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 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, 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 as follows:

In lieu of the matter proposed to be inserted by the House amendment, insert the following:

SECTION 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, whenever 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:

Sec. 1. Short title; references; table of contents.
Sec. 2. Definitions.

TITLE I—IMPROVING REGULATION OF DRUGS

Subtitle A—Fees Relating to Drugs
Sec. 101. Findings.
Sec. 102. Definitions.
Sec. 103. Authority to assess and use drug fees.
Sec. 104. Annual reports.
Sec. 105. Savings.
Sec. 106. Effective date.
Sec. 107. Termination of effectiveness.

Subtitle B—Other Improvements
Sec. 111. Pediatric studies of drugs.
Sec. 112. Expediting study and approval of fast track drugs.
Sec. 113. Information program on clinical trials for serious or life-threatening diseases.
Sec. 114. Health care economic information.
Sec. 115. Clinical investigations.
Sec. 116. Medical device changes for drugs.
Sec. 117. Streamlining clinical research on drugs.

Sec. 118. Data requirements for drugs and biologics.
Sec. 119. Content and review of applications.
Sec. 120. Scientific advisory panels.
Sec. 121. Positron emission tomography.
Sec. 122. Requirements for radiopharmaceuticals.
Sec. 123. Modernization of regulation.
Sec. 124. Pilot and small scale manufacture.
Sec. 125. Insulin and antibiotics.
Sec. 126. Elimination of certain labeling requirements.
Sec. 127. Application of Federal law to practice of pharmacy compounding.
Sec. 128. Reauthorizing of clinical pharmacology program.
Sec. 129. Regulations for sunscreen products.
Sec. 130. Reports of postmarketing approval studies.
Sec. 131. Notification of discontinuance of a life saving product.

TITLE II—IMPROVING REGULATION OF DEVICES

Sec. 201. Investigational device exemptions.
Sec. 202. Special review for certain devices.
Sec. 203. Expanding humanitarian use of devices.
Sec. 204. Device standards.
Sec. 205. Scientific advisory review; collaborative determinations of device data requirements.
Sec. 206. Premarket notification.
Sec. 207. Establishment of a premarket notification; premarket notification process.
Sec. 208. Classification panels.
Sec. 209. Certification of review timeframes; collaborative review process.
Sec. 211. Device tracking.
Sec. 212. Postmarket surveillance.
Sec. 213. Reports.
Sec. 214. Practice of medicine.
Sec. 215. Noninvasive blood glucose meter.
Sec. 216. Use of human tissue in devices.

TITLE III—IMPROVING REGULATION OF FOOD

Sec. 302. Petitions for claims.
Sec. 303. Nutrient content claims.
Sec. 304. Health claims for food products.
Sec. 305. Referral statements.
Sec. 306. Disposal of irradiation.
Sec. 307. Irradiation petition.
Sec. 308. Glass and ceramic ware.
Sec. 309. Food contact substances.

TITLE IV—GENERAL PROVISIONS

Sec. 401. Dissemination of information on new uses.
Sec. 402. Expanded access to investigational therapies and diagnostics.
Sec. 403. Availability of supplemental applications for approved products.
Sec. 404. Dispute resolution.
Sec. 405. Informal agency statements.
Sec. 406. Food and Drug Administration mission and annual report.
Sec. 407. Information system.
Sec. 408. Education and training.
Sec. 409. Centers for education and research on therapeutics.
Sec. 410. Mutual recognition agreements and global harmonization.
Sec. 411. Environmental impact review.
Sec. 412. National uniformity for nonprescription drugs.
Sec. 413. Food and Drug Administration study of mercury compounds in drugs and food.
Sec. 414. Interagency collaboration.
Sec. 415. Contracts for expert review.
Sec. 416. Product classification.
Sec. 417. Registration of foreign establishments.
Sec. 418. Clarification of seizure authority.
Sec. 419. Interstate commerce.
Sec. 420. Safety report share arrangements.
Sec. 421. Labeling and advertising regulations.

Sec. 422. Rule of construction.

TITLE V—EFFECTIVE DATE

Sec. 501. Effective date.

SEC. 2. DEFINITIONS.

In this Act, the terms "drug", "device", "food", and "dietary supplement" have the meaning defined in the chapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).
(l) in the subparagraph heading, by striking "NOT ACCEPTED" and inserting "REFUSED";
(ii) by striking "50 percent" and inserting "75 percent";
(iii) by striking subparagraph (B)(ii) and inserting subparagraph (B);
(iv) by striking "not accepted" and inserting "refused";
(v) by adding at the end the following:
"(E) EXCEPTION FOR DESIGNATED ORPHAN DRUG OR INDICATION.—A human drug application proposing to include in an application for a drug that has already been designated as a drug for a rare disease or condition pursuant to section 526 shall not be subject to a fee under subparagraph (A), if the application includes an indication for a rare disease or condition. A supplement proposing to include a new indication for a rare disease or condition in a human drug application shall be not 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.";
(ii) by striking "employees under contract" and inserting "and committees and to contracts with such contractors of the Food and Drug Administration,";
(iii) by striking "all that follows through "Administration," and inserting the following:
"and committees and to contractors, as described in subparagraph (D), of a large volume biological product intended for single dose injection for intravenous use or infusion;"
(ii) by striking "and committees" and inserting "and committees and to contracts with such contractors of the Food and Drug Administration;"
(iii) by striking "and committees" and inserting "and committees and to contracts with such contractors of the Food and Drug Administration;"
(ii) by striking "Aug. 1, 1992" and inserting "Aug. 1, 1992";
(iii) by striking "April of" and inserting "April of";
(ii) by striking "and committees, particularly those" and inserting "and committees, particularly those";
(i) by striking "section 254(d)" and inserting "section 254(d);
(i) by striking "employees under contract" and inserting "and committees and to contracts with such contractors of the Food and Drug Administration;"
(ii) by striking "employees under contract" and inserting "and committees, particularly those;"
(i) by striking "section 254(d)" and inserting "section 254(d);
(i) by striking "section 254(d)" and inserting "section 254(d);
(i) by striking "section 254(d)" and inserting "section 254(d);
(i) by striking "affiliated''" and inserting "affiliated";
appropriated for such fiscal year)''.

``fiscal year 1997''; and

U.S.C. 379h(f)(1)) is amended—

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

``(1) D EFINITION.ÐIn paragraph (1)(E), the Secretary may

findings in paragraph (1)(C), the Secretary may

``standard costs.'' and inserting the following:

``submitting its first human drug application to

the Secretary for review.''; and

(2) by striking ``The Secretary shall grant a''

and all that follows through ``finds that''— and inserting the following:

``(1) I N GENERAL.—The Secretary shall grant a

waiver from or a reduction of one or more fees
 assessed under subsection (a) where the Secre-

tary finds that—

(3) in subparagraph (C) (as so redesignated in

paragraph (1)), by striking ", or'' and inserting a comma;

(4) in subparagraph (D) (as so redesignated in

paragraph (1)), by striking the period by inserting and'';

(5) by inserting after subparagraph (D) (as so

redesignated in paragraph (1)) the following:

``(E) The applicant involved is a small business

submitting its first human drug application to

the Secretary for review.''; and

(6) by striking paragraph (0) (as redesignated

in paragraph (3), and all that follows through

``standard costs,''' and inserting the following:

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

use standard costs.

``(3) R OLES RELATING TO SMALL BUSINESSES.—

(A) In paragraph (1)(E), the term 'small business'

means an entity that has fewer than 500 employees, including employees of affiliates.

(B) W AIVER OF APPLICATION FEE.—The Secre-

tary shall waive under paragraph (1)(E) the

application fee for the first human drug

application that a small business or its affiliate sub-

mits to the Secretary for review. After a small

business or its affiliate is granted such a waiver,

the small business or its affiliate shall pay— (i) fee assessments for all subsequent human

drug applications submitted to the Secretary for

review in the same manner as an entity that
does not qualify as a small business; and

(ii) all supplement fees for all supplements to

human drug applications submitted to the

Secretary for review in the same manner as an

etity that does not qualify as a small business.''

The amendments made by this subtitle shall

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

certifies that the drug may be used in 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 (1) a timeframe for

completing such studies, and such studies are

completed within any such timeframe and the

report referred to therein submitted in accordance

with subsection (d)(2) or accepted in accordance with

subsection (d)(3) —

``(1)(A)(i) the period referred to in subsection

(c)(3)(D)(i) of section 505, is deemed to be five

years and six months rather than five years,

and the references in subsections (c)(3)(D)(ii) and

(j)(4)(D)(i) 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;

and

(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 three years; and

(B) if the drug is designated under section

526 for a rare disease or condition, the period

referred to in subsection 526 is deemed to be seven

years and six months rather than seven years;

and

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

(i) a listed patent for which a certification has

been submitted under subsection (b)(2)(A)(i) or

(j)(2)(A)(vi)(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)(i) or

(j)(2)(A)(vi)(ii) of section 505 and in subsections (b)(2)(A)(i) or (j)(2)(A)(vi)(ii) of such section, the period during which a

application may not be approved under section 505(c)(3) or section 505(i)(1)(B) shall be extended by a period of six months after the date the patent expires (including any patent
extensions); or

(B) if the drug is the subject of a listed

patent for which a certification has been submitted

under subsection (b)(2)(A)(i) or (j)(2)(A)(vi)(ii) of section 505 and in subsections (b)(2)(A)(iii) or (j)(2)(A)(viii)(iii) of section 505,

the period during which an application may not

be approved under section 505(c)(3) or section

505(i)(1)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).

``(1)(A)(i) if the drug is the subject of—

(ii) a listed patent for which a certification has

been submitted under subsection (b)(2)(A)(i) or

(j)(2)(A)(vi)(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)(i) or

(j)(2)(A)(vi)(ii) of section 505 and in subsections (b)(2)(A)(i) or (j)(2)(A)(vi)(ii) of such section, the period during which a

application may not be approved under section 505(c)(3) or section 505(i)(1)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

(B) if the drug is the subject of a listed

patent for which a certification has been submitted

under subsection (b)(2)(A)(i) or (j)(2)(A)(vi)(ii) of section 505 and in subsections (b)(2)(A)(iii) or (j)(2)(A)(viii)(iii) of section 505,

the period during which an application may not

be approved under section 505(c)(3) or section 505(i)(1)(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.

"(1) The list referred to in subsection (c)(3)(D)(ii) of section 505, and in subsection (j)(4)(D)(ii) of such section, is deemed to be five years after the date the patent expires, rather than three years, and the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of such section to four years, to forty-eight months, and to seven and one-half years, respectively, shall be deemed to have been running during any such timeframe, and the reports thereof are submitted in accordance with subsection (d)(2) or accepted in accordance with subsection (d)(3)."

"(2) If the drug is the subject of—

(a) a written request to the holder of an approved application under section 505(b)(1) for pediatric studies which have not yet been completed (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)(2) or accepted in accordance with subsection (d)(3); or

(b) a written request to the holder of an approved application under section 505(b)(2) or 505(j) until the determination under this section is satisfied, except that such determination may be made at any time after the receipt of a request under paragraph (1)."

