state veterans' cemeteries funded under the grant program. This provision would authorize the Secretary to grant up to 100 percent of the cost of improvements to the land to be purchased and up to 100 percent of the initial equipment costs. For existing cemeteries, the Secretary would be authorized to grant up to 100 percent of the cost of the improvements made to any additional land purchased for expansion or 100 percent of the cost of improvements to existing cemetery land.

Compromise agreement

The compromise bill contains no provision relating this subject.

**NOTICE**

Incomplete record of House proceedings. Except for concluding business which follows, today's House proceedings will be continued in the next issue of the Record.

**CONFERENCE REPORT ON S. 830, FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT OF 1997**

Mr. BLILEY submitted the following conference report and statement on the Senate bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes:

**CONFERENCE REPORT (H. REPT. 105-399)**

The Committee of conference on the disagreeing votes of the two Houses on the amendments to the House to the bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the Senate recede from its disagreement to the amendment of the House to the text of the bill and agree to the same with an amendment to the amendment of the House to the bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) as follows:

**SEC. 1. SHORT TITLE; REFERENCES; TABLE OF CONTENTS.**

(a) SHORT TITLE.—This Act may be cited as the “Food and Drug Administration Modernization Act of 1997”.

(b) REFERENCES.—Except as otherwise specified, wherever in this Act an amendment or repeal is expressed in terms of an amendment to or a repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(c) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

**SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CONTENTS.**

**TITLE I—IMPROVING REGULATION OF DRUGS**

Subtitle A—Fees Relating to Drugs

**Sec. 101. 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 1997 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 subtitle will be dedicated toward expediting the drug development process and the review of human drug applications as set forth in the goals identified, for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the chairmen of the Committee on Commerce of the House of Representatives and the chairman of...
the Committee on Labor and Human Resources of the Senate, as set forth in the Congressional Record.

SEC. 103. AUTHORITY TO ASSESS AND USE DRUG CONTROL, both of the business entities.

and inserting "105th Congress, 1st Session"; and

"April of "; and

contractors; "

tractors of the Food and Drug Administration; "

one or more prescription drug products are man-

ufactured within five miles of each other and at which

management means a foreign or domestic place of busi-

ness, which is at one general physical location consisting of one or more buildings all of which are within five miles of each other and at which

one or more prescription drug products are manu-

factured in final dosage form; "

(3) in paragraph (4), by striking "without" and

and inserting "without substantial;"

(4) by amending the first sentence of para-

graph (5) to read as follows:

"The term 'prescription drug establish-

ment' means a foreign or domestic place of busi-

ness which includes the following:

(5) the term 'prescription drug establish-

ment' means a foreign or domestic place of busi-

ness which includes the following:

(1) by striking "one business entity controls, or has the power to control, the other business entity; or"

(2) by striking "a third party controls, or has power to control, both of the business entities.";

SEC. 103. AUTHORITY TO ASSESS AND USE DRUG

CONTROL.

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

(1) by striking "Beginning in fiscal year 1993 and

inserting "Beginning in fiscal year 1998;"

(2) by striking paragraph (A)—

(A) by striking subparagraph (B) and inserting

the following:

"PAG. The fee required by subpara-

graph (B) 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 "(B)(i)" and inserting "(paragraph (B)); and"

(iv) by striking "not accepted" and inserting "rejected; and"

(v) by inserting at the end the following:

"(I) EXCEPTION FOR SPECIFICATIONS FOR PEDIA-

TRIC INDICATIONS.—A supplement to a human drug application proposing to include a new indica-

tion for use in pediatric populations shall not be assessed a fee under subparagraph (A).

"(II) REFUND OF FEE IF APPLICATION WITH-

DRAWN.—If an application is withdrawn after the application or supplement was filed, the Secretary may refund the fee or a portion of the fee if no substantial work was performed after the application or supplement was filed. The Secretary shall have the sole discretion to ref

refund a fee or a portion of the fee under this paragraph shall not be reviewable.

"(III) by striking paragraph (2) and inserting the following:

"(2) PRESCRIPTION DRUG ESTABLISHMENT

FEE.—(A) IN GENERAL.—Except as provided in sub-

paragraph (B), each application for a prescription drug establishment shall be assessed only once for each product for a fiscal year in

which the fee is payable.

"(C) in subparagraph (D), by striking "subparagraph (B)(i)" and inserting "subparagraph (C)(i);"

and

"(2) by striking "102d Congress, 2d Session" and inserting "109th Congress, 1st Session"; and

(7) by adding at the end the following:

"(9) the term 'affiliate' means a business en-

trprise for a drug that is not distributed com-

mercially, unless the human drug application includes an indica-

tion for use for a rare disease or condition.

A supplement proposing to include a new indi-

cation for a rare disease or condition in a human drug application shall not be subject to a fee under subparagraph (A), if 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.

"(10) the term 'foreign or domestic place of busi-

ness, which is at one general physical location consisting of one or more buildings all of which are within five miles of each other and at which

one or more prescription drug products are manufactured in final dosage form;"

and

"(11) by striking "employees under contract" and all that follows through "Administration,"

the second time it occurs and inserting "contractors of the Food and Drug Administration;"

and

"(12) by striking "and committees," and inserting "and committees;"

and

"(13) by striking "with contracts with such contractors; each of fiscal years 1999 and 2000, $38,000,000 in fiscal year 2001, and $35,600,000 in fiscal year 2002.


"(B) in subparagraph (D), by striking "505(j)."

"(F) EXCEPTION FOR SUPPLEMENTS FOR PEDI-

ATRIC INDICATIONS.—A supplement to a human drug application proposing to include a new indica-

tion for use in pediatric populations shall not be assessed a fee under subparagraph (A).

"(G) REFUND OF FEE IF APPLICATION WITH-

DRAWN.—If an application is withdrawn after the application or supplement was filed, the Secretary may refund the fee or a portion of the fee if no substantial work was performed after the application or supplement was filed. The Secretary shall have the sole discretion to ref

refund a fee or a portion of the fee under this paragraph shall not be reviewable.

"(1) in the subsection heading, by striking "IN-

CREASES AND'"
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 fees collected from each of the categories of fees described in paragraphs (2) and (3) of subsection (b) shall be set to equal the revenues collected from the category of applications for which fees are described in paragraph (1) of subsection (a),’’; and

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

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

‘‘(A) in subparagraph (A), by striking ‘‘Acts’’ and inserting ‘‘Cosmetic Act (as in effect on September 30, 1997). The term ‘person’ in such Acts shall continue to include an affiliate thereof.’’;

(6) by inserting at the end of subsection (b) the following:

‘‘(f) CREDITING AND AVAILABILITY OF FEES.—The Secretary of Health and Human Services shall prepare and submit to the Committee on Labor and Human Resources of the Senate a report, and to the Committee on Appropriations of the House of Representatives and the Committee on Labor and Human Resources of the House of Representatives and the Committee on Appropriations of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals that have been identified in the letters described in section 101(d) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals that have been identified in the letters described in section 101(d).’’

SEC. 105. SAVINGS.

In implementing section 105 of the Prescription Drug User Fee Act of 1992, the Secretary shall retain the authority to assess and collect any fee required by part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act for a human drug application or supplement accepted for filing prior to October 1, 1997, and to assess and collect any product or establishment fee required by such Act for a fiscal year prior to fiscal year 1998.

SEC. 106. EFFECTIVE DATE.

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

SEC. 107. TERMINATION OF EFFECTIVENESS.

The amendments made by sections 102 and 103 cease to be effective October 1, 2002, and section 104 ceases to be effective 120 days after such date.

Subtitle B—Other Improvements

SEC. 111. PEDIATRIC STUDIES OF DRUGS.

Chapter V (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 the use of a new drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include one or more completed studies), and such studies are completed within any such timeframe and the reports thereof submitted in accordance with subsection (d) or accepted in accordance with subsection (d)(3)—

‘‘(1) the period referred to in subsection (c)(3)(D) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(D) and (j)(4)(D)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

‘‘(ii) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(D) of such section, and in clauses (iii) and (iv) of subsection (j)(4)(D) of such section, is deemed to be seven years and six months rather than seven years; and

‘‘(B) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 526 is deemed to be seven years and six months rather than seven years; and

‘‘(2) if the drug is the subject of—

‘‘(I) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(i) or (j)(2)(A)(viii)(I) 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 subsections (b)(2)(A)(iii) or (j)(2)(A)(viii)(III) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

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

‘‘(IV) 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)(V) of section 505 and in the patent infringement litigation resulting from the submission of such certification, the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(c)(4)(B) 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 the Food and Drug Administration Modernization Act of 1997, the Secretary, after consultation with experts in pediatric research 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) The Effect Exclusivity for Already-Marketed Drugs.—If the Secretary makes a written request to the holder of an approved application under section 505(b)(1) for pediatric studies, the Secretary shall provide a timeframe for completing such studies concerning a drug identified in the list described in subsection (b), the holder agrees to the request, the studies are completed within any such timeframe, and the reports thereof are submitted in accordance with subsection (d)(1) or accepted in accordance with subsection (d)(3)—

(1) the period referred to in subsection (c)(3)(D)(iii) of section 505, and in subsection (j)(4)(D)(ii) of such section, is deemed to be five years rather than three years; and

(2) the references in subsections (c)(3)(D)(iii) and (j)(4)(D)(ii) of such section to four years, to forty-eight months, and to seven and one-half years, are respectively, to sixty months, and to seven years, respectively; or

(iii) the period referred to in clauses (i) and (ii) of subsection (c)(3)(D)(iv) of such section, is deemed to be three years and six months rather than three years; and

(2) if the drug is designated under section 526 for a rare disease or condition, the period referred to in subsection (c)(3)(D)(iv) of such section, is deemed to be seven years and six months rather than seven years; and

(3)(A) if the drug is the subject of—

(i) a listed patent for which a certification has not been submitted under subsection (b)(2)(B)(i) or (j)(2)(B)(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)(ii) or (j)(2)(A)(ii) 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 such litigation may not be approved under section 505(c)(3) or section 505(j)(4)(B); or

(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(iii) 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 such litigation may not be approved under section 505(c)(3) or section 505(j)(4)(B); or

(d) Conduct of Pediatric Studies.—

(1) Agreement for Studies.—The Secretary may, pursuant to a written request from the Secretary under subsection (a) or (c), after consultation with—

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

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

(C) the holder of an approved application for a drug under section 505(b)(2); or

D) the Secretary agrees 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 required under sections 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months during which an application may not be approved for filing and so notify the sponsor or holder.

(2) Other Methods to Meet the Studies Requirement.—If the sponsor or holder and the Secretary agree to the request for the protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied when such studies have been conducted 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, have been conducted in accordance with commonly accepted scientific principles and protocols, and have been reported in accordance with the requirements of the Secretary for filing.

(3) Delay of Effective Date for Certain Application.—If the Secretary determines that the acceptance or approval of an application under section 505(b)(2) or 505(j) for a new 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 extensions), the applicable period under clauses (ii) through (iv) of section 505(c)(3) or clauses (ii) through (iv) of section 505(j)(4)(D), but before the Secretary has determined whether of subsection (d) has been satisfied, the Secretary shall delay the acceptance or approval under section 505(b)(2) or 505(j) until the determination under subsection (d) is made, but any such delay shall not exceed 90 days. In the event that requirements of this section are satisfied, the applicable six-month period under subsection (a) or (c) shall be deemed to have been running during the period of delay.

(4) Notice of Determinations on Studies Requirement.—The Secretary shall publish a notice in the Federal Register of any requirement 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.

(5) Definitions.—As used in this section, the term ‘pediatric studies’ or ‘studies’ means at least one 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.

(6) Limitations.—A drug to which the six-month period under subsection (a) or (c) has already been applied—

(1) may receive an additional six-month period under subsection (c)(1)(A)(ii) for a subsequent application if all other requirements under this section are satisfied, except that such a drug may not receive any additional such period under subsection (c)(1)(B)(ii); and

(2) may not receive any additional such period under subsection (c)(1)(B)(ii).

(7) Reliance to Regulations.—Notwithstanding any other provision of law, if any pediatric study is required pursuant to regulations promulgated by the Secretary and such study may not be conducted or, in any event, require the satisfaction of other requirements of this section, such study shall be deemed to satisfy the requirement for market exclusivity pursuant to this section.

(8) Sunk-Off.—If any six-month period under subsection (a) or (c) unless the application for the drug under section 505(b)(1) is submitted on or before January 30, 2000, after January 30, 2000, a drug shall receive a six-month period under subsection (c) if—

(1) the drug was in commercial distribution on the date the written request referred to in paragraph (1) was submitted; and

(2) the drug was included by the Secretary on the list under subsection (b) as of January 1, 2000.

(9) The Secretary determines that there is a continuing need for information relating to the use of the drug in the pediatric population and that the drug may provide health benefits in that population; and

(10) all requirements of this section are met.

(k) Report.—The Secretary shall conduct a study and report to Congress not later than January 1, 2001, based on the experience under the program established under this section. 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 on taxpayers and consumers, including the impact of the program on lower cost generic drugs for patients, including on lower income patients; and

(4) any suggestions for modification that the Secretary determines to be desirable.

SEC. 112. EXPEDITING STUDY AND APPROVAL OF FAST TRACK DRUGS.

(a) In General.—Chapter V (21 U.S.C. 351 et seq.), as amended by section 125, is amended by inserting before section 508 the following:

SEC. 506. FAST TRACK PRODUCTS.

