Grocers Association (Texas); Health Advocacy Services (California); Independent Cosmetic Manufacturers & Distributors, Inc.; Indiana Manufacturers Association; Indiana Retail Council; Industry and Commerce Association of South Dakota; Interamerican College of Physicians and Surgeons; Iowa Retail Federal, Inc.; and Maryland Association of Chain Drug Stores.

Maryland Retailers Association; Medical Society of the State of New York; Medical Society of Virginia; Michigan Chamber of Commerce; Michigan Distributors and Venders Association, Inc.; Michigan State Medical Society; Minnesota Chamber of Commerce; Minnesota Grocers Association; Minnesota Retail Merchants Association; Mississippi Wholesale Distributors Association; Missouri Grocers Association; Missouri Retailers Association; Missouri State Medical Association; National Association of Chain Drug Stores; and National Association of Manufacturers.

National Coalition of Hispanic Health and Human Services; National Community Pharmacists Association; National Consumers League; National Council on the Aging; National Hispanic Council on Aging; National Retail Federation; National Wholesale Druggists' Association; New Hampshire Medical Society; New Mexico Pharmaceutical Association; Nonprescription Drug Manufacturers Association; North Carolina Retail Merchants Association; Ohio Council of Retail Merchants; Ohio Grocers Association; Ohio Wholesale Druggists Association; and Pennsylvania Association of Chain Drug Stores, Inc.

Philadelphia Association of Retail Druggists; Philadelphia College of Pharmacy; Retail Merchants Association of New Hampshire; Retailers Association of Massachusetts; Robbie Vierra-Lambert Spinal Cord Organization for Regaining Excellence; Safety & Health Council of New Hampshire; Safeway, Inc.; Senior Medication Awareness & Training Coalition, Sickle Cell Disease Association of America, Inc.; South Dakota Pharmacists Association; Tennessee Association of Business; Tennessee Grocers Association; Texas Association of Business & Chambers of Commerce; Texas Food Industry Association; and The 60 Plus Association.

United Seniors Association; United Seniors Health Cooperative; United States Hispanic Chamber of Commerce; Ukrop's; Vermont Board of Pharmacy; Vermont Chamber of Commerce; Vermont Grocers Association; Vermont Medical Society; Virginia Chamber of Commerce; Virginia Manufacturers Association; Virginia Pharmacists Association; Virginia Retail Merchants Association; Washington Retailers Association's Retail Pharmacy Council; Washington State Medical Association; White House Conference on Small Business, New Jersey Delegation; Wisconsin Grocers Association, Inc.; and Wisconsin Manufacturers and Commerce.

FORMER FDA COMMISSIONERS SUPPORTING NATIONAL UNIFORMITY

Charles C. Edwards, M.D.; Arthur Hull Hayes, Jr., M.D.; Donald Kennedy, Ph.D.; and Herbert Ley, Jr., M.D.

Mr. JEFFORDS. Madam President, we are nearing the end of the debate. I have no more requests for time that I am aware of. So I will make some comments and then go into a quorum call. But I want to alert Senators that if I do not have a request within the next 10 minutes, it is my intention to yield back the remainder of my time, assuming the minority would do the same thing, so that we can expedite the process and the movement of legislation through the Senate.

Madam President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

Mr. JEFFORDS. Madam President, I ask unanimous consent that the order for the quorum call be rescinded.

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

Mr. JEFFORDS. Madam President, I yield 6 minutes to the Senator from Arkansas.

CONSTITUTIONALITY OF MINING AMENDMENT

Mr. BUMPERS. Madam President, I rise today because I believe the Senate set a terrible precedent last Thursday when it voted to uphold a point of order that was made against an amendment that Senator GREGG and I offered to H.R. 2107, the Interior appropriations bill. This amendment proposed to collect the royalty from hardrock mining operations on public land and a reclamation fee from hardrock mining operations on land that was patented pursuant to the 1872 mining law. The receipts collected from the royalty and reclamation fee would have been deposited in a trust fund to be used to reclaim abandoned hardrock mines in the West.

Opponents of my amendment, in an attempt to prevent Senators from going on record in support of an effort to make the mining industry help pay for the environmental disasters it has created, raised a point of order arguing that the reclamation fee constituted a tax proposed by the Senate and thus the amendment violated the origination clause of the Constitution; that is, that all revenue measures must originate in the House. Unfortunately, the Senate voted to uphold the point of order even though the amendment was not even close to being unconstitutional.

The Supreme Court has held on numerous occasions that while a tax provision may not originate in the Senate, a governmental fee can. ''A statute that creates a particular governmental program and that raises revenue to support that program, as opposed to a statute that raises revenue to support government generally, it is not a 'bill for raising revenue' within the meaning of the origination clause.'' That is confirmed in United States versus Munoz-Florez. My amendment would have imposed a royalty and a fee in order to directly fund the reclamation of abandoned hardrock mines. It was not intended to raise revenues for the Treasury.

In fact, Madam President, the Parliamentarian has already ruled that the reclamation fee provision does not constitute a tax when the Parliamentarian referred S. 326, which includes the very same reclamation fee proposal that I had, to the Senate Energy and Natural Resources Committee rather than the Finance Committee. The House Parliamentarian made the very same ruling when he referred the House companion to S. 326 to the House Natural Resources Committee rather than the Ways and Means Committee.

I find it perplexing that anybody could argue that the amendment that Senator GREGG and I offered to the Interior appropriations bill could possibly constitute a tax. However, even if that were the case, it ought to be noted that the Interior appropriations bill originated in the House of Representatives in accordance with the origination clause of the Constitution. It does not matter that the amendment was offered in the Senate as long as the bill originated in the House. In *Flint* v. *Stone Tracy Company*, 220 U.S. 107 (1911), the Supreme Court ruled that legislation which created the tax on corporations complied with the origination clause even though the corporate tax was proposed by the Senate as a substitute to an inheritance tax that was included in the bill as reported by the House.

The fact that H.R. 2107 was reported by the Appropriations Committee rather than the Finance Committee is not relevant. The Senate has in the past added an amendment which modified the Tax Code to an appropriations bill. For example, in 1982 the Senate added a provision to the supplemental appropriations bill which limited the availability of certain tax deductions for Members of Congress.

Madam President, Senate rules do not permit the Parliamentarian to rule when a point of order is made against an amendment on constitutional grounds. If the Parliamentarian had been able to rule, the point of order would not have even been made and the decision would not have been close. Instead, the point of order was made with the knowledge that Senators would be able to defeat the Bumpers-Gregg amendment without actually going on record in support of allowing mining companies to continue acquiring billions of dollars worth of minerals from the taxpayers of this country without compensation and leaving those same taxpayers with environmental disasters to clean up.

Mr. President, I yield the floor.

Mr. JEFFORDS. Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER (Mr. DEWINE). The clerk will call the roll.

The bill clerk proceeded to call the roll.

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

The Senate continued with the consideration of the bill.

Mr. KENNEDY. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

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

Mr. KENNEDY. How much time remains, Mr. President?

The PRESIDING OFFICER. The Senator from Massachusetts has 7 minutes.

Mr. KENNEDY. Mr. President, I yield myself 3 minutes.

Just a short while ago, we heard some comments on the floor about how this whole process has taken a long period of time. It has taken a period of time. But I think one can see from any fair review of the history of the legislation that very substantial progress has been made in making this a better bill. As I pointed out earlier in the debate, of the 20 major health safety issues identified by the administration, 19 have been addressed, not only in our committee markup, but also in the negotiations that we had prior to the time of the legislation coming to the floor. There is the one remaining item, which deals with safety and medical devices. It is extremely important. We have given focus to this issue because it deserves the focus that we have given it.

Mr. President, I have in my hand the statement of the administration policy. It indicates that it has two major concerns with the bill. One is the technical provision with regard to the budget agreement and how they are going to allocate to PDUFA, which is a technical issue. But the other issue mentioned by the administration is this particular provision:

First, section 404 of the bill would lower the review standard for marketing approval by precluding the FDA from reviewing medical devices for uses other than those for which the manufacturer says they are intended.

The administration indicates, as they did in the letter in September, as they did in June, that this particular provision is dangerous in terms of the consumers in this country.

We have reviewed, over the course of the debate, the dangerous situations that have been the result of medical device disasters. We are committed to avoiding that kind of disaster in the future. We have a good safety record at the present time, but we are endangering that record with section 404. We noted that virtually every consumer group supports changing section 404. It is enormously important. It goes to the fundamental question of providing FDA with the power and authority to pursue the protections of the American health in the area of medical devices.

Mr. President, I ask unanimous consent that the statement of the administration policy supporting our position regarding 404 be printed in the RECORD.

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

EXECUTIVE OFFICE OF THE PRESIDENT, OFFICE OF MANAGEMENT AND BUDGET,
Washington, DC, September 24, 1997.

STATEMENT OF ADMINISTRATION POLICY

(This statement has been coordinated by OMB with the concerned agencies.)

S. 830—FDA MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

(Senator Jeffords (R) VT)

The Administration applauds the Senate for its bipartisan effort to improve S. 830 since it was reported by the Senate Committee on Labor and Human Resources, and appreciates the Senate's responsiveness to concerns that have been raised. Because of the importance of obtaining a five-year extension of the Prescription Drug User Fee Act (PDUFA), the Administration has no objection to passage of the bill by the Senate at this time. However, the Administration finds that the provisions identified below are unacceptable and as the legislative process continues, will work to ensure that our remaining concerns are resolved.

In general, this legislation represents a significant step toward accomplishing our mutual goal of assuring the agency's optimum performance while protecting the health of the American public. The Administration, however, continues to have two major concerns with the bill.

First, section 404 of the bill would lower the review standard for marketing approval by precluding the Food and Drug Administration (FDA) from reviewing new medical devices for uses other than those for which the manufacturer says they are intended. Second, the PDUFA trigger as proposed in S. 830 undercuts the bipartisan budget agreement (BBA) by requiring budget increases for FDA not envisioned by the BBA, and would interfere with HHS' ability to allocate resources appropriately throughout the Department.

In order to be able to support the final bill, the Administration will continue to work with the House of Representatives and in conference to resolve these and other identified issues.

Mr. KENNEDY. We hope that we can be convincing as this legislation goes forward. We have not been convincing here on the floor. We hope provisions can be accepted that will make 404 acceptable in terms of the public health issues. I want to express my sincere appreciation to the chairman of the committee, Senator JEFFORDS, who has been a chairman's chair. He is strong in his belief. He is a fighter for the things that he champions. He has been willing to accommodate differing views. He protects his strong posture and positions on his own views, and I respect that. I thank the other Members of this body for their courtesy during the course of what I know has been a continuing discussion and debate on a very important measure. I thank all of our Members for their courtesy and consideration as we move toward a vote on this legislation. I thank my chairman.

At the time when the Senator from Vermont is prepared to yield back his time, I will be prepared to do so likewise and move to our vote.

UNANIMOUS-CONSENT REQUEST

Mr. JEFFORDS. Mr. President, first, I have a unanimous-consent request, which has been cleared on both sides.

I ask unanimous consent that it be in order to consider amendment No. 1184, as modified, with changes that are at the desk; further, that the amendment be agreed to, and the motion to reconsider be laid upon the table.

I'm sorry, Mr. President, I withdraw that request at this moment.

The PRESIDING OFFICER. It is withdrawn.

Mr. JEFFORDS. Mr. President, first of all, I thank the ranking member for his help on this bill. We agree on 19 out of 20 provisions. His steadfast and articulate objection to the 20th, relative to section 404, has been done sincerely and very well done on that issue. I believe that we have a good bill, but we remain open to suggestions, as always, as to how the bill can be improved. I am extremely pleased that the Senate has overwhelmingly approved S. 830 yesterday. I believe this is an important step forward for ensuring a stronger and more efficient FDA.

Throughout this process, we have had the benefit of input from all interested parties on how best to modernize the Agency, while ensuring that its stellar standard for public safety remains as strong as ever. I am extremely proud of the strong support of this legislation expressed by the health community. For instance, the National Health Council, a coalition of over 100 health and patient organizations, has urged the Senate to move forward with this legislation. We have also received support from physician groups, including the American Medical Association and the American Academy of Pediatrics.

We must remember that drugs and medical devices delayed at the FDA are often lives lost. When cardiac defibrillators were first developed in the late 1980's, they brought new hope and opportunity to many of the 350,000 Americans who would otherwise suffer sudden cardiac death each year.

But the first version of this technology required opening the chest and separating the ribs to apply this technology to the heart. This procedure carried a 4.2 percent mortality rate.

Improvements to this defibrillator technology were widely available in Europe two years before patients could benefit in this country. The new technology did not require cracking the patients chest, but only a small incision to allow the technology to be threaded through a vein into the heart.

During this unnecessary 2-year delay, it is estimated that 1,056 Americans died from complications related to the more invasive technique. Delay does cost lives.

And far from allowing dangerous products on the market as Senator KENNEDY has alleged, section 404 of this bill keeps intact FDA's authority to investigate technological issues which raise new safety and effectiveness questions, does not limit FDA's enforcement authority, and does not touch FDA's regulations which require that medical device applications be truthful and not omit any material facts.

Section 404 does quite appropriately keep FDA out of regulating the practice of medicine. That is important and we should fight to protect the intent of this provision.

Patients will also benefit from other provisions of the bill including the registry of clinical trials, fast-track approval for drugs treating life-threatening diseases, expanded access to investigational therapies, and the incentives established to investigate pediatric uses of drugs.

I want to thank the patient, consumer, and physician groups, and all the others we have worked with, for their commitment to working toward real reforms that strengthen the FDA and the contributions they have made in crafting this bipartisan measure.

Mr. President, how much time do I have left?

The PRESIDING OFFICER. The Senator from Vermont has 9 minutes remaining.

Mr. JEFFORDS. I yield 2 minutes to the Senator from Florida.

The PRESIDING OFFICER. The Senator from Florida is recognized.

Mr. MACK. Mr. President, I thank Senator JEFFORDS for yielding.

First of all, I want to commend him for a tremendous amount of work. This is an incredibly complicated piece of legislation. It has involved a lot of different interest groups in some issues that have become very charged.

So I again want to thank the Senator from Vermont for his willingness to work with Senator FRIST and I as we worked on the so-called off-label issue.

I also want to express my appreciation to Senator KENNEDY. He had some deep concerns about the legislation, and as a result of extensive discussions we were able to find a compromise. I think it was one of the reasons that this bill was able to move forward.

So I thank Senator JEFFORDS and Senator KENNEDY. And I also want to put in a comment with respect to Mark Smith, my staffer who has worked on this issue for more than some 2½ years.

Again, I thank Senator JEFFORDS for what he has done.

Mr. JEFFORDS. I thank the Senator for his comments, and I want to praise him for his efforts with respect to off-label. This is an incredibly important amendment that Senator MACK and Senator FRIST have worked out with the FDA and the minority. That is going to give a great deal of assistance to people in this country who are in need of help in straightening out a relatively difficult area with such preciseness. The Senator from Florida did a good job.

AMENDMENT NO. 1184, AS MODIFIED

Mr. President, I ask unanimous consent that it be in order to consider amendment No. 1184, as modified, with changes that are at the desk; further, that the amendment be agreed to, and the motion to reconsider be laid upon the table.

The PRESIDING OFFICER. Is there objection? Without objection, it is so ordered.

The amendment (No. 1184), as modified, was agreed to, as follows:

Strike section 809 and insert the following:

SEC. 809. APPLICATION OF FEDERAL LAW TO THE PRACTICE OF PHARMACY COMPOUNDING.

Section 503 (21 U.S.C. 353) is amended by adding at the end the following:

''(h)(1) Sections 501(a)(2)(B), 502(f)(1), 502(1), 505, and 507 shall not apply to a drug product if—

''(A) the drug product is compounded for an identified individual patient, based on a medical need for a compounded product—

''(i) by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, on the prescription order of a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

''(ii) by a licensed pharmacist or licensed physician in limited quantities, prior to the receipt of a valid prescription order for the identified individual patient, and is compounded based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product that have been generated solely within an established relationship between the licensed pharmacist, or licensed physician, and—

''(I) the individual patient for whom the prescription order will be provided; or

''(II) the physician or other licensed practitioner who will write such prescription order; and

''(B) the licensed pharmacist or licensed physician—

''(i) compounds the drug product using bulk drug substances—

''(I) that—

''(aa) comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph; or

''(bb) in a case in which such a monograph does not exist, are drug substances that are covered by regulations issued by the Secretary under paragraph (3);

''(II) that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

''(III) that are accompanied by valid certificates of analysis for each bulk drug substance;

''(ii) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph and the United States Pharmacopeia chapter on pharmacy compounding;

''(iii) only advertises or promotes the compounding service provided by the licensed pharmacist or licensed physician and does not advertise or promote the compounding of any particular drug, class of drug, or type of drug;

''(iv) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective;

''(v) does not compound a drug product that is identified by the Secretary in regulation as presenting demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

''(vi) does not distribute compounded drugs outside of the State in which the drugs are compounded, unless the principal State agency of jurisdiction that regulates the practice of pharmacy in such State has entered into a memorandum of understanding with the Secretary regarding the regulation of drugs that are compounded in the State and are distributed outside of the State, that provides for appropriate investigation by the State agency of complaints relating to compounded products distributed outside of the State.

''(2)(A) The Secretary shall, after consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by States in complying with paragraph (1)(B)(vi).

''(B) Paragraph (1)(B)(vi) shall not apply to a licensed pharmacist or licensed physician, who does not distribute inordinate amounts of compounded products outside of the State, until—

''(i) the date that is 180 days after the development of the standard memorandum of understanding; or

''(ii) the date on which the State agency enters into a memorandum of understanding under paragraph (1)(B)(vi),

whichever occurs first.

''(3) The Secretary, after consultation with the United States Pharmacopeia Convention Incorporated, shall promulgate regulations limiting compounding under paragraph (1)(B)(i)(I)(bb) to drug substances that are components of drug products approved by the Secretary and to other drug substances as the Secretary may identify.

''(4) The provisions of paragraph (1) shall not apply—

''(A) to compounded positron emission tomography drugs as defined in section 201(ii); or

''(B) to radiopharmaceuticals.

''(5) In this subsection, the term 'compound' does not include to mix, reconstitute, or perform another similar act, in accordance with directions contained in approved drug labeling provided by a drug manufacturer and other drug manufacturer directions consistent with that labeling.''.

Mr. JEFFORDS. Mr. President, I ask unanimous consent that Senator ABRAHAM be added as a cosponsor of S. 830.

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

Mr. JEFFORDS. Mr. President, if the minority is ready and will yield all remaining time, I will yield mine.

It is my understanding the minority will yield this time. I yield the remainder of my time.

The PRESIDING OFFICER. Without objection, the minority time is yielded.

Mr. JEFFORDS. Mr. President, I ask unanimous consent that the administration policy that was received as a message be printed in the RECORD.

I thank them for bringing it to our attention at this time.

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

EXECUTIVE OFFICE OF THE PRESIDENT, OFFICE OF MANAGEMENT, AND BUDGET,

Washington, DC, September 24, 1997.

STATEMENT OF ADMINISTRATION POLICY

(THIS STATEMENT HAS BEEN COORDINATED BY OMB WITH THE CONCERNED AGENCIES.)