"(3) the economic impact of the program on taxpayers and consumers, including the impact of the program on lower cost and lower income patients, including on lower income patients; and

(4) any suggestions for modification that the Secretary determines would be beneficial.

SEC. 112. EXPANDING 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 designation may be made concurrently with, or at any time after, submission of an application for approval of the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

"(3) 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 criteria are met, 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.

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

"(1) In General.—The Secretary may approve 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) Approval Limitation.—Approval of a fast track product under this subsection may be subject to the requirements—

(a) that the sponsor conduct appropriate postapproval studies to determine whether the clinical endpoint or otherwise confirm the effect on the clinical endpoint; and

(b) that the sponsor submit copies of all postmarketing 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 thereof).

(4) TOLL-FREE TELEPHONE COMMUNICATIONS.—In the case of a product that is intended for serious or life-threatening diseases, the Secretary shall provide for toll-free telephone communications, available to the public, relating to the safety and efficacy of the product, including information about the risks and benefits of the product.

(5) RECORDING.—The Secretary shall maintain a record of any communications received under this paragraph.

(6) CAREER OPPORTUNITIES.—The Secretary shall provide career opportunities for individuals with disabilities who are interested in working on the development and approval of fast track products.

(7) REPORT.—Not later than two years after the date of enactment of this section, the Secretary shall submit a report to the Committee on Labor and Human Resources of the Senate relating to the implementation of the provisions of this section, including information on the number of fast track products approved and the impact of such products on the prevention and treatment of serious or life-threatening diseases.

SEC. 113. INFORMATION PROGRAM ON CLINICAL TRIALS FOR SERIOUS OR LIFE-THREATENING DISEASES.

(a) IN GENERAL.—Section 402 of the Public Health Service Act (42 U.S.C. 782) is amended—

(b) IN GENERAL.—Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 736 of the Federal Food, Drug, and Cosmetic Act, a new subsection as the Secretary determines to be appropriate, on the inclusion of women and minorities in clinical trials.

(c) STUDY AND REPORT.—The Comptroller General of the United States shall conduct a study of the implementation of the provisions of this section, including an assessment of the extent to which women and minorities are included in clinical trials. The report shall be submitted to the Congress and the Secretary of Health and Human Services not later than two years after the date of enactment of this Act.

SEC. 114. HEALTH CARE ECONOMIC INFORMATION.

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

(b) IN GENERAL.—Section 502(a) (21 U.S.C. 352(a)) is amended by inserting after section 736 of the Federal Food, Drug, and Cosmetic Act, a new subsection as the Secretary determines to be appropriate.
CHANGES.—For purposes of subsection (a)(2)(A), subparagraph (A) applies and categories to changes.

II. AUTHORITY REGARDING ANNUAL REPORTS.—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 the 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 findings of the Secretary as determines to be appropriate, and shall include the information developed under subsection (b) by the holder in validating the effects of the change.

III. MAJOR MANUFACTURING CHANGES.—For purposes of subsection (a)(2)(A), a major manufacturing change is a manufacturing change that is determined by the Secretary to be material to advance the drug by affecting the identity, strength, quality, purity, or potency of the drug as they relate to the safety or effectiveness of the drug. Such a change includes changes by the Secretary by regulation or guidance to have substantial potential to adversely affect the safety of the persons who are to be administered, or any controls used in connection therewith, and

(a) is made in the qualitative or quantitative formulation of the drug involved or in the specifications in the approved application or license referred to in paragraph (A) for the drug, unless exempted by the Secretary by regulation or guidance from the requirements of this subsection;

(b) is determined by the Secretary by regulation or guidance to require completion of an appropriate clinical study demonstrating equivalence of the drug to the drug as manufactured without the change; or

(c) is another type of change determined by the Secretary by regulation or guidance to have a substantial potential to adversely affect the safety or effectiveness of the drug.

IV. OTHER MANUFACTURING CHANGES.—

(a) In general.—For purposes of subsection (a)(2)(A), the Secretary may regulate drugs made with manufacturing changes that are not major manufacturing changes as follows:

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

(2) The Secretary in accordance with paragraph (1) may regulate drugs made with manufacturing changes that are not major manufacturing changes as follows:

(A) The Secretary may in accordance with paragraph (2) authorize holders to distribute such drugs, without submitting a supplemental application for such changes, if the Secretary determines that, prior to the distribution of such drugs, holders submit to the Secretary supplemental applications 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, if the Secretary determines that, prior to the distribution of such drugs, holders submit to the Secretary supplemental applications 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.

(3) Changes not requiring supplemental application.—

(A) Submission of report.—A holder making a manufacturing change 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 necessary for the safety of the persons who are to be administered, and which shall include the information developed under subsection (b) by the holder in validating the effects of the change. The report shall be submitted by such holder within 30 days of the date of such change.

(B) Authority regarding annual reports.—In the case of a holder that during a single year makes more than one manufacturing change to which paragraph (1)(A) applies, the Secretary may in carrying out subparagraph (A) authorize the holder to comply with such subparagraph with respect to one change for the year that provides the information required in such subparagraph for all the changes made by the holder during the year.

(C) Changes requiring supplemental application.—

(A) Submission of supplemental application. The supplemental application required under paragraph (1)(B) for a manufacturing change shall contain such information as the Secretary determines to be appropriate, which shall include such information developed under subsection (b) by the holder in validating the effects of the change.

(B) Authority for distribution.—In the case of a manufacturing change to which paragraph (1)(B) applies:

(i) the holder involved may commence distribution of the drug involved 30 days after the Secretary receives the supplemental application under such paragraph, unless the Secretary notifies the holder within such 30-day period that prior approval of the application is required before distribution may be commenced

(ii) the Secretary may designate a category of such changes for the purpose of providing the data necessary to establish such category, in the case of a major manufacturing change, the holder involved may commence distribution of the drug involved upon the receipt by the Secretary of a supplemental application for the change

(iii) if the Secretary disapproves the supplemental application, the Secretary may order the manufacturer to cease the distribution of the drugs that have been made with the manufacturing change.

(2) Transition rule.—The amendment made by subsection (a)(2)(A) shall apply to a change to which paragraph (1)(A) applies if the Secretary has received from the manufacturer or sponsor that change before the date of enactment of this Act.

(3) Changes requiring supplemental application. The Secretary may in carrying out subparagraph (A) of paragraph (1) make appropriate findings in writing, including

(i) 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 was administered, and the health status of the subjects involved;

(ii) the clinical hold should be issued for such other reason 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).

(4) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing, specifying the information developed therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

(5) Regulations under 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 being administered, or any controls used in connection therewith, 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 required to be given to the best interests of such human beings.

(6) In this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.
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—

(iii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(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.

A decision under subparagraph (C)(iii) by the director shall be in writing and may not directly or indirectly be changed by the field or compliance division 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 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), 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 (3), 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, the Secretary, and the administrative processes and procedures related to panel meetings.

(6) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation for each day so engaged, including traveltime, at rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above grade GS-15 of the General Schedule. While serving as a member of any panel established under part D of title II of the Act, panel members may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5705 of title 5, United States Code, except that the Government service employment intentionally.

(7) The Secretary shall ensure that scientific advisory panels meet regularly and at appropriate intervals so that no matter to be reviewed by such a panel can be presented to the panel not more than 60 days after the matter is ready for such review. Meetings of the panel may be held using electronic communication to convene the meetings.

(8) Within 90 days after a scientific advisory panel makes recommendations on any matter under review, the Federal administration 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 for no such decision has been reached. Each such final decision shall be documented including the rationale for the decision.

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 information and recommendations 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 appointing and oversight authority granted under section 904 to a director of a center or successor entity within the administrative structure.

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

(A) members selected by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the design, manufacture, or utilization of such drugs;

(B) members with diverse expertise in such fields as clinical and administrative medicine, pharmacology, pharmacoconomics, biological and physical sciences, and other related professions;

(C) representatives of consumer interests, and of the interests of the drug manufacturing industry not directly affected by the matter to be brought before the panel; and

(D) two or more members who are specialists or have other expertise in the particular disease or condition for which the drug under review is proposed to be indicated.

Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employment of the United States and engaged in the administration of the affairs of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

(4) Each member of a panel shall publicly disclose all conflicts of interest that may have with the work to be undertaken by the panel. No member of a panel may vote on any matter where the member or the immediate family of such member could gain financially from the advice given to the Secretary. The Secretary may not grant a waiver for a member of a panel when the member's own scientific work is involved.

(5) The Secretary shall, as appropriate, provide education and training to each panel member before such member participates in a panel's activities, including education regarding requirements under this Act and related regulations and the administrative processes and procedures related to panel meetings.

(6) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation for each day so engaged, including traveltime, at rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above grade GS-15 of the General Schedule. While serving as a member of any panel established under part D of title II of the Act, panel members may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5705 of title 5, United States Code, except that the Government service employment intentionally.
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 drug as it purports to be or represents to be, and that it purports or is represented to possess; or (3)

(2) SUNDAY.—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:

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

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

(B) E XCEPTION.ÐNothing in this Act shall require the submission of new drug applications or abbreviated new drug applications under subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for processing or approval of the following:

(i) biologics license applications under subsection (a) of section 351 of the Public Health Service Act (42 U.S.C. 262), unless an approved application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is required by the Secretary of Health and Human Services to be submitted for the approval of these drugs.

(ii) an application under section 351 of the Public Health Service Act (42 U.S.C. 262) for the approval of a biologics license under section 351(k) of the Public Health Service Act (42 U.S.C. 262), as amended by this Act.

(iii) an application for a license under subsection (a) of section 351 of the Public Health Service Act (42 U.S.C. 262) for the approval of a biological product for which a license has been approved under subsection (a) of section 351 of the Public Health Service Act (42 U.S.C. 262), as amended by this Act.

(iv) an application under section 351 of the Public Health Service Act (42 U.S.C. 262) for the approval of a biological product for which a license has been approved under subsection (a) of section 351 of the Public Health Service Act (42 U.S.C. 262), as amended by this Act.

(v) an application under section 351 of the Public Health Service Act (42 U.S.C. 262) for the approval of a biological product for which a license has been approved under subsection (a) of section 351 of the Public Health Service Act (42 U.S.C. 262), as amended by this Act.

(vi) an application under section 351 of the Public Health Service Act (42 U.S.C. 262) for the approval of a biological product for which a license has been approved under subsection (a) of section 351 of the Public Health Service Act (42 U.S.C. 262), as amended by this Act.

(b) D EFINITION.ÐAs used in this section, the term `biological product' means—

(1) an article that is intended to be used for the introduction into the body of man or other animal for the prevention, diagnosis, or treatment of disease, or for altering the structure or function of the body of man or other animal and that does not attain its effects from chemical or physical properties, other than those affecting the viability or growth of virus, bacteria, and other microorganisms, of the body of man or other animal in which it is administered.