(a) Designation of Drug as a Fast Track Product.—

(1) In General.—The Secretary shall, at the request of the sponsor of a new drug, facilitate the development and expedite the review of such drug if it is intended for the treatment of a serious or life-threatening condition and it demonstrates the potential to address unmet medical needs for such a condition. (In this section, such a drug is referred to as a ‘fast track product’.)

(2) Request for Designation.—The sponsor of a new drug may request the Secretary to designate the drug as a fast track product. 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)(3) of the Public Health Service Act.

(b) Designation.—Within 60 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 product and shall take such actions as are appropriate to expedite the development and review of the application for approval of such product.

(c) Approval of Application for a Fast Track Product.—

(1) In General.—The Secretary may approve for an application for a fast track product under section 505(c) or section 351 of the Public Health Service Act upon a determination that the drug has an effect on a clinical endpoint or on a surrogate endpoint that is reasonably likely to predict clinical benefit.

(2) Limitation.—Approval of a fast track product under this subsection may be subject to the requirements—

(A) that the sponsor conduct appropriate postmarketing studies to determine the clinical endpoint or otherwise confirm the effect on the clinical endpoint; and

(B) that the sponsor submit copies of all premarketing materials relating to the fast track product during the preapproval review period and, following approval and for such period
thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials.

(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a fast track product using expedited procedures (as prescribed by the Secretary in regulations which shall include an opportunity for an informal hearing).—

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

(b) a post-approval study of the fast track product fails to verify clinical benefit of the product;

(c) other evidence demonstrates that the fast track product is not safe or effective under the conditions of use; or

(d) the sponsor disseminates false or misleading promotional materials with respect to the product.

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

(1) IN GENERAL.—If the Secretary determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may meet the criteria for designation as a fast track product, the Secretary shall commence such review only if the applicant—

(A) provides a schedule for submission of information necessary to make the application complete by the date of enactment of this section;

(B) pays 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 time period for the review 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 this subsection (1) until the date on which the application is complete.

(d) AWARENESS EFFORTS.—The Secretary shall—

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

(2) establish a program to encourage the development of surrogate endpoints that are rationally related to clinical benefits in 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, acting through the Commissioner of Food and Drugs shall collaborate to determine the feasibility of including device investigations within the scope of the data bank under section 402(j) of the Public Health Service Act, and to the extent practicable, coordinate with the Department of Health and Human Services, and to the extent practicable, coordinated with other agencies of the Department of Health and Human Services, and to the extent practicable, coordinated with other data banks containing similar information.

(8) The Secretary shall establish the data bank 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.

(9) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. The Secretary shall disseminate such information through information systems, which shall include toll-free telephone communications, available to individuals with serious or life-threatening conditions, to other members of the public, to health care providers, and to researchers.

(10) 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 section 505(i) of the Federal Food, Drug, and Cosmetic Act, which provides a description of the purpose of each experimental drug, either with the consent of the protocol sponsor, or when a trial to test effectiveness begins. Information provided shall consist of eligibility criteria for the clinical trials, 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 shall be forwarded to the data bank by the sponsor of the trial not later than 21 days after the approval of the protocol.

(b) Information on experimental treatments for serious or life-threatening diseases and conditions that may be available—

(i) under a treatment investigational new drug application submitted to the Secretary under section 561(c) of the Federal Food, Drug, and Cosmetic Act; or

(ii) as a Group I cancer drug (as defined by the National Cancer Institute).

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.

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

(12) 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 shall not be used in carrying out this subsection.

(c) 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 data bank under section 402(j) of the Public Health Service Act.

(2) REPORT.—Not later than two 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 which—

(A) of the public health need, if any, for inclusion of device investigations within the scope of the data bank under section 402(j) of the Public Health Service Act;

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

(C) on such other issues relating to such section 402(j) as the Secretary determines to be appropriate.

SEC. 114. HEALTH CARE ECONOMIC INFORMATION.

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

"(i) under a treatment investigational new drug application submitted to the Secretary under section 561(c) of the Federal Food, Drug, and Cosmetic Act; or

(ii) as a Group I cancer drug (as defined by the National Cancer Institute)."

SEC. 115. CLINICAL INVESTIGATIONS.

(a) CLARIFICATION OF THE NUMBER OF REQUIRED CLINICAL INVESTIGATIONS FOR APPROVAL.—Section 505(d) (21 U.S.C. 355(d)) is amended by adding at the end the following: "If the Secretary determines, based on relevant science, that data from one adequate and well-controlled investigation is sufficient to demonstrate the safety and effectiveness of a drug, the term ‘clinical investigation’ means any study of the use of a drug the use of another drug, or 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 of this subsection and submit a report pursuant to section 352a(b) (21 U.S.C. 352a(b)) is amended by adding at the end the following: "If the Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (a)."

SEC. 116. MANUFACTURING CHANGES FOR DRUGS.

(a) IN GENERAL.—Chapter V, as amended by section 112, is amended by inserting after section 506 the following section:

"SEC. 506A. MANUFACTURING CHANGES FOR DRUGS.

(a) IN GENERAL.—With respect to a drug for which an approval or license under section 505 or 512 or a license under section 351 of the Public Health Service Act, a change from the manufacturing process approved pursuant to the license may be made, and the drug as made with the change may be distributed, if—

(1) the holder of the approved application or license (referred to in this subsection as the ‘holder’) has validated the effects of the change in accordance with subsection (b); and

(2) the application or license, or the holder, as applicable, has provided a written certification to the Secretary, in a form prescribed by the Secretary, that the change is consistent with the approved process and is not likely to result in a drug that is different from the drug approved for sale.

(b) APPLICATION OF CERTIFICATION.—A written certification under subsection (a) shall be effective only if—

(1) the certification is accompanied by a description of the changes made and an analysis that identifies, compares, or otherwise assesses the health care economic information directly relates to an investigation if the health care economic information presented pursuant to this paragraph shall be made available to the Secretary, and the term health care economic information means any analysis that identifies, measures, or compares the economic consequences, including costs and savings, associated with the presented health care intervention, or to no intervention.

(2) 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.

(3) The data bank shall include the following:

(1) 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 section 505(i) of the Federal Food, Drug, and Cosmetic Act, which provides a description of the purpose of each experimental drug, either with the consent of the protocol sponsor, or when a trial to test effectiveness begins. Information provided shall consist of eligibility criteria for the clinical trials, 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 shall be forwarded to the data bank by the sponsor of the trial not later than 21 days after the approval of the protocol.

(2) In carrying out paragraph (1), the Secretary shall—

(A) develop and disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a description of the provisions of this section applicable to fast track products; and

(B) establish a program to encourage the development of surrogate endpoints that are rationally related to clinical benefits in serious or life-threatening conditions, for which there exist significant unmet medical needs.

(3) Within 1 year after the date of enactment of this Act, the Comptroller General of the United States shall conduct a study of the implementation of the provisions of this subsection and submit a report containing the findings of the study.

(b) STUDY AND REPORT.—The Comptroller General of the United States shall conduct a study of the implementation of the provisions of this subsection and submit a report pursuant to section 352a(b) (21 U.S.C. 352a(b)) is amended by adding at the end the following: "If the Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (a)."

"SEC. 506A. MANUFACTURING CHANGES FOR DRUGS.

(a) IN GENERAL.—With respect to a drug for which an approval or license under section 505 or 512 or a license under section 351 of the Public Health Service Act, a change from the manufacturing process approved pursuant to the license may be made, and the drug as made with the change may be distributed, if—

(1) the holder of the approved application or license (referred to in this subsection as the ‘holder’) has validated the effects of the change in accordance with subsection (b); and

..."
"(2)(A) in the case of a major manufacturing change, the holder has complied with the requirements of subsection (c); or

(b) in the case of a change that is not a major manufacturing change, the holder has complied with the applicable requirements of subsection (d).

(2) V A L I D A T I O N O F E F F E C T S O F C H A N G E S.—For purposes of subsection (a)(1), a drug made with a manufacturing change (whether a major manufacturing change or otherwise) may be distributed only if, before the distribution of such drug, the Secretary determines that the change will not adversely affect the identity, strength, quality, purity, or potency of the drug as the change, the holder in validating the effects of the change.

(3) M A J O R M A N U F A C T U R I N G C H A N G E S.—For purposes of subsection (a)(1), a drug made with a major manufacturing change may be distributed only if, before the distribution of such drug, the holder has submitted to the Secretary a supplemental application for such change and the Secretary approves the application. The application shall contain such information as the Secretary determines to be appropriate, and shall include the information developed under subsection (b) by the holder in validating the effects of the change.

(4) C H A N G E S R E Q U I R I N G S U P P L E M E N T A R Y A P P L I C A T I O N.—For purposes of subsection (a)(2)(A), a drug made with a major manufacturing change may be distributed only if, before the distribution of such drug as so made, the holder involved submits to the Secretary a supplemental application for such change and the Secretary approves the application. The application shall contain such information as the Secretary determines to be appropriate, and shall include the information developed under subsection (b) by the holder in validating the effects of the change.

(a)(2)(B), the Secretary may regulate drugs contrary to subsection (a) for the drug (unless exempted by the Secretary by regulation or guidance from the requirements of this subsection; or

(c) OTHER MANUFACTURING CHANGES.—For purposes of subsection (a)(2)(A), a major manufacturing change is a manufacturing change that is determined by the Secretary to have the potential to adversely affect the identity, strength, quality, purity, or potency of the drug as the change, and the holder in validating the effects of the change.

A (A) in the case of a drug made with a manufacturing change (whether a major manufacturing change or otherwise) may be distributed only if, before the distribution of such drug, the holder involved submits to the Secretary a supplemental application for such change and the Secretary approves the application. The application shall contain such information as the Secretary determines to be appropriate, and shall include the information developed under subsection (b) by the holder in validating the effects of the change.

(b) TRANSITION RULE.—The amendment made by subsection (a) shall apply to a drug for which the drug application was initially filed after the date of the enactment of this Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended by adding at the end the following new paragraph:

(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary receives from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including—

(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

(B) adequate information on the chemistry and manufacturing controls available for the drug, and primary data tabulations from animal or human studies.

(3)(A) At any time, the Secretary may prohibit the submission of a clinical investigation from conducting the investigation (referred to in this paragraph as a ‘clinical hold’) if the Secretary determines that the investigation is not appropriate and the appropriate abbreviated report formats.

SEC. 118. DATA REQUIREMENTS FOR DRUGS AND BIOLOGICS.

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

SEC. 119. CONTENT AND REVIEW OF APPLICATIONS.

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

(2) (A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or 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 abbreviations are appropriate and the appropriate abbreviated report formats.

SEC. 121. V A L I D A T I O N O F E F F E C T S O F C H A N G E S.—For purposes of subsection (a)(1), a drug made with a major manufacturing change may be distributed only if, before the distribution of such drug, the holder involved submits to the Secretary a supplemental application for such change and the Secretary approves the application. The application shall contain such information as the Secretary determines to be appropriate, and shall include the information developed under subsection (b) by the holder in validating the effects of the change.

(3) By inserting ‘‘(1)’’ after ‘‘(3):’’;

(4) By striking the last two sentences; and

(5) By inserting as a new paragraph (1) (as designated by paragraph (2) of this section) the following new paragraphs:

(A) The Secretary may in accordance with paragraph (2) authorize holders to distribute such drugs without submitting a supplemental application for such changes.

(B) The Secretary may in accordance with paragraph (2) authorize holders to distribute such drugs without submitting a supplemental application for such changes.

(C) The Secretary may establish categories of such changes and designate categories to which subparagraph (A) applies and categories to which subparagraph (B) applies.

(2) CHANGES NOT REQUIRING SUPPLEMENTARY APPLICATION.—

(a) SUBMISSION OF REPORT.—A holder making a manufacturing changes to which paragraph (1)(A) applies shall submit to the Secretary a report on the change, which shall contain such information as the Secretary determines to be appropriate, and which shall include the information described in paragraphs (1) and (2) of this section (b) by the holder in validating the effects of the change.

(2) By inserting at the end the following:

(A) The drug involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the conditions under which the drug is being used, and the health status of the subjects involved; or

(b) When the clinical hold should be issued for other reasons as the Secretary may by regulation establish (including reasons established by regulation before the date of the enactment of the Food and Drug Administration Modernization Act of 1997).

(3) (A) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in whole or in part, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

(4) Regulations under this paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are administered of such investigations and controls, and such that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except that it is not necessary to obtain the consent to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.

SEC. 117. STREAMLINING CLINICAL RESEARCH.

Section 505(i) (21 U.S.C. 355(i)) is amended—

(1) by redesignating paragraphs (1) through (3) as subparagraphs (A) through (C), respectively;

(2) by inserting ‘‘(1)’’ after ‘‘(1):’’;

(3) by striking the last two sentences; and

(4) by inserting as a new paragraph (1) (as designated by paragraph (2) of this section) the following:

Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary receives from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including—

(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

(B) adequate information on the chemistry and manufacturing controls available for the drug, and primary data tabulations from animal or human studies.

(3) (A) At any time, the Secretary may prohibit the submission of a clinical investigation from conducting the investigation (referred to in this paragraph as a ‘clinical hold’) if the Secretary determines that the investigation is not appropriate and the appropriate abbreviated report formats.

(2) The Secretary shall meet with a sponsor of a clinical investigation from conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review applications.

(2) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 351 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(b)) and with a biologics license applicant 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 abbreviations are appropriate and the appropriate abbreviated report formats.

SEC. 118. DATA REQUIREMENTS FOR DRUGS AND BIOLOGICS.

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

SEC. 119. CONTENT AND REVIEW OF APPLICATIONS.

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

(2) (A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or section 351 of the Public Health Service Act, which shall relate to the promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review applications.

