in section 501(a)(2)(B).

''(2) Within 90 days after the filing of an application pursuant to paragraph (1), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall (A) issue an order approving the application if the Secretary then finds that none of the grounds for denying approval specified in paragraph (3) applies, or (B) give the applicant notice of an opportunity for a hearing before the Secretary under paragraph (3) on the question whether such application is approvable. The procedure governing such a hearing shall be the procedure set forth in the last two sentences of subsection (c)(1).

''(3) If the Secretary, after due notice to the applicant in accordance with paragraph (2) and giving the applicant an opportunity for a hearing in accordance with such paragraph, finds, on the basis of information submitted to the Secretary as part of the application, on the basis of a preapproval inspection, or on the basis of any other information before the Secretary—

''(A) that the application is incomplete, false, or misleading in any particular;

''(B) that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such animal feed are inadequate to preserve the identity, strength, quality, and purity of the new animal drug therein; or

''(C) that the facility manufactures animal feeds bearing or containing new animal drugs in a manner that does not accord with the specifications for manufacture or labels animal feeds bearing or containing new animal drugs in a manner that does not accord with the conditions or indications of use that are published pursuant to subsection (i), the Secretary shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that subparagraphs (A) through (C) do not apply, the Secretary shall issue an order approving the application. An order under this subsection approving an application for a license to manufacture animal feeds bearing or containing new animal drugs shall permit a facility to manufacture only those animal feeds bearing or containing new animal drugs for which there are in effect regulations pursuant to subsection (i) relating to the use of such drugs in or on such animal feed.

''(4)(A) The Secretary shall, after due notice and opportunity for hearing to the applicant, revoke a license to manufacture animal feeds bearing or containing new animal drugs under this subsection if the Secretary finds—

''(i) that the application for such license contains any untrue statement of a material fact; or

''(ii) that the applicant has made changes that would cause the application to contain any untrue statements of material fact or that would affect the safety or effectiveness of the animal feeds manufactured at the facility unless the applicant has supplemented the application by filing with the Secretary adequate information respecting all such changes and unless there is in effect an approval of the supplemental application.

If the Secretary (or in the Secretary's absence the officer acting as the Secretary) finds that there is an imminent hazard to the health of humans or of the animals for which such animal feed is intended, the Secretary may suspend the license immediately, and give the applicant prompt notice of the action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this sentence shall not be delegated.

''(B) The Secretary may also, after due notice and opportunity for hearing to the applicant, revoke a license to manufacture animal feed under this subsection if the Secretary finds—

''(i) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order under paragraph (5)(A) of this subsection or section 504(a)(3)(A), or the applicant has refused to permit access to, or copying or verification of, such records as required by subparagraph (B) of such paragraph or section 504(a)(3)(B);

''(ii) that on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such license was issued, the methods used in, or the facilities and controls used for, the manufacture, processing, packing, and holding of such animal feed are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drug therein, and were not made adequate within a reasonable time after receipt of written notice from the Secretary, specifying the matter complained of;

''(iii) that on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such license was issued, the labeling of any animal feeds, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or

''(iv) that on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such license was issued, the facility has manufactured, processed, packed, or held animal feed bearing or containing a new animal drug adulterated under section 501(a)(6) and the facility did not discontinue the manufacture, processing, packing, or holding of such animal feed within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

''(C) The Secretary may also revoke a license to manufacture animal feeds under this subsection if an applicant gives notice to the Secretary of intention to discontinue the manufacture of all animal feed covered under this subsection and waives an opportunity for a hearing on the matter.

''(D) Any order under this paragraph shall state the findings upon which it is based.

''(5) When a license to manufacture animal feeds bearing or containing new animal drugs has been issued—

''(A) the applicant shall establish and maintain such records, and make such reports to the Secretary, or (at the option of the Secretary) to the appropriate person or persons holding an approved application filed under subsection (b), as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or paragraph (4); and

''(B) every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

''(6) To the extent consistent with the public health, the Secretary may promulgate regulations for exempting from the operation of this subsection facilities that manufacture, process, pack, or hold animal feeds bearing or containing new animal drugs.''.

(c) TRANSITIONAL PROVISION.—A person engaged in the manufacture of animal feeds bearing or containing new animal drugs who holds at least one approved medicated feed application for an animal feed bearing or containing new animal drugs, the manufacture of which was not otherwise exempt from the requirement for an approved medicated feed application on the date of the enactment of this Act, shall be deemed to hold a license for the manufacturing site identified in the approved medicated feed application. The revocation of license provisions of section 512(m)(4) of the Federal Food, Drug, and Cosmetic Act, as amended by this Act, shall apply to such licenses. Such license shall expire within 18 months from the date of enactment of this Act unless the person submits to the Secretary a completed license application for the manufacturing site accompanied by a copy of an approved medicated feed application for such site, which license application shall be deemed to be approved upon receipt by the Secretary.

## UNANIMOUS–CONSENT AGREEMENT

Mr. FRIST. Mr. President, I ask unanimous consent that the previous order be amended so that the Senate stands in adjournment until 9:30 tomorrow morning and the routine morning requests be deemed agreed to.

The PRESIDING OFFICER. Without objection, it is so ordered.