(2) a product for which a license has been approved under section 351(k) of the Public Health Service Act (42 U.S.C. 262), as amended by this Act.

(3) the commercial product of the biological product referred to in paragraph (1) or (2) of this section.

(c) REQUIREMENTS FOR RADIOPHARMACEUTICALS

(1) REQUIREMENTS.—

(A) PROPOSED REGULATIONS.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services, after consultation with patient advocacy groups, associations, physicians licensed to use radiopharmaceuticals, and the regulated industries, shall propose new 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 of the radiopharmaceutical (including any carrier or ligand component of the radiopharmaceutical), and the estimated absorbed radiation dose of the radiopharmaceutical.

(B) F I N A L 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 such radiopharmaceutical is approved for marketing may, in appropriate cases, refer to manifestations of disease (such as biochemical, physiological, anatomical, or pathological processes) common to, or present in, one or more disease states.

(d) E NFORCEMENT.ÐThe Secretary of Health and Human Services shall enforce the provisions of this section, and revocation of biologics licenses issued in accordance with subsection (c).

(e) C O NFORMING AMENDM ENT.ÐSection 353(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(i)(4)) is amended—

(1) in subparagraph (A) by striking `biological product' and inserting `biological product shall not be required to human prescribing physicians to request a sample of a biological product for which a license has been approved under subsection (a) of section 351 of the Public Health Service Act (42 U.S.C. 262)'; and

(2) in subparagraph (B) by striking `biological product' and inserting `biological product that is 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.'
(h) Examinations and procedures.—Paragraph (3) of section 353(d)(3) of the Public Health Service Act (42 U.S.C. 263d(a)) is amended to read as follows:

"(3) If the investigations relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of referral, then the Secretary shall notify the applicant who is to be responsible for the investigations conducted.

(3) Publication.—For purposes of this section, the Secretary is authorized to make available to the public the established name of each antibiotic drug that was the subject of any application for marketing received by the Secretary for Health and Human Services under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357) before the date of enactment of this Act.

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

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

(2) COMPOUNDED DRUG.—

(A) LICENSED PHARMACIST AND LICENSED PHYSICIAN.—A drug may be compounded under subsection (a) if the licensed pharmacist or licensed physician—

(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations—

(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 drug substances that are components of drugs approved by the Secretary under section 505(i), and

(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 published by the Secretary in the Federal Register a drug product in which there is a change, made as determined by the prescribing practitioner, for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.

(B) compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because of safety or therapeutic concerns, or that the drug product is one that has been found to be unsafe or not effective; and

(D) is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of the drug product; and

(E) such drug product is compounded in a State—

(i) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for an investigation by the State agency of complaints relating to compounded drug products distributed outside such State; or

(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) the drug products outside the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such practitioner.

The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)."

"(3) DRUG PRODUCT.—

(A) I N GENERAL.—The Secretary shall—

(1) adopt regulation, a report for such an agreement shall be submitted within 6 months after the date of the issuance of the regulations under paragraph (1).

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

(i) to identify the sponsor; and

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

(C) STATUS OF STUDIES AND REPORTS.—The Secretary shall annually publish in the Federal Register a report containing—

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

(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.

SECT. 131. REAUTHORIZATION OF CLINICAL PHARMACOLOGY PROGRAM.

Section 2 of Public Law 102-222 (105 Stat. 1677) is amended—

(1) in subsection (a), by striking "a grant" and all that follows through "designated...medical schools. Such grants;" and

(2) in subsection (b), by striking "to carry out this section" and inserting "for fiscal years 1998 through 2000 $3,000,000 for each fiscal year, to carry out this section".

SEC. 129. REGULATIONS FOR SUNSCREEN PRODUCTS.

Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue regulations for over-the-counter sunscreen products for the prevention or treatment of sunburn.

SECT. 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.

(b) 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 Administration Modernization Act of 1997, to conduct a postmarketing study of a drug shall be subject to the requirements of paragraph (1)."

"SEC. 132. DISCONTINUATION OF A LIFE SAVING PRODUCT.

(a) IN GENERAL.—A manufacturer that is the sole manufacturer of a drug—

(1) that is—

(A) life-saving; or

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

(2) for which an application has been approved under section 506(b) or 506(j), and

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

(i) to identify the sponsor; and

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

(c) STATUS OF STUDIES AND REPORTS.—The Secretary shall annually publish in the Federal Register a report containing—

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

(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.

SECT. 131. NOTIFICATION OF DISCONTINUATION 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. 506B. NOTIFICATION OF DISCONTINUATION OF A LIFE SAVING PRODUCT.

(a) IN GENERAL.—A manufacturer that is the sole manufacturer of a drug—

(1) that is—

(A) life-saving; or

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

(2) for which an application has been approved under section 506(b) or 506(j), and

(3) that is not a 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.

(2) REDUCTION IN NOTIFICATION PERIOD.—The notification period required under subsection (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 where

(1) a public health problem may result from the discontinuance of the manufacturing for the 6-month period;

(2) the materials shortage prevents the continuation of the manufacturing for the 6-month period;

(3) a liability problem may exist for the manufacturer if the manufacturing is continued for the 6-month period;

(4) the manufacturer may continue the distribution of the drug involved for 6 months.

(c) DISTRIBUTION.—To the maximum extent practicable, the Secretary shall distribute information on the discontinuation of the drug in subsection (a) to appropriate physicians and patient organizations.

TITLe II—IMPROVING REGULATION OF HUMAN SUBJECTS

SEC. 201. INVESTIGATIONAL DEVICE EXEMPTIONS.

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

``(6)(A) Not later than 1 year after the date of enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall establish, with respect to a device for which an exemption under this subsection is in effect, procedures and conditions that, without requiring an additional approval of an investigational device exemption for the manufacturer, or the approval of a supplement to such an application, permit—

(i) developmental changes in the device (including manufacturing changes) that do not constitute a significant change in design or in basic principles of operation and that are made in response to information gathered during the course of the investigations; and

(ii) changes or modifications to clinical protocols that do not affect—

(I) validity of data or information resulting from the completion of an approved protocol, or the relationship of likely patient risk to benefit relied upon to approve a protocol;

(ii) the soundness of an investigational plan submitted under paragraph (3)(A); or

(iii) the rights, safety, or welfare of the human subjects involved in the investigation.

(B) Regulations under subparagraph (A) shall provide that a change or modification described in such subparagraph may be made if—

(i) the investigation determines, on the basis of credible information (as defined by the Secretary) that the applicable conditions under subparagraph (A) are met; and

(ii) the sponsor submits to the Secretary, not later than 5 days after making the change or modification, a notice of the change or modification.

(7)(A) In the case of a person intending to investigate the safety or effectiveness of a class III device or any implantable device, the Secretary shall ensure that the person has an opportunity to submit an application to the Secretary or to an institutional review committee, to submit to the Secretary, for review, an investigational plan (including a clinical protocol). If the Secretary, not later than 30 days after receiving the request, meet with the applicant for the purpose of reaching agreement regarding the investigational plan (including a clinical protocol). The written request shall include—

(i) a proposed clinical protocol, a detailed description of the proposed conditions of use of the device, a proposed plan (including a clinical protocol) for determining whether there is a reasonable assurance of effectiveness, and, if available, information regarding the expected performance of the device.

(B) Any agreement regarding the parameters of an investigational plan (including a clinical protocol) 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.

(C) A decision to authorize an investigational plan shall not be changed, except—

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

(ii) pursuant to a decision, made in accordance with subparagraph (C) by the director of the office in which the device involved is reviewed, that a substantial scientific issue essential to determining the safety or effectiveness of the device involved has been identified.

(D) A decision under subparagraph (B)(ii) by the director shall be in writing, and may be made available to the sponsor or applicant for an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director and the sponsor or applicant make a joint determination as to whether the device involved meets the conditions of subparagraph (B) or (C).

(a) ACTION ON APPLICATION.—Section 513(d)(1)(B) (21 U.S.C. 360e(d)(1)(B)) is amended by adding at the end the following:

``(ii) The Secretary shall accept and review statistically valid and reliable data and any other information from investigations conducted under the authority of regulations required by section 520(g) to make a determination of whether there is a reasonable assurance of safety and effectiveness of a device subject to a pending application under this section;

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

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

SEC. 202. SPECIAL REVIEW FOR CERTAIN DEVICES.

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

(1) by redesignating paragraph (3) as paragraph (4); and

(2) by adding at the end the following:

``(5) In order to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions, the Secretary shall provide review priority for devices—

(A) representing breakthrough technologies;

(B) for which no approved alternatives exist, or

(C) which offer significant advantages over existing approved alternatives, or

(D) the availability of which is in the best interest of the patients.''

SEC. 203. EXCLUSTING HUMANITARIAN USE OF DEVICES

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

(1) by adding after and below subparagraph (C) the following sentences:—

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

(2) in paragraph (4)—

``(A) In subparagraph (B), by inserting after ''(2)(A)'' the following: ''. unless a physician determines in an emergency situation that approval of a local institutional review committee, the physician shall, after the use of the device, notify the chairperson of the local 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 of the device.''; and

(3) by amending paragraph (5) to read as follows:

``(5) The Secretary may suspend or withdraw an exemption from the effectiveness requirements of sections 514 and 515 for a humanitarian device only after providing notice and an opportunity for an informal hearing.''

SEC. 204. DEVICE STANDARDS.

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

``(b) Recognition of a Standard

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

 (B) If a person elects to use a standard recognized by the Secretary under subparagraph (A) to meet the requirements described in such subparagraph, the person shall submit a declaration of conformity to the Secretary that certifies that the device is in conformity with such standard. A person may elect to use data, or information from other than an appropriate standard recognized under subparagraph (A) to meet any requirement regarding devices under this Act.

 (2) The Secretary may withdraw such recognition of a standard through publication of a notice in the Federal Register if the Secretary determines that the standard is no longer appropriate for meeting a requirement regarding devices under this Act.

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

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

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

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

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

(b) Section 801—Section 801 (21 U.S.C. 331) is amended by adding at the end the following:

(2) by inserting at the end the following:

(iii) The determination of the Secretary with respect to the effectiveness of a device that is intended for a use which is of substantial importance in preventing impairment of human health, or of the health of the medical condition that presents a potential unreasonable risk of illness or injury.

(2) Beginning on the date that is 1 day after the date of enactment of the Food and Drug Administration Modernization Act of 1997:

(a) Section 515(d)—Section 515(d) (21 U.S.C. 360d) is amended by adding after subsection (b) the following:

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

(ii) The holder of an approved application who submits a notice under clause (i) with respect to a nonclinical change, or a manufacturing change of a device that may distribute 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 supplement within 135 days after the receipt of the supplement. The time used by the Secretary to review the notice of the manufacturing change shall be deducted from the 135-day review period if the notice meets appropriate content requirements for premarket approval supplements.

(iii) Nonclinical data demonstrate that the design modification creates the intended additional capacity, function, or performance of the device.