(3) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 351 of the Public Health Service Act if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an effective- ness claim. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials contained in any such request shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

(4) (A) Any agreement regarding the parameters of the design and size of a clinical trial of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant
shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific, regulatory, or effectiveness issue has been identified after the testing begins.

(D) A decision under subparagraph (C)(iii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls)."

(2) CONFORMING AMENDMENTS.—Section 505(j) (21 U.S.C. 355(j)), as amended by paragraph (1), is further amended—

(A) in paragraph (2)(A)(i), by striking "(6)" and inserting "(7)";

(B) in paragraph (4) (as redesignated in paragraph (3)), by striking "(4)" and inserting "(5)";

(C) in paragraph (4)(I) (as redesignated in paragraph (1)), by striking "(5)" and inserting "(6)";

(D) in paragraph (7)(C) (as redesignated in paragraph (1)), by striking "(5)" each place it appears and inserting "(6)";

(E) The written decisions of the reviewing division are made after the date of enactment of the Public Health Service Act (including all scientific and medical matters, chemistry, manufacturing, and controls).

(b) Section 505. (1) AMENDMENT.—Section 505(j) (21 U.S.C. 355(j)) is amended—

(A) redesignating paragraphs (3) through (8) as paragraphs (4) through (9), respectively; and

(B) by adding after paragraph (2) the following:

"(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals and applications, such as—"

"(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant requests a face-to-face meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies required for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

"(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant;

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific, regulatory, or effectiveness issue has been identified after the testing begins.

(D) A decision under subparagraph (C)(iii) by the director of the reviewing division shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls)."

(2) CONFORMING AMENDMENTS.—Section 505(j) (21 U.S.C. 355(j)), as amended by paragraph (1), is further amended—

(A) in paragraph (2)(A)(i), by striking "(6)" and inserting "(7)";

(B) in paragraph (4) (as redesignated in paragraph (3)), by striking "(4)" and inserting "(5)";

(C) in paragraph (4)(I) (as redesignated in paragraph (1)), by striking "(5)" and inserting "(6)";

(D) in paragraph (7)(C) (as redesignated in paragraph (1)), by striking "(5)" each place it appears and inserting "(6)";

(E) The written decisions of the reviewing division are made after the date of enactment of the Public Health Service Act (including all scientific and medical matters, chemistry, manufacturing, and controls).

(c) Subsection 501(a). (1) I N GENERAL .—Section 501(a) (21 U.S.C. 351(a)) is amended by adding at the end the following:

"(8) Within 90 days after a scientific advisory panel makes recommendations on any matter under review, the Federal communications or the Secretary may request the panel or an administrative official responsible for the matter shall review the conclusions and recommendations of the panel, and notify the affected persons of the final decision on the matter, or of the reasons that no such decision has been reached. Each such final decision shall be documented including the rationale for the decision."

(2) SEC. 120. SCIENTIFIC ADVISORY PANELS. Section 505 (21 U.S.C. 355) is amended by adding at the end the following:

"(n)(1) For the purpose of providing expert scientific and regulatory input to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under section 505 or section 351 of the Public Health Service Act, the Secretary shall establish panels of experts or use panels of experts established before the date of enactment of the Food and Drug Administration Modernization Act of 1997, or both.

"(2) The Secretary may delegate the appointment and oversight authority granted under section 904 to a director of a center or successor entity within the Food and Drug Administration.

"(3) The Secretary shall make appointments to each panel established under paragraph (1) so that each panel shall consist of—

(A) members with diverse expertise in such fields as clinical, regulatory, and scientific standards, and which shall apply equally to all individuals and applications, such as—"

"(B) members with diverse expertise in such fields as clinical, regulatory, and scientific standards, and which shall apply equally to all individuals and applications, such as—"

"(C) the term 'compounded positron emission tomography drug'—

"(1) means a drug that—

(ii) is a drug that—

(iii) is a drug that—

(iv) is a drug that—

(v) is a drug that—

(vi) is a drug that—

(vii) is a drug that—

(viii) is a drug that—

(ix) is a drug that—

(x) is a drug that—

(xi) is a drug that—

(xii) is a drug that—

(xiii) is a drug that—

(xiv) is a drug that—

(xv) is a drug that—

(xvi) is a drug that—

(xvii) is a drug that—

(xviii) is a drug that—

(xix) is a drug that—

(xx) is a drug that—

(2) includes any radioactive 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.''

(d) ADULTERATION.—

"(1) IN GENERAL.—Section 501(a) (21 U.S.C. 351(a)) is amended by striking "; or (3)" and inserting "; or (3)", or if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, storing, holding, or distributing 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 Pharmacopoeia to assure that such drug meets the requirements of this Act as to safety and has the identity, strength, and purity of the biological product that it purports or is represented to possess; or


(4) 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. 123. MODERNIZATION OF REGULATION.

(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 shall, 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. 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 consideration of the proposed use of the radiopharmaceutical in the practice of medicine, the pharmacological and toxicological activity, and the stability of the radiopharmaceutical (including any载体 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 radiopharmaceuticals.

(2) SPECIAL RULE.—In the case of a radiopharmaceutical, the indications for which are to be specified by regulation and labeling, the regulations shall provide, for such drugs, that the Secretary of Health and Human Services shall require, after consultation with patient advocacy groups, associations, physician licensed to use radiopharmaceuticals, and scientists licensed to make or use positron emission tomography drugs or who have relevant experience in the review of similar drugs, that the Secretary establish procedures and requirements under paragraph (1), whichever is longer.

(b) CONFORMING AMENDMENT.—Section 351(c) of the Public Health Service Act (42 U.S.C. 262(c)) is amended—

(1) in subparagraph (A) by striking “virus, serum,” and all that follows it; and

(2) by striking “262(a)” and inserting “262(a)”.

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

“(A) No person shall falsely label or mark any package or container of any biological product or any reagent, solution, capsule, or label or mark on the package or container of the biological product so as to falsify the label or mark.

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

(1) 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 350(d)(4)(C) in section 353(k)(4) (21 U.S.C. 353(k)(4)) is amended—

(1) by striking “biological license application under section (a) or (d)” and inserting “biological license application under section (a)”;

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

“(A) The Secretary shall approve a biologics license application under section (a) or (d) if the application is safe, pure, and potent; and

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

“(B) The Secretary shall approve a biologics license application under section (a) or (d) if the application is safe, pure, and potent; and

(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 new drug applications under section (a) or (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

(g) APPLICATION OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Section 351(b) of the Public Health Service Act (42 U.S.C. 262), as amended by subsection (d), is further amended by adding at the end the following:

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

(2) the facility in which the biological product is manufactured, processed, packaged, or held is constructed and operated in such a manner as to assure that the biological product continues to be safe, pure, and potent; and

(3) that the person (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 under investigation shall be exempt from the requirements of paragraph (1).”.

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(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 on 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 DRUGS.—

(1) PROCEDURES AND REQUIREMENTS.—

(A) IN GENERAL.—In order to take account of the special characteristics of 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

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

(B) INVESTIGATION.—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. For the purposes of establishing the procedures and requirements, the Secretary of Health and Human Services shall consult with patient advocacy groups, professional associations, manufacturers, physicians licensed to use radiopharmaceuticals, and scientists licensed to make or use positron emission tomography drugs or who have relevant experience in the review of similar drugs.

(ii) by striking paragraph (1), whichever is longer.

(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 approved 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 (d)), for a period of 4 years after the date of enactment of this Act, or for 2 years after the date on which the Secretary establishes procedures and requirements under paragraph (1), whichever is longer.

(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 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)).

(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 any inconsistent regulations or rules.


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(h) Examinations and Procedures.—Paragraph (3) of section 353(d) of the Public Health Service Act (42 U.S.C. 263a(d)) is amended to read as follows:

(3) if the examinations and procedures identified in paragraph (2) are laboratory examinations and procedures that have been approved by the Food and Drug Administration for use in tests for such disease or condition under section 507.

(i) The third and fourth sentences of subsection (b)(1) (regarding the filing and publication of patent information); and

(ii) Subsections (b)(2)(A), (b)(2)(B), (b)(3), and (c)(2) are each amended—

(A) by striking paragraph (2) and by redesignating paragraph (3) as paragraph (2); and

(B) In paragraph (1), by striking "certificated by the Secretary, is authorized to approve labeling for compounding", and by redesignating paragraph (2) as paragraph (1).
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“(2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and

(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between—

(i) the licensed pharmacist or licensed physician; and

(ii) such individual patient for whom the prescription order will be provided; or

(ii) the physician or other licensed practitioner who will write such prescription order.

(2) COMPOUNDED DRUG.—

(A) Licensed Pharmacist and Licensed Physician.—It may be compounded under subsection (a) if the licensed pharmacist or licensed physician—

(i) complies with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(ii) if such a monograph does not exist, are drugs substances that are components of drugs approved by the Secretary; or

(iii) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations in consultation with the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary.

(B) Limiting Compounding.—The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (a)(ii)(A)(ii) for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify.

(d) Application.—This section shall not apply to—

(1) compounded position emission tomography drugs as defined in section 201(iii); or

(2) radiopharmaceuticals.

(2) DEFINITION.—As used in this section, the term ‘compounding’ does not include mixing, reconstituting, or other such acts that are performed in accordance with an approved labeling provided by the product manufacturer and other manufacturer directions consistent with that labeling.

(3) EFFECTIVE DATE.—Section 503A of the Federal Food, Drug, and Cosmetic Act, added by subsection (a), shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act, the Secretary shall issue regulations for over-the-counter sunscreen products for the prevention or treatment of sunburn.

SEC. 130. REPORTS OF POSTMARKETING APPROVAL STUDIES.

(a) In General.—Chapter V, as amended by section 116, is further amended by inserting after section 506A the following:

SEC. 506B. 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 is prescribed by the Secretary in regulations issued by the Secretary.

(2) AGREEMENTS PRIOR TO EFFECTIVE DATE.—Any agreement entered into between the Secretary and a sponsor of a drug, prior to the date of enactment of the Food and Drug Modernization Act of 1997, to conduct a postmarketing study of a drug shall be subject to the requirements of paragraph (1). Not later than 6 months after the date of issuance of the regulations under paragraph (1), the Secretary shall adopt such regulations as are necessary to implement subsection (a).

(2) Status of Studies and Reports.—The Secretary shall annually develop and publish in the Federal Register a report containing information on the 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 Oversight and Government Reform of the House of Representatives a report containing—

(1) a summary of the reports submitted under section 506B of the Federal Food, Drug, and Cosmetic Act; and

(2) an evaluation of—

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

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

(3) any legislative recommendations respecting the postmarketing studies.

SEC. 131. NOTIFICATION OF DISCONTINUANCE OF A LIFE SAVING PRODUCT.

(a) In General.—Chapter V, as amended by section 130, is further amended by inserting after section 506B the following:

SEC. 506C. DISCONTINUANCE OF A LIFE SAVING PRODUCT.

(a) In General.—A manufacturer that is the sole manufacturer of a drug—

(1) that is—

(A) life-saving;

(B) life-sustaining; or

(C) intended for use in the prevention of a debilitating disease or condition; and

(2) for which an application has been approved under section 505(b) or 505(j); and

(3) which is the product that was originally derived from human tissue and was replaced by a recombinant product,
shall notify the Secretary of a discontinuance of the manufacture of the drug at least 6 months prior to the date of the discontinuance.

(b) REDUCTION IN NOTIFICATION PERIOD.—The notification period required under subparagraph (a) for a manufacturer may be reduced if the manufacturer certifies to the Secretary that good cause exists for the reduction, such as a situation described in subparagraph (B) in which a physician uses a device without an approval from a local institutional review committee.

SEC. 201. INVESTIGATIONAL DEVICE EXEMPTIONS.

(a) IN GENERAL.—Section 520(g) (21 U.S.C. 360j(g)) is amended by adding at the end the following:

"(7)(A) In the case of a person intending to conduct a clinical protocol, the written request shall be submitted to the Secretary or to an 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 described in subparagraph (B) in which a physician uses a device without an approval from a local institutional review committee.

SEC. 202. SPECIAL REVIEW FOR CERTAIN DEVICES.

§ 513(d)(1)(B) (21 U.S.C. 360e(d)(1)(B)) is amended by adding at the end the following:

"(B) the following:

"(i) with the written agreement of the sponsor or applicant; or

"(ii) pursuant to a decision, in accordance with paragraph (C) by the director of the Office in which the device involved is reviewed, that good cause exists for the reduction, such as a reasonable assurance of effectiveness, and, if available, information regarding the expected performance of the device.

"(C) A decision under subparagraph (B)(i) shall be in writing and made available to the sponsor or applicant upon request.

SEC. 203. EXPANDING HUMANITARIAN USE OF DEVICES.

SEC. 204. DEVICE STANDARDS.

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

"(7)(A) In the case of a person intending to conduct a clinical protocol, the written request shall be submitted to the Secretary or to an 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 described in subparagraph (B) in which a physician uses a device without an approval from a local institutional review committee.

"(B) the following:

"(i) with the written agreement of the sponsor or applicant; or

"(ii) pursuant to a decision, in accordance with paragraph (C) by the director of the Office in which the device involved is reviewed, that good cause exists for the reduction, such as a reasonable assurance of effectiveness, and, if available, information regarding the expected performance of the device.

"(C) A decision under subparagraph (B)(i) shall be in writing and made available to the sponsor or applicant upon request.

SEC. 205. CONCLUSION.
and information demonstrating conformity of the device to the standard for a period of two years after the date of the classification or approval of the device by the Secretary or a period equal to the time required for the manufacturer to demonstrate design control of the device, whichever is longer.