S. 830—FDA Modernization and Accountability Act of 1997

(Sen. Jeffords (R) VT)

The Administration applauds the Senate for its bipartisan effort to improve S. 830 since it was reported by the Senate Committee on Labor and Human Resources, and appreciates the Senate's responsiveness to concerns that have been raised. Because of the

importance of obtaining a five-year extension of the Prescription Drug User Fee Act (PDUFA), the Administration has no objection to passage of the bill by the Senate at this time. However, the Administration finds that the provisions identified below are unacceptable and as the legislative process continues, will work to ensure that our remaining concerns are resolved.

In general, this legislation represents a significant step toward accomplishing our mutual goal of assuring the agency's optimum performance while protecting the health of the American public. The Administration, however, continues to have two major concerns with the bill.

First, section 404 of the bill would lower the review standard for marketing approval by precluding the Food and Drug Administration (FDA) from reviewing new medical devices for uses other than those for which the manufacturer says they are intended. Second, the PDUFA trigger as proposed in S. 830 undercuts the bipartisan budget agreement (BBA) by requiring budget increases for FDA not envisioned by the BBA, and would interfere with HHS' ability to allocate resources appropriately throughout the Department.

In order to be able to support the final bill, the Administration will continue to work with the House of Representatives and in conference to resolve these and other identified issues.

Mr. JEFFORDS. Mr. President, I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The yeas and nays were ordered.

The PRESIDING OFFICER. The question is on the engrossment and third reading of the bill.

The bill was ordered to be engrossed for a third reading, and was read the third time.

The PRESIDING OFFICER. The bill having been read the third time, the question is, Shall it pass? On this question, the yeas and nays have been ordered, and the clerk will call the roll.

The assistant legislative clerk called the roll.

The PRESIDING OFFICER (Mr. SANTORUM). Are there any other Senators in the Chamber who desire to vote?

The result was announced—yeas 98, nays 2, as follows:

[Rollcall Vote No. 256 Leg.]

YEAS—98

Abraham	D'Amato	Hutchinson
Akaka	Daschle	Hutchison
Allard	DeWine	Inhofe
Ashcroft	Dodd	Inouye
Baucus	Domenici	Jeffords
Bennett	Dorgan	Johnson
Biden	Durbin	Kempthorne
Bingaman	Enzi	Kerrey
Bond	Faircloth	Kerry
Boxer	Feingold	Kohl
Breaux	Feinstein	Kyl
Brownback	Ford	Landrieu
Bryan	Frist	Lautenberg
Bumpers	Glenn	Leahy
Burns	Gorton	Levin
Byrd	Graham	Lieberman
Campbell	Gramm	Lott
Chafee	Grams	Lugar
Cleland	Grassley	Mack
Coats	Gregg	McCain
Cochran	Hagel	McConnell
Collins	Harkin	Mikulski
Conrad	Hatch	Moseley-Braun
Coverdell	Helms	Moynihan
Craig	Hollings	Murkowski
Murray	Sarbanes	Thomas
Nickles	Sessions	Thompson
Reid	Shelby	Thurmond
Robb	Smith (NH)	Torricelli
Roberts	Smith (OR)	Warner
Rockefeller	Snowe	Wellstone
Roth	Specter	Wyden
Santorum	Stevens	

NAYS—2

Kennedy	Reed

The bill (S. 830), as amended, was passed, as follows:

S. 830

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Food and Drug Administration Modernization and Accountability Act of 1997''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

SEC. 3. REFERENCES.

Except as otherwise expressly provided, wherever 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.).

TITLE I—IMPROVING PATIENT ACCESS

SEC. 101. MISSION OF THE FOOD AND DRUG ADMINISTRATION.

Section 903 (21 U.S.C. 393) is amended—

(1) by redesignating subsections (b) and (c) as subsections (c) and (d), respectively; and

(2) by inserting after subsection (a) the following:

''(b) MISSION.—

''(1) IN GENERAL.—The Secretary, acting through the Commissioner, and in consultation, as determined appropriate by the Secretary, with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products, shall protect the public health by taking actions that help ensure that—

''(A) foods are safe, wholesome, sanitary, and properly labeled;

''(B) human and veterinary drugs, including biologics, are safe and effective;

''(C) there is reasonable assurance of safety and effectiveness of devices intended for human use;

''(D) cosmetics are safe; and

''(E) public health and safety are protected from electronic product radiation.

''(2) SPECIAL RULES.—The Secretary, acting through the Commissioner, shall promptly and efficiently review clinical research and take appropriate action on the marketing of regulated products in a manner that does not unduly impede innovation or product availability. The Secretary, acting through the Commissioner, shall participate with other countries to reduce the burden of regulation, to harmonize regulatory requirements, and to achieve appropriate reciprocal arrangements with other countries.''.

SEC. 102. EXPANDED ACCESS TO INVESTIGATIONAL THERAPIES.

Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''Subchapter D—Unapproved Therapies and Diagnostics

''SEC. 551. EXPANDED ACCESS TO UNAPPROVED THERAPIES AND DIAGNOSTICS.

''(a) EMERGENCY SITUATIONS.—The Secretary may, under appropriate conditions determined by the Secretary, authorize the shipment of investigational drugs (including investigational biological products), or investigational devices, (as defined in regulations prescribed by the Secretary) for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.

''(b) INDIVIDUAL PATIENT ACCESS TO INVESTIGATIONAL PRODUCTS INTENDED FOR SERIOUS DISEASES.—Any person, acting through a physician licensed in accordance with State law, may request from a manufacturer or distributor, and any manufacturer or distributor may provide to such physician after compliance with the provisions of this subsection, an investigational drug (including an investigational biological product), or investigational device, (as defined in regulations prescribed by the Secretary) for the diagnosis, monitoring, or treatment of a serious disease or condition if—

''(1) the licensed physician determines that the person has no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat the disease or condition involved, and that the risk to the person from the investigational drug or investigational device is not greater than the risk from the disease or condition;

''(2) the Secretary determines that there is sufficient evidence of safety and effectiveness to support the use of the investigational drug or investigational device in the case described in paragraph (1);

''(3) the Secretary determines that provision of the investigational drug or investigational device will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval; and

''(4) the product sponsor, or clinical investigator, of the investigational drug or investigational device submits to the Secretary a clinical protocol consistent with the provisions of section 505(i) or 520(g) and any regulations promulgated under section 505(i) or 520(g) describing the use of investigational drugs or investigational devices in a single patient or a small group of patients.

''(c) TREATMENT INDS/IDES.—Upon submission by a product sponsor or a physician of a protocol intended to provide widespread access to an investigational product for eligible patients, the Secretary shall permit an investigational drug (including an investigational biological product) or investigational device to be made available for expanded access under a treatment investigational new drug application or investigational device exemption (as the terms are described in regulations prescribed by the Secretary) if the Secretary determines that—

''(1) under the treatment investigational new drug application or investigational device exemption, the investigational drug or investigational device is intended for use in the diagnosis, monitoring, or treatment of a serious or immediately life-threatening disease or condition;

''(2) there is no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat that stage of disease or condition in the population of patients to which the investigational drug or investigational device is intended to be administered;

''(3)(A) the investigational drug or investigational device is under investigation in a controlled clinical trial for the use described in paragraph (1) under an effective investigational new drug application or investigational device exemption; and

''(B) all clinical trials necessary for approval of that use of the investigational drug or investigational device have been completed;

''(4) the sponsor of the controlled clinical trials is actively pursuing marketing approval of the investigational drug or investigational device for the use described in paragraph (1) with due diligence;

''(5) the provision of the investigational drug or investigational device will not interfere with the enrollment of patients in ongoing clinical investigations under section 505(i) or 520(g);

''(6) in the case of serious diseases, there is sufficient evidence of safety and effectiveness to support the use described in paragraph (1); and

''(7) in the case of immediately life-threatening diseases, the available scientific evidence, taken as a whole, provides a reasonable basis to conclude that the product may be effective for its intended use and would not expose patients to an unreasonable and significant risk of illness or injury.

A protocol submitted under this subsection shall be subject to the provisions of section 505(i) or 520(g) and regulations promulgated under section 505(i) or 520(g). The Secretary may inform national, State, and local medical associations and societies, voluntary health associations, and other appropriate persons about the availability of an investigational drug or investigational device under expanded access protocols submitted under this subsection. The information provided by the Secretary, in accordance with the preceding sentence, shall be of the same type of information that is required by section 402(j)(3).

''(d) TERMINATION.—The Secretary may, at any time, with respect to a person, manufacturer, or distributor described in this section, terminate expanded access provided under this section for an investigational drug (including an investigational biological product) or investigational device if the requirements under this section are no longer met.''.

SEC. 103. EXPANDED HUMANITARIAN USE OF DEVICES.

Section 520(m) (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (2), by adding at the end the following flush sentences:

''The request shall be in the form of an application submitted to the Secretary. Not later than 75 days after the date of the receipt of the application, the Secretary shall issue an order approving or denying the application.'';

(2) in paragraph (4)—

(A) in subparagraph (B), by inserting after ''(2)(A)'' the following: '', unless a physician determines that waiting for such an approval from an institutional review committee will cause harm or death to a patient, and makes a good faith effort to obtain the approval, and does not receive a timely response from an institutional review committee on the request of the physician for approval to use the device for such treatment or diagnosis''; and

(B) by adding at the end the following flush sentences:

''In a case in which a physician described in subparagraph (B) uses a device without an approval from an institutional review committee, the physician shall, after the use of the device, notify the chairperson of the institutional review committee of such use. Such notification shall include the identification of the patient involved, the date on which the device was used, and the reason for the use.''; and

(3) by striking paragraph (5) and inserting the following:

''(5) The Secretary may require a person granted an exemption under paragraph (2) to demonstrate continued compliance with the requirements of this subsection if the Secretary believes such demonstration to be necessary to protect the public health or if the Secretary has reason to believe that the criteria for the exemption are no longer met.''.

TITLE II—INCREASING ACCESS TO EXPERTISE AND RESOURCES

SEC. 201. INTERAGENCY COLLABORATION.

Section 903(b) (21 U.S.C. 393(b)), as added by section 101(2), is amended by adding at the end the following:

''(3) INTERAGENCY COLLABORATION.—The Secretary shall implement programs and policies that will foster collaboration between the Administration, the National Institutes of Health, and other science-based Federal agencies, to enhance the scientific and technical expertise available to the Secretary in the conduct of the duties of the Secretary with respect to the development, clinical investigation, evaluation, and postmarket monitoring of emerging medical therapies, including complementary therapies, and advances in nutrition and food science.''.

SEC. 202. SENSE OF THE COMMITTEE REGARDING MUTUAL RECOGNITION AGREEMENTS AND GLOBAL HARMONIZATION EFFORTS.

It is the sense of the Committee on Labor and Human Resources of the Senate that—

(1) the Secretary of Health and Human Services should support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in efforts to move toward the acceptance of mutual recognition agreements relating to the regulation of drugs, biological products, devices, foods, food additives, and color additives, and the regulation of good manufacturing practices, between the European Union and the United States;

(2) the Secretary of Health and Human Services should regularly participate in meetings with representatives of other foreign governments to discuss and reach agreement on methods and approaches to harmonize regulatory requirements; and

(3) the Office of International Relations of the Department of Health and Human Services (as established under section 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 383)) should have the responsibility of ensuring that the process of harmonizing international regulatory requirements is continuous.

SEC. 203. CONTRACTS FOR EXPERT REVIEW.

Chapter IX (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

"SEC. 906. CONTRACTS FOR EXPERT REVIEW.

''(a) IN GENERAL.—

''(1) AUTHORITY.—The Secretary may enter into a contract with any organization or any individual (who is not an employee of the Department) with expertise in a relevant discipline, to review, evaluate, and make recommendations to the Secretary on part or all of any application or submission (including a petition, notification, and any other similar form of request) made under this Act for the approval or classification of an article or made under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) with respect to a biological product. Any such contract shall be subject to the requirements of section 708 relating to the confidentiality of information.

''(2) INCREASED EFFICIENCY AND EXPERTISE THROUGH CONTRACTS.—The Secretary shall use the authority granted in paragraph (1) whenever the Secretary determines that a contract described in paragraph (1) will improve the timeliness or quality of the review of an application or submission described in paragraph (1), unless using such authority would reduce the quality, or unduly increase the cost, of such review. Such improvement may include providing the Secretary increased scientific or technical expertise that is necessary to review or evaluate new therapies and technologies.

''(b) REVIEW OF EXPERT REVIEW.—

''(1) IN GENERAL.—Subject to paragraph (2), the official of the Food and Drug Administration responsible for any matter for which expert review is used pursuant to subsection (a) shall review the recommendations of the organization or individual who conducted the expert review and shall make a final decision regarding the matter within 60 days after receiving the recommendations.

''(2) LIMITATION.—A final decision under paragraph (1) shall be made within the applicable prescribed time period for review of the matter as set forth in this Act or in the Public Health Service Act (42 U.S.C. 201 et seq.).

''(3) AUTHORITY OF SECRETARY.—Notwithstanding subsection (a), the Secretary shall retain full authority to make determinations with respect to the approval or disapproval of an article under this Act, the approval or disapproval of a biologics license with respect to a biological product under section 351(a) of the Public Health Service Act, or the classification of an article as a device under section 513(f)(1).''.

SEC. 204. ACCREDITED-PARTY REVIEWS.

(a) IN GENERAL.—Subchapter A of chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"SEC. 523. ACCREDITED-PARTY PARTICIPATION.

''(a) ACCREDITATION.—Not later than 1 year after the date of enactment of this section, the Secretary shall accredit entities or individuals who are not employees of the Federal Government to review reports made to the Secretary under section 510(k) for devices and make recommendations to the Secretary regarding the initial classification of such devices under section 513(f)(1), except that this paragraph shall not apply to a report made to the Secretary under section 510(k) for a device that is—

''(1) for a use in supporting or sustaining human life;

''(2) for implantation in the human body for more than 1 year; or

''(3) for a use that is of substantial importance in preventing the impairment of human health.

''(b) ACCREDITATION.—Within 180 days after the date of enactment of this section, the Secretary shall adopt methods of accreditation that ensure that entities or individuals who conduct reviews and make recommendations under this section are qualified, properly trained, knowledgeable about handling confidential documents and information, and free of conflicts of interest. The Secretary shall publish the methods of accreditation in the Federal Register on the adoption of the methods.

''(c) WITHDRAWAL OF ACCREDITATION.—The Secretary may suspend or withdraw the accreditation of any entity or individual accredited under this section, after providing notice and an opportunity for an informal hearing, if such entity or individual acts in a manner that is substantially not in compliance with the requirements established by the Secretary under subsection (b), including the failure to avoid conflicts of interest, the failure to protect confidentiality of information, or the failure to competently review premarket submissions for devices.

''(d) SELECTION AND COMPENSATION.—A person who intends to make a report described in subsection (a) to the Secretary shall have the option to select an accredited entity or individual to review such report. Upon the request by a person to have a report reviewed by an accredited entity or individual, the Secretary shall identify for the person no less than 2 accredited entities or individuals from whom the selection may be made. Compensation for an accredited entity or individual shall be determined by agreement between the accredited entity or individual and the person who engages the services of the accredited entity or individual and shall be paid by the person who engages such services.

''(e) REVIEW BY SECRETARY.—

''(1) IN GENERAL.—The Secretary shall require an accredited entity or individual, upon making a recommendation under this section with respect to an initial classification of a device, to notify the Secretary in writing of the reasons for such recommendation.

''(2) TIME PERIOD FOR REVIEW.—Not later than 30 days after the date on which the Secretary is notified under paragraph (1) by an accredited entity or individual with respect to a recommendation of an initial classification of a device, the Secretary shall make a determination with respect to the initial classification.

''(3) SPECIAL RULE.—The Secretary may change the initial classification under section 513(f)(1) that is recommended by the accredited entity or individual under this section, and in such case shall notify in writing the person making the report described in subsection (a) of the detailed reasons for the change.

''(f) DURATION.—The authority provided by this section terminates—

''(1) 5 years after the date on which the Secretary notifies Congress that at least 2 persons accredited under subsection (b) are available to review at least 60 percent of the submissions under section 510(k); or

''(2) 4 years after the date on which the Secretary notifies Congress that at least 35 percent of the devices that are subject to review under subsection (a), and that were the subject of final action by the Secretary in the fiscal year preceding the date of such notification, were reviewed by the Secretary under subsection (e),

whichever occurs first.

''(g) REPORT.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary shall contract with an independent research organization to prepare and submit to the Secretary a written report examining the use of accredited entities and individuals to conduct reviews under this section. The Secretary shall submit the report to Congress not later than 6 months prior to the conclusion of the applicable period described in subsection (f).

''(2) CONTENTS.—The report by the independent research organization described in paragraph (1) shall identify the benefits or detriments to public and patient health of using accredited entities and individuals to conduct such reviews, and shall summarize all relevant data, including data on the review of accredited entities and individuals (including data on the review times, recommendations, and compensation of the entities and individuals), and data on the review of the Secretary (including data on the review times, changes, and reasons for changes of the Secretary).''.

(b) RECORDKEEPING.—Section 704 (21 U.S.C. 374) is amended by adding at the end the following:

''(f)(1) A person accredited under section 523 to review reports made under section 510(k) and make recommendations of initial classifications of devices to the Secretary shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person in accordance with section 523(d), and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

''(2) Within 15 days after the receipt of a written request from the Secretary to a person accredited under section 523 for copies of records described in paragraph (1), the person shall produce the copies of the records at the place designated by the Secretary.''.

SEC. 205. DEVICE PERFORMANCE STANDARDS.

(a) ALTERNATIVE PROCEDURE.—Section 514 (21 U.S.C. 360d) is amended by adding at the end the following:

''Recognition of a Standard

''(c)(1)(A) In addition to establishing performance standards under this section, the Secretary may, by publication in the Federal Register, recognize all or part of a performance standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet premarket submission requirements or other requirements under this Act to which such standards are applicable.

''(B) If a person elects to use a performance standard recognized by the Secretary under subparagraph (A) to meet the requirements described in subparagraph (A), the person shall provide a declaration of conformity to the Secretary that certifies that the device is in conformity with such standard. A person may elect to use data, or information, other than data required by a standard recognized under subparagraph (A) to fulfill or satisfy any requirement under this Act.

''(2) The Secretary may withdraw such recognition of a performance standard through publication of a notice in the Federal Register that the Secretary will no longer recognize the standard, if the Secretary determines that the standard is no longer appropriate for meeting the requirements under this Act.

''(3)(A) Subject to subparagraph (B), the Secretary shall accept a declaration of conformity that a device is in conformity with a standard recognized under paragraph (1) unless the Secretary finds—

''(i) that the data or information submitted to support such declaration does not demonstrate that the device is in conformity with the standard identified in the declaration of conformity; or

''(ii) that the standard identified in the declaration of conformity is not applicable to the particular device under review.

''(B) The Secretary may request, at any time, the data or information relied on by the person to make a declaration of conformity with respect to a standard recognized under paragraph (1).

''(C) A person relying on a declaration of conformity with respect to a standard recognized under paragraph (1) shall maintain the data and information demonstrating conformity of the device to the standard for a period of 2 years after the date of the classification or approval of the device by the Secretary or a period equal to the expected design life of the device, whichever is longer.''.