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

SEC. 206. SCOPE OF REVIEW; COLLABORATIVE DETERMINATIONS OF DEVICE DATA REQUIREMENTS.

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

(i) any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 510(k).

(ii) Any clinical data, including one or more well-controlled investigations, specified in a report under subsection (k) to provide a reasonable assurance of safety and effectiveness. Each type of class II device that does require a report under subsection (k) to provide a reasonable assurance of safety and effectiveness.

SEC. 207. PREMARKET NOTIFICATION.

(a) Section 510—Section 510 (21 U.S.C. 360) is amended by adding after paragraph (1), in the second sentence, the following:

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

(b) Section 512—Section 512 (21 U.S.C. 360b) is amended by adding after paragraph (5), in the matter preceding paragraph (6), the following:

(2) Beginning on the date that is 1 day after the date of enactment of the Food and Drug Administration Modernization Act of 1997:

(i) any determination by the Secretary or a report to the Secretary could be contrary to the public health.

(II) clinical data from the approved application and any supplement to the approved application provide a reasonable assurance of safety and effectiveness for the device.
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) subsection (f) of section 513(f) of this Act and making a determination of the initial classification of a device for purposes of a determination of substantial equivalence under subsection (f) or of such device for purposes of the Food and Drug Administration Modernization Act of 1997, the Secretary shall issue guidance specifying the general principles and procedures to be followed in making such determinations. Such guidance shall be published in the Federal Register after the Secretary, on the basis of a written request submitted to the Secretary for prompt transmittal to the classification panel; and

(ii) the same access to data and information submitted to a classification panel (except for data and information that are not available for public disclosure under section 352 of title 5, United States Code) as the Secretary; and

(iii) the opportunity to submit, for review by a classification panel, information that is based on the data and information in the record in the docket or otherwise provided to the Secretary in the application submitted under section 515 by the person, which information shall be submitted to the Secretary for prompt transmittal to the classification panel.

(b) Any meetings of a classification panel shall be open to the public. The Secretary shall encourage and open participation by all interested persons.

(2) After receiving a classification panel's conclusions and recommendations on a matter, the Secretary shall review the conclusions and recommendations, make a final decision on the matter in accordance with section 515(d)(2), and notify all interested persons of the decision in writing and, if the decision differs from the conclusions and recommendations of the panel, shall include the reasons for the difference.

(b) A classification panel under this subsection shall not be subject to the annual chartering and annual report requirements of the Federal Advisory Committee Act.

(c) Special rule. The Secretary may amend or rescind any classification panel's recommendation in writing and, if the decision differs from the recommendations of the panel, shall include the reasons for the difference.

(b) A classification panel under this subsection shall not be subject to the annual chartering and annual report requirements of the Federal Advisory Committee Act.

(2) By redesigning paragraphs (2) and (3) as paragraphs (3) and (4), respectively; and

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

(ii) the same access to data and information submitted to a classification panel (except for data and information that are not available for public disclosure under section 352 of title 5, United States Code) as the Secretary.

(c) CERTAINTY OF REVIEW TIMEFRAMES; COLLABORATIVE REVIEW PROCESS.

(a) CERTAINTY OF REVIEW TIMEFRAMES. The Secretary shall establish and publish in the Federal Register announcing such classification.

(b) COLLABORATIVE REVIEW PROCESS. The Secretary shall establish and publish in the Federal Register announcing such classification.

(b) ACCREDITATION.

(1) Programs. The Secretary shall establish and publish in the Federal Register announcing such classification.

(2) Accreditation. The Secretary shall establish and publish in the Federal Register announcing such classification.

(b) IN GENERAL. Not later than 180 days after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall establish and publish in the Federal Register criteria to accredit or deny accreditation to persons who request to perform the duties specified in subsection (a). The Secretary shall respond to a request for accreditation within 60 days of the receipt of the request. The accreditation of such person shall specify the particular activities under subsection (a) for which the person is accredited.

(B) WITHDRAWAL OF ACCREDITATION. The Secretary may suspend or withdraw accreditation of any person accredited under this paragraph for cause, including providing the opportunity for an informal hearing, when such person is substantially not in compliance with the
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 on-site 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 shall prescribe.

(D) ANNUAL REPORT.—The Secretary shall include in the annual report required under section 903(g) the names of all accredited persons who shall be included in the annual report required under section 212 of this Act for at least 35 percent of the persons accredited under this section.

(8) Qualifications.—An accredited person shall, at a minimum, meet the following requirements:

(A) Such person may not be an employee of the Federal Government.

(B) Such person shall be an independent organization which is not owned or controlled by a manufacturer, supplier, or vendor of devices and which has no organizational, material, or financial affiliation with such a manufacturer, supplier, or vendor.

(C) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

(D) Such person shall not engage in the design, manufacture, promotion, or sale of devices.

(E) The operations of such person shall be in accordance with generally accepted professional and ethical business practices and shall agree in writing that as a minimum it will—

(i) certify that reported information accurately reflects data reviewed;

(ii) limit work to that for which competence and capacity are available;

(iii) treat information received, records, reports, and recommendations as proprietary information;

(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and

(v) protect against disclosure, in carrying out subsection (b) with respect to a device, of any officer or employee of the person who has a financial interest in a device and annually make available to the public disclosures of the extent to which the person, and the officers and employees of the person, have maintained such activities with requirements under this section.

(F) SELECTION OF ACCREDITED PERSONS.—The Secretary shall designate by regulation the person or persons which the program of accreditation required by this Act, the Comptroller General of the United States 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 extent to which the person or persons designated to conduct the surveillance under this Act will ensure that the services or information provided to such person or persons is free from conflicts of interest.

(G) COMPENSATION.—A person accredited under section 523 of this Act shall be compensated for the services of the accredited person, and the person who engages such person for the services of the accredited person, and the person who engages such person for the services of the accredited person, shall be determined by agreement between the person designated to conduct the surveillance and the person who engages such person for the services of the accredited person.

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

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

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

(I) CONFORMING AMENDMENT.—Section 301 (21 U.S.C. 331), as amended by section 204(b), is amended by adding at the end the following:

(1) In the case of a drug, device, or food for human consumption, or (2) the supporting or recommending person or entity, it is false or misleading in any material particular;

(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 responsibility delegated to such person under this Act.

(J) 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 Committee 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 person or persons designated to conduct the surveillance under this Act will ensure that the services or information provided to such person or persons is free from conflicts of interest.

(B) EVALUATION OF PROGRAM.—Not later than 6 months 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 its duties under such section; that the person designated to conduct the surveillance under such section, with respect to the person, shall be paid by the person who engages such services.

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

(1) 4 years after the date on which the Secretary notifies Congress that at least 2 persons accredited under subsection (b) are available to review at least 60 percent of the submissions under section 510(k); and

(2) 4 years after the date on which the Secretary notifies Congress that the Secretary has made a determination described in paragraph (2)(B) of subsection (a) for at least 35 percent of the devices that are subject to review under paragraph (1) of such subsection, whenever occurs first.

SEC. 211. DEVICE TRACKING.

Effective 90 days after the date of the enactment of this Act, section 519(e) (21 U.S.C. 360i(e)) is amended to read as follows:

(1) The Secretary may by order require a manufacturer to adopt a method of tracking a class I or class III device—

(A) the failure of which would be reasonably likely to have serious adverse health consequences; or

(B) which is—

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

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

(iii) a device which the failure of which would be reasonably likely to have serious adverse health consequences or which is intended to be—

(l) implanted in the human body for more than one year;

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

(B) SURVEILLANCE APPROVAL.—Each manufacturer required to conduct a surveillance of a device shall, within 30 days of receiving an order from the Secretary prescribing that the manufacturer is required under this section to conduct such surveillance, submit, for the approval of the Secretary, a plan for the required surveillance. The Secretary, within 60 days of the receipt of such plan, shall determine if the person designated to conduct the surveillance has appropriate qualifications and experience to undertake such surveillance and if the plan will result in the collection of useful data that can reasonably be repressed adverse events or other information necessary to protect the public health. The Secretary, in consultation with the manufacturer, may by order modify such surveillance plan. The Secretary may by order require a manufacturer, importer, or distributor to conduct such surveillance of a device during the surveillance period of up to 36 months. Any determination by the Secretary that a longer period is necessary shall be made by mutual agreement between the Secretary and the manufacturer or, if no agreement can be reached, after the completion of a dispute resolution process as described in section 562;.

SEC. 222. POSTMARKET SURVEILLANCE.

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

SEC. 522. (a) IN GENERAL.—The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer which is a class I or class III device—

(A) the failure of which would be reasonably likely to have serious adverse health consequences or which is intended to be—

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

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

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

(1) 4 years after the date on which the Secretary notifies Congress that at least 2 persons accredited under subsection (b) are available to review at least 60 percent of the submissions under section 510(k); and

(2) 4 years after the date on which the Secretary notifies Congress that the Secretary has made a determination described in paragraph (2)(B) of subsection (a) for at least 35 percent of the devices that are subject to review under paragraph (1) of such subsection, whenever occurs first.

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

(1) in subsection (a)—

(A) by striking "manufacturer or importer" and inserting "manufacturer or importer"; and

(B) in paragraph (4), by striking "manufacturer, importer, or distributor" and inserting "manufacturer or importer";

(C) in paragraph (7), by adding "and" after the semicolon at the end;

(D) in paragraph (8)—

(i) by striking "manufacturer, importer, or distributor" each place such term appears and inserting "manufacturer or importer"; and

(ii) by striking the semicolon at the end of such paragraph;

(E) by striking paragraph (9); and

(F) by inserting at the end the following sentence—"The Secretary shall by regulation require the manufacturer, importer, or distributor to keep such records available to the Secretary upon request.

Paragraphs (4) and (8) apply to distributors to...
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'.

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

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

(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.".

DEVICE USER FACILITIES.—

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

(A) in 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; and

(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. 360i) 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;

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

"(C) In the process 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 petition is received 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. 215. NONINVASIVE BLOOD GLUCOSE METER.

"(1) Findings.—The Congress finds that—

(a) the use of a non-invasive blood glucose meter would likely improve control and management of diabetes by increasing the number of tests conducted by people with diabetes, particularly children;

(b) a safe and effective noninvasive blood glucose meter would likely improve control and management of diabetes by increasing transport of test blood glucose levels,

(c) the existence of a non-invasive 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; Product Development Protocol.

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

"(4)(A) Any information contained in an application for premarket approval filed with the Secretary pursuant to section 513(c) (including all information from clinical and preclinical tests or studies that demonstrate the safety and effectiveness of a device, including the results of patient studies that demonstrate the safety and effectiveness of a device, but excluding information respecting the safety and effectiveness of a device which is not available through the submission of a petition for a finding of substantial equivalence, or if such information is not submitted within the time permitted under subsection (l)), shall be available for use by the Secretary as the evidentiary basis for the agency actions described in subparagraph (A).