(b) Section 513—Section 513 (21 U.S.C. 360c) is amended by adding the following:

(3) A holder of an approved application for a manufacturing change of a device may submit the device 30 days after the date on which the Secretary receives the notice, unless the Secretary determines that such report is not necessary to assure the safety and effectiveness of the device. The Secretary shall review the report 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.

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

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

(2) by inserting at the end the following:

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

(d) Amendments—Section 514(a) (21 U.S.C. 360(a)) is amended—

(1) in paragraph (1), in the second sentence, by striking "under this section" and inserting "under subsection (b)"; and

(2) in paragraph (2), in the matter preceding subparagraph (A), by striking "under this section" and inserting "under subsection (b)"; and

(3) in paragraph (3), by striking "under this section" and inserting "under subsection (b)"; and

(4) in paragraph (4), in the matter preceding subparagraph (A), by striking "this section" and inserting "this subsection and subsection (b)".

SEC. 205. SCOPE OF REVIEW; COLLABORATIVE DETERMINATIONS OF DEVICE DATA REQUIREMENTS.

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

(iii) The determination of the Secretary with respect to effectiveness can be reduced through the extent of data that otherwise would have been submitted, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly.

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

(ii) The Secretary, upon the written request of the Secretary for purposes of approval of an application with respect to effectiveness can be reduced through reliance on postmarket controls.

(II) specify the limitations on the use of the device not included in the proposed labeling;

(iii) The determination of the Secretary with respect to effectiveness can be reduced through the extent of data that otherwise would have been submitted, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly.

(ii) The Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not such labeling is false or misleading.

(i) The Secretary shall consider the extent to which such labeling is false or misleading.

(iv) The determination of the Secretary with respect to effectiveness can be reduced through the extent of data that otherwise would have been submitted, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly.

(e) Subject to clause (ii), the following:

(i) Such determination shall—

(x) The falsification of a declaration of conformity referred to as the `Director') may require on the date of the enactment of the Food and Drug Administration Modernization Act of 1997.

(ii) the requirements of section 520(f).

(iii) The responsibilities of the Director under this subparagraph may not be delegated.

(iv) This subparagraph has no legal effect after the expiration of the five-year period beginning on the date of the enactment of the Food and Drug Administration Modernization Act of 1997.

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

(1) in paragraph (1)(A), by adding after and below clause (ii) the following:

(iv) This subparagraph has no legal effect after the expiration of the five-year period beginning on the date of the enactment of the Food and Drug Administration Modernization Act of 1997.

(2) Beginning on the date that is 1 day after the date of enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall publish in the Federal Register a list of each class I device that is intended for a use which is of substantial importance in preventing impairment of health or lengthening, or restoring health, or which presents a potential unreasonable risk of illness or injury.

(3) Beginning on the date that is 1 day after the date of publication of a list under the section subsection (k) to provide a reasonable assurance of safety and effectiveness.

(4) in paragraph (2) the following:

(iii) The responsibilities of the Director under this subparagraph may not be delegated.

(iv) This subparagraph has no legal effect after the expiration of the five-year period beginning on the date of the enactment of the Food and Drug Administration Modernization Act of 1997.

(iii) The responsibilities of the Director under this subparagraph may not be delegated.

(iv) This subparagraph has no legal effect after the expiration of the five-year period beginning on the date of the enactment of the Food and Drug Administration Modernization Act of 1997.

(2) Beginning on the date that is 1 day after the date of publication of a list under the subsection (k) to provide a reasonable assurance of safety and effectiveness.

(3) Beginning on the date that is 1 day after the date of publication of a list under the subsection (k) to provide a reasonable assurance of safety and effectiveness.

(4) in paragraph (2) the following:

(iii) The responsibilities of the Director under this subparagraph may not be delegated.

(iv) This subparagraph has no legal effect after the expiration of the five-year period beginning on the date of the enactment of the Food and Drug Administration Modernization Act of 1997.
regarding the exemption of the device that was the subject of the notice. If the Secretary fails to respond to a petition within 180 days of receiving it, the petition shall be deemed to be granted.

(b) **SECTION 513(f).**—Section 513(f) (21 U.S.C. 360c(f)) is amended by adding at the end the following:

(15) The Secretary may not withhold a determination of the initial classification of a device under paragraph (1) because of a failure to comply with the Federal Register criteria to accredit or deny accreditation of persons for the purpose of reviewing reports submitted under section 510(k) and making recommendations to the Secretary regarding the initial classification of devices.

(16) **REQUIREMENTS REGARDING REVIEW.—**

(a) **IN GENERAL.**—In making a recommendation to the Secretary under paragraph (1), an accredited person shall provide in writing the reasons for the recommendation.

(b) **TIME PERIOD FOR REVIEW.**—Not later than 30 days after the date on which the Secretary is notified under subparagraph (A) by an accredited person with respect to a recommendation of an initial classification of a device, the Secretary shall make a determination with respect to the initial classification.

(c) **SPECIAL RULE.**—The Secretary may change the initial classification under subsection (f)(1) that is recommended under paragraph (1) by an accredited person in a case in which the Secretary provides written notice to the applicant of the reasons for the recommendation and the applicant has the opportunity to submit a written response.

(d) **CERTAINTY OF REVIEW TIMEFRAMES.**—The Secretary shall:

(1) ensure that the initial classification of a device is made not later than 180 days after the date on which the Secretary is notified under subparagraph (A) by an accredited person with respect to the initial classification.

(2) adjust the time period for review for a year in which the Secretary makes more than 6 percent of the determinations under subsection (f)(1) that are recommended under paragraph (1) by an accredited person.

(e) **BREADTH OF DETERMINATIONS.**—The Secretary shall ensure that the classifications under subsection (f) include the following:

(1) a class III device;

(2) a class II device which is intended to be permanently implantable or life sustaining or life supporting;

(3) a class I device which includes data in the report submitted under section 510(k) for the device, except that the number of reports submitted to the Secretary under the applicable reporting requirements for the device is less than 25;

(4) a class II device which requires clinical data and is based on clinical data and information that are not available for public disclosure under section 515(d), as amended by section 101 of the Food and Drug Administration Modernization Act of 1997, the Secretary shall, in writing and prior to the release of the recommendations from the initial classification, provide to such person, and the person who submitted the report under section 510(k) for the device, a statement explaining in detail the reasons for the classification.

(f) **PROGRAMS.**—The Secretary shall ensure that the classifications under subsection (f) include the following:

(1) a class III device;

(2) a class II device which is intended to be permanently implantable or life sustaining or life supporting;

(3) a class I device which includes data in the report submitted under section 510(k) for the device, except that the number of reports submitted to the Secretary under the applicable reporting requirements for the device is less than 25;

(4) a class II device which requires clinical data and is based on clinical data and information that are not available for public disclosure under section 515(d), as amended by section 101 of the Food and Drug Administration Modernization Act of 1997, the Secretary shall, in writing and prior to the release of the recommendations from the initial classification, provide to such person, and the person who submitted the report under section 510(k) for the device, a statement explaining in detail the reasons for the classification.

(g) **CERTAINTY OF REVIEW TIMEFRAMES.**—The Secretary shall:

(1) provide a written description of any deficiencies in the application, or

(2) the opportunity to submit, for review by a classification panel, information that is based on an interim review of the application submitted under section 513(f) by the person, which information shall be submitted to the Secretary for prompt transmittal to the classification panel.

(h) **Collaborative Review Process.**—For purposes of subsection (a), the Secretary shall:

(1) provide a written description of any deficiencies in the application, or

(2) the opportunity to submit, for review by a classification panel, information that is based on an interim review of the application.

(3) **SPECIAL RULE.**—The Secretary may change the initial classification under subsection (f)(1) that is recommended under paragraph (1) by an accredited person in a case in which the Secretary provides written notice to the applicant of the reasons for the recommendation and the applicant has the opportunity to submit a written response.

(d) **CERTAINTY OF REVIEW TIMEFRAMES.**—The Secretary shall:

(1) ensure that the initial classification of a device is made not later than 180 days after the date on which the Secretary is notified under subparagraph (A) by an accredited person with respect to the initial classification.

(2) adjust the time period for review for a year in which the Secretary makes more than 6 percent of the determinations under subsection (f) that are recommended under paragraph (1) by an accredited person.

(e) **BREADTH OF DETERMINATIONS.**—The Secretary shall ensure that the classifications under subsection (f) include the following:

(1) a class III device;

(2) a class II device which is intended to be permanently implantable or life sustaining or life supporting;

(3) a class I device which includes data in the report submitted under section 510(k) for the device, except that the number of reports submitted to the Secretary under the applicable reporting requirements for the device is less than 25;

(4) a class II device which requires clinical data and is based on clinical data and information that are not available for public disclosure under section 515(d), as amended by section 101 of the Food and Drug Administration Modernization Act of 1997, the Secretary shall, in writing and prior to the release of the recommendations from the initial classification, provide to such person, and the person who submitted the report under section 510(k) for the device, a statement explaining in detail the reasons for the classification.

(f) **PROGRAMS.**—The Secretary shall ensure that the classifications under subsection (f) include the following:

(1) a class III device;

(2) a class II device which is intended to be permanently implantable or life sustaining or life supporting;

(3) a class I device which includes data in the report submitted under section 510(k) for the device, except that the number of reports submitted to the Secretary under the applicable reporting requirements for the device is less than 25;

(4) a class II device which requires clinical data and is based on clinical data and information that are not available for public disclosure under section 515(d), as amended by section 101 of the Food and Drug Administration Modernization Act of 1997, the Secretary shall, in writing and prior to the release of the recommendations from the initial classification, provide to such person, and the person who submitted the report under section 510(k) for the device, a statement explaining in detail the reasons for the classification.

(g) **CERTAINTY OF REVIEW TIMEFRAMES.**—The Secretary shall:

(1) provide a written description of any deficiencies in the application, or

(2) the opportunity to submit, for review by a classification panel, information that is based on an interim review of the application.

(3) **SPECIAL RULE.**—The Secretary may change the initial classification under subsection (f)(1) that is recommended under paragraph (1) by an accredited person in a case in which the Secretary provides written notice to the applicant of the reasons for the recommendation and the applicant has the opportunity to submit a written response.

(h) **PROGRAMS.**—The Secretary shall ensure that the classifications under subsection (f) include the following:

(1) a class III device;

(2) a class II device which is intended to be permanently implantable or life sustaining or life supporting;

(3) a class I device which includes data in the report submitted under section 510(k) for the device, except that the number of reports submitted to the Secretary under the applicable reporting requirements for the device is less than 25;

(4) a class II device which requires clinical data and is based on clinical data and information that are not available for public disclosure under section 515(d), as amended by section 101 of the Food and Drug Administration Modernization Act of 1997, the Secretary shall, in writing and prior to the release of the recommendations from the initial classification, provide to such person, and the person who submitted the report under section 510(k) for the device, a statement explaining in detail the reasons for the classification.
requirements of this section or poses a threat to public health or fails to act in a manner that is consistent with the purposes of this section.

(C) PERFORMANCE AUDITING.—To ensure that persons accredited under this section will continue to meet the standards of accreditation, the Secretary shall—

(i) make onsite visits on a periodic basis to each accredited person to audit the performance of such person; and

(ii) take such additional measures as the Secretary deems appropriate to assure that such person is in compliance with the terms and conditions of accreditation.

(D) ANNUAL REPORT.—The Secretary shall include in the annual report required under section 503(f) of the Federal Food, Drug, and Cosmetic Act (as added by section 1(c)(2) of the Food and Drug Modernization Act, 42 U.S.C. 350a-1) and which has been revised to read as follows:

(1) the submission of a report or recommendation by a person accredited under section 523 that is false or misleading in any material respect;

(2) the disclosure by a person accredited under section 523 of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

(3) the receipt by a person accredited under section 523 of a bribe in any form or the doing of any corrupt act by such person associated with a responsible delegation to such person under this Act.

(d) REPORTS ON PROGRAM OF ACCREDITATION.—

(1) COMPTROLLER GENERAL.—(A) IMPLEMENTATION OF PROGRAM.—Not later than 5 years after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committees on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the extent to which the amendment made by subsection (a) has been implemented.

(B) EVALUATION OF PROGRAM.—Not later than 6 years after the date of the enactment of this Act, the Comptroller General shall submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the use of accredited persons under such section 523, including an evaluation of the extent to which such use assisted the Secretary in carrying out the duties of the Secretary under such Act with respect to devices, and the extent to which such use promoted actions which are contrary to the purposes of such Act.

(2) INCLUSION OF CERTAIN DEVICES WITHIN PROGRAM.—Not later than 3 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report providing a determination by the Secretary of whether, in the period ending 2 years before the date of the enactment of this Act, the Secretary undertook to conduct postmarket surveillance for any device of the class II or class III device which the failure of which would be reasonably likely to have serious adverse health consequences or which is intended to—

(i) implanted in the human body for more than one year, or

(ii) a life sustaining or life supporting device used outside a device user facility.

(3) a life sustaining or life supporting device the use of which is intended to assist an individual with a disability to which such person is delegated under such Act.

(2) Any patient receiving a device subject to the amendment made by subsection (a), in the program of accreditation established under such Act, shall be treated as a patient described in clause (i) of section 510(k) of the Federal Food, Drug, and Cosmetic Act (as added by section 1(c)(2) of the Food and Drug Modernization Act, 42 U.S.C. 350a-1).

SEC. 212. POSTMARKET SURVEILLANCE.