(b) SECTION 301.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

''(x) The falsification of a declaration of conformity submitted under subsection (c) of section 514 or the failure or refusal to provide data or information requested by the Secretary under section 514(c)(3).''.

(c) SECTION 501.—Section 501(e) (21 U.S.C. 351(e)) is amended—

(1) by striking ''(e)'' and inserting ''(e)(1)''; and

(2) by inserting at the end the following:

''(2) If it is declared to be, purports to be, or is represented as, a device that is in conformity with any performance standard recognized under section 514(c) unless such device is in all respects in conformity with such standard.''.

TITLE III—IMPROVING COLLABORATION AND COMMUNICATION

SEC. 301. COLLABORATIVE DETERMINATIONS OF DEVICE DATA REQUIREMENTS.

Section 513(a)(3) (21 U.S.C. 360c(a)(3)) is amended by adding at the end the following:

''(C)(i)(I) The Secretary, upon the written request of any person intending to submit an application under section 515, shall meet with such person to determine the type of valid scientific evidence (within the meaning of subparagraphs (A) and (B)) that will be necessary to demonstrate the effectiveness of a device for the conditions of use proposed by such person, to support an approval of an application. The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, a proposed plan for determining whether there is a reasonable assurance of effectiveness, and, if available, information regarding the expected performance from the device. Within 30 days after such meeting, the Secretary shall specify in writing the type of valid scientific evidence that will provide a reasonable assurance that a device is effective under the conditions of use proposed by such person.

''(II) Any clinical data, including 1 or more well-controlled investigations, specified in writing by the Secretary for demonstrating a reasonable assurance of device effectiveness shall be specified as a result of a determination by the Secretary—

''(aa) that such data are necessary to establish device effectiveness; and

''(bb) that no other less burdensome means of evaluating device effectiveness is available that would have a reasonable likelihood of resulting in an approval.

''(ii) The determination of the Secretary with respect to the specification of valid scientific evidence under clause (i) shall be binding upon the Secretary, unless such determination by the Secretary could be contrary to the public health.''.

SEC. 302. COLLABORATIVE REVIEW PROCESS.

Section 515(d) (21 U.S.C. 360e(d)) is amended—

(1) in paragraph (1)(A), by striking ''paragraph (2) of this subsection'' each place it appears and inserting ''paragraph (4)'';

(2) by redesignating paragraphs (2) and (3) as paragraphs (4) and (5), respectively; and

(3) by inserting after paragraph (1) the following:

''(2)(A)(i) The Secretary shall, upon the written request of an applicant, meet with the applicant, not later than 100 days after the receipt of an application from the applicant that has been filed as complete under subsection (c), to discuss the review status of the application.

''(ii) If the application does not appear in a form that would require an approval under this subsection, the Secretary shall in writing, and prior to the meeting, provide to the applicant a description of any deficiencies in the application identified by the Secretary based on an interim review of the entire application and identify the information that is required to correct those deficiencies.

''(iii) The Secretary and the applicant may, by mutual consent, establish a different schedule for a meeting required under this paragraph.

''(B) The Secretary shall notify the applicant immediately of any deficiency identified in the application that was not described as a deficiency in the written description provided by the Secretary under subparagraph (A).''.

TITLE IV—IMPROVING CERTAINTY AND CLARITY OF RULES

SEC. 401. POLICY STATEMENTS.

Section 701(a) (21 U.S.C. 371(a)) is amended—

(1) by striking ''(a) The'' and inserting ''(a)(1) The''; and

(2) by adding at the end the following:

''(2) Not later than February 27, 1999, the Secretary, after evaluating the effectiveness of the Good Guidance Practices document published in the Federal Register at 62 Fed. Reg. 8961, shall promulgate a regulation specifying the policies and procedures of the Food and Drug Administration for the development, issuance, and use of guidance documents.''.

SEC. 402. PRODUCT CLASSIFICATION.

Chapter VII (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

''Subchapter D—Classification of Products and Environmental Impact Reviews

''SEC. 741. CLASSIFICATION OF PRODUCTS.

''(a) REQUEST.—A person who submits an application or submission (including a petition, notification, and any other similar form of request) under this Act, may submit a request to the Secretary respecting the classification of an article as a drug, biological product, device, or a combination product subject to section 503(g) or respecting the component of the Food and Drug Administration that will regulate the article. In submitting the request, the person shall recommend a classification for the article, or a component to regulate the article, as appropriate.

''(b) STATEMENT.—Not later than 60 days after the receipt of the request described in subsection (a), the Secretary shall determine the classification of the article or the component of the Food and Drug Administration that will regulate the article and shall provide to the person a written statement that identifies the classification of the article or the component of the Food and Drug Administration that will regulate the article and the reasons for such determination. The Secretary may not modify such statement except with the written consent of the person or for public health reasons.

''(c) INACTION OF SECRETARY.—If the Secretary does not provide the statement within the 60-day period described in subsection (b), the recommendation made by the person under subsection (a) shall be considered to be a final determination by the Secretary of the classification of the article or the component of the Food and Drug Administration that will regulate the article and may not be modified by the Secretary except with the written consent of the person or for public health reasons.''.

SEC. 403. USE OF DATA RELATING TO PREMARKET APPROVAL.

(a) IN GENERAL.—Section 520(h)(4) (21 U.S.C. 360j(h)(4)) is amended to read as follows:

''(4)(A) Any information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c) (including information from clinical and preclinical tests or studies that demonstrate the safety and effectiveness of a device, but excluding descriptions of methods of manufacture and product composition) shall be available, 6 years after the application has been approved by the Secretary, for use by the Secretary in—

''(i) approving another device;

''(ii) determining whether a product development protocol has been completed, under section 515 for another device;

''(iii) establishing a performance standard or special control under this Act; or

''(iv) classifying or reclassifying another device under section 513 and subsection (l)(2).

''(B) The publicly available detailed summaries of information respecting the safety and effectiveness of devices required by paragraph (1)(A) shall be available for use by the Secretary as the evidentiary basis for the agency actions described in subparagraph (A).''.

(b) CONFORMING AMENDMENT.—Section 517(a) (21 U.S.C. 360g(a)) is amended—

(1) in paragraph (8), by adding ''or'' at the end;

(2) in paragraph (9), by striking '', or'' and inserting a comma; and

(3) by striking paragraph (10).

SEC. 404. CONSIDERATION OF LABELING CLAIMS FOR PRODUCT REVIEW.

(a) PREMARKET APPROVAL.—Section 515(d)(1)(A) (21 U.S.C. 360e(d)(1)(A)) is amended by adding at the end the following flush sentences:

''In making the determination whether to approve or deny the application, the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither false nor misleading. In determining whether or not such labeling is false or misleading, the Secretary shall fairly evaluate all material facts pertinent to the proposed labeling.''.

(b) PREMARKET NOTIFICATION.—Section 513(i)(1) (21 U.S.C. 360c(i)(1)) is amended by adding at the end the following:

''(C) Whenever the Secretary requests information to demonstrate that the devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to make a substantial equivalence determination. In making such a request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and shall request information accordingly.

''(D) The determination of the Secretary under this subsection and section 513(f)(1) with respect to the intended use of a device shall be based on the intended use included in the proposed labeling of the device submitted in a report under section 510(k).''.

(c) RULE OF CONSTRUCTION.—Nothing in the amendments made by subsections (a) and (b) shall be construed to alter any authority of the Secretary of Health and Human Services to regulate any tobacco product, or any additive or ingredient of a tobacco product.

SEC. 405. CERTAINTY OF REVIEW TIMEFRAMES.

(a) CLARIFICATION ON THE 90-DAY TIMEFRAME FOR PREMARKET NOTIFICATION REVIEWS.—Section 510(k) (21 U.S.C. 360) is amended by adding at the end the following flush sentence:

''The Secretary shall review the report required by this subsection and make a determination under section 513(f)(1) not later than 90 days after receiving the report.''.

(b) ONE-CYCLE REVIEW.—Section 515(d) (21 U.S.C. 360e(d)), as amended by section 302, is amended by inserting after paragraph (2) the following:

''(3) Except as provided in paragraph (1), the period for the review of an application by the Secretary under this subsection shall be not more than 180 days. Such period may not be restarted or extended even if the application is amended. The Secretary is not required to review a major amendment to an application, unless the amendment is made in response to a request by the Secretary for information.''.

SEC. 406. LIMITATIONS ON INITIAL CLASSIFICATION DETERMINATIONS.

Section 510 (21 U.S.C. 360) is amended by adding at the end the following:

''(m) The Secretary may not withhold a determination of the initial classification of a device under section 513(f)(1) because of a failure to comply with any provision of this Act that is unrelated to a substantial equivalence decision, including a failure to comply with the requirements relating to good manufacturing practices under section 520(f).''.

SEC. 407. CLARIFICATION WITH RESPECT TO A GENERAL USE AND SPECIFIC USE OF A DEVICE.

Not later than 270 days after the date of enactment of this section, the Secretary of Health and Human Services shall promulgate a final regulation specifying the general principles that the Secretary of Health and Human Services will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)).

SEC. 408. CLARIFICATION OF THE NUMBER OF REQUIRED CLINICAL INVESTIGATIONS FOR APPROVAL.

(a) DEVICE CLASSES.—Section 513(a)(3)(A) (21 U.S.C. 360c(a)(3)(A)) is amended by striking ''clinical investigations'' and inserting ''1 or more clinical investigations''.

(b) NEW DRUGS.—Section 505(d) (21 U.S.C. 355(d)) is amended by adding at the end the following: ''Substantial evidence may, as appropriate, consist of data from 1 adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation), if the Secretary determines, based on relevant science, that such data and evidence are sufficient to establish effectiveness.''.

SEC. 409. PROHIBITED ACTS.

Section 301(l) (21 U.S.C. 331(l)) is repealed.

TITLE V—IMPROVING ACCOUNTABILITY

SEC. 501. AGENCY PLAN FOR STATUTORY COMPLIANCE AND ANNUAL REPORT.

Section 903(b) (21 U.S.C. 393(b)), as amended by section 201, is further amended by adding at the end the following:

''(4) AGENCY PLAN FOR STATUTORY COMPLIANCE.—

''(A) IN GENERAL.—Not later than 180 days after the date of enactment of this paragraph, the Secretary, after consultation with relevant experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry, shall develop and publish in the Federal Register a plan bringing the Secretary into compliance with each of the obligations of the Secretary under this Act and other relevant statutes. The Secretary shall biannually review the plan and shall revise the plan as necessary, in consultation with such persons.

''(B) OBJECTIVES OF AGENCY PLAN.—The plan required by subparagraph (A) shall establish objectives, and mechanisms to be used by the Secretary, acting through the Commissioner, including objectives and mechanisms that—

''(i) minimize deaths of, and harm to, persons who use or may use an article regulated under this Act;

''(ii) maximize the clarity of, and the availability of information about, the process for review of applications and submissions (including petitions, notifications, and any other similar forms of request) made under this Act, including information for potential consumers and patients concerning new products;

''(iii) implement all inspection and postmarket monitoring provisions of this Act by July 1, 1999;

''(iv) ensure access to the scientific and technical expertise necessary to ensure compliance by the Secretary with the statutory obligations described in subparagraph (A);

''(v) establish a schedule to bring the Administration into full compliance by July 1, 1999, with the time periods specified in this Act for the review of all applications and submissions described in clause (ii) and submitted after the date of enactment of this paragraph; and

''(vi) reduce backlogs in the review of all applications and submissions described in clause (ii) for any article with the objective of eliminating all backlogs in the review of the applications and submissions by January 1, 2000.

''(5) ANNUAL REPORT.—

''(A) CONTENTS.—The Secretary shall prepare and publish in the Federal Register and solicit public comment on an annual report that—

''(i) provides detailed statistical information on the performance of the Secretary under the plan described in paragraph (4);

''(ii) compares such performance of the Secretary with the objectives of the plan and with the statutory obligations of the Secretary;

''(iii) analyzes any failure of the Secretary to achieve any objective of the plan or to meet any statutory obligation;

''(iv) identifies any regulatory policy that has a significant impact on compliance with any objective of the plan or any statutory obligation; and

''(v) sets forth any proposed revision to any such regulatory policy, or objective of the plan that has not been met.

''(B) STATISTICAL INFORMATION.—The statistical information described in subparagraph (A)(i) shall include a full statistical presentation relating to all applications and submissions (including petitions, notifications, and any other similar forms of request) made under this Act and approved or subject to final action by the Secretary during the year covered by the report. In preparing the statistical presentation, the Secretary shall take into account the date of—

''(i) the submission of any investigational application;

''(ii) the application of any clinical hold;

''(iii) the submission of any application or submission (including a petition, notification, and any other similar form of request) made under this Act for approval or clearance;

''(iv) the acceptance for filing of any application or submission described in clause (iii) for approval or clearance;

''(v) the occurrence of any unapprovable action;

''(vi) the occurrence of any approvable action; and

''(vii) the approval or clearance of any application or submission described in clause (iii).

''(C) SPECIAL RULE.—If the Secretary provides information in a report required by section 705 of the Food and Drug Administration Modernization and Accountability Act of 1997 or a report required by the amendments made by the Government Performance and Results Act of 1993 and that information is required by this paragraph, the report shall be deemed to satisfy the requirements of this paragraph relating to that information.''.

TITLE VI—BETTER ALLOCATION OF RESOURCES BY SETTING PRIORITIES

SEC. 601. MINOR MODIFICATIONS.

(a) ACTION ON INVESTIGATIONAL DEVICE EXEMPTIONS.—Section 520(g) (21 U.S.C. 360j(g)) is amended by adding at the end the following:

''(6)(A) The Secretary shall, not later than 120 days after the date of enactment of this paragraph, by regulation modify parts 812 and 813 of title 21, Code of Federal Regulations to update the procedures and conditions under which a device intended for human use may, upon application by the sponsor of the device, be granted an exemption from the requirements of this Act.

''(B) The regulation shall permit developmental changes in a device (including manufacturing changes) in response to information collected during an investigation without requiring an additional approval of an application for an investigational device exemption or the approval of a supplement to such application, if the sponsor of the investigation determines, based on credible information, prior to making any such changes, that the changes—

''(i) do not affect the scientific soundness of an investigational plan submitted under paragraph (3)(A) or the rights, safety, or welfare of the human subjects involved in the investigation; and

''(ii) do not constitute a significant change in design, or a significant change in basic principles of operation, of the device.''.

(b) ACTION ON APPLICATION.—Section 515(d)(1)(B) (21 U.S.C. 360e(d)(1)(B)) is amended by adding at the end the following:

''(iii) The Secretary shall accept and review data and any other information from investigations conducted under the authority of regulations required by section 520(g), to make a determination of whether there is a reasonable assurance of safety and effectiveness of a device subject to a pending application under this section if—

''(I) the data or information is derived from investigations of an earlier version of the device, the device has been modified during or after the investigations (but prior to submission of an application under subsection (c)) and such a modification of the device does not constitute a significant change in the design or in the basic principles of operation of the device that would invalidate the data or information; or

''(II) the data or information relates to a device approved under this section, is available for use under this Act, and is relevant to the design and intended use of the device for which the application is pending.''.

(c) ACTION ON SUPPLEMENTS.—Section 515(d) (21 U.S.C. 360e(d)), as amended by section 302, is further amended by adding at the end the following:

''(6)(A)(i) A supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of

manufacturing and the holder of the approved application submits a written notice to the Secretary that describes in detail the change, summarizes the data or information supporting the change, and informs the Secretary that the change has been made under the requirements of section 520(f).

''(ii) The holder of an approved application who submits a notice under clause (i) with respect to a manufacturing change of a device may distribute the device 30 days after the date on which the Secretary receives the notice, unless the Secretary within such 30-day period notifies the holder that the notice is not adequate and describes such further information or action that is required for acceptance of such change. If the Secretary notifies the holder that a premarket approval supplement is required, the Secretary shall review the supplement within 135 days after the receipt of the supplement. The time used by the Secretary to review the notice of the manufacturing change shall be deducted from the 135-day review period if the notice meets appropriate content requirements for premarket approval supplements.

''(B)(i) Subject to clause (ii), in reviewing a supplement to an approved application, for an incremental change to the design of a device that affects safety or effectiveness, the Secretary shall approve such supplement if—

''(I) nonclinical data demonstrate that the design modification creates the intended additional capacity, function, or performance of the device; and

''(II) clinical data from the approved application and any supplement to the approved application provide a reasonable assurance of safety and effectiveness for the changed device.

''(ii) The Secretary may require, when necessary, additional clinical data to evaluate the design modification of the device to provide a reasonable assurance of safety and effectiveness.''.

SEC. 602. ENVIRONMENTAL IMPACT REVIEW.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 402, is further amended by adding at the end the following:

''SEC. 742. ENVIRONMENTAL IMPACT REVIEW.

''Notwithstanding any other provision of law, an environmental impact statement prepared in accordance with the regulations published in part 25 of title 21, Code of Federal Regulations (as in effect on August 31, 1997) in connection with an action carried out under (or a recommendation or report relating to) this Act, shall be considered to meet the requirements for a detailed statement under section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)).''.

SEC. 603. EXEMPTION OF CERTAIN CLASSES OF DEVICES FROM PREMARKET NOTIFICATION REQUIREMENT.

(a) CLASS I AND CLASS II DEVICES.—Section 510(k) (21 U.S.C. 360(k)) is amended by striking ''intended for human use'' and inserting ''intended for human use (except a device that is classified into class I under section 513 or 520 unless the Secretary determines such device is intended for a use that is of substantial importance in preventing impairment of human health or such device presents a potential unreasonable risk of illness or injury, or a device that is classified into class II under section 513 or 520 and is exempt from the requirements of this subsection under subsection (l))''.

(b) PUBLICATION OF EXEMPTION.—Section 510 (21 U.S.C. 360) is amended by inserting after subsection (k) the following:

''(l)(1) Not later than 30 days after the date of enactment of this subsection, the Secretary shall publish in the Federal Register a list of each type of class II device that does not require a notification under subsection (k) to provide reasonable assurance of safety and effectiveness. Each type of class II device identified by the Secretary not to require the notification shall be exempt from the requirement to provide notification under subsection (k) as of the date of the publication of the list in the Federal Register.

''(2) Beginning on the date that is 1 day after the date of the publication of a list under this subsection, the Secretary may exempt a class II device from the notification requirement of subsection (k), upon the Secretary's own initiative or a petition of an interested person, if the Secretary determines that such notification is not necessary to assure the safety and effectiveness of the device. The Secretary shall publish in the Federal Register notice of the intent of the Secretary to exempt the device, or of the petition, and provide a 30-day period for public comment. Within 120 days after the issuance of the notice in the Federal Register, the Secretary shall publish an order in the Federal Register that sets forth the final determination of the Secretary regarding the exemption of the device that was the subject of the notice.''.

SEC. 604. EVALUATION OF AUTOMATIC CLASS III DESIGNATION.

Section 513(f) (21 U.S.C. 360c(f)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (B), by striking ''paragraph (2)'' and inserting ''paragraph (3)''; and

(B) in the last sentence, by striking ''paragraph (2)'' and inserting ''paragraph (2) or (3)'';

(2) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively; and

(3) by inserting after paragraph (1) the following:

''(2)(A) Any person who submits a report under section 510(k) for a type of device that has not been previously classified under this Act, and that is classified into class III under paragraph (1), may request, within 30 days after receiving written notice of such a classification, the Secretary to classify the device under the criteria set forth in subparagraphs (A) through (C) subsection (a)(1). The person may, in the request, recommend to the Secretary a classification for the device. Any such request shall describe the device and provide detailed information and reasons for the recommended classification.