(2) CONFORMING AMENDMENTS.—Section 517(a) (21 U.S.C. 360e(a)(1)) is amended—

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

(B) in paragraph (9), by striking `", or" and inserting a comma; and

(C) by striking paragraph (10).

b) Product Development Protocol.—Section 515(f)(2) (21 U.S.C. 360f(f)(2)) is amended by striking `he shall' and all that follows and inserting the following: `the Secretary'.

(b) In the fourth sentence (as amended by section 515(f)(2)), the Secretary shall refer the proposed protocol to the appropriate panel under section 513 for its recommendation respecting approval of the protocol; or if the Secretary determines that such action is necessary—

"(A) by striking `the claim under this paragraph.

(b) sense of Congress.—It is the sense of the Congress that—

(1) enabling consumers to develop and maintain healthy dietary practices;

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

(3) ensuring 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.

(c) proposing regulations.—The Secretary shall, if the Secretary determines that such action is necessary—

"(i) by enabling consumers to develop and maintain healthy dietary practices;

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

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

(b) Product Development Protocol.—Section 515(f)(2) (21 U.S.C. 360f(f)(2)) is amended by striking `the Secretary' and all that follows and inserting the following: `the Secretary'.
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 protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Science or one of its divisions has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers;

"(ii) a person has submitted to the Secretary, at least 120 days (during which the Secretary may notify any person who is making a claim as authorized by clause (c) that such person has not submitted all the information required by such clause) 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 been satisfied, (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), and (B)(ii) and (c)(i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this 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 to which the claim refers, an employee of the food for which the claim is made are in compliance with clause (A)(iii) and are otherwise in compliance with paragraph (a) and section 201(n); and

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

For purposes of this 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 to which the claim refers, an employee of the food for which the claim is made are in compliance with clause (A)(iii) and are otherwise in compliance with paragraph (a) and section 201(n); and

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

SEC. 305. REFERRAL STATEMENTS.

Section 403(r)(2)(B) (21 U.S.C. 343(r)(2)(B)) is amended by inserting after paragraph (2) the following flush sentence: "(B) if a claim described in subparagraph (1)(A)(i) is made with respect to a nutrient in a food and the Secretary makes a determination that the claim could not be made under this section prescribing the conditions under which such additive may be safely used; or

SEC. 306. DISCLOSURE OF IRRADIATION.

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

"SEC. 403C. (a) In section 201(n), 403(a), or 409 shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than any other disclosure of ingredients required by section 403(k)(2).

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

SEC. 307. IRRADIATION PETITION.

Not later than 60 days following the date of the enactment of this Act, the Secretary of Health and Human Services may conduct a final determination on any petition pending with the Food and Drug Administration that would permit the irradiation of red meat under section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act. If the Secretary does not make such determination, the Secretary shall, not later than 60 days following the final determination of this Act, provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate with a comprehensive report of the scientific evidence followed by the Food and Drug Administration in reviewing the petition referred to in paragraph (1) and the reasons action on the petition was delayed.

SEC. 308. GLASS AND CERAMIC WARE. 

(a) In General.—The Secretary may not implement any requirement which would ban, as contrary to law, food adhesive cadmium based enamel in the lip and rim area of glass and ceramic ware before the expiration of one year after the date such requirement is published.

(b) Lead and Cadmium Based Enamel.—Unless the Secretary determines, based on available data, that lead and cadmium based enamel on glass and ceramic ware—

"(1) which has less than 60 millimeters of decorating area below the external rim, and

"(2) which is, not by design, representation, or customary usage intended for use by or for children, is unsafe, the Secretary shall not take any action before January 1, 2003, to ban lead and cadmium based enamel on such glass and ceramic ware.

(c) Action following a statement by the Secretary.—Any action taken after January 1, 2003, to ban such enamel on such glass and ceramic ware as an unapproved food additive shall be taken by regulation and such regulation shall provide that such products shall not be removed from the market before 1 year after publication of the final regulation.

SEC. 309. FOOD CONTACT SUBSTANCES.

Subsection (b) of section 409 (21 U.S.C. 349b) is amended—

"(1) by striking the matter following paragraph (4) and inserting "(4) by striking the matter following paragraph (5); and

"(2) by striking the following flush sentence:

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

SEC. 310. NOTIFICATION RELATING TO A FOOD CONTACT SUBSTANCE.

"(h) Subject to such regulations as may be promulgated under paragraph (3), a manufacturer or supplier of a food contact substance shall, not later than 60 days following the date of the enactment of this Act, provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate with a comprehensive report of the scientific evidence followed by the Food and Drug Administration in reviewing the petition referred to in paragraph (1) and the reasons action on the petition was delayed.

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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 the Secretary receives the notification.

(B) The Secretary is authorized to promulgate regulations to identify the circumstances in which a notification may be designated for a separate review or be filed under subsection (b) and shall consider criteria 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).

(3) The Secretary shall keep confidential any information provided in a notification under paragraph (1) for 120 days after receipt by the Secretary.

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

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

(3)(B) The Secretary is authorized to promulgate regulations to identify the circumstances in which a notification may be designated for a separate review or be filed under subsection (b) and shall consider criteria 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.

(5) The Secretary determines 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 appropriation referred to in subsection (b) equals or exceeds the amount appropriated for such fiscal year for carrying out such program during such period; and

(6) 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 appropriation referred to in subsection (b) equals or exceeds the amount appropriated for such fiscal year for carrying out such program during such period; and

(7) 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 appropriation referred to in subsection (b) equals or exceeds the amount appropriated for such fiscal year for carrying out such program during such period; and

(8) 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 appropriation referred to in subsection (b) equals or exceeds the amount appropriated for such fiscal year for carrying out such program during such period; and

(9) 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 appropriation referred to in subsection (b) equals or exceeds the amount appropriated for such fiscal year for carrying out such program during such period; and

(10) 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 appropriation referred to in subsection (b) equals or exceeds the amount appropriated for such fiscal year for carrying out such program during such period; and

(11) A copy of the information to be disseminated under this subsection (d) or (e) of section 513, an order under subsection (f) of such section, or the approval of an application under section 515, and any technical effect in such food.''

(iii) the identification of any person that has information already includes such bibliographic information.

(iv) the official labeling for the drug or device and all updates with respect to the labeling;

(v) if applicable, a statement that there are products or treatments that have been approved or cleared for the use that is the subject of the information being disseminated pursuant to subsection (a)(1); and

(vi) the identification of any person that has provided funding for the conduct of a study relating to the new use of a drug or device for which such information is being disseminated.

(B) A bibliography of other articles from a scientific reference publication or scientific or medical journal that have been previously published about the use of the drug or device covered by the information disseminated, unless the information already includes such bibliography.

(C) ADDITIONAL INFORMATION.—If the Secretary determines, after providing notice of such determination and an opportunity for a meeting with respect to such determination, that the information submitted by a manufacturer under subsection (b)(3)(B), with respect to the use of a drug or device for which the manufacturer intends to disseminate information, fails to provide data, analyses, or other written matter that is objective and balanced, the Secretary may require the manufacturer to disseminate—

(1) additional objective and scientifically sound information that pertains to the safety or effectiveness of the use and is necessary to provide context, including any information that the manufacturer has authority to make available to the public; and

(2) an objective statement of the Secretary, based on data or other scientifically sound information that bears on the safety or effectiveness of the new use of the drug or device.
SEC. 552. INFORMATION AUTHORIZED TO BE DISSEMINATED.

(a) AUTHORIZED INFORMATION.—A manufacturer may disseminate information under section 551 on the information—

(1) is in the form of an unabridged—

(A) reprint or copy of an article, peer-reviewed by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device involved, which was published in a scientific or medical journal (as defined in section 551) which is about a clinical investigation with respect to the drug or device, and which would be considered to be scientifically sound by such experts; or

(B) a presentation, described in subsection (b), that includes information about a clinical investigation with respect to the drug or device that would be considered to be scientifically sound by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device involved, and which would not pose a significant risk to the public health.

(b) REFERENCE PUBLICATION.—A reference publication referred to in section (a)(1)(B) is a publication—

(1) has not been written, edited, excerpted, or published specifically for, or at the request of, a manufacturer of a drug or device;

(2) is not solely distributed through such a manufacturer but is generally available in bookstores or other distribution channels where medical textbooks are sold;

(4) does not focus on any particular drug or device of a manufacturer that disseminates information under section 551 and does not have a primary focus on new uses of drugs or devices that are marketed or under investigation by a manufacturer supporting the dissemination of information; and

(5) presents materials that are not false or misleading.

SEC. 553. ESTABLISHMENT OF LIST OF ARTICLES AND PUBLICATIONS DISSEMINATED AND LIST OF PROVIDERS THAT RECEIVED ARTICLES AND REFERENCE PUBLICATIONS.

(a) IN GENERAL.—A manufacturer may disseminate information under section 551 on a new use only if the manufacturer prepares and submits to the Secretary a list containing—

(1) the articles and references to the new use of drugs or devices that were disseminated by the manufacturer within the 6-month period preceding the date on which the manufacturer submitted the list to the Secretary; and

(2) a list that identifies the categories of providers (as described in section 553(a)) that received the articles and reference publications for the 6-month period described in paragraph (1).

(b) REQUIREMENT ON MANUFACTURER THAT DISSEMINATES INFORMATION UNDER SECTION 551.—A manufacturer that disseminates information under section 551 shall keep records that may be used by the manufacturer when, pursuant to section 555, such manufacturer is required to take corrective action and shall be made available to the Secretary, upon request, for purposes of ensuring or taking corrective action as necessary by the Secretary. Such records, at the Secretary’s discretion, may identify the recipient of information provided pursuant to section 551 or the categories of such recipients.

SEC. 554. REQUIREMENT REGARDING SUBMISSION OF SUPPLEMENTAL APPLICATION FOR NEW USE; EXEMPTION FROM REQUIREMENT

(a) IN GENERAL.—A manufacturer may disseminate information under section 551 on a new use only if the information—

(1) is on the list submitted by the manufacturer; and

(2) is not false or misleading and would not pose a significant risk to the public health.

(b) RECORDS.—A manufacturer that disseminates information under section 551 shall keep records, at the Secretary's discretion, may identify the recipient of information provided pursuant to section 551 or the categories of such recipients.

(1) the manufacturer makes the condition described in subsection (b) or (c) (relating to a certification that the manufacturer will submit such an application); or

(2) the manufacturer makes an application for an exemption under subsection (d) from the requirement of paragraph (1).

(b) CERTIFICATION ON SUPPLEMENTAL APPLICATION; CONDUCT OF CASED STUDIES.—For purposes of subsection (a)(1)(B), a manufacturer may disseminate information on a new use if the manufacturer has submitted to the Secretary a supplemental application containing a certification that—

(1) the studies needed for the submission of a supplemental application for the new use have been completed; and

(2) the supplemental application will be submitted to the Secretary not later than 6 months after the date of the last dissemination of information under section 551.