Effective 90 days after the date of the enactment of this Act, section 522 (21 U.S.C. 360l) is amended to read as follows:

(a) POSTMARKET SURVEILLANCE.—

(1) A person accredited under section 523 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a) of such section) may require a manufacturer to conduct postmarket surveillance for any device of the manufacturer which is a class II or class III device the use of which is intended to be—

(i) intended to be implanted in the human body for more than one year, or

(ii) a life sustaining or life supporting device used outside a device user facility.

(2) A patient receiving a device subject to the amendment made by subsection (a), in the program of accreditation established under such Act, shall be treated as a patient described in clause (i) of section 510(k) of the Federal Food, Drug, and Cosmetic Act (as added by section 1(c)(2) of the Food and Drug Modernization Act, 42 U.S.C. 350a-1) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a) of such section).
the same extent and in the same manner as such paragraphs apply to manufacturers and importers.

(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 310(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 (other than the manufacturer or the initial importer) 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.

(c) DEVICE USER FACILITIES.—

(1) IN GENERAL.—Section 519(b) (21 U.S.C. 360(b)) is amended—

(A) by redesignating paragraph (1)(C)—

(i) in the first sentence, by striking "a semiannual basis" and inserting "an annual basis";

(ii) in the second sentence, by striking "and July 1"; and

(iii) by striking the matter after and below clause (iv); and

(B) in paragraph (2)—

(i) in subparagraph (A), by inserting "or" after the comma at the end;

(ii) by striking subparagraph (B), by striking "", or" at the end and inserting a period; and

(iii) by striking subparagraph (C).

(2) SENTINEL SYSTEM.—Section 519(b) (21 U.S.C. 360(b)) is amended—

(A) by redesigning paragraph (5) as paragraph (6); and

(B) by inserting after paragraph (4) the following paragraph:

"(5) With respect to device user facilities:

"(A) The Secretary shall by regulation plan and implement a program under which the Secretary limits user reporting under paragraphs (1) through (4) to a subset of user facilities that constitutes a representative profile of user reports for device deaths and serious injuries or illnesses. By adding after the period at the end of subsection (a)(1)(A), by inserting "or" at the end of the sentence:

"(2) During the period of planning the program under subparagraph (A), paragraphs (1) through (4) continue to apply.

(C) In the case in which the Secretary is providing for a transition to the full implementation of the program, paragraphs (1) through (4) apply except to the extent that the Secretary determines otherwise.

(D) On and after the date on which the program is fully implemented, paragraphs (1) through (4) do not apply to a user facility unless the notice required in subparagraph (A) is included in the subset referred to in subparagraph (A).

(E) Not later than 2 years after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall submit to the Committee on Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the plan developed by the Secretary under subparagraph (A) and the progress that has been made toward the implementation of the plan.

SEC. 214. PRACTICE OF MEDICINE.

Chapter IX is amended by adding at the end the following:

"SEC. 906. PRACTICE OF MEDICINE.

"Nothing in this Act shall be construed to limit the authority of a health care practitioner to prescribe or administer any legally marketed device to patient for any condition or disease within a legitimate health care practitioner-patient relationship. This section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the sale, dispensing, or using, at the time of labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations. Further, the regulations shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices."

SEC. 215. NONINVASIVE BLOOD GLUCOSE METER.

(A) The Secretary shall by regulation plan and implement a program under which the Secretary in—

(i) I N GENERAL.—Section 520(h)(4) (21 U.S.C. 360(h)(4)) is amended—

(1) by striking paragraph (10).

(C) by striking paragraph (10).

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

"(4) the pain associated with existing blood testing devices creates a disincentive for people with diabetes to test blood glucose levels, particularly children;

(5) a safe and effective noninvasive blood glucose meter would likely improve control and management of diabetes, and existing blood testing devices require repeated piercing of the skin of the patient;

(6) blood testing devices are a critical tool for the control and management of diabetes, and the pain associated with existing blood testing devices creates a disincentive for people with diabetes to test blood glucose levels, particularly children;

(7) a safe and effective noninvasive blood glucose meter would likely improve control and management of diabetes, and the pain associated with existing blood testing devices creates a disincentive for people with diabetes to test blood glucose levels, particularly children;

(8) the Food and Drug Administration is responsible for regulating medical devices, including noninvasive blood glucose meters; and

(9) the availability of a safe, effective, noninvasive blood glucose meter would greatly enhance the health and well-being of all people with diabetes across America and the world.

SEC. 216. USE OF DATA RELATING TO PREMARKET APPROVAL; PRODUCT DEVELOPMENT PROTOCOL.

(a) USE OF DATA RELATING TO PREMARKET APPROVAL.—

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

"(4) 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, including the number of tests conducted by people with diabetes, particularly children; and

(1) in the first sentence, by striking "a semiannual basis" and inserting "an annual basis;"

(2) in the fourth sentence (as amended by this subsection), by inserting after the comma at the end;

(3) by adding after the period at the end of subsection (a), by striking "or" at the end of the sentence and inserting "importer, or distributor" each place it appears and inserting "or importer";

(4) in the second sentence, by striking "and July 1"; and

(5) by striking the matter after and below clause (iv); and

(b) PRODUCT DEVELOPMENT PROTOCOL.—Section 515(f)(2) (21 U.S.C. 360(f)(2)) is amended by striking "he shall" and all that follows and inserting the following: "the Secretary shall submit to the Committee on Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate the reasons action on the regulation did not occur within such 540 days, the Secretary shall provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate the reasons action on the regulation did not occur within such 540 days.

SEC. 301. FLEXIBILITY FOR REGULATIONS REGARDING CLAIMS.

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

"(I) enable consumers to develop and maintain healthy dietary practices;

(II) enable consumers to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food; or

(III) ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible; or

"(B) to enable the Secretary to act promptly to ban or modify a claim under this paragraph.

Such proposed regulations shall be deemed final agency action for purposes of judicial review.

SEC. 302. PETITIONS FOR CLAIMS.


(1) in the first sentence, by striking "the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner.

(2) in the fourth sentence as amended by paragraph (1) by inserting immediately before the comma the following: "or the petition is deemed to be denied; and

(3) by adding at the end the following:

"If the Secretary does not act within such 90 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner. If the Secretary issues a proposed regulation, the rulemaking shall be completed within 540 days of the date the petition is received by the Secretary.

"(B) The publicly available detailed summaries of information respecting the safety and effectiveness of a product as described in subparagraph (A) shall be available for use by the Secretary as the evidentiary basis for the agency actions described in subparagraph (A).

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

(i) a scientific body of the United States Government with official responsibility for public health or human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions 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 clause refers;

(ii) a person has submitted to the Secretary, at least 120 days before the first introduction into interstate commerce of the food with a label containing the claim, (i) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have not been met, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature relating to the nutrient level to which the claim refers;

(iii) the claim and the food for which the claim is made are in compliance with clauses (A) and (B) of this paragraph 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 understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the scientific body made in the individual capacity of the employee.

CONGRESSIONAL RECORD — HOUSE

SEC. 305. REFERRAL STATEMENTS.

Section 403(r)(2)(B) (21 U.S.C. 343(r)(2)(B)) is amended—

(1) by striking in paragraph (2) the words "in the case of a food additive as defined in this Act that is a food contact substance, there is—"

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

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

"(h)(1) Subject to such regulations as may be prescribed by the Secretary of Health and Human Services, notify the manufacturer, distributor, or supplier of a food contact substance intended for use by reason of bearing or containing such a substance, is in effect, and has not been delayed.

(h)(2) in the case of a food additive that is effective,";

(3) by striking the matter following paragraph (3) as added by paragraph (3) and inserting the following flush statement:

"While such a regulation relating to a food additive, or such a notification under subsection (h)(1) relating to a food additive that is a food contact substance, is in effect, and has not been delayed, any action taken under this section prescribing the conditions under which such additive may be safely used; or

"(B) a notification submitted under subsection (h)(1) that is effective, and"

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

"While such a regulation relating to a food additive, or such a notification under subsection (h)(1) relating to a food additive that is a food contact substance, is in effect, and has not been delayed, any action taken under this section prescribing the conditions under which such additive may be safely used; or

"(B) a notification submitted under subsection (h)(1) that is effective, and"

(5) 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 thereof in contact with food and the Secretary determines that the food contains a nutrient at a level that

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

"(C) by striking "paragraph (3) of subsection (a),";

"(D) by inserting after subsection (g) 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 thereof in contact with food and the Secretary determines that the food contains a nutrient at a level that
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 conditions of use described in subsection (c)(3)(A). The notification shall contain the information that forms the basis of the determination 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 on which it is 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 notification and review of an application under subsection (b) is necessary to provide adequate assurance of safety, or where the Secretary and any manufacturer or supplier agree that such an application submitted under paragraph (1), 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 made available to any interested party except for any matter in the notification that is a trade secret or confidential commercial information.

(5) Provided in clause (ii), the notification program established under this subsection shall not operate in any fiscal year unless:

(I) an appropriation equal to or exceeding the applicable amount under clause (iv) is made for such fiscal year for carrying out such program in such fiscal year; and

(II) the Secretary certifies that the amount appropriated for such fiscal year for the Center for Food Safety and Applied Nutrition of the Food and Drug Administration (exclusive of the appropriate amount under clause (iv) or exceeds the amount appropriated for the Center for fiscal year 1997, excluding any amount appropriated for new programs.

(I) In the last six months of fiscal year 1999, the applicable amount under this clause is $1,500,000, or the amount specified in the budget request of the President for the six-month period ending with the date specified in the budget request of the President for the fiscal year for carrying out the notification program under this subsection, whichever is less.

(I) For fiscal year 2000 and subsequent fiscal years, the applicable amount under this clause is the amount specified in the budget request of the President for the fiscal year for carrying out the notification program under this subsection, whichever is less.

(3) For purposes of carrying out the notification program under this subsection, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1999 through fiscal year 2003, except that such authorizations of appropriations are not effective for any fiscal year for any amount that is less than the applicable amount under clause (iii) or (iv) of subparagraph (A), whichever is applicable.

(4) Not later than April 1 of fiscal year 1998 and February 1 of each fiscal year thereafter, the Secretary shall submit a report to the Committees on Appropriations of the House of Representatives and the Senate, the Committee on Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate that provides an estimate of the Secretary of the costs of carrying out the notification program under this subsection for the next fiscal year.

(5) 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 subsection (j), as so redesignated by section 551, an order under subsection (f) of section 513, an order under section 515, or a summary of such information; and

(4) in subsection (j) in which a petition shall be filed under subsection (b) to (h) and inserting ‘subsections (b) to (h)’.

IV—GENERAL PROVISIONS

SEC. 410. DISSEMINATION OF INFORMATION ON NEW USES.

(1) in subparagraph (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).

(2) in subsection (b) to (i), as so redesignated by subsection (j), as so redesignated by section 551, an order under subsection (f) of section 513, an order under section 515, or a summary of such information; and

IV—GENERAL PROVISIONS

(1) in subparagraph (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).

(2) in subsection (b) to (i), as so redesignated by subsection (j), as so redesignated by section 551, an order under subsection (f) of section 513, an order under section 515, or a summary of such information; and

IV—GENERAL PROVISIONS

(1) in subparagraph (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).

(2) in subsection (b) to (i), as so redesignated by subsection (j), as so redesignated by section 551, an order under subsection (f) of section 513, an order under section 515, or a summary of such information; and

IV—GENERAL PROVISIONS

(1) in subparagraph (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).

(2) in subsection (b) to (i), as so redesignated by subsection (j), as so redesignated by section 551, an order under subsection (f) of section 513, an order under section 515, or a summary of such information; and

IV—GENERAL PROVISIONS

(1) in subparagraph (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).

(2) in subsection (b) to (i), as so redesignated by subsection (j), as so redesignated by section 551, an order under subsection (f) of section 513, an order under section 515, or a summary of such information; and

IV—GENERAL PROVISIONS

(1) in subparagraph (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).

(2) in subsection (b) to (i), as so redesignated by subsection (j), as so redesignated by section 551, an order under subsection (f) of section 513, an order under section 515, or a summary of such information; and

IV—GENERAL PROVISIONS

(1) in subparagraph (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).

(2) in subsection (b) to (i), as so redesignated by subsection (j), as so redesignated by section 551, an order under subsection (f) of section 513, an order under section 515, or a summary of such information; and

IV—GENERAL PROVISIONS

(1) in subparagraph (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).

(2) in subsection (b) to (i), as so redesignated by subsection (j), as so redesignated by section 551, an order under subsection (f) of section 513, an order under section 515, or a summary of such information; and

IV—GENERAL PROVISIONS

(1) in subparagraph (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).

(2) in subsection (b) to (i), as so redesignated by subsection (j), as so redesignated by section 551, an order under subsection (f) of section 513, an order under section 515, or a summary of such information; and
secrecy, the Secretary shall consider (in addition to any other considerations the Secretary finds appropriate)—

(i) the lack of the availability under law of any data the manufacturer would have exclusive marketing rights with respect to the new use involved; and

(ii) the size of the population expected to benefit from approval of the supplemental application.

(2) The Secretary makes a determination that, for reasons defined by the Secretary, it would be unethical to conduct the studies necessary for the supplemental application. In making such determination, the Secretary shall consider (in addition to any other considerations the Secretary finds appropriate) whether the new use involved is the standard of medical care for a health condition.

(3) Time for Consideration of Application; Deemed Approval

(a) In General.—The Secretary shall approve or deny an application under paragraph (1) for an exemption not later than 60 days after the receipt of the application. If the Secretary does not comply with the preceding sentence, the application is deemed to be approved.