''(B)(i) Not later than 60 days after the date of the submission of the request under subparagraph (A) for classification of a device under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1), the Secretary shall by written order classify the device. Such classification shall be the initial classification of the device for purposes of paragraph (1) and any device classified under this paragraph shall be a predicate device for determining substantial equivalence under paragraph (1).

''(ii) A device that remains in class III under this subparagraph shall be deemed to be adulterated within the meaning of section 501(f)(1)(B) until approved under section 515 or exempted from such approval under section 520(g).

''(C) Within 30 days after the issuance of an order classifying a device under this paragraph, the Secretary shall publish a notice in the Federal Register announcing such classification.''.

SEC. 605. SECRETARY'S DISCRETION TO TRACK DEVICES.

(a) RELEASE OF INFORMATION.—Section 519(e) (21 U.S.C. 360i(e)) is amended by adding at the end the following flush sentence:

''Any patient receiving a device subject to tracking under this section may refuse to release, or refuse permission to release, the patient's name, address, social security number, or other identifying information for the purpose of tracking.''.

(b) PUBLICATION OF CERTAIN DEVICES.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall develop and publish in the Federal Register a list that identifies each type of device subject to tracking under section 519(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(e)(1)). Each device not identified by the Secretary of Health and Human Services under this subsection or designated by the Secretary under section 519(e)(2) shall be deemed to be exempt from the mandatory tracking requirement under section 519 of such Act. The Secretary of Health and Human Services shall have authority to modify the list of devices exempted from the mandatory tracking requirements.

SEC. 606. SECRETARY'S DISCRETION TO CONDUCT POSTMARKET SURVEILLANCE.

(a) IN GENERAL.—Section 522 (21 U.S.C. 360l) is amended by striking ''SEC. 522.'' and all that follows through ''(2) DISCRETIONARY SURVEILLANCE.—The'' and inserting the following:

''SEC. 522. (a) DISCRETIONARY SURVEILLANCE.—The''.

(b) SURVEILLANCE APPROVAL.—Section 522(b) (21 U.S.C. 360l(b)) is amended to read as follows:

''(b) SURVEILLANCE APPROVAL.—

''(1) IN GENERAL.—Each manufacturer that receives notice from the Secretary that the manufacturer is required to conduct surveillance of a device under subsection (a) shall, not later than 30 days after receiving the notice, submit for the approval of the Secretary, a plan for the required surveillance.

''(2) DETERMINATION.—Not later than 60 days after the receipt of the plan, the Secretary shall determine if a person proposed in the plan to conduct the surveillance has sufficient qualifications and experience to conduct the surveillance and if the plan will result in the collection of useful data that can reveal unforeseen adverse events or other information necessary to protect the public health and to provide safety and effectiveness information for the device.

''(3) LIMITATION ON PLAN APPROVAL.—The Secretary may not approve the plan until the plan has been reviewed by a qualified scientific and technical review committee established by the Secretary.''.

SEC. 607. REPORTING.

(a) REPORTS.—Section 519 (21 U.S.C. 360i) is amended—

(1) in subsection (a)—

(A) in the first sentence by striking ''make such reports, and provide such information,'' and inserting ''and each such manufacturer or importer shall make such reports, provide such information, and submit such samples and components of devices (as required by paragraph (10)),'';

(B) in paragraph (8), by striking ''; and'' and inserting a semicolon; and

(C) by striking paragraph (9) and inserting the following:

''(9) shall require distributors to keep records and make such records available to the Secretary upon request; and'';

(2) by striking subsection (d); and

(3) in subsection (f), by striking '', importer, or distributor'' each place it appears and inserting ''or importer''.

(b) REGISTRATION.—Section 510(g) (21 U.S.C. 360(g)) is amended—

(1) by redesignating paragraph (4) as paragraph (5);

(2) by inserting after paragraph (3), the following:

''(4) any distributor who acts as a wholesale distributor of devices, and who does not

manufacture, repackage, process, or relabel a device; or''; and

(3) by adding at the end the following flush sentence:

''In this subsection, the term 'wholesale distributor' means any person who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.''.

SEC. 608. PILOT AND SMALL-SCALE MANUFACTURE.

(a) NEW DRUGS.—Section 505(c) (21 U.S.C. 355(c)) is amended by adding at the end the following:

''(4) A new drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the new drug and to obtain approval of the new drug prior to scaling up to a larger facility, unless the Secretary determines that a full scale production facility is necessary to ensure the safety or effectiveness of the new drug.''.

(b) NEW ANIMAL DRUGS.—Section 512(c) (21 U.S.C. 360b(c)) is amended by adding at the end the following:

''(4) A new animal drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the new drug and to obtain approval of the new drug prior to scaling up to a larger facility, unless the Secretary determines that a full scale production facility is necessary to ensure the safety or effectiveness of the new drug.''.

SEC. 609. REQUIREMENTS FOR RADIOPHARMACEUTICALS.

(a) REQUIREMENTS.—

(1) REGULATIONS.—

(A) PROPOSED REGULATIONS.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services, after consultation with patient advocacy groups, associations, physicians licensed to use radiopharmaceuticals, and the regulated industry, shall issue proposed regulations governing the approval of radiopharmaceuticals designed for diagnosis and monitoring of diseases and conditions. The regulations shall provide that the determination of the safety and effectiveness of such a radiopharmaceutical under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) shall include (but not be limited to) consideration of the proposed use of the radiopharmaceutical in the practice of medicine, the pharmacological and toxicological activity of the radiopharmaceutical (including any carrier or ligand component of the radiopharmaceutical), and the estimated absorbed radiation dose of the radiopharmaceutical.

(B) FINAL REGULATIONS.—Not later than 18 months after the date of enactment of this Act, the Secretary shall promulgate final regulations governing the approval of the radiopharmaceuticals.

(2) SPECIAL RULE.—In the case of a radiopharmaceutical intended to be used for diagnostic or monitoring purposes, the indications for which such radiopharmaceutical is approved for marketing may, in appropriate cases, refer to manifestations of disease (such as biochemical, physiological, anatomic, or pathological processes) common to, or present in, 1 or more disease states.

(b) DEFINITION.—In this section, the term ''radiopharmaceutical'' means—

(1) an article—

(A) that is intended for use in the diagnosis or monitoring of a disease or a manifestation of a disease in humans; and

(B) that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons; or

(2) any nonradioactive reagent kit or nuclide generator that is intended to be used in the preparation of any such article.

SEC. 610. MODERNIZATION OF REGULATION OF BIOLOGICAL PRODUCTS.

(a) LICENSES.—

(1) IN GENERAL.—Section 351(a) of the Public Health Service (42 U.S.C. 262(a)) is amended to read as follows:

''(a)(1) Except as provided in paragraph (4), no person shall introduce or deliver for introduction into interstate commerce any biological product unless—

''(A) a biologics license is in effect for the biological product; and

''(B) each package of the biological product is plainly marked with—

''(i) the proper name of the biological product contained in the package;

''(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

''(iii) the expiration date of the biological product.

''(2)(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.

''(B) The Secretary shall approve a biologics license application on the basis of a demonstration that—

''(i) the biological product that is the subject of the application is safe, pure, and potent; and

''(ii) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

''(3) A biologics license application shall be approved only if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

''(4) The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).''.

(2) ELIMINATION OF EXISTING LICENSE REQUIREMENT.—Section 351(d) of the Public Health Service Act (42 U.S.C. 262(d)) is amended—

(A) by striking ''(d)(1)'' and all that follows through ''of this section.'';

(B) in paragraph (2)—

(i) by striking ''(2)(A) Upon'' and inserting ''(d)(1) Upon;'' and

(ii) by redesignating subparagraph (B) as paragraph (2); and

(C) in paragraph (2) (as so redesignated by subparagraph (B)(ii))—

(i) by striking ''subparagraph (A)'' and inserting ''paragraph (1)''; and

(ii) by striking ''this subparagraph'' each place it appears and inserting ''this paragraph''.

(b) LABELING.—Section 351(b) of the Public Health Service Act (42 U.S.C. 262(b)) is amended to read as follows:

''(b) No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark.''.

(c) INSPECTION.—Section 351(c) of the Public Health Service Act (42 U.S.C. 262(c)) is amended by striking ''virus, serum,'' and all that follows and inserting ''biological product.''.

(d) DEFINITION; APPLICATION.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

''(i) In this section, the term 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.''.

(e) CONFORMING AMENDMENT.—Section 503(g)(4) (21 U.S.C. 353(g)(4)) is amended—

(1) in subparagraph (A)—

(A) by striking ''section 351(a)'' and inserting ''section 351(i)''; and

(B) by striking ''262(a)'' and inserting ''262(i)''; and

(2) in subparagraph (B)(iii), by striking ''product or establishment license under subsection (a) or (d)'' and inserting ''biologics license application under subsection (a)''.

(f) SPECIAL RULE.—The Secretary of Health and Human Services shall take measures to minimize differences in the review and approval of products required to have approved biologics license applications under section 351 of the Public Health Service Act (42 U.S.C. 262) and products required to have approved full new drug applications under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)).

SEC. 611. APPROVAL OF SUPPLEMENTAL APPLICATIONS FOR APPROVED PRODUCTS.

(a) PERFORMANCE STANDARDS.—Not later than 180 days after the date of enactment of this section, the Secretary of Health and Human Services shall publish in the Federal Register performance standards for the prompt review of supplemental applications submitted for approved articles under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

(b) GUIDANCE TO INDUSTRY.—Not later than 180 days after the date of enactment of this section, the Secretary of Health and Human Services shall issue final guidances to clarify the requirements for, and facilitate the submission of data to support, the approval of supplemental applications for the approved articles described in subsection (a). The guidances shall—

(1) clarify circumstances in which published matter may be the basis for approval of a supplemental application;

(2) specify data requirements that will avoid duplication of previously submitted data by recognizing the availability of data previously submitted in support of an original application; and

(3) define supplemental applications that are eligible for priority review.

(c) RESPONSIBILITIES OF CENTERS.—The Secretary of Health and Human Services shall designate an individual in each center within the Food and Drug Administration (except the Center for Food Safety and Applied Nutrition) to be responsible for—

(1) encouraging the prompt review of supplemental applications for approved articles; and

(2) working with sponsors to facilitate the development and submission of data to support supplemental applications.

(d) COLLABORATION.—The Secretary of Health and Human Services shall implement programs and policies that will foster collaboration between the Food and Drug Administration, the National Institutes of Health, professional medical and scientific societies, and other persons, to identify published and unpublished studies that may support a supplemental application, and to encourage sponsors to make supplemental applications or conduct further research in support of a supplemental application based, in whole or in part, on such studies.

SEC. 612. HEALTH CARE ECONOMIC INFORMATION.

(a) IN GENERAL.—Section 502(a) (21 U.S.C. 352(a)) is amended by adding at the end the

following: ''Health care economic information provided to a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations, shall not be considered to be false or misleading if the health care economic information directly relates to an indication approved under section 505 or 507 or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for such drug and is based on competent and reliable scientific evidence. The requirements set forth in section 505(a), 507, or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request. In this paragraph, the term 'health care economic information' means any analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention.''.

(b) STUDY AND REPORT.—The Comptroller General of the United States shall conduct a study of the implementation of the provisions added by the amendment made by subsection (a). Not later than 4 years and 6 months after the date of enactment of this Act, the Comptroller General of the United States shall prepare and submit to Congress a report containing the findings of the study.

SEC. 613. EXPEDITING STUDY AND APPROVAL OF FAST TRACK DRUGS.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.), as amended by section 102, is further amended by adding at the end the following:

''Subchapter E—Fast Track Drugs and Reports of Post-Market Approval Studies

''SEC. 561. FAST TRACK DRUGS.

''(a) DESIGNATION OF DRUG AS A FAST TRACK DRUG.—

''(1) IN GENERAL.—The Secretary shall facilitate development, and expedite review and approval of new drugs and biological products that are intended for the treatment of serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for such conditions. In this Act, such products shall be known as 'fast track drugs'.

''(2) REQUEST FOR DESIGNATION.—The sponsor of a drug (including a biological product) may request the Secretary to designate the drug as a fast track drug. A request for the designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) or section 351(a)(4) of the Public Health Service Act.

''(3) DESIGNATION.—Within 30 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track drug and shall take such actions as are appropriate to expedite the development and review of the drug.

''(b) APPROVAL OF APPLICATION FOR A FAST TRACK DRUG.—

''(1) IN GENERAL.—The Secretary may approve an application for approval of a fast track drug under section 505(b) or section 351 of the Public Health Service Act (21 U.S.C. 262) upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit.

''(2) LIMITATION.—Approval of a fast track drug under this subsection may be subject to the requirements—

''(A) that the sponsor conduct appropriate post-approval studies to validate the surrogate endpoint or otherwise confirm the clinical benefit of the drug; and

''(B) that the sponsor submit copies of all promotional materials related to the fast track drug during the preapproval review period and following approval, at least 30 days prior to dissemination of the materials for such period of time as the Secretary deems appropriate.

''(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a fast track drug using expedited procedures (as prescribed by the Secretary in regulations) including a procedure that provides an opportunity for an informal hearing, if—

''(A) the sponsor fails to conduct any required post-approval study of the fast track drug with due diligence;

''(B) a post-approval study of the fast track drug fails to verify clinical benefit of the fast track drug;

''(C) other evidence demonstrates that the fast track drug is not safe or effective under conditions of use of the drug; or

''(D) the sponsor disseminates false or misleading promotional materials with respect to the fast track drug.

''(c) REVIEW OF INCOMPLETE APPLICATIONS FOR APPROVAL OF A FAST TRACK DRUG.—

''(1) IN GENERAL.—If preliminary evaluation by the Secretary of clinical efficacy data for a fast track drug under investigation shows evidence of effectiveness, the Secretary shall evaluate for filing, and may commence review of, portions of an application for the approval of the drug if the applicant provides a schedule for submission of information necessary to make the application complete and any fee that may be required under section 736.

''(2) EXCEPTION.—Any time period for review of human drug applications that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the review of human drug applications) shall not apply to an application submitted under paragraph (1) until the date on which the application is complete.

''(d) AWARENESS EFFORTS.—The Secretary shall—

''(1) develop and widely disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a comprehensive description of the provisions applicable to fast track drugs established under this section; and

''(2) establish an ongoing program to encourage the development of surrogate endpoints that are reasonably likely to predict clinical benefit for serious or life-threatening conditions for which there exist significant unmet medical needs.''.

(b) GUIDANCE.—Within 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance for fast track drugs that describes the policies and procedures that pertain to section 561 of the Federal Food, Drug, and Cosmetic Act.

SEC. 614. MANUFACTURING CHANGES FOR DRUGS AND BIOLOGICS.

(a) IN GENERAL.—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 602, is further amended by adding at the end the following:

''Subchapter E—Manufacturing Changes

''SEC. 751. MANUFACTURING CHANGES.

''(a) IN GENERAL.—A change in the manufacture of a new drug, including a biological product, or a new animal drug may be made in accordance with this section.

''(b) CHANGES.—

''(1) VALIDATION.—Before distributing a drug made after a change in the manufacture of the drug from the manufacturing process established in the approved new drug application under section 505, the approved new animal drug application under section 512, or the license application under section 351 of the Public Health Service Act, the applicant shall validate the effect of the change on the identity, strength, quality, purity, and potency of the drug as the identity, strength, quality, purity, and potency may relate to the safety or effectiveness of the drug.

''(2) REPORTS.—The applicant shall report the change described in paragraph (1) to the Secretary and may distribute a drug made after the change as follows:

''(A) MAJOR MANUFACTURING CHANGES.—

''(i) IN GENERAL.—Major manufacturing changes, which are of a type determined by the Secretary to have substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as the identity, strength, quality, purity, and potency may relate to the safety or effectiveness of a drug, shall be submitted to the Secretary in a supplemental application and drugs made after such changes may not be distributed until the Secretary approves the supplemental application.

''(ii) DEFINITION.—In this subparagraph, the term 'major manufacturing changes' means—

''(I) changes in the qualitative or quantitative formulation of a drug or the specifications in the approved marketing application for the drug (unless exempted by the Secretary from the requirements of this subparagraph);

''(II) changes that the Secretary determines by regulation or issuance of guidance require completion of an appropriate human study demonstrating equivalence of the drug to the drug manufactured before such changes; and

''(III) other changes that the Secretary determines by regulation or issuance of guidance have a substantial potential to adversely affect the safety or effectiveness of the drug.

''(B) OTHER MANUFACTURING CHANGES.—

''(i) IN GENERAL.—As determined by the Secretary, manufacturing changes other than major manufacturing changes shall—

''(I) be made at any time and reported annually to the Secretary, with supporting data; or

''(II) be reported to the Secretary in a supplemental application.

''(ii) DISTRIBUTION OF THE DRUG.—In the case of changes reported in accordance with clause (i)(II)—

''(I) the applicant may distribute the drug 30 days after the Secretary receives the supplemental application unless the Secretary notifies the applicant within such 30-day period that prior approval of such supplemental application is required;

''(II) the Secretary shall approve or disapprove each such supplemental application; and

''(III) the Secretary may determine types of manufacturing changes after which distribution of a drug may commence at the time of submission of such supplemental application.''.

(b) EXISTING LAW.—The requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) and the Public Health Service Act (42 U.S.C. 201 et seq.) that are in effect on the date of enactment of this Act with respect to manufacturing changes shall remain in effect—

(1) for a period of 24 months after the date of enactment of this Act; or

(2) until the effective date of regulations promulgated by the Secretary of Health and Human Services implementing section 751 of the Federal Food, Drug, and Cosmetic Act,

whichever is sooner.

SEC. 615. DATA REQUIREMENTS FOR DRUGS AND BIOLOGICS.

Within 12 months after the date of enactment of this Act, the Secretary of the Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue guidance that describes when abbreviated study reports may be submitted, in lieu of full reports, with a new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and with a biologics license application under section 351 of the Public Health Service Act (42 U.S.C. 262) for certain types of studies. Such guidance shall describe the kinds of studies for which abbreviated reports are appropriate and the appropriate abbreviated report formats.

SEC. 616. FOOD CONTACT SUBSTANCES.

(a) FOOD CONTACT SUBSTANCES.—Section 409(a) (21 U.S.C. 348(a)) is amended—

(1) in paragraph (1)—

(A) by striking ''subsection (i)'' and inserting ''subsection (j)''; and

(B) by striking at the end ''or'';

(2) by striking the period at the end of paragraph (2) and inserting ''; or'';

(3) by inserting after paragraph (2) the following:

''(3) in the case of a food additive as defined in this Act that is a food contact substance, there is—

''(A) in effect, and such substance and the use of such substance are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used; or

''(B) a notification submitted under subsection (h) that is effective.''; and

(4) by striking the matter following paragraph (3) (as added by paragraph (2)) and inserting the following flush sentence:

''While such a regulation relating to a food additive, or such a notification under subsection (h) relating to a food additive that is a food contact substance, is in effect, and has not been revoked pursuant to subsection (i), a food shall not, by reason of bearing or containing such a food additive in accordance with the regulation or notification, be considered adulterated under section 402(a)(1).''.