(c) CERTIFICATION ON SUPPLEMENTAL APPLICATION; CONDITION IN CASE OF PLANNED STUDIES.—

(1) IN GENERAL.—For purposes of subsection (a)(1)(B), a manufacturer may disseminate information on a new use if—

(A) the manufacturer has submitted to the Secretary an application containing—

(i) a proposed protocol and schedule for conducting the studies needed for the submission of a supplemental application for the new use; and

(ii) a certification that the supplemental application will be submitted to the Secretary not later than 36 months after the date of the initial publication under section 551 (or, as applicable, not later than such date as the Secretary may specify pursuant to an extension under paragraph (3)); and

(B) the Secretary has determined that the proposed protocol is adequate and that the schedule for completing such studies is reasonable.

(2) PROGRESS REPORTS ON STUDIES.—A manufacturer that submits to the Secretary an application under paragraph (1) shall submit to the Secretary periodic reports describing the status of the studies involved.

(3) EXTENSION OF TIME REGARDING PLANNED STUDIES.—The period of 36 months authorized in paragraph (1) for the completion of studies may be extended by the Secretary if—

(A) the Secretary determines that the studies needed to submit such an application cannot be completed within the 36-month period; or

(B) the manufacturer involved submits to the Secretary a written request for the extension and the Secretary determines that the manufacturer is in the process of conducting the studies in a timely manner, except that an extension under this subparagraph may not be provided for more than 24 additional months.

(4) EXEMPTION FROM REQUIREMENT OF SUPPLEMENTAL APPLICATION.—

(1) IN GENERAL.—For purposes of subsection (a)(2), a manufacturer may disseminate information on a new use if the manufacturer—

(A) has submitted to the Secretary an application for an exemption from the requirement of subsection (a)(1); and

(B) the Secretary has approved the application in accordance with paragraph (2); or

(ii) the Secretary has approved the application in accordance with paragraph (2); or

(ii) the Secretary has approved the application in accordance with paragraph (2); or

(iii) the application is deemed approved (unless such approval is terminated pursuant to paragraph (3)).

(2) CONDITIONS FOR APPROVAL.—The Secretary may approve an application under paragraph (1) for an exemption if the Secretary makes a determination described in subparagraph (A) or (B)

(A) The Secretary makes a determination that, for reasons defined by the Secretary, it would be economically prohibitive with respect to the manufacturer to require the manufacturer to incur the costs necessary for the submission of a supplemental application. In making such determination, the Secretary shall consider (in addition to any other considerations the Secretary finds appropriate)—

(i) the lack of the availability under law of an approved use; or

(ii) the manufacturer would have exclusive marketing rights with respect to the new use involved; and

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

(B) 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 paragraphs (1) and (2) do not provide for a deemed approval under paragraph (A) a manufacturer disseminates written information under section 551 on a new use, the Secretary may, at any time terminate such approval and order the manufacturer to cease disseminating the information.

(4) REQUIREMENTS REGARDING APPLICATIONS.—Applications under this section shall be submitted in the form and manner prescribed by the Secretary.

SEC. 555. CORRECTIVE ACTIONS; CESSION OF DISSEMINATION

(a) POSTDISSEMINATION DATA REGARDING SAFETY AND EFFECTIVENESS.—

(1) CORRECTIVE ACTIONS.—With respect to data or information disseminated by the Secretary, the Secretary may order the manufacturer to cease the dissemination of information if the Secretary determines that the new use may not be effective or may present a significant risk to public health, or if the manufacturer fails to take corrective action as the Secretary deems appropriate in light of such data.

(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.

(3) 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 (1)(A) applies) has provided an opportunity for a meeting with the manufacturer with respect to such intent. If the failure of the manufacturer constitutes a minor violation of this subchapter, the Secretary may order the manufacturer to cease the dissemination of information.
Secretary shall delay issuing the order and provide to the manufacturer an opportunity to correct the violation.

(2) SUPPLEMENTAL APPLICATIONS.—The Secretary may order a 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), the Secretary determines that the supplemental application does not contain adequate information for approval, or the 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 the 6-month period involved, submitted 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 determines, after an informal hearing, 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) terminating a deemed approval of an exemption, the Secretary may order the manufacturer involved to cease disseminating the information. A manufacturer shall comply with an order under the preceding sentence not later than 60 days after the receipt of the order.

(4) CORRECTIVE ACTIONS BY MANUFACTURERS.—

(A) IN GENERAL.—In any case in which under this subchapter the Secretary orders a manufacturer to cease disseminating information, the Secretary may provide to the manufacturer an opportunity to correct the information that has been disseminated, except as provided in paragraph (2).

(B) TERMINATION OF DEEMED APPROVAL OF EXEMPTION REGARDING SUPPLEMENTAL APPLICATIONS.—In the case of an order under subsection (b)(3) to cease disseminating information, the Secretary may order the manufacturer involved to take action to correct the information that has been disseminated unless the Secretary determines that the new use described in the information would pose a significant risk to the public health.

(5) SEC. 556. DEFINITIONS.

(a) Definitions:—

(1) SEC. 556. DEFINITIONS.ÐIn the case of an order under subsection (a), (f), or (o) of section 502, or any other provision of law, the dissemination of information relating to a new use of a drug or device, in accordance with section 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 its official labeling of the drug or device. Such dissemination shall not be considered by the Secretary as labeling, adulteration, or misbranding of the drug or device.

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

(c) 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 or medical journal, or a physician, or other individual who is a producer of health care, who manufactures a drug or device, or who is liable to the Secretary under subsection (b)(3) to cease disseminating information pursuant to section 551, 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.

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

"(e) The dissemination of information in violation of section 551."

(e) REGULATIONS.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services and the Secretary shall promulgate regulations to implement the amendments made by this section.

(f) EFFECTIVE DATE.—The amendments made by this section take effect 6 months after the date of enactment of this Act, and the Secretary shall publish in the Federal Register a notice of the date on which these regulations become effective.

(g) IN GENERAL.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct the study required by paragraph (2), and to prepare and submit the report required by paragraph (3), under an arrangement by which the actual expenses incurred in the course of the study and preparing the report will be paid by the Secretary. If the Institute of Medicine of the National Academy of Sciences determines, on or after the date of enactment of this Act, or upon the Secretary’s issuance of final regulations pursuant to subsection (c), whichever is sooner, to conduct the study required by subsection (d), the Secretary shall provide to the Institute of Medicine of the National Academy of Sciences to conduct the study required by paragraph (2), and to prepare and submit the report required by paragraph (3), under an arrangement by which the actual expenses incurred in the course of the study and preparing the report will be paid by the Secretary. If the Institute of Medicine of the National Academy of Sciences determines, on or after the date of enactment of this Act, or upon the Secretary’s issuance of final regulations pursuant to subsection (c), whichever is sooner, to conduct the study required by subsection (d), the Secretary shall provide to the Institute of Medicine of the National Academy of Sciences, and the Secretary shall make the report available to the public.

(h) SEC. 561. EXPANDED ACCESS TO UNAPPROVED THERAPIES AND DIAGNOSTICS.

(a) EMERGENCY SITUATIONS.—The Secretary may, under appropriate arrangements determined by the Secretary, authorize the shipment of investigational drugs or investigational devices for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.

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

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

(2) The Secretary determines that there is sufficient evidence of safety and effectiveness to support the use of the investigational drug or investigational device.

(3) The Secretary determines that provision of the investigational drug or investigational device to the patient, without interfering with the clinical investigation, and the completion of clinical investigations to support marketing approval; and
"(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), including any regulations promulgated 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.

"(c) TREATMENT INVESTIGATIONAL NEW DRUG APPLICATIONS AND TREATMENT INVESTIGATIONAL DEVICE EXEMPTIONS.—Upon submission by a sponsor of a protocol, including any regulations promulgated 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, the Secretary shall 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 that stage of disease or condition in the population of patients to which the investigational drug or investigational device is intended to apply; and

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

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

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

(5) in the case 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 establishment of the investigational new drug applications or investigational device exemption in effect under section 505(i) or investigational device exemption in effect under section 520(g);

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

(7) in the case of investigational devices, the available scientific evidence, taken as a whole, provides a reasonable basis to conclude that 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 any regulations promulgated under section 505(i) or 520(g). The Secretary may in national, State, and local medical associations and societies, voluntary health associations, and other appropriate persons about the availability of an investigational drug or investigational device under expanded access protocols submitted under this subsection. The information provided by the Secretary, in accordance with the preceding sentence, shall be the same type of information required under expanded access protocols described in section 402(j)(3) of the Public Health Service Act.

"(d) TERMINATION.—The Secretary may, at any time, with respect to a sponsor, physician, manufacturer, or device distributor described in this section, terminate expanded access provided under this section for an investigational 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 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 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 THE CENTER.—The Secretary shall designate in each center within the Food and Drug Administration, the National Institutes of Health, professional medical and scientific societies, and other persons who identify published and unpublished studies that support a supplemental application, and to encourage sponsors to make supplemental applications or conduct further research in support of a supplemental application based, in whole or in part, on such studies.

SEC. 404. DISPUTE RESOLUTION.

Subsection B of chapter V, as added by section 402, is amended by adding at the end the following:

"SEC. 562. DISPUTE RESOLUTION.

"(a) In general.—If, regarding the development of drugs or devices under this Act or section 351 of the Public Health Service Act, there is a scientific controversy between the Secretary and a sponsor, applicant, or manufacturer, the Secretary shall—

(1) clarify circumstances in which published and unpublished studies that support a supplemental application or that are or may support such an application are required to be made available to the public;

(2) specify data requirements that will avoid duplication of 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.

(b) RESPONSIBILITIES OF THE CENTER.—The Secretary shall designate in each center within the Food and Drug Administration, the National Institutes of Health, professional medical and scientific societies, and other persons who identify published and unpublished studies that support a supplemental application, and to encourage sponsors to make supplemental applications or conduct further research in support of a supplemental application based, in whole or in part, on such studies.

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

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

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

(2) by inserting after subsection (a) the follow- ing:

(d) MISSION.—The Administration shall—

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

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

(A) human and veterinary drugs are safe, wholesome, sanitary, and properly labeled;

(B) drugs and biologicals are properly labeled; and

(C) human and veterinary drugs are safe and effective.

SEC. 407. INTEGAL AGENCY STATEMENTS.

Section 701 (21 U.S.C. 371) is amended by adding at the end the following:
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(D) cosmetics are safe and properly labeled; and  
(E) public health and safety are protected from electronic product radiation;  

(3) improve the appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal access for regulated industry, shall develop and publish in the Federal Register a plan bringing the Secretary into compliance with each of the obligations of the Secretary for the Food and Drug Administration; 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. 742. EDUCATION AND TRAINING.  

"(a) In General.—The Secretary shall conduct training and education programs for the employees of the Food and Drug Administration relating to the regulatory responsibilities and policies established by this Act, including programs for—  

(1) scientific training;  

(2) training to improve the skill of officers and employees authorized to conduct inspections under section 704;  

(3) training to achieve product specialization in such inspections; and  

(4) training in administrative process and procedure and integrity issues.  