(b) Termination of Deemed Approval.—If pursuant to a deemed approval under paragraph (1)(A) a manufacturer disseminates written information under section 551 on a new use, the Secretary may at any time terminate such approval by written notice to the manufacturer.

(c) Requirements Regarding Applications.—Applications under this section shall be submitted in the form and manner prescribed by the Secretary.

SEC. 555. CORRECTIVE ACTIONS; CESSATION OF DISSEMINATION

(a) Postdissemination Data Regarding Safety and Effectiveness.—

(1) Corrective Actions.—With respect to dissemination of information under section 551 by a manufacturer has begun (whether received pursuant to paragraph (2) or otherwise), if the Secretary determines that the new use involved may not be effective or may present a significant risk to public health, which may include ordering that the manufacturer cease the dissemination of the information.

(2) Responsibilities of Manufacturers to Submit Data.—After a manufacturer disseminates information under section 551, the manufacturer shall submit to the Secretary a notification of any additional knowledge of the manufacturer on clinical research or other data that relate to the safety or effectiveness of the new use involved. If the manufacturer is in possession of the data, the notification shall include the data. The Secretary shall by regulation establish the scope of the responsibilities of manufacturers under this paragraph, including such limits on the responsibilities of the Secretary as the Secretary determines to be appropriate for the protection of the public health, which may include ordering that the manufacturer cease the dissemination of the information.

(b) Failure of Manufacturer to Comply with Requirements.—The Secretary may order a manufacturer to cease the dissemination of information pursuant to section 551 if the Secretary determines that the information being disseminated does not comply with the requirements established in this subchapter. Such an order may be issued only if the Secretary has provided notice to the manufacturer of the intent of the Secretary to issue the order and (unless paragraph (2)(B) applies) has provided an opportunity for a hearing with respect to such intent. If the failure of the manufacturer constitutes a minor violation of this subchapter, the
Secretary shall delay issuing the order and provide to the manufacturer an opportunity to correct the violation.

(2) SUPPLEMENTAL APPLICATIONS.—The Secretary shall request the manufacturer to cease the dissemination of information pursuant to section 551 if—

(A) in the case of a manufacturer that has submitted a supplemental application for a new use pursuant to section 554(a)(1), the Secretary determines that the supplemental application does not contain adequate information for approval, for a new use for which the application was submitted;

(B) in the case of a manufacturer that has submitted a certification under section 554(b), the manufacturer, within 6 months, did not, or (ii) if the Secretary determines that the supplemental application referred to in the certification; or

(C) in the case of a manufacturer that has submitted a certification under section 554(c) but has not yet submitted the supplemental application referred to in the certification, the Secretary, after an informal hearing, determines that the manufacturer is not acting with due diligence to complete the studies involved.

(3) TERMINATION OF DEEMED APPROVAL OF EXEMPTION REGARDING SUPPLEMENTAL APPLICATIONS.—In the case of an order under subsection (b)(3) to cease disseminating the information, the Secretary may not order the manufacturer involved to cease disseminating the information if the Secretary determines that the new use described in the information would pose a significant risk to the public health.

SEC. 556. DEFINITIONS.

For purposes of this chapter—

(1) the term ‘health care practitioner’ means a physician, or other individual who is a provider of health care, who is licensed under the law of a State to prescribe drugs or devices.

(2) the term ‘health insurance issuer’ and ‘group health plan’ have the meaning given such terms under section 2791 of the Public Health Service Act.

(3) the term ‘manufacturer’ means a person who manufactures a drug or device, or who is licensed by such person to distribute or market the drug or device.

(4) the term ‘new use’—

(A) with respect to a drug, means a use that is not included in the labeling of the approved drug; and

(B) with respect to a device, means a use that is not included in the labeling for the approved or cleared device.

(5) 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 such 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 the regular peer-review procedures of the organization;

(C) that is generally recognized to be of national scope and reputation;

(D) that is indexed by the Index Medicus of the National Library of Medicine of the National Institutes of Health; and

(E) that is not in the form of a special supplement that has been funded in whole or in part by one or more manufacturers.

SEC. 557. RULES OF CONSTRUCTION.

(1) UNSOLICITED REQUEST.—Nothing in section 551 shall be construed as prohibiting a manufacturer from disseminating information in response to an unsolicited request from a health care practitioner.

(2) DISSEMINATION OF INFORMATION ON DRUGS OR DEVICES NOT EVIDENCE OF INTENDED USE.—Notwithstanding subsection (a), (f), or (i) 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 551, 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 for the official labeling of the drug or device. Such dissemination shall not be considered by the Secretary as labeling, misbranding, or misusing of the drug or device.

(3) PATENT PROTECTION.—Nothing in section 551 shall affect patent rights in any manner.

(4) AUTHORIZATION FOR DISSEMINATION OF ARTICLES AND FEES FOR REPRINTS OF ARTICLES.—Nothing in section 551 shall be construed as prohibiting an entity that publishes a scientific journal (as defined in section 556(5)) from requiring authorization from the entity to disseminate an article published by such entity or charging fees for the purchase of reprints of published articles.

(b) PROHIBITED ACT.—Section 301 (21 U.S.C. 331), as amended by section 210, is amended by adding at the end the following:

(2) The dissemination of information in violation of section 551.

(c) REGULATIONS.—Not later than 1 year after the date of enactment of this Act, the Secretary, after consultation with the National Institutes of Health, the National Library of Medicine of the National Institutes of Health, and the National Institutes of Health, shall promulgate regulations to implement the amendments made by this section.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect 60 days after the date of enactment of this Act.

SEC. 561. EXPANDED ACCESS TO UNAPPROVED THERAPIES AND DIAGNOSTICS.

(a) EMERGENCY SITUATIONS.—The Secretary, under appropriate consultation with the National Institutes of Health, shall conduct a study to determine the impact of subchapter D of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by section 13, on the Department of Health and Human Services.

(b) STUDIES AND REPORTS.—(1) IN GENERAL.—In any case in which under section 551 the Secretary determines that provision of the investigational drug or investigational device for the diagnosis, monitoring, or treatment of a serious or life-threatening disease or condition in emergency situations, the Secretary, after consultation with the National Institutes of Health, and the National Library of Medicine of the National Institutes of Health, shall prepare and submit to the Committee on Commerce of the House of Representatives, and the Committee on Finance of the Senate, and the Committee on Commerce of the House of Representatives a report of the results of the study required by paragraph (2).

(2) The report made available to the public.

SEC. 402. EXPANDED ACCESS TO INVESTIGATIONAL THERAPIES AND DIAGNOSTICS.

Chapter V (21 U.S.C. 351 et seq.), as amended in section 401, is further amended by adding at the end the following:

"SUBCHAPTER E—GENERAL PROVISIONS RELATING TO DRUGS AND DEVICES "SEC. 561. EXPANDED ACCESS TO UNAPPROVED THERAPIES AND DIAGNOSTICS.

(a) EMERGENCY SITUATIONS.—The Secretary, under appropriate consultation with the National Institutes of Health, shall conduct a study to determine the impact of subchapter D of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by section 13, on the Department of Health and Human Services.

(b) STUDIES AND REPORTS.—(1) IN GENERAL.—In any case in which under appropriate consultation with the National Institutes of Health, the Secretary determines that provision of the investigational drug or investigational device for the diagnosis, monitoring, or treatment of a serious or life-threatening disease or condition in emergency situations.

(2) The Secretary shall—

(i) the effectiveness of such subchapter with the investigational drug or investigational device for the diagnosis, monitoring, or treatment of a serious or life-threatening disease or condition in emergency situations.

(3) The Secretary, after consultation with the National Institutes of Health, the National Library of Medicine of the National Institutes of Health, and the National Institutes of Health, shall promulgate regulations to implement the amendments made by this section.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect 60 days after the date of enactment of this Act.
“(4) the 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 the Secretary, after evaluating the effectiveness of such documents and the documents submitted under section 505(i) or 520(g), describing the use of the investigational drug or investigational device in a single patient or a small group of patients, determines that—

"(c) Treatment Investigational New Drug Applications and Treatment Investigational Device Exemptions.—Upon submission by a sponsor or clinical investigator of a protocol that the Secretary determine provide widespread access to an investigational drug or investigational device for eligible patients (referred to in this subsection as an "expanded access protocol''), the Secretary may in his discretion permit such investigational drug or investigational device to be made available for expanded access under a treatment investigational new drug application or treatment investigational device exemption if the Secretary determines that—

"(1) under the treatment investigational new drug application or treatment 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 such serious or immediately life-threatening disease or condition;

"(3)(A) the investigational drug or investigational device is under investigation in a controlled clinical trial for the use described in subsection (a). The guidelines shall—

"(A) define circumstances in which published matter may be the basis for approval of a supplemental application;

"(B) 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)(B) in the case of serious diseases, there is sufficient evidence of safety and effectiveness to support the use described in paragraph (1) of an investigational drug or investigational device described in paragraph (3)(A), the provision of the investigational drug or investigational device will not interfere with the entrance into such clinical investigations under section 505(i) or investigational device exemption in effect under section 520(g); or

"(5) in the case of serious diseases, there is sufficient evidence of safety and effectiveness to support the use described in paragraph (1) or paragraph (3)(A); and

"(7) in the case of investigational drugs or investigational devices intended for use in investigational new drug applications or investigational device exemptions, the investigational drug or investigational device 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), including regulations promulgated under section 505(i) or 520(g). The Secretary may in his discretion extend the use 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 the same type available to the Secretary under expanded access protocols submitted under this subsection. The information provided by the Secretary, in accordance with the preceding sentence, shall be the same type available to the Secretary under expanded access protocols submitted under this subsection.

"(d) Termination.—The Secretary may, at any time, with respect to a sponsor, physician, manufacturer, or investigator described in paragraph (1), (2), (4), or (5), terminate expanded access under the investigational new drug or investigational device if the requirements under this section are no longer met.

"(e) Definitions.—In this section, the terms 'investigational drug', 'investigational device', 'treatment investigational new drug application', and 'treatment investigational device exemption' shall have the meanings given the terms in regulations prescribed by the Secretary.''

SEC. 403. APPROVAL OF SUPPLEMENTAL APPLICATIONS FOR APPROVED PRODUCTS.

(a) Standards.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall publish in the Federal Register for prompt review of supplemental applications submitted for approved articles under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(b) Guidance to Industry.—Not later than 180 days after the date of enactment of this Act, the Secretary shall issue final guidelines 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 guidelines 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 shall—

"(1) develop recommendations that policy decisions be made within each center within the Food and Drug Administration (except the Center for Food Safety and Applied Nutrition) to be responsible for—

"(I) encouraging the prompt review of supplemental applications and the consideration of data previously submitted in support of an original application; and

"(II) developing and using guidance documents for supplemental applications;

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

"(3) implementing policies and programs that will foster collaboration between the Food and Drug Administration, the National Institutes of Health, professional medical and scientific societies, and other persons for the purposes of publicly identifying published and developed and using guidance documents for supplemental applications; and

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

(d) Collaboration.—The Secretary shall—

"(1) develop and use guidance documents for the development, issuance, and use of guidance documents; and

"(2) ensure that information identifying the existence and content of such documents and the documents are publicly distributed and available to the public in electronic form and, as feasible, through electronic means. Such documents shall not create or confer any rights for or on any person, although they present the views of the Secretary on matters under the jurisdiction of the Food and Drug Administration.

"(e) Definitions.—In this section, the terms "investigational drug", "investigational device", "treatment investigational new drug application", and "treatment investigational device exemption" shall have the meanings given the terms in regulations prescribed by the Secretary.''

SEC. 406. FOOD AND DRUG ADMINISTRATION MIS- SION AND ANNUAL REPORT.

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

"(1) redesignating subsections (e) and (f) as subsections (d) and (e), respectively; and

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

"(b) The Administration shall—

"(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of new medical products in a timely manner;

"(2) with respect to such products, protect the public health by ensuring that—

"(A) the products are safe, wholesome, sanitary, and properly labeled;

"(B) human and veterinary drugs are safe and effective; and

"(C) there is reasonable assurance of the safety and effectiveness of devices intended for human use;
"(D) cosmetics are safe and properly labeled; and
"(E) public health and safety are protected from electronic product radiation; 

(3) the conduct of appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal recognition agreements relating to the regulation of food, drugs, and medical devices; and

(4) as determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with experts in science, medicine, public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.

(b) ANNUAL REPORT.—Section 903 (21 U.S.C. 393), as amended by subsection (a), is further amended by adding at the end the following:

"SEC. 407. INFORMATION SYSTEM. 

(a) FOOD AND DRUG ADMINISTRATION.—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 407, is further amended by adding at the end the following:

"SEC. 408. EDUCATION AND TRAINING. 

(a) FOOD AND DRUG ADMINISTRATION.—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 407, is further amended by adding at the end the following:

"SEC. 409. CENTERS FOR EDUCATION AND RESEARCH ON THERAPEUTICS. 

Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended by adding at the end of part A the following new section:

"SEC. 317G. FELLOWSHIP AND TRAINING PROGRAMS. 

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish fellowship and training programs to be conducted by such Centers to train individuals to develop skills in epidemiology, surveillance, laboratory analysis, and other disease detection and prevention methods. Such programs shall be designed to enable public health professionals and health personnel trained under such programs to work, after receiving such training, in local, State, national, and international efforts toward the prevention and control of diseases, injuries, and disabilities. Such fellowships and training may be administered through the use of either appointment or non-appointment procedures.

"SEC. 407. INFORMATION SYSTEM. 