(b) NOTIFICATION FOR FOOD CONTACT SUBSTANCES.—Section 409 (21 U.S.C. 348), as amended by subsection (a), is further amended—

(1) by redesignating subsections (h) and (i), as subsections (i) and (j), respectively;

(2) by inserting after subsection (g) the following:

''Notification Relating to a Food Contact Substance

''(h)(1) Subject to such regulations as may be promulgated under paragraph (3), a manufacturer or supplier of a food contact substance may, at least 120 days prior to the introduction or delivery for introduction into interstate commerce of the food contact substance, notify the Secretary of the identity and intended use of the food contact substance, and of the determination of the manufacturer or supplier that the intended use of such food contact substance is safe under the standard described in subsection (c)(3)(A). The notification shall contain the information that forms the basis of the determination, the fee required under paragraph (5), and all information required to be submitted by regulations promulgated by the Secretary.

''(2)(A) A notification submitted under paragraph (1) shall become effective 120 days after the date of receipt by the Secretary and the food contact substance may be introduced or delivered for introduction into interstate commerce, unless the Secretary makes a determination within the 120-day period that, based on the data and information before the Secretary, such use of the food contact substance has not been shown to be safe under the standard described in subsection (c)(3)(A), and informs the manufacturer or supplier of such determination.

''(B) A decision by the Secretary to object to a notification shall constitute final agency action subject to judicial review.

''(C) In this paragraph, the term 'food contact substance' means the substance that is the subject of a notification submitted under paragraph (1), and does not include a similar or identical substance manufactured or prepared by a person other than the manufacturer identified in the notification.

''(3)(A) The process in this subsection shall be utilized for authorizing the marketing of a food contact substance except where the Secretary determines that submission and review of a petition under subsection (b) is necessary to provide adequate assurance of safety, or where the Secretary and any manufacturer or supplier agree that such manufacturer or supplier may submit a petition under subsection (b).

''(B) The Secretary is authorized to promulgate regulations to identify the circumstances in which a petition shall be filed under subsection (b), and shall consider criteria such as the probable consumption of such food contact substance and potential toxicity of the food contact substance in determining the circumstances in which a petition shall be filed under subsection (b).

''(4) The Secretary shall keep confidential any information provided in a notification under paragraph (1) for 120 days after receipt by the Secretary of the notification. After the expiration of such 120 days, the information shall be available to any interested party except for any matter in the notification that is a trade secret or confidential commercial information.

''(5)(A) Each person that submits a notification regarding a food contact substance under this section shall be subject to the payment of a reasonable fee. The fee shall be based on the resources required to process the notification including reasonable administrative costs for such processing.

''(B) The Secretary shall conduct a study of the costs of administering the notification program established under this section and, on the basis of the results of such study, shall, within 18 months after the date of enactment of the Food and Drug Administration Modernization and Accountability Act of 1997, promulgate regulations establishing the fee required by subparagraph (A).

''(C) A notification submitted without the appropriate fee is not complete and shall not become effective for the purposes of subsection (a)(3) until the appropriate fee is paid.

''(D) Fees collected pursuant to this subsection—

''(i) shall not be deposited as an offsetting collection to the appropriations for the Department of Health and Human Services;

''(ii) shall be credited to the appropriate account of the Food and Drug Administration; and

''(iii) shall be available in accordance with appropriation Acts until expended, without fiscal year limitation.

''(6) In this section, the term 'food contact substance' means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.'';

(3) in subsection (i), as so redesignated by paragraph (1), by adding at the end the following: ''The Secretary shall by regulation prescribe the procedure by which the Secretary may deem a notification under subsection (h) to no longer be effective.''; and

(4) in subsection (j), as so redesignated by paragraph (1), by striking ''subsections (b) to (h)'' and inserting ''subsections (b) to (i)''.

(c) EFFECTIVE DATE.—Notifications under section 409(h) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b), may be submitted beginning 18 months after the date of enactment of this Act.

SEC. 617. HEALTH CLAIMS FOR FOOD PRODUCTS.

Section 403(r)(3) (21 U.S.C. 343(r)(3)) is amended by adding at the end the following:

''(C) Notwithstanding the provisions of clauses (A)(i) and (B), a claim of the type described in subparagraph (1)(B) that is not authorized by the Secretary in a regulation promulgated in accordance with clause (B) shall be authorized and may be made if—

''(i) an authoritative scientific body of the Federal Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention), the National Academy of Sciences, or a subdivision of the scientific body or the National Academy of Sciences, has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers;

''(ii) a person has submitted to the Secretary at least 120 days before the first introduction of a food into interstate commerce a notice of the claim, including a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied;

''(iii) the claim and the food for which the claim is made are in compliance with clause (A)(ii), and are otherwise in compliance with paragraph (a) and section 201(n); and

''(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this paragraph, a statement shall be regarded as an authoritative statement of such a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

''(D) A claim submitted under the requirements of clause (C), may be made until—

''(i) such time as the Secretary issues an interim final regulation—

''(I) under the standard in clause (B)(i), prohibiting or modifying the claim; or

''(II) finding that the requirements of clause (C) have not been met; or

''(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (C) have not been met.

Where the Secretary issues a regulation under subclause (i), good cause shall be deemed to exist for the purposes of subsections (b)(B) and (d)(3) of section 553 of title 5, United States Code. The Secretary shall solicit comments in response to a regulation promulgated under subclause (i) and shall publish a response to such comments.''.

SEC. 618. PEDIATRIC STUDIES MARKETING EXCLUSIVITY.

(a) GENERAL AUTHORITY.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21

U.S.C. 351 et seq.) is amended by inserting after section 505 the following:

"SEC. 505A. PEDIATRIC STUDIES OF DRUGS.

''(a) MARKET EXCLUSIVITY FOR NEW DRUGS.—If, prior to approval of an application that is submitted under section 505(b)(1), the Secretary determines that information relating to the use of a drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which may include a timeframe for completing such studies), and such studies are completed within any such timeframe and the reports thereof submitted in accordance with subsection (d)(2) or completed within any such timeframe and the reports thereof are accepted in accordance with subsection (d)(3)—

''(1)(A) the period during which an application may not be submitted under subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 to four years, to forty-eight months, and to seven and one-half years shall be deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

''(B) the period of market exclusivity under subsections (c)(3)(D) (iii) and (iv) and (j)(4)(D) (iii) and (iv) of section 505 shall be three years and six months rather than three years; and

''(2)(A) if the drug is the subject of—

''(i) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

''(ii) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under subsection (c)(3) or (j)(4)(B) of section 505 shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

''(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under subsection (c)(3) or (j)(4)(B) of section 505 shall be extended by a period of six months after the date the patent expires (including any patent extensions).

''(b) SECRETARY TO DEVELOP LIST OF DRUGS FOR WHICH ADDITIONAL PEDIATRIC INFORMATION MAY BE BENEFICIAL.—Not later than 180 days after the date of enactment of this section, the Secretary, after consultation with experts in pediatric research (such as the American Academy of Pediatrics, the Pediatric Pharmacology Research Unit Network, and the United States Pharmacopoeia) shall develop, prioritize, and publish an initial list of approved drugs for which additional pediatric information may produce health benefits in the pediatric population. The Secretary shall annually update the list.

''(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—If the Secretary makes a written request for pediatric studies (which may include a timeframe for completing such studies) concerning a drug identified in the list described in subsection (b) to the holder of an approved application under section 505(b)(1) for the drug, the holder agrees to the request, and the studies are completed within any such timeframe and the reports thereof submitted in accordance with subsection (d)(2) or completed within any such timeframe and the reports thereof accepted in accordance with subsection (d)(3)—

''(1)(A) the period during which an application may not be submitted under subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 to four years, to forty-eight months, and to seven and one-half years shall be deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

''(B) the period of market exclusivity under subsections (c)(3)(D) (iii) and (iv) and (j)(4)(D) (iii) and (iv) of section 505 shall be three years and six months rather than three years; and

''(2)(A) if the drug is the subject of—

''(i) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

''(ii) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under subsection (c)(3) or (j)(4)(B) of section 505 shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

''(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under subsection (c)(3) or (j)(4)(B) of section 505 shall be extended by a period of six months after the date the patent expires (including any patent extensions).

''(d) CONDUCT OF PEDIATRIC STUDIES.—

''(1) AGREEMENT FOR STUDIES.—The Secretary may, pursuant to a written request for studies, after consultation with—

''(A) the sponsor of an application for an investigational new drug under section 505(i);

''(B) the sponsor of an application for a drug under section 505(b)(1); or

''(C) the holder of an approved application for a drug under section 505(b)(1),

agree with the sponsor or holder for the conduct of pediatric studies for such drug.

''(2) WRITTEN PROTOCOLS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary agree upon written protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied upon the completion of the studies and submission of the reports thereof in accordance with the original written request and the written agreement referred to in paragraph (1). Not later than 60 days after the submission of the report of the studies, the Secretary shall determine if such studies were or were not conducted in accordance with the original written request and the written agreement and reported in accordance with the requirements of the Secretary for filing and so notify the sponsor or holder.

''(3) OTHER METHODS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary have not agreed in writing on the protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied when such studies have been completed and the reports accepted by the Secretary. Not later than 90 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within the 90 days, whether the studies fairly respond to the written request, whether such studies have been conducted in accordance with commonly accepted scientific principles and protocols, and whether such studies have been reported in accordance with the requirements of the Secretary for filing.

''(e) DELAY OF EFFECTIVE DATE FOR CERTAIN APPLICATIONS; PERIOD OF MARKET EXCLUSIVITY.—If the Secretary determines that the acceptance or approval of an application under subsection (b)(2) or (j) of section 505 for a drug may occur after submission of reports of pediatric studies under this section, which were submitted prior to the expiration of the patent (including any patent extension) or market exclusivity protection, but before the Secretary has determined whether the requirements of subsection (d) have been satisfied, the Secretary shall delay the acceptance or approval under subsection (b)(2) or (j), respectively, of section 505 until the determination under subsection (d) is made, but such delay shall not exceed 90 days. In the event that requirements of this section are satisfied, the applicable period of market exclusivity referred to in subsection (a) or (c) shall be deemed to have been running during the period of delay.

''(f) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—The Secretary shall publish a notice of any determination that the requirements of subsection (d) have been met and that submissions and approvals under subsection (b)(2) or (j) of section 505 for a drug will be subject to the provisions of this section.

''(g) LIMITATION.—The holder of an approved application for a new drug that has already received six months of market exclusivity under subsection (a) or (c) may, if otherwise eligible, obtain six months of market exclusivity under subsection (c)(1)(B) for a supplemental application, except that the holder is not eligible for exclusivity under subsection (c)(2).

''(h) STUDY AND REPORT.—The Secretary shall conduct a study and report to Congress not later than January 1, 2003 based on the experience under the program. The study and report shall examine all relevant issues, including—

''(1) the effectiveness of the program in improving information about important pediatric uses for approved drugs;

''(2) the adequacy of the incentive provided under this section;

''(3) the economic impact of the program; and

''(4) any suggestions for modification that the Secretary deems appropriate.

''(i) TERMINATION OF MARKET EXCLUSIVITY EXTENSION AUTHORITY FOR NEW DRUGS.—Except as provided in section 618(b) of the Food and Drug Administration Modernization and Accountability Act of 1997, no period of market exclusivity shall be extended under subsection (a) for a drug if—

''(1) the extension would be based on studies commenced after January 1, 2004; and

''(2) the application submitted for the drug under section 505(b)(1) was not approved by January 1, 2004.

''(j) DEFINITIONS.—In this section, the term 'pediatric studies' or 'studies' means at least 1 clinical investigation (that, at the Secretary's discretion, may include pharmacokinetic studies) in pediatric age-groups in which a drug is anticipated to be used.''.

(b) MARKET EXCLUSIVITY UNDER OTHER AUTHORITY.—

(1) THROUGH CALENDAR YEAR 2003.—

(A) DETERMINATION.—If the Secretary requests or requires pediatric studies, prior to January 1, 2004, under Federal law other than section 505A of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)), from the sponsor of an application, or the holder of an approved application, for a drug under section 505(b) of such Act (21 U.S.C. 355(b)), the Secretary shall determine whether the studies meet the completeness, timeliness, and other submission requirements of the Federal law involved.

(B) MARKET EXCLUSIVITY.—If the Secretary determines that the studies meet the requirements involved, the Secretary shall ensure that the period of market exclusivity for the drug involved is extended for 6 months in accordance with the requirements of subsection (a), (c), (e), and (g) (as appropriate) of section 505A of such Act (as in effect on the date of enactment of this Act.).

(2) CALENDAR YEAR 2004 AND SUBSEQUENT YEARS.—

(A) NEW DRUGS.—Effective January 1, 2004, if the Secretary requests or requires pediatric studies, under Federal law other than section 505A of the Federal Food, Drug, and Cosmetic Act, from the sponsor of an application for a drug under section 505(b) of such Act, nothing in such law shall be construed to permit or require the Secretary to ensure that the period of market exclusivity for the drug is extended.

(B) ALREADY MARKETED DRUGS.—

(i) DETERMINATION.—Effective January 1, 2004, if the Secretary requests or requires pediatric studies, under Federal law other than section 505A of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)), from the holder of an approved application for a drug under section 505(b) of such Act, the Secretary shall determine whether the studies meet the completeness, timeliness, and other submission requirements of the Federal law involved.

(ii) MARKET EXCLUSIVITY.—If the Secretary determines that the studies meet the requirements involved, the Secretary shall ensure that the period of market exclusivity for the drug involved is extended for 6 months in accordance with the requirements of subsection (a), (c), (e), and (g) (as appropriate) of section 505A of such Act (as in effect on the date of enactment of this Act.).

(3) DEFINITIONS.—In this subsection:

(A) DRUG.—The term ''drug'' has the meaning given the term in section 201 of such Act.

(B) PEDIATRIC STUDIES.—The term ''pediatric studies'' has the meaning given the term in section 505A of such Act.

(C) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

SEC. 619. POSITRON EMISSION TOMOGRAPHY.

(a) REGULATION OF COMPOUNDED POSITRON EMISSION TOMOGRAPHY DRUGS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

(1) DEFINITION.—Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

''(ii) The term 'compounded positron emission tomography drug'—

''(1) means a drug that—

''(A) exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and

''(B) has been compounded by or on the order of a practitioner who is licensed by a State to compound or order compounding for a drug described in subparagraph (A), and is compounded in accordance with that State's law, for a patient or for research, teaching, or quality control; and

''(2) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.''.

(b) ADULTERATION.—

(1) IN GENERAL.—Section 501(a)(2) (21 U.S.C. 351(a)(2)) is amended by striking ''; or (3)'' and inserting the following: ''; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopeia to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess; or (3)''.

(2) SUNSET.—Section 501(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(C)) shall not apply 4 years after the date of enactment of this Act or 2 years after the date or which the Secretary of Health and Human Services establishes the requirements described in subsection (c)(1)(B), whichever is later.

(c) REQUIREMENTS FOR REVIEW OF APPROVAL PROCEDURES AND CURRENT GOOD MANUFACTURING PRACTICES FOR POSITRON EMISSION TOMOGRAPHY.—

(1) PROCEDURES AND REQUIREMENTS.—

(A) IN GENERAL.—In order to take account of the special characteristics of compounded positron emission tomography drugs and the special techniques and processes required to produce these drugs, not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall establish—

(i) appropriate procedures for the approval of compounded positron emission tomography drugs pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); and

(ii) appropriate current good manufacturing practice requirements for such drugs.

(B) CONSIDERATIONS AND CONSULTATION.—In establishing the procedures and requirements required by subparagraph (A), the Secretary of Health and Human Services shall take due account of any relevant differences between not-for-profit institutions that compound the drugs for their patients and commercial manufacturers of the drugs. Prior to establishing the procedures and requirements, the Secretary of Health and Human Services shall consult with patient advocacy groups, professional associations, manufacturers, and physicians and scientists licensed to make or use compounded positron emission tomography drugs.

(2) SUBMISSION OF NEW DRUG APPLICATIONS AND ABBREVIATED NEW DRUG APPLICATIONS.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary of Health and Human Services shall not require the submission of new drug applications or abbreviated new drug applications under subsection (b) or (j) of section 505 (21 U.S.C. 355), for compounded positron emission tomography drugs that are not adulterated drugs described in section 501(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(C)) (as amended by subsection (b)), for a period of 4 years after the date of enactment of this Act, or for 2 years after the date or which the Secretary establishes procedures and requirements under paragraph (1), whichever is later.

(B) EXCEPTION.—Nothing in this Act shall prohibit the voluntary submission of such applications or the review of such applications by the Secretary of Health and Human Services. Nothing in this Act shall constitute an exemption for a compounded positron emission tomography drug from the requirements of regulations issued under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) for such drugs.

(d) REVOCATION OF CERTAIN INCONSISTENT DOCUMENTS.—Within 30 days after the date of enactment of this Act, the Secretary of Health and Human Services shall publish in the Federal Register a notice terminating the application of the following notices and rule, to the extent the notices and rule relate to compounded positron emission tomography drugs:

(1) A notice entitled ''Regulation of Positron Emission Tomographic Drug Products: Guidance; Public Workshop'', published in the Federal Register on February 27, 1995.

(2) A notice entitled ''Guidance for Industry: Current Good Manufacturing Practices for Positron Emission Tomographic (PET) Drug Products; Availability'', published in the Federal Register on April 22, 1997.

(3) A final rule entitled ''Current Good Manufacturing Practice for Finished Pharmaceuticals; Positron Emission Tomography'', published in the Federal Register on April 22, 1997.

(e) DEFINITION.—As used in this section, the term ''compounded positron emission tomography drug'' has the meaning given the term in section 201 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321).

SEC. 620. DISCLOSURE.

Chapter IV (21 U.S.C. 341 et seq.) is amended by adding after section 403B the following:

''DISCLOSURE

''SEC. 403C. (a) No provision of section 403(a), 201(n), or 409 shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients required by section 403(i)(2).

''(b) In this section, the term 'radiation disclosure statement' means a written statement that discloses that a food or a component of the food has been intentionally subject to radiation.''.

SEC. 621. REFERRAL STATEMENTS RELATING TO FOOD NUTRIENTS.

Section 403(r)(2)(B) (21 U.S.C. 343(r)(2)(B)) is amended to read as follows:

''(B) If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food, and the Secretary makes a determination that the food contains a nutrient at a level that increases to persons in the general population the risk of a disease or health-related condition that is diet related, then the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, the following statement: 'See nutrition information panel for ___ content.' The blank shall identify the nutrient associated with the increased disease or health-related condition risk. In making the determination described in this clause, the Secretary shall take into account the significance of the food in the total daily diet.''.

TITLE VII—FEES RELATING TO DRUGS

SEC. 701. SHORT TITLE.

This title may be cited as the ''Prescription Drug User Fee Reauthorization Act of 1997''.

SEC. 702. FINDINGS.