"(b) Centers for Disease Control and Prevention Programs.—The Secretary, acting through the Commissioner, may, through fellowships and other training programs, conduct and support intramural research training for predoctoral and postdoctoral scientists and physicians.".  

(c) Centers for Disease Control and Prevention.—(1) In General.—Part B of title III of the Public Health Service Act is amended by inserting after section 317F (42 U.S.C. 247b-7) the following:  

"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, an other disease detection and prevention methods. Such programs shall be designed to enable 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 nonappointment procedures.".  

(2) Effective Date.—The amendment made by this subsection is deemed to have taken effect July 1, 1995.  

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. 905. DEMONSTRATION PROGRAM REGARDING CLINICAL AND RESEARCH ON THERAPEUTICS.  

"(a) In General.—The Secretary, acting through the Administrator and in consultation with the Commissioner of Food and Drugs, shall establish a demonstration program for the purpose of making one or more grants for the establishment and operation of one or more centers to carry out the activities specified in subsection (b).  

(b) Required Activities.—The activities referred to in subsection (a) are the following:  

(1) The conduct of state-of-the-art clinical and laboratory research for the following purposes:  

(A) to increase awareness of—  

(i) new uses of drugs, biological products, and devices;  

(ii) ways to improve the effective use of drugs, biological products, and devices; and  

(iii) risks of new uses and risks of combination of drugs and biological products.  

(B) to provide objective clinical information to the following individuals and entities:  

(i) health care practitioners or other providers of health care goods or services.  

(ii) pharmacy benefit managers.  

(iii) Health maintenance organizations or other managed health care organizations.  

(iv) health care insurers or governmental agencies.  

(C) to improve the quality of health care while reducing the cost of health care through—  

(i) the appropriate use of drugs, biological products, or devices; and  

(ii) the prevention of adverse effects of drugs, biological products, and devices and the consequences of such effects, such as unnecessary hospitalizations.  

(2) The conduct of research on the comparative effectiveness and safety of drugs, biological products, and devices.  

(3) Such other activities as the Secretary determines to be appropriate, except that the grant may be expended to assist the Secretary in the review of new drugs.  

(c) Application for Grant.—A grant under subsection (a) may be made only if the application for the grant has undergone appropriate technical and scientific peer review.  

(d) Authorization of Appropriations.—For the purpose of carrying out this section, there are authorized to be appropriated $2,000,000 for fiscal year 1998, and $3,000,000 for each of fiscal years 1999 through 2002.".  

SEC. 410. MUTUAL RECOGNITION AGREEMENTS AND GLOBAL HARMONIZATION.  

(a) Good Manufacturing Practice Requirements.—Section 520(f)(1)(B) (21 U.S.C. 360j(f)(1)(B)) is amended—  

(1) by striking clause (i), and inserting "and", and at the end of clause (ii), by striking "", and at the end and inserting a semicolon;  

(2) in clause (ii), by striking the period and inserting "", and; and  

(3) by inserting after clause (ii) the following:  

"(iii) that ensure such regulation conforms, to the extent practicable, with internationally recognized standards defining quality systems, or parts of the standards, for medical devices.".  

(b) Harmonization Efforts.—Section 803 (21 U.S.C. 383) is amended by adding at the end the following:  

"(c)(1) The Secretary shall support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in discussions with representatives of other countries to discuss methods and approaches to reduce the burden of regulation and harmonize regulatory requirements if the Secretary determines that such harmonization and consumer protections consistent with the purposes of this Act.  

(2) The Secretary shall support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in efforts to move toward the acceptance of mutual recognition agreements relating to the regulation of drugs, biological products, devices, foods, for the environment, and color additives, and the regulation of good manufacturing practices, between the European Union and the United States.  

(c) The Secretary shall regularly participate in meetings with representatives of other foreign governments to discuss and reach agreement on
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 (3) shall not apply with respect to products defined in section 210(f).

SEC. 411. ENVIRONMENTAL IMPACT REVIEW.

Chapter 411 (21 U.S.C. 371 et seq.), as amended by section 410, is further amended by adding at the end thereof:

"SUBCHAPTER E—ENVIRONMENTAL IMPACT REVIEW"

"SEC. 416. ENVIRONMENTAL IMPACT.

"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 and section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C))."

SEC. 412. NATIONAL UNIFORMITY FOR NONPRESCRIPTION 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 the end thereof:

"SUBCHAPTER F—NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS AND PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS"

"SEC. 751. NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS.

"(a) IN GENERAL.—Except as provided in subsection (b), (c), (d), (e), or (f), no State or political subdivision thereof, the Secretary of Health and Human Services, 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) (21 U.S.C. 352(b));

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

(b) EXEMPTION.—

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

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

(B) would not cause any drug to be in violation of any applicable requirement or prohibition under this Act or the regulations thereunder; and

(C) would not unduly burden interstate commerce.

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

(c) SCOPE.—

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

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

(B) any State or political subdivision requirement for a drug that is specifically named in the prescription of a practitioner licensed by law to administer such drug.

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

(3) EXCEPTIONS.—

(1) IN GENERAL.—In the case of a drug described in subsection (a)(1) that is not the subject of an application approved under section 505 or section 307 (as in effect on the day before October 31, 1990), enforcement of any applicable requirement or prohibition that relates to the practice of pharmacy; and

(2) would otherwise be unprotected, including the health and safety of children;

(3) that relates to the regulation of a drug that is not subject to the requirements of section 374(a)(1) is amended by striking "prescription or nonprescription drug" and inserting "prescription drug";

(4) that would not cause a cosmetic to be in violation of any applicable requirement or prohibition under Federal law, and

(5) Paragraphs (1) through (4) shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.

(d) PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS.

(1) 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 relating to the practice of pharmacy that is different from or in addition to, or that is otherwise not identical with, a requirement specifically applicable to a particular cosmetic or class of cosmetics under this Act, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

(2) 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—

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

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

(C) would not unduly burden interstate commerce.

(e) STATE INITIATIVE.—This section shall not apply to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under this Act for packaging or labeling. Such a statute includes any State requirement relating to public information or any other form of public communication.

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

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

(h) INSPECTIONS.—Section 704(a)(1) (21 U.S.C. 374(a)(1)) is amended to read as follows:

"(1)(A) If it is a drug, unless its label bears, where required by the Secretary, on such label (and on any labeling on the immediate container, as prescribed in regulation promulgated by the Secretary, except that nothing in such a statute shall be construed to require that any trade secret be divulged, and except that the requirements of this subclass with respect to alphabetical order shall apply only to nonprescription drugs that are not also cosmetics and that this subclass shall not apply to nonprescription drugs not intended for human use.

(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.

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

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

(k) STATE INITIATIVE.—This section shall not apply to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under this Act for packaging or labeling. Such a statute includes any State requirement relating to public information or any other form of public communication.

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

(m) STATE INITIATIVE.—This section shall not apply to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under this Act for packaging or labeling. Such a statute includes any State requirement relating to public information or any other form of public communication.

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

(o) STATE INITIATIVE.—This section shall not apply to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under this Act for packaging or labeling. Such a statute includes any State requirement relating to public information or any other form of public communication.

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

(q) STATE INITIATIVE.—This section shall not apply to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under this Act for packaging or labeling. Such a statute includes any State requirement relating to public information or any other form of public communication.

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

(s) STATE INITIATIVE.—This section shall not apply to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under this Act for packaging or labeling. Such a statute includes any State requirement relating to public information or any other form of public communication.

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

(u) STATE INITIATIVE.—This section shall not apply to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under this Act for packaging or labeling. Such a statute includes any State requirement relating to public information or any other form of public communication.

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

(w) STATE INITIATIVE.—This section shall not apply to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under this Act for packaging or labeling. Such a statute includes any State requirement relating to public information or any other form of public communication.

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

(y) STATE INITIATIVE.—This section shall not apply to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under this Act for packaging or labeling. Such a statute includes any State requirement relating to public information or any other form of public communication.

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

(c) STUDY OF MERCURY SALES.—
(1) STUDY.—The Secretary of Health and Human Services, acting through the Food and Drug Administration, shall conduct, or subject to paragraph (2), 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 drug or 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, or 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) I NTERAGENCY COLLABORATION.—The Secretary shall implement programs and policies that will foster collaboration between the Administrator of the National Institutes of Health, and other Federal agencies, and, when necessary, with other Federal agencies and Federal agents, 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, evaluation, and postmarket monitoring of emerging medical therapies, including complementary therapies, and to improve and coordinate the following:

(1) increased efficiency and expertise through contracts.—The Secretary may use the authority granted in paragraph (1) whenever the conditions that use 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 such authority 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 determining whether 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.

(2) REVIEW OF EXPERT REVIEW.—
"(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall designate an organization or individual who conducted the expert review and shall notify the person or entity of such designation.

(2) LIMITATION.—A final decision by the Secretary shall be made within the applicable prescribed time period for review of the matter as set forth in this Act or in the Public Health Service Act (42 U.S.C. 301 et seq.).

SEC. 414. PRODUCT CLASSIFICATION.
Subchapter E of chapter V, as amended by section 404, is further amended by adding at the end the following:

"SEC. 503. CLASSIFICATION OF PRODUCTS.

(a) REQUEST.—A person who submits an application for the product, or a component to regulate the product, or the component of the Food and Drug Administration that will regulate the product, in the application for the 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 regulation by the Secretary, or the component of the Food and Drug Administration 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 appropriate.

(b) STATEMENT.—Not later than 60 days after the receipt of the request described in subsection (a), the Secretary shall provide to the person a written statement that includes—
(1) the Secretary's decision regarding the product, or component, to classify the product, or component, as a drug, biological product, device, or a combination product subject to regulation by the Secretary, or the component of the Food and Drug Administration that will regulate the product; or the component of the Food and Drug Administration that will regulate the product, as appropriate.

"SEC. 415. CONTRACTS FOR EXPERT REVIEW.

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 412, is further amended by adding at the end the following:

"SEC. 707. CONTRACTS FOR EXPERT REVIEW.

"(a) IN GENERAL.—

(1) AUTHORITY.—The Secretary may enter into a contract with any organization or any individual who has relevant expertise to perform a contract for expert review under this section. Except as provided in paragraph (2), the Secretary may enter into a contract with any organization or any individual who has relevant expertise to perform a contract for expert review under this section.

(2) I NCREASED EFFICIENCY AND EXPERTISE THROUGH CONTRACTS.—The Secretary may use the authority granted in paragraph (1) whenever the conditions that use 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 such authority 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 determining whether 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.

"SEC. 416. PRODUCT CLASSIFICATION.

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

"SEC. 503. 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 regulation by the Secretary, or the component of the Food and Drug Administration 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 appropriate.

(b) STATEMENT.—Not later than 60 days after the receipt of the request described in subsection (a), the recommendation made by the Secretary under subsection (a) shall be considered to be a final determination respecting the classification of the product, or the component of the Food and Drug Administration that will regulate the product, as appropriate, and shall not constitute a final determination respecting the classification of the product, or the component of the Food and Drug Administration that will regulate the product, as appropriate.