(a) The Secretary shall establish and maintain an information system to track the progress of each application or submission (including a petition, notification, or other similar form of request) submitted to the Food and Drug Administration requesting agency action.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall submit a report to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives on the status of the system to be established under this amendment made by subsection (a), including the projected costs of the system and concerns about confidentiality.

"SEC. 408. EDUCATION AND TRAINING. 

(a) Food and Drug Administration.—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 407, is further amended by adding at the end the following:

"SEC. 409. CENTERS FOR EDUCATION AND RESEARCH ON THERAPEUTICS. 

Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended by adding at the end of part A the following new section:

"SEC. 317G. FELLOWSHIP AND TRAINING PROGRAMS. 

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish fellowship and training programs to be conducted by such Centers to train individuals to develop skills in epidemiology, surveillance, laboratory analysis, and other disease detection and prevention methods. Such programs shall be designed to enable public health professionals and health personnel trained under such programs to work, after receiving such training, in local, State, national, and international efforts toward the prevention and control of diseases, injuries, and disabilities. Such fellowships and training may be administered through the use of either appointment or non-appointment procedures.

"SEC. 407. INFORMATION SYSTEM. 

(a) The Secretary shall establish and maintain an information system to track the progress of each application or submission (including a petition, notification, or other similar form of request) submitted to the Food and Drug Administration requesting agency action.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall submit a report to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives on the status of the system to be established under this amendment made by subsection (a), including the projected costs of the system and concerns about confidentiality.

"SEC. 408. EDUCATION AND TRAINING. 

(a) Food and Drug Administration.—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 407, is further amended by adding at the end the following:

"SEC. 409. CENTERS FOR EDUCATION AND RESEARCH ON THERAPEUTICS. 

Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended by adding at the end of part A the following new section:

"SEC. 317G. FELLOWSHIP AND TRAINING PROGRAMS. 

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish fellowship and training programs to be conducted by such Centers to train individuals to develop skills in epidemiology, surveillance, laboratory analysis, and other disease detection and prevention methods. Such programs shall be designed to enable public health professionals and health personnel trained under such programs to work, after receiving such training, in local, State, national, and international efforts toward the prevention and control of diseases, injuries, and disabilities. Such fellowships and training may be administered through the use of either appointment or non-appointment procedures.

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"SEC. 409. CENTERS FOR EDUCATION AND RESEARCH ON THERAPEUTICS. 

Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended by adding at the end of part A the following new section:

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The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish fellowship and training programs to be conducted by such Centers to train individuals to develop skills in epidemiology, surveillance, laboratory analysis, and other disease detection and prevention methods. Such programs shall be designed to enable public health professionals and health personnel trained under such programs to work, after receiving such training, in local, State, national, and international efforts toward the prevention and control of diseases, injuries, and disabilities. Such fellowships and training may be administered through the use of either appointment or non-appointment procedures.

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(a) Food and Drug Administration.—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 407, is further amended by adding at the end the following:

"SEC. 409. CENTERS FOR EDUCATION AND RESEARCH ON THERAPEUTICS. 

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The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish fellowship and training programs to be conducted by such Centers to train individuals to develop skills in epidemiology, surveillance, laboratory analysis, and other disease detection and prevention methods. Such programs shall be designed to enable public health professionals and health personnel trained under such programs to work, after receiving such training, in local, State, national, and international efforts toward the prevention and control of diseases, injuries, and disabilities. Such fellowships and training may be administered through the use of either appointment or non-appointment procedures.

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methods and approaches to harmonize regulatory requirements.

"(4) The Secretary shall, not later than 180 days after the date of enactment of the Food and Drug Administration Modernization Act of 1997, make public a plan that establishes a framework for achieving mutual recognition of good manufacturing practices inspections.

"(5) Paragraph (1) shall not apply with respect to products defined in section 101(ff)".

**SEC. 411. ENVIRONMENTAL IMPACT REVIEW.**

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 407, is further amended by adding at the end the following:

"SUBCHAPTER E—ENVIRONMENTAL IMPACT REVIEW

**SEC. 746. ENVIRONMENTAL IMPACT.**

"(A) 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. 412. NATIONAL UNIFORMITY FOR NON-PRESCRIPTION DRUGS AND COSMETICS.**

(a) NONPRESCRIPTION DRUGS.—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 411, 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. 751. NATIONAL UNIFORMITY FOR NON-PRESCRIPTION DRUGS.**

(a) IN GENERAL.—Except as provided in subsection (b), (c), (d), (e), or (f), no State or political subdivision thereof shall 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 502(b)(1), 503(i), 506, or 507; or

(2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this Act or the Poison Prevention Packaging Act (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, except from subsection (a), under such conditions as may be prescribed in such regulation, a State or political subdivision requirement for labeling or packaging that—

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

(2) would not cause any drug to be in violation of any applicable requirement 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 each cosmetic as a requirement specifically applicable to that 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 Packag- ing and Labeling Act (15 U.S.C. 1451 et seq.).

**SEC. 752. PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS.**

(a) IN GENERAL.—Except as provided in subsection (b), (d), or (e), no State or political subdivision of a State may establish 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 that 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 Packag- ing 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, except from subsection (a), under such conditions as may be prescribed in such regulation, a State or political subdivision requirement for labeling or 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 requirement 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 each cosmetic as a requirement specifically applicable to that 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 Packag- ing and Labeling Act (15 U.S.C. 1451 et seq.).

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

"(A) with respect to alphabetical order shall apply

"(B) with respect to alphabetical order shall apply

"(C) with respect to alphabetical order shall apply

"(D) with respect to alphabetical order shall apply

"(E) with respect to alphabetical order shall apply

"(F) with respect to alphabetical order shall apply

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"(W) with respect to alphabetical order shall apply

"(X) with respect to alphabetical order shall apply

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"(Z) with respect to alphabetical order shall apply

November 9, 1997

CONGRESSIONAL RECORD—HOUSE

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Drug Administration, shall conduct a study of the effect on humans of the use of mercury compounds in nasal sprays. Such study shall include data from other studies that have been made or are to be made. . .

(c) STUDY OF MERCURY SALES.—

(1) Study.—The Secretary of Health and Human Services, acting through the Food and Drug Administration, and subject to such regulations, shall conduct, or shall contract with the Institute of Medicine of the National Academy of Sciences to conduct, a study of the effect on human health of the use of elemental, organic, or inorganic mercury when offered for sale as a drug or dietary supplement. Such study shall, among other things, evaluate

(A) the scope of mercury use as a drug or dietary supplement; and

(B) the adverse effects on health of children and other sensitive populations resulting from exposure to, or ingestion or inhalation of, mercury when so used.

In conducting such study, the Secretary shall consult with the Administrator of the Environmental Protection Agency, the Chair of the Consumer Product Safety Commission, and the Administrator of the Agency for Toxic Substances and Disease Registry, and, to the extent necessary or appropriate, with any other Federal or private entity.

(2) Regulations.—If, in the opinion of the Secretary, the use of elemental, organic, or inorganic mercury for sale as a dietary supplement poses a threat to human health, the Secretary shall promulgate regulations restricting the sale of mercury intended for such use. At a minimum, such regulations shall be designed to protect the health of children and other sensitive populations from adverse effects resulting from exposure to, or ingestion or inhalation of, mercury. Such regulations, to the extent feasible, should not unnecessarily interfere with the availability of mercury for use in religious ceremonies.

SEC. 413. INTERAGENCY COLLABORATION.

Section 903 (21 U.S.C. 393), as amended by section 406, is further amended by inserting after subsection (b) the following:

(c) 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, notification, evaluation, and postmarket monitoring of emerging medical therapies, including complementary therapies, and advancing and evaluating policy and practice.

SEC. 414. CONTRACTS FOR EXPERT REVIEW.

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 214, is further amended by adding at the end the following:

(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 relevant expertise, to review and evaluate, for the purpose of making 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 may use the authority granted in paragraph (1) whenever the Secretary determines that use of a contract described in paragraph (1) will improve the timeliness 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. The Secretary may use such authority whenever the Secretary determines that use of a contract described in paragraph (1) will improve the quality of the review of an application or submission described in paragraph (1), unless using such authority would unduly increase the cost of such review. In creating such authority, improvement in timeliness or quality 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 reviewing such an application or submission described in paragraph (1) and reviewing such an application or submission described in paragraph (1) or reviewing the recommendations of the organization or individual who conducted the expert review and shall make a final decision regarding the matter in a timely manner.

(2) LIMITATION.—A final decision by the Secretary shall be made with the authority granted in paragraph (1) when the Secretary determines that the timely and quality of such review shall not be compromised.

SEC. 415. CONTRACTS FOR EXPERT REVIEW.

Subchapter E of chapter V, as amended by section 404, is further amended by adding at the end the following:

SEC. 906. 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 for a product, may submit a request to the Secretary respecting the classification of the product as a drug, biological product, device, or a combination product subject to subsection (b). Such a request shall contain a statement that will regulate the product. In submitting the request, the person shall recommend a classification for the product, or a component to regulate the product, as applicable, and may not be modified by the Secretary except with the written consent of the person, or for public health reasons based on scientific evidence.

(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 product under subsection (a), or the component of the product that will regulate the product. In submitting the request, the person shall recommend a classification for the product, or a component to regulate the product, as applicable, and may not be modified by the Secretary except with the written consent of the person, or for public health reasons based on scientific evidence.

SEC. 416. REGISTRATION OF FOREIGN ESTABLISHMENTS.

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

(i) A request shall be made at any time during the lifetime of a permit application and/or the term of a permit and shall be submitted in the manner prescribed by the Secretary. Such a request shall be made in the manner prescribed by the Secretary.

(ii) The Secretary may grant a permit for any foreign establishment to manufacture, prepare, propagate, or process food, drug, or cosmetic products, or any component thereof, for importation into the United States, upon determining that the foreign establishment meets all applicable requirements of this Act.

SEC. 417. REGISTRATION OF FOREIGN ESTABLISHMENTS.

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

(i) A request shall be made at any time during the lifetime of a permit application and/or the term of a permit and shall be submitted in the manner prescribed by the Secretary. Such a request shall be made in the manner prescribed by the Secretary.

(ii) The Secretary may grant a permit for any foreign establishment to manufacture, prepare, propagate, or process food, drug, or cosmetic products, or any component thereof, for importation into the United States, upon determining that the foreign establishment meets all applicable requirements of this Act.

SEC. 418. CLASSIFICATION OF SECRECY AUTHORITY.

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

(1) in the fifth sentence, by striking "paragraphs (1) and (2) of section 801(a)"); and inserting—

"subparagraphs (A) and (B) of section 801(a); and"

(2) by inserting after the first sentence the following—

"Any person seeking to export an import article pursuant to any of the provisions of this subsection shall establish that the article intended for export at the time the article entered commerce.

SEC. 419. INTERSTATE COMMERCE.

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

SEC. 420. SAFETY REPORT DISCLAIMERS.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 412, is further amended by adding at the end the following:

"SUBCHAPTER G—SAFETY REPORTS

SEC. 756. 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 that is a food, drug, device, dietary supplement, or cosmetic) under this Act and any release by the Secretary of the report or information, such information shall not be construed to reflect necessarily a conclusion by the entity or the Secretary that the report or information constitutes an admission that the product involved malfunctioned, caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, or serious illness. 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 malfunctioned, caused or contributed to a death, serious injury, or serious illness.

SEC. 421. LABELING AND ADVERTISING REGARDING COMPLIANCE WITH STATUTORY REQUIREMENTS.

Section 301 (21 U.S.C. 331) is amended by striking paragraph (i).

SEC. 422. RULE OF CONSTRUCTION.

Nothing in this Act or the amendments made by this Act shall be construed to affect the question of whether the Secretary of Health and Human Services has any authority to regulate any tobacco product, tobacco ingredient, or tobacco additive. Such authority, if any, shall be exercised under the Federal Food, Drug, and Cosmetic Act or any other Federal law, effective as of the date before the date of the enactment of this Act.

TITLE V—EFFECTIVE DATE

SECTION 501. EFFECTIVE DATE.

Except as otherwise provided in this Act, this Act and the amendments made by this Act, other than the provisions of section 301, shall take effect on the 90th day after the date of enactment of this Act.

That the House recede from its amendment to the title of the bill.
November 9, 1997

JAMES GREENWOOD,  
RICHARD BURR,  
ED WHITFIELD,  
JOHN D. DINGELL,  
SHERROD BROWN,  
HENRY A. WAXMAN,  
RON KLINK,  
Managers of the Part of the House.  
JIM EFFORDS,  
DON COATS,  
LUO GREGG,  
BILL FRIST,  
MIKE DEWINE,  
EDWARD M. KENNEDY,  
CHRISTOPHER DODD,  
TOM HARKIN,  
BARBARA A. MIKULSKI,  
Managers of the Part of the Senate.  

J O I N T E X P L A N A T O R Y S T A T E M E N T O F  
T H E C O M M I T T E E O F C O N F E R E N C E  

The managers on the part of the House and the Senate at the conference on the disagreeing votes of the two Houses on the amendments of the House to the bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes, submit the following joint statement to the House and the Senate in explanation of the effect of the agreement upon the managers and recommended in the accompanying conference report:

The House amendment to the bill struck all of the Senate bill after the enacting clause and inserted a substitute text.