Congress finds that—

(1) prompt approval of safe and effective new drugs and other therapies is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease;

(2) the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food

and Drug Administration that are devoted to the process for review of human drug applications;

(3) the provisions added by the Prescription Drug User Fee Act of 1992 have been successful in substantially reducing review times for human drug applications and should be—

(A) reauthorized for an additional 5 years, with certain technical improvements; and

(B) carried out by the Food and Drug Administration with new commitments to implement more ambitious and comprehensive improvements in regulatory processes of the Food and Drug Administration; and

(4) the fees authorized by amendments made in this title will be dedicated toward expediting the drug development process and the review of human drug applications as set forth in the goals identified in appropriate letters from the Secretary of Health and Human Services to the chairman of the Committee on Commerce of the House of Representatives and the chairman of the Committee on Labor and Human Resources of the Senate.

SEC. 703. DEFINITIONS.

Section 735 (21 U.S.C. 379g) is amended—

(1) in the second sentence of paragraph (1)—

(A) by striking ''Service Act, and'' and inserting ''Service Act,''; and

(B) by striking ''September 1, 1992.'' and inserting the following: ''September 1, 1992, does not include an application for a licensure of a biological product for further manufacturing use only, and does not include an application or supplement submitted by a State or Federal Government entity for a drug or biological product that is not distributed commercially. Such term does include an application for licensure, as described in subparagraph (D), of a large volume biological product intended for single dose injection for intravenous use or infusion.'';

(2) in the second sentence of paragraph (3)—

(A) by striking ''Service Act, and'' and inserting ''Service Act,''; and

(B) by striking ''September 1, 1992.'' and inserting the following: ''September 1, 1992, does not include a biological product that is licensed for further manufacturing use only, and does not include a drug or biological product that is not distributed commercially and is the subject of an application or supplement submitted by a State or Federal Government entity. Such term does include a large volume biological product intended for single dose injection for intravenous use or infusion.'';

(3) in paragraph (4), by striking ''without'' and inserting ''without substantial'';

(4) by striking paragraph (5) and inserting the following:

''(5) The term 'prescription drug establishment' means a foreign or domestic place of business which is at 1 general physical location consisting of 1 or more buildings all of which are within 5 miles of each other, at which 1 or more prescription drug products are manufactured in final dosage forms.'';

(5) in paragraph (7)(A)—

(A) by striking ''employees under contract'' and all that follows through ''Administration,'' and inserting ''contractors of the Food and Drug Administration,''; and

(B) by striking ''and committees,'' and inserting ''and committees and to contracts with such contractors,'';

(6) in paragraph (8)—

(A) in subparagraph (A)—

(i) by striking ''August of'' and inserting ''April of''; and

(ii) by striking ''August 1992'' and inserting ''April 1997'';

(B) by striking subparagraph (B) and inserting the following:

''(B) 1 plus the decimal expression of the total percentage increase for such fiscal year since fiscal year 1997 in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.''; and

(C) by striking the second sentence; and

(7) by adding at the end the following:

''(9) The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

''(A) 1 business entity controls, or has the power to control, the other business entity; or

''(B) a third party controls, or has power to control both of the business entities.''.

SEC. 704. AUTHORITY TO ASSESS AND USE DRUG FEES.

(a) TYPES OF FEES.—Section 736(a) (21 U.S.C. 379h(a)) is amended—

(1) by striking ''Beginning in fiscal year 1993'' and inserting ''Beginning in fiscal year 1998'';

(2) in paragraph (1)—

(A) by striking subparagraph (B) and inserting the following:

''(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the application or supplement.'';

(B) in subparagraph (D)—

(i) in the subparagraph heading, by striking ''NOT ACCEPTED'' and inserting ''REFUSED'';

(ii) by striking ''50 percent'' and inserting ''75 percent'';

(iii) by striking ''subparagraph (B)(i)'' and inserting ''subparagraph (B)''; and

(iv) by striking ''not accepted'' and inserting ''refused''; and

(C) by adding at the end the following:

''(E) EXCEPTION FOR DESIGNATED ORPHAN DRUG OR INDICATION.—A human drug application for a prescription drug product that has been designated as a drug for a rare disease or condition pursuant to section 526 shall not be subject to a fee under subparagraph (A), unless the human drug application includes indications for other than rare diseases or conditions. A supplement proposing to include a new indication for a rare disease or condition in a human drug application shall not be subject to a fee under subparagraph (A), provided that the drug has been designated pursuant to section 526 as a drug for a rare disease or condition with regard to the indication proposed in such supplement.

''(F) EXCEPTION FOR SUPPLEMENTS FOR PEDIATRIC INDICATIONS.—A supplement to a human drug application for an indication for use in pediatric populations shall not be assessed a fee under subparagraph (A).

''(G) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an application or supplement is withdrawn after the application or supplement is filed, the Secretary may waive and refund the fee or a portion of the fee if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to waive and refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a waiver or refund under this paragraph shall not be reviewable.'';

(3) by striking paragraph (2) and inserting the following:

''(2) PRESCRIPTION DRUG ESTABLISHMENT FEE.—

''(A) IN GENERAL.—Each person that—

''(i) is named as the applicant in a human drug application; and

''(ii) after September 1, 1992, had pending before the Secretary a human drug application or supplement;

shall be assessed an annual fee established in subsection (b) for each prescription drug establishment listed in its approved human drug application as an establishment that manufactures the prescription drug product named in the application. The annual establishment fee shall be assessed in each fiscal year in which the prescription drug product named in the application is assessed a fee under paragraph (3) unless the prescription drug establishment listed in the application does not engage in the manufacture of the prescription drug product during the fiscal year. The establishment fee shall be payable on or before January 31 of each year. Each such establishment shall be assessed only 1 fee per establishment, notwithstanding the number of prescription drug products manufactured at the establishment. In the event an establishment is listed in a human drug application by more than 1 applicant, the establishment fee for the fiscal year shall be divided equally and assessed among the applicants whose prescription drug products are manufactured by the establishment during the fiscal year and assessed product fees under paragraph (3).

''(B) EXCEPTION.—If, during the fiscal year, an applicant initiates or causes to be initiated the manufacture of a prescription drug product at an establishment listed in its human drug application—

''(i) that did not manufacture the product in the previous fiscal year; and

''(ii) for which the full establishment fee has been assessed in the fiscal year at a time before manufacture of the prescription drug product was begun;

the applicant will not be assessed a share of the establishment fee for the fiscal year in which manufacture of the product began.''; and

(4) in paragraph (3)—

(A) in subparagraph (A)—

(i) in clause (i), by striking ''is listed'' and inserting ''has been submitted for listing''; and

(ii) by striking ''Such fee shall be payable'' and all that follows through ''section 510.'' and inserting the following: ''Such fee shall be payable for the fiscal year in which the product is first submitted for listing under section 510, or for relisting under section 510 if the product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable.''; and

(B) in subparagraph (B), by striking ''505(j).'' and inserting the following: ''505(j), or under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984, or is a product approved under an application filed under section 507 that is abbreviated.''.

(b) FEE AMOUNTS.—Section 736(b) (21 U.S.C. 379h(b)) is amended to read as follows:

''(b) FEE AMOUNTS.—Except as provided in subsections (c), (d), (f), and (g), the fees required under subsection (a) shall be determined and assessed as follows:

''(1) APPLICATION AND SUPPLEMENT FEES.—

''(A) FULL FEES.—The application fee under subsection (a)(1)(A)(i) shall be $250,704 in fiscal year 1998, $256,338 in each of fiscal years 1999 and 2000, $267,606 in fiscal year 2001, and $258,451 in fiscal year 2002.

''(B) OTHER FEES.—The fee under subsection (a)(1)(A)(ii) shall be $125,352 in fiscal year 1998, $128,169 in each of fiscal years 1999 and 2000, $133,803 in fiscal year 2001, and $129,226 in fiscal year 2002.

''(2) FEE REVENUES FOR ESTABLISHMENT FEES.—The total fee revenues to be collected

in establishment fees under subsection (a)(2) shall be $35,600,000 in fiscal year 1998, $36,400,000 in each of fiscal years 1999 and 2000, $38,000,000 in fiscal year 2001, and $36,700,000 in fiscal year 2002.

''(3) TOTAL FEE REVENUES FOR PRODUCT FEES.—The total fee revenues to be collected in product fees under subsection (a)(3) in a fiscal year shall be equal to the total fee revenues collected in establishment fees under subsection (a)(2) in that fiscal year.''.

(c) INCREASES AND ADJUSTMENTS.—Section 736(c) (21 U.S.C. 379h(c)) is amended—

(1) in the subsection heading, by striking ''INCREASES AND'';

(2) in paragraph (1)—

(A) by striking ''(1) REVENUE'' and all that follows through ''increased by the Secretary'' and inserting the following: ''(1) INFLATION ADJUSTMENT.—The fees and total fee revenues established in subsection (b) shall be adjusted by the Secretary'';

(B) in subparagraph (A), by striking ''increase'' and inserting ''change'';

(C) in subparagraph (B), by striking ''increase'' and inserting ''change''; and

(D) by adding at the end the following flush sentence:

''The adjustment made each fiscal year by this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 1997 under this subsection.'';

(3) in paragraph (2), by striking ''October 1, 1992,'' and all that follows through ''such schedule.'' and inserting the following: ''September 30, 1997, adjust the establishment and product fees described in subsection (b) for the fiscal year in which the adjustment occurs so that the revenues collected from each of the categories of fees described in paragraphs (2) and (3) of subsection (b) shall be set to be equal to the revenues collected from the category of application and supplement fees described in paragraph (1) of subsection (b).''; and

(4) in paragraph (3), by striking ''paragraph (2)'' and inserting ''this subsection''.

(d) FEE WAIVER OR REDUCTION.—Section 736(d) (21 U.S.C. 379h(d)) is amended—

(1) by redesignating paragraphs (1), (2), (3), and (4) as subparagraphs (A), (B), (C), and (D), respectively, and indenting appropriately;

(2) by striking ''The Secretary shall grant a'' and all that follows through ''finds that—'' and inserting the following:

''(1) IN GENERAL.—The Secretary shall grant a waiver from or a reduction of 1 or more fees assessed under subsection (a) where the Secretary finds that—'';

(3) in subparagraph (C) (as so redesignated by paragraph (1)), by striking '', or'' and inserting a comma;

(4) in subparagraph (D) (as so redesignated by paragraph (1)), by striking the period and inserting '', or'';

(5) by inserting after subparagraph (D) (as so redesignated by paragraph (1)) the following:

''(E) the applicant is a small business submitting its first human drug application to the Secretary for review.''; and

(6) by striking ''In making the finding in paragraph (3),'' and all that follows through ''standard costs.'' and inserting the following:

''(2) USE OF STANDARD COSTS.—In making the finding in paragraph (1)(C), the Secretary may use standard costs.

''(3) RULES RELATING TO SMALL BUSINESSES.—

''(A) DEFINITION.—In paragraph (1)(E), the term 'small business' means an entity that has fewer than 500 employees, including employees of affiliates.

''(B) WAIVER OF APPLICATION FEE.—The Secretary shall waive under paragraph (1)(E) the application fee for the first human drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay—

''(i) application fees for all subsequent human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business; and

''(ii) all supplement fees for all supplements to human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business.''.

(e) ASSESSMENT OF FEES.—Section 736(f)(1) (21 U.S.C. 379h(f)(1)) is amended—

(1) by striking ''fiscal year 1993'' and inserting ''fiscal year 1997''; and

(2) by striking ''fiscal year 1992'' and inserting ''fiscal year 1997 (excluding the amount of fees appropriated for such fiscal year)''.

(f) CREDITING AND AVAILABILITY OF FEES.—Section 736(g) (21 U.S.C. 379h(g)) is amended—

(1) in paragraph (1), by adding at the end the following: ''Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of human drug applications within the meaning of section 735(6).'';

(2) in paragraph (2)—

(A) in subparagraph (A), by striking ''Acts'' and inserting ''Acts, or otherwise made available for obligation,''; and

(B) in subparagraph (B), by striking ''over such costs for fiscal year 1992'' and inserting ''over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997''; and

(3) by striking paragraph (3) and inserting the following:

''(3) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated for fees under this section—

''(A) $106,800,000 for fiscal year 1998;

''(B) $109,200,000 for fiscal year 1999;

''(C) $109,200,000 for fiscal year 2000;

''(D) $114,000,000 for fiscal year 2001; and

''(E) $110,100,000 for fiscal year 2002,

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by application, supplement, establishment, and product fees.

''(4) OFFSET.—Any amount of fees collected for a fiscal year which exceeds the amount of fees specified in appropriation Acts for such fiscal year, shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under appropriation Acts for a subsequent fiscal year.''.

(g) REQUIREMENT FOR WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND FEES.—Section 736 (21 U.S.C. 379h) is amended—

(1) by redesignating subsection (i) as subsection (j); and

(2) by inserting after subsection (h) the following:

''(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for a waiver or reduction under subsection (d), or for a refund, of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.''.

(h) SPECIAL RULE FOR WAIVER, REFUNDS, AND EXCEPTIONS.—Any requests for waivers, refunds, or exceptions for fees paid prior to the date of enactment of this Act shall be submitted in writing to the Secretary of Health and Human Services within 1 year after the date of enactment of this Act.

SEC. 705. ANNUAL REPORTS.

(a) FIRST REPORT.—Beginning with fiscal year 1998, not later than 60 days after the end of each fiscal year during which fees are collected under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letter described in section 702(4) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(b) SECOND REPORT.—Beginning with fiscal year 1998, not later than 120 days after the end of each fiscal year during which fees are collected under the part described in subsection (a), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

SEC. 706. EFFECTIVE DATE.

The amendments made by this title shall take effect October 1, 1997.

SEC. 707. TERMINATION OF EFFECTIVENESS.

The amendments made by sections 703 and 704 cease to be effective October 1, 2002 and section 705 ceases to be effective 120 days after such date.

TITLE VIII—MISCELLANEOUS

SEC. 801. REGISTRATION OF FOREIGN ESTABLISHMENTS.

Section 510(i) (21 U.S.C. 360(i)) is amended to read as follows:

''(i)(1) Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or a device that is imported or offered for import into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.

''(2) The establishment shall also provide the information required by subsection (j).

''(3) The Secretary is authorized to enter into cooperative arrangements with foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether drugs or devices manufactured, prepared, propagated, compounded, or processed by an establishment described in paragraph (1), if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a).''.

SEC. 802. ELIMINATION OF CERTAIN LABELING REQUIREMENTS.

(a) PRESCRIPTION DRUGS.—Section 503(b)(4) (21 U.S.C. 353(b)(4)) is amended to read as follows:

''(4)(A) A drug that is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol 'Rx only'.

''(B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded

if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A).''.

(b) MISBRANDED DRUG.—Section 502(d) (21 U.S.C. 352(d)) is repealed.

(c) CONFORMING AMENDMENTS.—

(1) Section 503(b)(1) (21 U.S.C. 353(b)(1)) is amended—

(A) by striking subparagraph (A); and

(B) by redesignating subparagraphs (B) and (C) as subparagraphs (A) and (B), respectively.

(2) Section 503(b)(3) (21 U.S.C. 353(b)(3)) is amended by striking ''section 502(d) and''.

(3) Section 102(9)(A) of the Controlled Substances Act (21 U.S.C. 802(9)(A)) is amended—

(A) in clause (i), by striking ''(i)''; and

(B) by striking ''(ii)'' and all that follows.

SEC. 803. CLARIFICATION OF SEIZURE AUTHORITY.

Section 304(d)(1) (21 U.S.C. 334(d)(1)) is amended—

(1) in the fifth sentence, by striking ''paragraphs (1) and (2) of section 801(e)'' and inserting ''subparagraphs (A) and (B) of section 801(e)(1)''; and

(2) by inserting after the fifth sentence the following: ''Any person seeking to export an imported article pursuant to any of the provisions of this subsection shall establish that the article was intended for export at the time the article entered commerce.''.

SEC. 804. INTRAMURAL RESEARCH TRAINING AWARD PROGRAM.

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 203, is further amended by adding at the end the following:

''SEC. 907. INTRAMURAL RESEARCH TRAINING AWARD PROGRAM.

''(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, may, directly or through grants, contracts, or cooperative agreements, conduct and support intramural research training in regulatory scientific programs by predoctoral and postdoctoral scientists and physicians, including support through the use of fellowships.

''(b) LIMITATION ON PARTICIPATION.—A recipient of a fellowship under subsection (a) may not be an employee of the Federal Government.

''(c) SPECIAL RULE.—The Secretary, acting through the Commissioner of Food and Drugs, may support the provision of assistance for fellowships described in subsection (a) through a Cooperative Research and Development Agreement.''.

SEC. 805. DEVICE SAMPLES.

(a) RECALL AUTHORITY.—

(1) IN GENERAL.—Section 518(e)(2) (21 U.S.C. 360h(e)(2)) is amended by adding at the end the following:

''(C) If the Secretary issues an amended order under subparagraph (A), the Secretary may require the person subject to the order to submit such samples of the device and of components of the device as the Secretary may reasonably require. If the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of 1 or more such devices readily available for examination and testing.''.

(2) TECHNICAL AMENDMENT.—Section 518(e)(2)(A) (21 U.S.C. 360h(e)(2)(A)) is amended by striking ''subparagraphs (B) and (C)'' and inserting ''subparagraph (B)''.

(b) RECORDS AND REPORTS ON DEVICES.—Section 519(a) (21 U.S.C. 360i(a)) is amended by inserting after paragraph (9) the following:

''(10) may reasonably require a manufacturer or importer to submit samples of a device and of components of the device that may have caused or contributed to a death or serious injury, except that if the submission of such samples is impracticable or unduly burdensome, the requirement of this paragraph may be met by the submission of complete information concerning the location of 1 or more such devices readily available for examination and testing.''.

SEC. 806. INTERSTATE COMMERCE.

Section 709 (21 U.S.C. 379a) is amended by striking ''a device'' and inserting ''a device, food, drug, or cosmetic''.

SEC. 807. NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS AND COSMETICS.

(a) NONPRESCRIPTION DRUGS.—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 614(a), is further amended by adding at the end the following:

''Subchapter F—National Uniformity for Nonprescription Drugs and Preemption for Labeling or Packaging of Cosmetics

''SEC. 761. NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS.

''(a) IN GENERAL.—Except as provided in subsection (b), (c)(1), (d), (e), or (f), no State or political subdivision of a State may establish or continue in effect any requirement—

''(1) that relates to the regulation of a drug that is not subject to the requirements of section 503(b)(1) or 503(f)(1)(A); and

''(2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this Act, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

''(b) EXEMPTION.—

''(1) IN GENERAL.—Upon application of a State or political subdivision thereof, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a State or political subdivision requirement that—

''(A) protects an important public interest that would otherwise be unprotected, including the health and safety of children;

''(B) would not cause any drug to be in violation of any applicable requirement or prohibition under Federal law; and

''(C) would not unduly burden interstate commerce.

''(2) TIMELY ACTION.—The Secretary shall make a decision on the exemption of a State or political subdivision requirement under paragraph (1) not later than 120 days after receiving the application of the State or political subdivision under paragraph (1).

''(c) SCOPE.—

''(1) IN GENERAL.—This section shall not apply to—

''(A) any State or political subdivision requirement that relates to the practice of pharmacy; or

''(B) any State or political subdivision requirement that a drug be dispensed only upon the prescription of a practitioner licensed by law to administer such drug.