The Senate recedes from its disagreement to the amendment of the House with an amendment to substitute for the Senate bill and the House amendment. The difference between the Senate bill, the House amendment, and the substitute agreed to in conference is the following:

1. The conference agreement provides a continuation of the Prescription Drug User Fee Act of 1992; (2) the improvement of regulation of drugs through such reforms as those pertaining to the pediatric studies of drugs, procedures relating to fast track drugs and market exclusivity; (3) the improvement of regulation of medical devices through such reforms as those pertaining to device standards and data requirements, procedures relating to humanitarian and breakthrough devices, tracking and postmarket surveillance, and accredited party review; (4) the improvement of regulation of medical devices through such reforms as those pertaining to device standards and data requirements, procedures relating to humanitarian and breakthrough devices, tracking and postmarket surveillance, and accredited party review; (5) general provisions pertaining to the dissemination of information about clinical trials of investigational therapies, and consumer access to information about clinical trials of investigational therapies.

Certain matters agreed to in conference are noted below:

T I T L E I — I M P R O V I N G R E G U L A T I O N O F D R U G S  
P r o s c r i p t i o n D r u g U s e F e e A c t ( S u b t i t l e A )  

The conferences believe it is important to place the PDUFA reauthorization provisions of the Senate bill into the context of the legislative agreements which have been put into place by the 1997 Balanced Budget Agree-
Application of Federal law to practice of pharmacy compounding (Sec. 127)

The conference report includes provisions on pharmacy compounding that reflect the conferences' extensive work with the Food and Drug Administration and other interested parties to reach consensus. It is the intent of the conferees to ensure continued availability of compounded drug products as a component of safe and effective therapy, while limiting the scope of compounding so as to prevent manufacturing under the guise of compounding. Section 503A establishes parameters for compounded drugs that are appropriate and lawful. The conditions set forth in Section 503A should be used by the state boards of pharmacy and medicine for proper regulation of compounding in addition to existing state-specific regulations.

The conferees intend that, as defined in subparagraph (b)(2), copies of commercially available drug products do not include drug products in which the change from the commercially available drug product produces a "significant difference" for the particular patient. For example, the removal of a dye from a commercially available drug product for a particular patient who is allergic to such dye shall be presumed to be a "significant difference." The conferees intend that FDA and the courts will accord great deference to the licensed prescriber's judgment in determining whether the change is a "significant difference." However, where it is readily apparent, based on the circumstances, the "significant difference" is a mere pretense to allow compounding of products that are essentially copies of commercially available products, such compounding would be presumed copying of commercially available products and would not qualify for the compounding exemptions if performed regularly or in inordinate amounts. Such circumstances may include, for example, instances in which minor changes in strength (such as from .08% to .09%) are made that are not known to be significant or instances in which the prescribing physician is receiving remuneration or other financial incentives to write prescription for compounded products.

The conferees also expect that the Secretary will not publish a list of bulk drug substances described in subsection (b)(1)(A)(i)(II) within one year from the date of enactment. It is the intent of the conferees to allow compounding of products that are essentially copies of commercially available products if performed only in amounts, including any circumstances under which the conferees believe that this language is necessary to and consistent with improving communication between FDA and regulated persons, increasing regulatory efficiency, and increasing the length of product review and approval.

Premature notification (Sec. 206)

The conference agreement addresses the issue of regulation of devices by ensuring that the impact of the Secretary's necessary review, approval, and oversight functions is not inappropriate. This assurance is achieved by requiring the Secretary to continue, in consultation with an applicant for device approval, the method for evaluating the device's effectiveness, which would appropriately limit the likelihood of any device's approval. The conferees believe that this language is necessary to and consistent with improving communications between FDA and regulated persons. The conferees believe that this language is necessary to and consistent with improving communications between FDA and regulated persons. The conferees believe that this language is necessary to and consistent with improving communications between FDA and regulated persons. The conferees believe that this language is necessary to and consistent with improving communications between FDA and regulated persons. The conferees believe that this language is necessary to and consistent with improving communications between FDA and regulated persons.
that the reports under this section are not required from any manufacturer, importer, or distributor who also is regulated and required to make such reports under the Radiation Control for Health and Safety Act of 1968 (21 U.S.C. 30111).

Practice of medicine (Sec. 214)

The conference agreement includes a provision intended by the conferees to emphasize that the practice of medicine is a practice of science. Specifically, the conferees note that the off-label use of a medical device by a physician using his or her best medical judgment is determined by the American Medical Association and when to use the medical product for the care of a particular patient is not the province of the FDA. It is the intent of the conferees that the FDA not be construed to affect medical professional liability.

TITLE III—IMPROVING REGULATION OF FOOD

Flexibleities for regulations regarding claims (Sec. 301)

The conference agreement clarifies the parameters within which the Secretary may use the authority granted by the existing provisions of the Federal Food Drug and Cosmetic Act (FFDCA) to regulate labeling of foods treated with ionizing radiation. The conferees expect final regulation to the labeling of foods treated with ionizing radiation. The conferees expect final regulation to be issued not more than 12 months after the date of enactment of this measure. The public comment process should be utilized by the Secretary to provide an opportunity for further comments by those interested in the labeling of foods treated with ionizing radiation. It is the intention of the conferees that submission and review of proposed regulations be commenced within 6 months after the enactment of this measure.

Food contact substances (Sec. 309)

The conference agreement establishes a notation process for the regulation of components, known as food contact substances, which is intended to expedite authorization of the marketing of a food contact substance except where the Secretary determines that submission and review of a food additive petition is necessary to provide adequate determination of safety. The agreement also authorizes appropriations to the new notification process. To protect the Agency from having to reallocate resources within CF SAN to meet the costs of implementation, the conference agreement provided that it is to be triggered only when the FDA receives an appropriation sufficient to fund the program. The conferees strongly encourage the House and Senate to continue to fund the effort. The conference also urge the Committees of jurisdiction, when reauthorizing the notification program, to reevaluate fully its operational effectiveness, the adequacy of funding, and its protection of the public health.

Food contact substances (Sec. 309)

On the subject of food contact substances, the conference wishes to commend the FDA and the Environmental Protection Agency (EPA) for developing an Administration policy on the question of returning from FDA to EPA regulatory authority over antimicrobials used as food contact substances. This policy addresses the uncertainty unintentionally created by the Food Quality Protection Act of 1996 (FQPA) over the authority for regulating antimicrobials used as food contact substances. Although the legislative language effectuated by the agreement was considered by the conferees to be outside the scope of this conference, the conferees acknowledge the significant need for this change and urge FDA and EPA to work with the Congress to identify and develop an appropriate and expedient vehicle for action on this matter. In the interim, the conference urges the agencies not to delay active review of pending petitions and the pursuit of the most immediate means to achieve resolution of this jurisdictional issue.

TITLE IV—GENERAL PROVISIONS

Dissemination of treatment information (Sec. 401)

The conference agreement’s inclusion of this section is intended to provide that health care practitioners can obtain important scientific information about uses that are not included in the approved labeling of drugs, biological products, and devices. The conferees also wish to encourage that these new labeling and patient information notices be as voluntary and as comprehensive as possible. Therefore, the agreement includes strong incentives to conduct the research needed and to file a supplemental application for such uses. A manufacturer who seeks to disseminate information about a new use must either certify that it will file a supplemental application or submit a proposed protocol and information in an expedited rulemaking process. The necessary studies and a certification that a supplemental application will be filed.
patients who have failed existing approved therapies.

Information system (Sec. 407)
The conferees intend that the information system shall provide access to the information by the public and to the Committees by the Secretary, except that access shall not be provided under any particular form of information system to any applicant until appropriate safeguards are in place to ensure that integrity and confidentiality of the information for which access is provided.

Education and training (Sec. 408)
The conference agreement authorizes the Centers for Disease Control and Prevention to conduct intramural research to provide fellowships and training to appropriate undergraduate, pre-doctoral, and post-doctoral candidates. In the past, FDA’s Centers have provided for a limited number of scientific training positions through Full Time Equivalent programs or interagency agreements with other federal agencies which have the statutory authority to hire trainees through third parties. However, many of the benefits of the training program have been reduced because FDA has not had the statutory authority to conduct and support them. In light of the additional overhead costs, reduced training flexibility, increased paperwork, and hiring delays that have occurred as a result of these limitations, it is impractical for FDA to hire trainees as FTE Service Fellows. As a result, the Intramural Research and Training Authority is authorized in this conference agreement to provide the FDA the authority to conduct and support directly the training of such candidates as non-FTE positions. The conference agreement also provides similar authority for the Centers for Disease Control and Prevention, Centers for education and research on therapeutics (Sec. 409).

The conference agreement establishes a demonstration program to conduct research and increase awareness of new products and ways to improve their effective use, and to increase awareness of risks of both new uses and combinations of therapies. In carrying out this demonstration program, the Secretary is directed to act through the Agency for Health Care Policy and Research (AHCPR) in coordination with the FDA Commissioner. The conference designated AHCPR as the lead agency because of its expertise in the evaluation of the effectiveness of clinical care, its customary role, and its close working relationship with the health care community in the improvement of the quality of care. Accordingly, this section establishes a new Section 928 in Title IX of the Public Health Service Act, the authorizing statute for AHCPR.

To ensure appropriate coordination and to avoid unnecessary duplication, AHCPR is required to consult closely with the FDA in the development and operation of this demonstration program. The conference expanded the focus of this demonstration to include ways to improve the effective use of drugs, biological products, and devices as well as risks of new combinations of such products and directed that the clinical information gained in the project would be provided to consumers as well as health care practitioners and insurers. Finally, the conference directed AHCPR to consider the appropriate use of products in meeting the purposes of this section.

Environmental impact review (Sec. 411)
The conference believes that FDA’s new procedures under the National Environmental Policy Act (NEPA) appropriately eliminate unnecessary paperwork and delays associated with prior agency practices. Section 411 makes clear that an environmental impact statement (EIS) prepared in accordance with those regulations will meet the requirements of NEPA. The conferees do not intend this section to preclude judicial review of EISs. The conferees understand that the FDA may modify its regulations periodically, in consultation with the Council on Environmental Quality and the FDA’s authorizing committees, as new circumstances or information warrants.

Because the conference agreement authorizes production of limited quantities of Class I and Class II substances for use in medical devices, there will be a continuing, but limited, need to apply for these substances. FDA shall not dictate, promote or otherwise encourage a policy preference for disposal by incineration of the contents of metered-dose inhalers, but instead allow such contents to be recaptured, recycled or reused consistent with Section 600(a)(3) of the Clean Air Act until such time that Congress conducts oversight hearings into the issue.

National uniformity for nonprescription drugs and cosmetics (Sec. 412)
Confidentiality of OTC company self-audits

Public policy should encourage drug manufacturers to conduct audits of their activities that are the potential problems so that they can be addressed quickly and effectively. If FDA were to assert routine access to these audits, it would create an unwarranted burden on drug companies to conduct these appropriate audits and preparing thorough reports of the results. FDA already has a policy of not ordinarily requesting audit records, unless it is determined that the records are necessary to carry out the FDA’s responsibilities.

The conference agreement authorizes the FDA to make clear that OTC drug firms would be subject to the same policies as prescription drug firms. Thus, during routine inspections of OTC drug establishments, FDA would not be expected to request or to review or copy reports and records that result from the firm’s own audits and inspections of its operations to assure compliance with applicable FDA requirements such as good manufacturing practice (GMP) regulations. FDA would reserve the right to review such audits in certain limited circumstances as outlined in the compliance guide.

OTC and cosmetics inspection

The conference intend that FDA exercise its new records inspection authority fairly and carefully, especially with regard to inspections at facilities that manufacture products that are both cosmetics and over-the-counter drugs. Cosmetic products that are also OTC drugs will, under the provisions of this bill, benefit from full national uniformity relating to all regulatory requirements, including those associated with ingredients, labeling, and packaging. Therefore, under these provisions, manufacturers of such OTC products will be subject to records inspection by FDA. The conferees want to make clear that any records inspection applies only to those products for which there is full national uniformity. This new records inspection authority applies only to products determined to be over-the-counter drugs. It does not apply to products that are solely cosmetics.

In the case of an inspection at a facility which produces both cosmetic products that are OTC drugs and those that are not, FDA inspectors do not have access to any records relating to the cosmetic products. Further, the conferees intend that there is no records inspection authority under these provisions for facilities dealing exclusively with cosmetics.

Finally, the conferees intend to make clear that FDA will provide sufficient time and guidance to the over-the-counter drug industry prior to initiating any program of records inspection and in the early stages of implementing this new requirement.

Effect of national uniformity on state enforcement “little FTC” laws

All states have laws prohibiting false and misleading advertising, modeled on the Federal Trade Commission Act. These laws have been applied to prohibitions stated by, for example, the labeling and packaging of, or if they go beyond labeling and packaging, to requirements relating to warnings. Thus, advertising issues relating to claims substantiation, fair balance, and misleading or deceptive claims are outside the scope of preemption.

Effect of national uniformity on state food labeling laws

This provision is not intended to preempt existing State laws from regulating the labeling of food which derives from animals treated with non-prescription drugs. Nor are these provisions intended to void State regulations on the use of these drugs.

Product classification (Sec. 416)

Subsections (b) and (c) have been amended to make clear that FDA may only modify product classifications for public health reasons based on scientific information.

LEAVE OF ABSENCE

By unanimous consent, leave of absence was granted to:

Mr. UNDERWOOD (at the request of Mr. GEPHARDT) for today and the balance of the week, on account of official business.

Mr. YATES (at the request of Mr. GEPHARDT) for November 8 after 12 noon and November 9, on account of personal reasons.

SENATE BILLS AND CONCURRENT RESOLUTION REFERRED

Bills and a concurrent resolution of the Senate of the following titles were taken from the Speaker’s table and, under the rule, referred as follows:

S. 501: An act to provide for the relief of Mai Hoa “Jasmine” Salehi; to the Committee on the Judiciary.