''(2) SAFETY OR EFFECTIVENESS.—For purposes of subsection (a), a requirement that relates to the regulation of a drug shall be deemed to include any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug.

''(d) EXCEPTIONS.—

''(1) IN GENERAL.—In the case of a drug described in subsection (a)(1) that is not the subject of an application approved under section 505 or 507 or a final regulation promulgated by the Secretary establishing conditions under which the drug is generally recognized as safe and effective and not misbranded, subsection (a) shall apply only with respect to a requirement of a State or political subdivision of a State that relates to the same subject as, but is different from or in addition to, or that is otherwise not identical with—

''(A) a regulation in effect with respect to the drug pursuant to a statute described in subsection (a)(2); or

''(B) any other requirement in effect with respect to the drug pursuant to an amendment to such a statute made on or after the date of enactment of this section.

''(2) STATE INITIATIVES.—This section shall not apply to a State public initiative enacted prior to the date of enactment of this section.

''(e) NO EFFECT ON PRODUCT LIABILITY LAW.—Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

''(f) STATE ENFORCEMENT AUTHORITY.—Nothing in this section shall prevent a State or political subdivision thereof from enforcing, under any relevant civil or other enforcement authority, a requirement that is identical to a requirement of this Act.''.

(b) INSPECTIONS.—Section 704(a)(1) (21 U.S.C. 374(a)(1)) is amended by striking ''prescription drugs'' each place it appears and inserting ''prescription drugs, nonprescription drugs intended for human use,''.

(c) MISBRANDING.—Paragraph (1) of section 502(e) (21 U.S.C. 352(e)(1)) is amended to read as follows:

''(1)(A) If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula)—

''(i) the established name (as defined in subparagraph (3)) of the drug, if there is such a name;

''(ii) the established name and quantity or, if deemed appropriate by the Secretary, the proportion of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not the established name and quantity or if deemed appropriate by the Secretary, the proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: *Provided,* That the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this paragraph, shall not apply to nonprescription drugs not intended for human use; and

''(iii) the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package and, if deemed appropriate by the Secretary, on the immediate container, as prescribed in regulation promulgated by the Secretary, but nothing in this clause shall be deemed to require that any trade secret be divulged: *Provided,* That the requirements of this clause with respect to alphabetical order shall apply only to nonprescription drugs that are not also cosmetics: and *Provided further*, That this clause shall not apply to nonprescription drugs not intended for human use.

''(B) For any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) shall be printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient: *Provided,* That to the extent that compliance with the requirements of clause (A)(ii) or (iii) or this clause of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.''.

(d) COSMETICS.—Subchapter F of chapter VII, as amended by subsection (a), is further amended by adding at the end the following:

"SEC. 762. PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS.

''(a) IN GENERAL.—Except as provided in subsection (b), (d), or (e), a State or political subdivision of a State shall not impose or continue in effect any requirement for labeling or packaging of a cosmetic that is different from or in addition to, or that is otherwise not identical with a requirement specifically applicable to a particular cosmetic or class of cosmetics under this Act, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

''(b) EXEMPTION.—Upon application of a State or political subdivision thereof, the Secretary may by regulation after notice and opportunity for written and oral presentation of views, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a State or political subdivision requirement for labeling and packaging that—

''(1) protects an important public interest that would otherwise be unprotected;

''(2) would not cause a cosmetic to be in violation of any applicable requirements or prohibition under Federal law; and

''(3) would not unduly burden interstate commerce.

''(c) SCOPE.—For purposes of subsection (a), a reference to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under this Act for packaging or labeling, including any State requirement relating to public information or any other form of public communication.

''(d) NO EFFECT ON PRODUCT LIABILITY LAW.—Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

''(e) STATE INITIATIVE.—This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.''.

SEC. 808. INFORMATION PROGRAM ON CLINICAL TRIALS FOR SERIOUS OR LIFE-THREATENING DISEASES.

(a) IN GENERAL.—Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended—

(1) by redesignating subsections (j) and (k) as subsections (k) and (l), respectively; and

(2) by inserting after subsection (i), the following:

''(j)(1) The Secretary, acting through the Director of the National Institutes of Health and subject to the availability of appropriations, shall establish, maintain, and operate a program with respect to information on research relating to the treatment, detection, and prevention of serious or life-threatening diseases and conditions. The program shall, with respect to the agencies of the Department of Health and Human Services, be integrated and coordinated, and, to the extent practicable, coordinated with other data banks containing similar information.

''(2)(A) After consultation with the Commissioner of Food and Drugs, the directors of the appropriate agencies of the National Institutes of Health (including the National Library of Medicine), and the Director of the Centers for Disease Control and Prevention, the Secretary shall, in carrying out paragraph (1), establish a data bank of information on clinical trials for drugs, and biologicals, for serious or life-threatening diseases and conditions.

''(B) In carrying out subparagraph (A), the Secretary shall collect, catalog, store, and disseminate the information described in such subparagraph. The Secretary shall disseminate such information through information systems, which shall include toll-free telephone communications, available to individuals with serious or life-threatening diseases and conditions, to other members of the public, to health care providers, and to researchers.

''(3) The data bank shall include the following:

''(A) A registry of clinical trials (whether federally or privately funded) of experimental treatments for serious or life-threatening diseases and conditions under regulations promulgated pursuant to sections 505 and 520 of the Federal Food, Drug, and Cosmetic Act that provides a description of the purpose of each experimental drug or biological protocol, either with the consent of the protocol sponsor, or when a trial to test efficacy begins. Information provided shall consist of eligibility criteria, a description of the location of trial sites, and a point of contact for those wanting to enroll in the trial, and shall be in a form that can be readily understood by members of the public. Such information must be forwarded to the data bank by the sponsor of the trial not later than 21 days after the approval by the Food and Drug Administration.

''(B) Information pertaining to experimental treatments for serious or life-threatening diseases and conditions that may be available—

''(i) under a treatment investigational new drug application that has been submitted to the Food and Drug Administration pursuant to part 312 of title 21, Code of Federal Regulations; or

''(ii) as a Group C cancer drug.

The data bank may also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatments.

''(4) The data bank shall not include information relating to an investigation if the sponsor has provided a detailed certification to the Secretary that disclosure of such information would substantially interfere with the timely enrollment of subjects in the investigation, unless the Secretary, after the receipt of the certification, provides the sponsor with a detailed written determination that finds that such disclosure would not substantially interfere with such enrollment.

''(5) For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary. Fees collected under section 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h) shall not be authorized or appropriated for use in carrying out this subsection.''.

(b) COLLABORATION AND REPORT.—

(1) IN GENERAL.—The Secretary of Health and Human Services, the Director of the National Institutes of Health, and the Commissioner of Food and Drugs shall collaborate to determine the feasibility of including device investigations within the scope of the registry requirements set forth in subsection (j) of section 402 of the Public Health Service Act.

(2) REPORT.—Not later than 2 years after the date of enactment of this section, the Secretary of Health and Human Services shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report that shall consider, among other things—

(A) the public health need, if any, for inclusion of device investigations within the scope of the registry requirements set forth in subsection (j) of section 402 of the Public Health Service Act; and

(B) the adverse impact, if any, on device innovation and research in the United States if information relating to such device investigation is required to be publicly disclosed.

SEC. 809. APPLICATION OF FEDERAL LAW TO THE PRACTICE OF PHARMACY COMPOUNDING.

Section 503 (21 U.S.C. 353) is amended by adding at the end the following:

''(h)(1) Sections 501(a)(2)(B), 502(f)(1), 502(l), 505, and 507 shall not apply to a drug product if—

''(A) the drug product is compounded for an identified individual patient, based on a medical need for a compounded product—

''(i) by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, on the prescription order of a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

''(ii) by a licensed pharmacist or licensed physician in limited quantities, prior to the receipt of a valid prescription order for the identified individual patient, and is compounded based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product that have been generated solely within an established relationship between the licensed pharmacist, or licensed physician, and—

''(I) the individual patient for whom the prescription order will be provided; or

''(II) the physician or other licensed practitioner who will write such prescription order; and

''(B) the licensed pharmacist or licensed physician—

''(i) compounds the drug product using bulk drug substances—

''(I) that—

''(aa) comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph; or

''(bb) in a case in which such a monograph does not exist, are drug substances that are covered by regulations issued by the Secretary under paragraph (3);

''(II) that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

''(III) that are accompanied by valid certificates of analysis for each bulk drug substance;

''(ii) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph and the United States Pharmacopeia chapter on pharmacy compounding;

''(iii) only advertises or promotes the compounding service provided by the licensed pharmacist or licensed physician and does not advertise or promote the compounding of any particular drug, class of drug, or type of drug;

''(iv) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective;

''(v) does not compound a drug product that is identified by the Secretary in regulation as presenting demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

''(vi) does not distribute compounded drugs outside of the State in which the drugs are compounded, unless the principal State

agency of jurisdiction that regulates the practice of pharmacy in such State has entered into a memorandum of understanding with the Secretary regarding the regulation of drugs that are compounded in the State and are distributed outside of the State, that provides for appropriate investigation by the State agency of complaints relating to compounded products distributed outside of the State.

''(2)(A) The Secretary shall, after consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by States in complying with paragraph (1)(B)(vi).

''(B) Paragraph (1)(B)(vi) shall not apply to a licensed pharmacist or licensed physician, who does not distribute inordinate amounts of compounded products outside of the State, until—

''(i) the date that is 180 days after the development of the standard memorandum of understanding; or

''(ii) the date on which the State agency enters into a memorandum of understanding under paragraph (1)(B)(vi),

whichever occurs first.

''(3) The Secretary, after consultation with the United States Pharmacopeia Convention Incorporated, shall promulgate regulations limiting compounding under paragraph (1)(B)(i)(I)(bb) to drug substances that are components of drug products approved by the Secretary and to other drug substances as the Secretary may identify.

''(4) The provisions of paragraph (1) shall not apply—

''(A) to compounded positron emission tomography drugs as defined in section 201(ii); or

''(B) to radiopharmaceuticals.

''(5) In this subsection, the term 'compound' does not include to mix, reconstitute, or perform another similar act, in accordance with directions contained in approved drug labeling provided by a drug manufacturer and other drug manufacturer directions consistent with that labeling.''.

SEC. 810. REPORTS OF POSTMARKETING APPROVAL STUDIES.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.), as amended by section 613(a), is further amended by adding at the end the following:

''SEC. 562. REPORTS OF POSTMARKETING STUDIES.

''(a) SUBMISSION.—

''(1) IN GENERAL.—A sponsor of a drug that has entered into an agreement with the Secretary to conduct a postmarketing study of a drug shall submit to the Secretary, within 1 year after the approval of such drug and annually thereafter until the study is completed or terminated, a report of the progress of the study or the reasons for the failure of the sponsor to conduct the study. The report shall be submitted in such form as prescribed by the Secretary in regulations issued by the Secretary.

''(2) AGREEMENTS PRIOR TO EFFECTIVE DATE.—An agreement entered into between the Secretary and a sponsor of a drug, prior to the date of enactment of this section, to conduct a postmarketing study of a drug shall be subject to the requirements of paragraph (1). An initial report for such an agreement shall be submitted within 6 months after the date of the issuance of the regulations under paragraph (1).

''(b) CONSIDERATION OF INFORMATION AS PUBLIC INFORMATION.—Any information pertaining to a report described in paragraph (1) shall be considered to be public information to the extent that the information is necessary—

''(1) to identify the sponsor; and

''(2) to establish the status of a study described in subsection (a) and the reasons, if any, for any failure to carry out the study.

''(c) STATUS OF STUDIES AND REPORTS.—The Secretary shall annually develop and publish in the Federal Register a report that provides a status of the postmarketing studies—

''(1) that sponsors have entered into agreements to conduct; and

''(2) for which reports have been submitted under subsection (a)(1).''.

(b) REPORT TO CONGRESSIONAL COMMITTEES.—Not later than October 1, 2001, the Secretary shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report containing—

(1) a summary of the reports submitted under section 562 of the Federal Food, Drug, and Cosmetic Act; and

(2) an evaluation of—

(A) the performance of the sponsors in fulfilling the agreements with respect to the conduct of postmarketing studies described in such section of such Act;

(B) the timeliness of the Secretary's review of the postmarketing studies; and

(C) any legislative recommendations respecting postmarketing studies.

SEC. 811. INFORMATION EXCHANGE.

(a) IN GENERAL.—Chapter VII (2 U.S.C. 371 et seq.), as amended by section 807, is further amended by adding at the end the following:

''Subchapter G—Dissemination of Treatment Information

''SEC. 771. DISSEMINATION OF TREATMENT INFORMATION ON DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES.

''(a) DISSEMINATION OF TREATMENT INFORMATION.—

''(1) IN GENERAL.—Notwithstanding sections 301(d), 502(f), 505, and 507 and section 351 of the Public Health Service Act (42 U.S.C. 262), and subject to the requirements of paragraphs (2) through (6) and subsection (b), a manufacturer may disseminate to a health care practitioner, a pharmacy benefit manager, a health maintenance organization or other managed health care organization, or a health care insurer or governmental agency, written information concerning the safety, effectiveness, or benefit (whether or not such information is contained in the official labeling) of a drug, biological product, or device for which—

''(A) an approval of an application filed under section 505(b), 505(j), or 515, a clearance in accordance with section 510(k), an approval in accordance with section 507, or a biologics license issued under section 351 of the Public Health Service Act, is in effect; and

''(B) if the use is not described in the approved labeling of the product, the manufacturer has submitted to the Secretary a certification that a supplemental application for that use will be submitted to the Secretary pursuant to paragraph (3) or the manufacturer has received an exemption under paragraph (3)(C).

''(2) AUTHORIZED INFORMATION.—A manufacturer may disseminate the written information under paragraph (1) only if the information—

''(A) is in the form of an unabridged—

''(i) reprint or copy of a peer-reviewed article from a scientific or medical journal (as defined in subsection (c)(5)) of a clinical investigation, with respect to a drug, biological product or device, that would be considered to be scientifically sound by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug, biological product, or device that is the subject of such clinical investigation; or

''(ii) reference textbook (as defined in subsection (c)(4)) that includes information about a clinical investigation with respect to a drug, biological product, or device, that would be considered to be scientifically sound by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug, biological product, or device that is the subject of such clinical investigation; and

''(B) is not false, not misleading, and would not pose a significant risk to the public health.

''(3) COMMITMENT TO FILE A SUPPLEMENTAL APPLICATION; INCENTIVES FOR RESEARCH.—

''(A) IN GENERAL.—A manufacturer may disseminate information about a use not described in the approved labeling of a drug, biological product, or device pursuant to paragraph (1) only if—

''(i) the manufacturer has submitted to the Secretary a certification that the studies needed to file a supplemental application for such use have been completed and such supplement will be filed within 6 months after the date of the initial dissemination of information under paragraph (1); or

''(ii)(I) the manufacturer has submitted to the Secretary a proposed protocol and schedule for conducting the studies needed to submit a supplemental application for such use and has certified that the supplement will be submitted within 36 months after the date of the initial dissemination of information under paragraph (1); and

''(II) the Secretary has determined that the protocol for conducting such studies is adequate and that the schedule for completing such studies is reasonable.

''(B) EXTENSION.—

''(i) LONGER PERIOD OF TIME.—The Secretary may grant a longer period of time for a manufacturer to submit a supplemental application pursuant to subparagraph (A) if the Secretary determines that the studies needed to submit a supplemental application cannot be completed and submitted within 36 months.

''(ii) EXTENSION OF 3-YEAR PERIOD.—The Secretary may extend the time within which a manufacturer must submit a supplemental application pursuant to subparagraph (A) if the manufacturer demonstrates that the manufacturer has acted with due diligence to conduct the studies in a timely manner. Such extension shall not exceed a period of 24 months.

''(C) EXEMPTIONS.—A manufacturer may file a request for an exemption from the requirements set forth in subparagraph (A). Such request shall be submitted in the form and manner prescribed by the Secretary and shall demonstrate that—

''(i) due to the size of the patient population or the lack of potential benefit to the sponsor, the cost of obtaining clinical information and submitting a supplemental application is economically prohibitive; or

''(ii) it would be unethical to conduct the studies necessary to obtain adequate evidence for approval of a supplemental application.

The Secretary shall act on a request for an exemption under this subparagraph within 60 days after the receipt of the request. If the Secretary fails to act within 60 days, the manufacturer may begin to disseminate information pursuant to paragraph (1) without complying with subparagraph (A). If the Secretary subsequently denies the request for an exemption, the manufacturer either shall cease dissemination or shall comply with the requirements of subparagraph (A) within 60 days after such denial. If the manufacturer ceases dissemination pursuant to this subparagraph solely on the basis that the manufacturer does not comply with subparagraph (A), the Secretary may take appropriate corrective action, but may not order the manufacturer to take corrective action.

''(D) REPORT.—A manufacturer who submits a certification to the Secretary under

subparagraph (A) shall provide the Secretary periodic reports that describe the status of the studies being conducted to obtain adequate evidence for approval of a supplemental application.

''(4) INFORMATION ON NEW USES.—

''(A) IN GENERAL.—If the information being disseminated under paragraph (1) meets the requirements of this section, a manufacturer may disseminate information under paragraph (1) concerning the new use of a drug, biological product, or device (described in paragraph (1)) 60 calendar days after the manufacturer has submitted to the Secretary—

''(i) a copy of the information; and

''(ii) any clinical trial information the manufacturer has relating to the safety or efficacy of the new use, any reports of clinical experience pertinent to the safety of the new use, and a summary of such information.

If any of the information required to be provided under clause (ii) has already been provided to the Secretary, the manufacturer may meet the requirements of clause (ii) by providing any such information obtained by the manufacturer since the manufacturer's last submission to the Secretary and a summary that identifies the information previously provided.

''(B) ADDITIONAL INFORMATION.—If the Secretary determines that the information submitted by a manufacturer under subparagraph (A)(i) with respect to a new use of a drug, biological product, or device fails to provide data, analyses, or other written matter, that is objective and balanced, the Secretary may require the manufacturer to disseminate along with the information described in subparagraph (A)—

''(i) additional information with respect to the new use of the drug, biological product, or device that—

''(I) is in the form of an article described in paragraph (2)(A); and

''(II) provides data, analyses, or other written matter, that is scientifically sound;

''(ii) additional objective and scientifically sound information that pertains to the safety or efficacy of the use and is necessary to provide objectivity and balance, including any information that the manufacturer has submitted to the Secretary, or where appropriate, a summary of such information, or any other information that the Secretary has authority to make available to the public;

''(iii) an objective statement prescribed by the Secretary based on information described in clause (i) or (ii), provided the manufacturer has access to the data that forms the basis of such statement unless the Secretary is prohibited from making such data available to the manufacturer; and

''(iv) a statement that describes any previous public announcements by the Secretary relevant to the new use.

''(5) NEW INFORMATION.—If a manufacturer that is disseminating information pursuant to paragraph (1) becomes aware of new information relating to the safety or efficacy of a new use of a drug, biological product, or device for which information was disseminated under paragraph (1), the manufacturer shall notify the Secretary with respect to the new information. If the Secretary determines that the new information demonstrates that a drug, biological product, or device may not be effective or may present a significant risk to public health, the Secretary shall, in consultation with the manufacturer, take such appropriate action as the Secretary determines necessary to ensure public health and safety. The Secretary may limit the types of new information that must be submitted under this paragraph.

''(6) CESSATION OF DISSEMINATION; CORRECTIVE ACTION.—The Secretary may order a manufacturer to cease the dissemination of all information being disseminated pursuant to paragraph (1) if—

''(A) the Secretary finds that a supplemental application does not contain adequate information for approval for the use that is the subject of the information;

''(B) the Secretary determines, after an informal hearing, that the manufacturer is not acting with due diligence to complete the studies necessary to file a supplemental application for the use that is the subject of the information being disseminated; or

''(C) the Secretary determines that the information being disseminated does not comply with the requirements set forth in this section, after providing notice, an opportunity for a meeting, and for minor violations of this section (if there has been substantial compliance with this section), an opportunity to correct such information.

If the Secretary orders cessation of dissemination pursuant to this paragraph, the Secretary may order the manufacturer to take appropriate corrective action.

''(7) SPONSORED RESEARCH.—If a manufacturer has sponsored research that results in information as described in paragraph (2)(A), another manufacturer may not distribute the information under this section, unless such manufacturer is required by the Secretary to distribute the information.

''(b) DISCLOSURE STATEMENT.—In order to afford a full and fair evaluation of the information described in subsection (a), a manufacturer disseminating the information shall include along with the information—

''(1) a prominently displayed statement that discloses—

''(A) that the information concerns a use of a drug, biological product, or device or other attribute of a drug, biological product, or device that has not been approved by the Food and Drug Administration;

''(B) if applicable, that the information is being disseminated at the expense of the manufacturer;

''(C) if applicable, the name of any authors of the information who are employees of, or consultants to, or have received compensation from, the manufacturer, or who have a significant financial interest in the manufacturer;

''(D) the official labeling for the drug, biological product, or device and all updates with respect to the labeling;

''(E) if applicable, a statement that there are products or treatments that have been approved for the use that is the subject of the information being disseminated pursuant to subsection (a)(1); and

''(F) the identification of any person that has provided funding for the conduct of a study relating to a new use of a drug, biological product, or device for which such information is being disseminated; and

''(2) a bibliography of other articles from a scientific reference textbook or scientific or medical journal that have been previously published about the new use of a drug, biological product, or device covered by the information disseminated (unless the information already includes such bibliography).

''(c) DEFINITIONS.—As used in this section:

''(1) HEALTH CARE PRACTITIONER.—The term 'health care practitioner' means a medical provider that is licensed to prescribe a drug or biological product, or to prescribe or use a device, for the treatment of a disease or other medical condition.

''(2) MANUFACTURER.—The term 'manufacturer' includes a person who manufactures, distributes, or markets a drug, biological product, or device.

''(3) NEW USE.—The term 'new use' used with respect to a drug, biological product, or device means a use of a drug, biological product, or device not included in the approved labeling of such drug, biological product, or device.

''(4) REFERENCE TEXTBOOK.—The term 'reference textbook' means a reference publication that—

''(A) has not been written, edited, excerpted, or published specifically for, or at the request of a manufacturer of a drug, biological product, or device;

''(B) has not been edited or significantly influenced by a manufacturer of a drug, biological product, or device;

''(C) is not solely distributed through a manufacturer of a drug, biological product, or device but is generally available in bookstores or other distribution channels where medical textbooks are sold;

''(D) does not focus on any particular drug, biological product, or device of a manufacturer that disseminates information under subsection (a), and does not have a primary focus on new uses of drugs, biological products, or devices that are marketed or under investigation by a manufacturer supporting the dissemination of information; and

''(E) presents materials that are not false or misleading.

''(5) SCIENTIFIC OR MEDICAL JOURNAL.—The term 'scientific or medical journal' means a scientific or medical publication—

''(A) that is published by an organization—

''(i) that has an editorial board;

''(ii) that utilizes experts, who have demonstrated expertise in the subject of an article under review by the organization and who are independent of the organization, to review and objectively select, reject, or provide comments about proposed articles; and

''(iii) that has a publicly stated policy, to which the organization adheres, of full disclosure of any conflict of interest or biases for all authors or contributors involved with the journal or organization;

''(B) whose articles are peer-reviewed and published in accordance with the regular peer-review procedures of the organization;

''(C) that is generally recognized to be of national scope and reputation;

''(D) that is indexed in the Index Medicus of the National Library of Medicine of the National Institutes of Health;

''(E) that presents materials that are not false or misleading; and

''(F) that is not in the form of a special supplement that has been funded in whole or in part by 1 or more manufacturers.

''(d) CONSTRUCTION.—Nothing in this section shall be construed as prohibiting a manufacturer from disseminating information in response to an unsolicited request from a health care practitioner.

''(e) STUDIES AND REPORTS.—

''(1) GENERAL ACCOUNTING OFFICE.—

''(A) IN GENERAL.—The Comptroller General of the United States shall conduct a study to determine the impact of this section on the resources of the Department of Health and Human Services.

''(B) REPORT.—Not later than January 1, 2002, the Comptroller General of the United States shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report of the results of the study.

''(2) DEPARTMENT OF HEALTH AND HUMAN SERVICES.—

''(A) IN GENERAL.—In order to assist Congress in determining whether the provisions of this section should be extended beyond the termination date specified in section 811(e) of the Food and Drug Administration Modernization and Accountability Act of 1997, the Secretary of Health and Human Services shall, in accordance with subparagraph (B),

arrange for the conduct of a study of the scientific issues raised as a result of the enactment of this section, including issues relating to—

''(i) the effectiveness of this section with respect to the provision of useful scientific information to health care practitioners;

''(ii) the quality of the information being disseminated pursuant to the provisions of this section;

''(iii) the quality and usefulness of the information provided, in accordance with this section, by the Secretary or by the manufacturer at the request of the Secretary; and

''(iv) the impact of this section on research in the area of new uses, indications, or dosages, particularly the impact on pediatric indications and rare diseases.

''(3) PROCEDURE FOR STUDY.—

''(A) IN GENERAL.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct the study required by paragraph (2), and to prepare and submit the report required by subparagraph (B), under an arrangement by which the actual expenses incurred by the Institute of Medicine in conducting the study and preparing the report will be paid by the Secretary. If the Institute of Medicine is unwilling to conduct the study under such an arrangement, the Secretary shall enter into a similar arrangement with another appropriate nonprofit private group or association under which the group or association will conduct the study and prepare and submit the report.

''(B) REPORT.—Not later than September 30, 2005, the Institute of Medicine, the group, or association, as appropriate, shall prepare and submit to the Committee on Labor and Human Resources of the Senate, the Committee on Commerce of the House of Representatives, and the Secretary a report of the results of the study required by paragraph (2). The Secretary, after the receipt of the report, shall make the report available to the public.

''(4) AUTHORIZATION OF APPROPRIATION.—There are authorized to be appropriated such sums as are necessary to carry out this subsection.

''SEC. 772. ESTABLISHMENT OF LIST OF ARTICLES AND TEXTBOOKS DISSEMINATED AND LIST OF PROVIDERS THAT RECEIVED ARTICLES AND REFERENCE TEXTBOOKS.

''(a) IN GENERAL.—A manufacturer that disseminates information in the form of articles or reference textbooks under section 771 shall prepare and submit to the Secretary biannually—

''(1) a list containing the titles of the articles and reference textbooks relating to the new use of drugs, biological products, and devices that were disseminated by the manufacturer to a person described in section 771(a)(1) for the 6-month period preceding the date on which the manufacturer submits the list to the Secretary; and

''(2) a list that identifies the categories of providers (as described in section 771(a)(1)) that received the articles and reference textbooks for the 6-month period described in paragraph (1).

''(b) RECORDS.—A manufacturer that disseminates information under section 771 shall keep records that identify the recipients of articles and textbooks provided pursuant to section 771. Such records are to be used by the manufacturer when, pursuant to section 771(a)(6), such manufacturer is required to take corrective action and shall be made available to the Secretary, upon request, for purposes of ensuring or taking corrective action pursuant to paragraph (3), (5), or (6) of section 771(a).

''SEC. 773. CONSTRUCTION.

''(a) DISSEMINATION OF INFORMATION ON DRUGS OR DEVICES NOT EVIDENCE OF INTENDED USE.—Notwithstanding subsection (a), (f), or (o) of section 502, or any other provision of law, the dissemination of information relating to a new use of a drug or device, in accordance with section 771, shall not be construed by the Secretary as evidence of a new intended use of the drug or device that is different from the intended use of the drug or device set forth in the official labeling of the drug or device. Such dissemination shall not be considered by the Secretary as labeling, adulteration, or misbranding of the drug or device.

''(b) PATENT PROTECTION.—Nothing in section 771 shall affect patent rights in any manner.

''(c) AUTHORIZATION FOR DISSEMINATION OF ARTICLES AND FEES FOR REPRINTS OF ARTICLES.—Nothing in section 771 shall be construed as prohibiting an entity that publishes a scientific journal (as defined in section 771(c)(5)) from requiring authorization from the entity to disseminate an article published by such entity and from charging fees for the purchase of reprints of published articles from such entity.''.

(b) PROHIBITED ACT.—Section 301 (21 U.S.C. 331), as amended by section 205(b), is further amended by adding at the end the following:

''(y) The dissemination of information pursuant to section 771 by a manufacturer who fails to comply with the requirements of such section.''.

(c) REGULATIONS.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate regulations to implement the amendments made by this section.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect 1 year after the date of enactment of this Act, or upon the Secretary's issuance of final regulations pursuant to subsection (c), whichever is sooner.

(e) TERMINATION OF EFFECTIVENESS.—The amendments made by this section cease to be effective September 30, 2006, or 7 years after the date on which the Secretary promulgates the regulations described in subsection (c), whichever is later.

SEC. 812. REAUTHORIZATION OF CLINICAL PHARMACOLOGY PROGRAM.

Section 2 of Public Law 102–222 (105 Stat. 1677) is amended—

(1) in subsection (a), by striking ''a grant'' and all that follows through ''Such grant'' and inserting the following: ''grants for a pilot program for the training of individuals in clinical pharmacology at appropriate medical schools. Such grants''; and

(2) in subsection (b), by striking ''to carry out this section'' and inserting '', and for fiscal years 1998 through 2002 $3,000,000 for each fiscal year, to carry out this section''.

SEC. 813. MONOGRAPH FOR SUNBURN PRODUCTS.

Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue a final monograph for over-the-counter sunburn products for prevention or treatment of sunburn.

SEC. 814. SAFETY REPORT DISCLAIMERS.

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 804, is further amended by adding at the end the following:

''SEC. 908. SAFETY REPORT DISCLAIMERS.

''With respect to any entity that submits or is required to submit a safety report or other information in connection with the safety of a product (including a product which is a food, drug, new drug, device, dietary supplement, or cosmetic) under this Act (and any release by the Secretary of that report or information), such report or information shall not be construed to necessarily reflect a conclusion by the entity or the Secretary that the report or information constitutes an admission that the product involved caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, serious illness, or malfunction. Such an entity need not admit, and may deny, that the report or information submitted by the entity constitutes an admission that the product involved caused or contributed to an adverse experience or caused or contributed to a death, serious injury, serious illness, or malfunction.''.

Mr. JEFFORDS. Mr. President, I move to reconsider the vote.

Mr. COATS. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

Mr. JEFFORDS. Mr. President, I thank my colleagues and I thank them profusely for their vote, for their support in the committee, and all the work that has gone into this. But, as we all know, there are people who work behind the scenes, those who are probably more responsible for this vote than we on the floor are. I just want to take a moment to thank the staff.

In the office of Senate Legislative Counsel, Robin Bates, Elizabeth Aldridge, and Bill Baird worked tirelessly to produce countless bill drafts and amendments. And how they came out with them as expeditiously as they did, I'm not sure.

The staff at CRS, especially Donna Vogt, and at GAO, including Bernice Steinhardt deserve thanks for their willingness to provide essential information and documents on extremely short notice. We must always remember to appreciate these organizations that provide so much assistance to the Congress.

The staff to the members of the committee contributed greatly to the success of this bill. In particular, Vince Ventimiglia with Senator COATS' staff worked closely with ours in a true partnership on all aspects of S. 830.

In addition, Kimberly Spaulding with Senator GREGG, Sue Ramthun with Senator FRIST, Saira Sultan with Senator DEWINE, and Kate Lambrew-Hull with Senator HUTCHINSON all played important roles in fashioning compromises on key provisions of this bill. Also, Mark Smith with Senator MACK's staff worked very hard to make the agreement on off-label dissemination of information possible.

I would also like to thank the many staff of the administration who have worked on this legislation.

In particular, I want to thank Bill Schultz, Diane Thompson, and Peggy Dotzel, of the FDA.

Similarly, three staffers for members of the minority on the committee played pivotal roles even before committee markup took place in making this bill a bipartisan success.

Lynne Lawrence with Senator MIKULSKI deserves special mention in recognition of her hard work in the last Congress on FDA reform and her willingness to put her future career plans

on hold to commit herself again to the long hard job of bringing this bill to the floor this year. Jeanne Ireland with Senator DODD and Linda DeGutis, a fellow with Senator WELLSTONE also provided invaluable assistance.

Of course I would like to thank the Labor and Human Resources Committee majority and minority staffs who did the most work on this. In particular, I want to recognize Susan Hattan who stayed on with the committee after Senator Kassebaum's retirement.

She, and another Senator Kassebaum staffer, Jane Williams, who is now on the staff of Representative FRED UPTON, worked long hours last year to put FDA reform on the Senate agenda and brought a bill to successful committee markup in the last Congress—we stand here today in large part due to their hard work.

On the minority staff, I would like to thank Nick Littlefield and David Nexon and two minority fellows Diane Robertson and Debbie Kochever. Finally, I would like to thank the majority staff director Mark Powden, Jay Hawkins, and majority fellow Sean Donohue.

I want to take a moment to elaborate on my comments regarding one of the majority staff who has worked so diligently on this measure—Jay Hawkins. Jay joined my staff in January—literally hit the ground running—and I don't think he has stopped moving since.

He has set a new standard of dedication for professional staff to find the best solution in a difficult and controversial policy arena. He has been saluted by other Senators' staffs, from both majority and minority offices, for his willingness to include them in all aspects of this effort.

Mr. President, part of the job description for Senate staff is to take abuse. Jay unfortunately received more than his share, but it said more about his critics than him.

More recently—a little more than a month ago—Jay lost his mother to her 4-year battle with cancer. My friend, Senator HATCH, acknowledged on the floor just yesterday this hardship Jay faced and was eloquent in his praise for both Jay and for his mother—Donna Lotz Hawkins. Mrs. Hawkins was not unfamiliar with challenge and adversity. She was an experienced mountain climber and conquered some of the world's most difficult mountains in the Alaska range, the Tetons, the Alps, and the Himalayas. She was a dedicated ocean swimmer and conquered the white waters in Waikiki and Maui.

It is clear to us who know Jay that he too has the spirit of taking on the task when faced with adversity and challenge. We know the source of that sense of commitment and we cannot thank him enough for his efforts on this bill.

I yield the floor.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, in typical fashion, Senator JEFFORDS has given great credit where credit is due, and as I mentioned just before, the chairman of our committee really deserves credit for the passage of this very important bill. I commend him.

If I could, I will just take a moment of the Senate's time, but I think it is important to mention on our side David Nexon and Diane Robertson, who worked so closely with us; Jim Manly, Debbie Kochevar, Meg Archdeacon, Burt Cowgill, Susan Hammersten, Jonathan Halperin, and Danielle Drissel, Carrie Coberly and Addy Schmidt; Bonnie Hogue on Senator REED's staff and Deborah Walker on Senator BINGAMAN's staff; Sabrina Corlette with Senator HARKIN and Anne-Marie Murphy with Senator DURBIN.

I would like to believe the staffs have been helpful to all of us and don't work so much in a partisan way as in a common spirit, to try to advance the common interests. That has been, certainly, true on this legislation.

I thank all of those, and the majority staff as well, for all of their courtesies and for their cooperation. I think the record ought to show the dedication of, really, an outstanding group of men and women who have really served the Senate very, very well. I thank the chairman.

Mr. JEFFORDS. Mr. President, I thank the ranking minority member on my committee for his words. I commend him, also. We disagreed rather strongly on one issue here, but 19 out of 20 we were together and worked together, and certainly that's a pretty good average.

Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. FAIRCLOTH. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

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

DISTRICT OF COLUMBIA APPROPRIATIONS ACT, 1998

Mr. FAIRCLOTH. Mr. President, I ask unanimous consent that the Senate now turn to consideration of Calendar No. 155, S. 1156, the District of Columbia appropriations bill.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

A bill (S. 1156) making appropriations for the government of the District of Columbia and other activities chargeable in whole or in part against the revenues of said District for the fiscal year ending September 30, 1998, and for other purposes.

The PRESIDING OFFICER. Without objection, the Senate will proceed to the consideration of the bill.

The Senator from North Carolina.

PRIVILEGE OF THE FLOOR

Mr. FAIRCLOTH. Mr. President, I send to the desk a list of staff. I ask unanimous consent they be allowed full privilege of the floor during the consideration of S. 1156, the D.C. appropriations bill.

The list follows:

Mary Beth Nethercutt; Jay Kimmitt; Terry Sauvain; Neyla Arnas;s Kate O'Malley; David Landers; Liz Tankersley; Quinn Dodd; and Jim Hyland.

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

Mr. FAIRCLOTH. Mr. President, I am pleased to present the fiscal year 1998 District of Columbia appropriations bill to the Senate.

This budget is the first I have had the opportunity to present to the Senate since becoming the chairman of the District of Columbia Appropriations Subcommittee. This is essentially a clean bill, with no new policy riders.

I am very pleased that this budget was reported favorably by the full Appropriations Committee by a vote of 27 to 1. This is a bipartisan bill, and a bill that reflects the consensus of both the Financial Control Board established by Congress and the city's elected leadership.

This budget of $4.2 billion is a smaller budget than last year's $5.1 billion budget for two reasons.

First, the Federal Government is providing the city with fewer Federal dollars. This past July, Congress enacted landmark legislation restructuring the city's budget, transferring some city functions to the Federal Government, and in exchange, cutting the Federal payment to the District.

That legislation also added some important management reforms at my urging. I'll have more to say about these structural changes and management reforms in a moment.

Second, this is a smaller budget because it is the first balanced budget submitted to the Congress by city officials since 1993. That one proved very unbalanced. This one will be balanced.

As many of my colleagues know, the law enacted by Congress in 1995 creating a Financial Control Board included a timetable requiring the city of Washington, DC to submit a balanced budget to Congress by next year.

Fortunately, the Control Board and the D.C. Council managed to agree on enough spending cuts to submit a balanced budget to Congress 1 year ahead of schedule. That is essentially the budget before the Senate today.

This balanced budget cuts roughly $85 million from last year's operating budget, not to mention a reduction of over $500 million in the direct Federal contribution to the city, from $712 million last year down to $190 million this year.

Most agencies in the District of Columbia government have been cut. One exception is the police department, which received a modest increase reflecting a citywide effort—and I might say a nationwide effort—to crack down on crime within the city.

Perhaps the most important point is that both the Control Board and the D.C. Council have agreed to these cuts.