"SEC. 417. REGISTRATION OF FOREIGN ESTABLISHMENTS.

Section 351(i) (21 U.S.C. 360(i)) is amended to read as follows:

"(i)(1) Any establishment within any foreign country that is a manufacturer of, or bonded to, a drug or a device that is imported or offered for import into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.

"(2) The establishment shall also provide the information and documentation required by paragraph (1)(i)(1).

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

SEC. 418. CLASSIFICATION OF SEIZURE AUTHORITY.

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

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

(2) by inserting after the fifth sentence the following:

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

SEC. 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:

"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 report or 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 was 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 an adverse experience, or otherwise 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 (l).

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 as in effect on the date before the date of the enactment of this Act.

TITLE V—EFFECTIVE DATE

SEC. 501. EFFECTIVE DATE.

Except as otherwise provided in this Act, this Act and the amendments made by this Act, other than the provisions of this Act made by sections 111, 121, 125, and 307, shall take effect 90 days after the date of enactment of this Act.

And the House agree to the same.
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 reached by 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 substituting for the Senate bill the House amendment. The differences between the Senate bill, the House amendment, and the substitute agreed to in conference are noted below, except for clerical corrections, conforming changes made necessary by agreements reached by the conferees, and minor drafting and clerical changes.

The conference agreement on S. 830, the Food and Drug Administration Modernization Act of 1997, provides for: (1) the reauthorization of the Prescription Drug User Fee Act of 1992; (2) the improvement of regulation of drugs through such reforms as those pertaining to pediatric studies of drugs; (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 break-through devices, tracking and postmarket surveillance, and accredited private review; (4) the improvement of regulation of food through such reforms as those pertaining to the timetable and regulatory authority of the Secretary in processing health and nutrition content claims, premarket substantiation, notification, and information relating to irradiation treatment; and (5) general provisions pertaining to the dissemination of information relating to investigational therapies, and consumer access to information about clinical trials of investigational therapies. Certain matters agreed to in conference are noted below:

**TITLE I—IMPROVING REGULATION OF DRUGS**

The conference believes it is important to place the PDUFA reauthorization provisions of the Act and the PDUFA and PDUFA II reauthorization of the biotechnology agreements which have been put into place by the 1997 Balanced Budget Agreement (BBA). This Act preserves the original PDUFA adjustment factor and therefore the basic understanding behind the 1992 enactment of this provision: that the industry will contribute enhanced performance in the drug approval process. Nevertheless the conferees acknowledge that the 1997 BBA places tight constraints on the appropriations process, particularly in the out years. The conferees expect the appropriators will make every effort to meet the trigger so that FDA is allowed to collect and expend user fees. However, it must be acknowledged that particularly in the fifth year of BBA, budgetary pressures on all discretionary spending will be great.

Breakdowns of the actual spending levels at FDA have not traditionally been provided to the appropriators, making it difficult to conduct oversight in Fiscal Year 1998. Appropriators will require FDA to submit a directed operating budget as part of the annual budget request. This will serve as a functional breakdown of how appropriated dollars are spent, similar to the report FDA submits annually to show how the agency spent collected PDUFA user fees.

The conferees expect the President’s budgetary request for FDA for salaries and expenses to meet the PDUFA levels specified for each year. However, based on any assumption of the enactment of new substitutive user fees on other FDA regulated industries.

Pediatric studies of drugs (Sec. 111)

The conference agreement provides that if the Secretary determines that information about a drug may promote health benefits in a pediatric population and makes a written request for pediatric studies (including a time frame for completing the studies), and the studies are completed and are accepted by the Secretary, then the sponsor or manufacturer shall conduct the studies within 5 years of the date of the request for pediatric studies (including a time frame for completing the studies), and the studies are completed and are accepted by the Secretary.

The Secretary may also withdraw the request for a pediatric study at any time. The conferees emphasize that such studies should be sought, conducted, and completed at the earliest possible opportunity. The conferees do not intend that such studies be artificially timed for market advantage.

The agreement provides that no new market exclusivity may be applied to any new drug resulting from the pediatric studies unless the drug was approved before January 1, 2002. These drugs will be eligible for market exclusivity if the Secretary determines that information required by the Secretary may be used, in addition to data collected after such request or requirement in satisfying the provisions of this section.

Clinical investigations (Sec. 115)

The conferees note that the requirement for the Secretary to review existing guidance and develop additional guidance, as appropriate, on the inclusion of women and minorities in clinical trials is required participation of women and minorities in any particular trial. Furthermore, FDA is required to consult with the National Institutes of Health, which has developed inclusion guidelines for subjects in federally funded clinical research, and with representatives of the drug manufacturing industry, to ensure that ethical, scientific, and legal issues specific to privately funded clinical research are considered. The conferees expect the Secretary’s policy regarding: the inclusion of women and minorities in drug development research; population-specific analyses of clinical data and assessment of potential therapeutic differences; and the conduct of specific additional studies in women or minorities, where appropriate.

Content and review of applications (Sec. 119)

The conference agreement provides for regulation of positron emission tomography (PET) products and replaces earlier industry guidance and regulatory standards for PET products. The agreement provides that, until the Secretary establishes procedures under subsection (c) described below, neither a New Drug Application (NDA) nor an Abbreviated New Drug Application (ANDA) is required by a licensed practitioner to produce a compounded PET product in accordance with United States Pharmacopeia (USP) standards.

The agreement requires the Secretary, in two years to establish procedures for approving PET products, including compounded PET products, and good manufacturing practices for such products, taking account of relevant differences between commercial manufacturers and non-profit organizations and in consultation with patient groups, physicians, and others. The Secretary may not require NDAs or ANDAs for these products after this period unless the procedures mentioned above are established.

A compounded PET drug, by definition, must be compounded pursuant to a valid prescription order and in accordance with state law, among other requirements. A PET drug that fails to meet these requirements is not a "compounded PET drug" and therefore is not eligible for protection from section 505(a) (21 U.S.C. 355(a)(2)(B)) or from subsections (b) and (j) of section 505 (21 USC 355). PET drugs that fail to meet the definition of a "compounded PET drug" shall be subject to the same procedures and requirements established by the Secretary under subsection (c)(1).
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 (FDA) and other interested parties to reach consensus. It is the intent of the conferences to ensure continued availability of compounded drug products as a component of effective and appropriate practice, while limiting the scope of compounding so as to prevent manufacturing under the guise of compounding. Section 503A establishes parameters for compound drug compounding 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 compound drug compounding in addition to existing state-specific regulations.

The conferences intend, 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 conference expects that the FDA and the courts will accord great deference to the licensed prescriber’s judgment in determining whether the change constitutes a “significant difference.” However, where it is readily apparent, based on the circumstances, the “significant difference” is a mere pretext to allow compounding of products that are essentially copies of commercially available products, such compounding would be considered copying of commercially available products and would not qualify for the compounding exemptions if it is done regularly or in inordinate amounts. Such circumstances may include, for example, instances in which minor changes in strength (such as from 0.8% to 0.9%) 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 for compounded product.

The conferences also expect that the Secretary will not include 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 conferences to allow compounding of products that are readily apparent, based on the circumstances, that an accredited person may not review a particular patient who is allergic to a particular product. The conferees believe that this language is necessary to simplify these regulations under State tort laws. Currently, FDA requires distributors to keep records for two years from the date of the complaint is received by the distributor, including the distributor record keeping requirements of section 510(k) continue to apply. This provision also requires the appropriate listing and reporting requirements for devices.

Title II—Improving Regulation of Devices

The conference agreement amends Sections 510(k) of the Federal Food, Drug and Cosmetic Act to reduce the reporting requirements for distributors and importers, however, are required to comply with the existing requirements for medical device reporting. The amendment to section 510(k) requires distributors to keep records for two years from the date of the complaint is received by the distributor, including the distributor record keeping requirements of section 510(k) continue to apply.

The conference agreement provides that the Secretary must keep these records for other than a fixed period and make them available to the Secretary on request. Because distributors will no longer be submitting reports to the Secretary, copiers of reports will be sent to the manufacturers. This is not intended to provide the FDA with any new statutory authority to require distributors to keep additional records. The FDA is urged to allow all record keeping, including distributor record keeping, to be accomplished through either electronic means or written documentation. The FDA is also urged to revise its current regulations on distributor record keeping (21 C.F.R. §803.35(b)) to provide for consistent and improved communications between the FDA and regulated persons, increasing regulatory efficiency, and decreasing the length of product review and approval.

Premature notification (Sec. 206)

The conference agreement exempts class I devices from premarket notification under section 510(k), except those types that present a potential unreasonable risk of injury or death, that involve substantial importance in preventing impairment of human health. The conference also requires the Secretary to publish a notice listing the types of class I devices that will not be exempt from premarket notification. The Secretary must publish this initial list within 60 days.

Thereafter, class II devices may be exempted by the Secretary on the Secretary’s own initiative or through a petition process. The agreement provides that the Secretary must respond to any such petitions within 60 days and the petition will be deemed granted.

The conference does not intend by this provision for the Secretary to classify low-risk class I device in order to avoid exempting them. The conferences believe the appropriate exemption of class I and certain class II devices will allow the Secretary to expend limited premarket review resources on potentially risky and technologically advanced devices. Focusing resources in this manner will ensure devices to be adequately protected and will still benefit from the earlier availability of new products. Accredited party review (Sec. 210)

The conference agreement makes modifications to the FDA’s responsibilities to establish the process by which the Secretary will classify biomedical devices, including any circumstances under which devices will allow the Secretary to expend limited premarket review resources on potentially risky and technologically advanced devices.

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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, Health, and Safety Act of 1968 (21 U.S.C. 3010).

Practice of medicine (Sec. 214)

The conference agreement includes a provision intended by the conferees to emphasize that the FDA should not interfere with the practice of medicine. Specifically, the conferees note that the off-label use of a medical device by a physician using his or her best medical judgment and determination is permitted 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 this provision not be construed to affect medical professional liability.

Title III—Improving Regulation of Food

FLEXIBILITY FOR REGULATIONS REGARDING CLAIMS (Sec. 301)

The conference agreement clarifies the parameters within which the Secretary may use the new authority to expedite the review of petitions to make health claims based on author- itative scientific literature. The agreement recognizes that this new authority may be used when the Secretary determines that it is necessary to expedite the review of petitions to make health claims, and provides that this authority may be used under specific circumstances, to seriously or immediately affect the health or welfare of a patient. The conference agreement makes clear that the Secretary should only use this new authority when it is necessary to expedite the review of a petition to make a health claim, and that the Secretary should consider the health of the patient in making this determination.

Health and nutrient content claims (Secs. 303, 304)

The conference agreement makes streamlined procedures available for the Secretary to permit more scientifically sound nutrition information to be provided to consumers through health and nutrient content claims. The agreement includes new provisions that authorize the Secretary to expedite the review of petitions to make health and nutrient content claims based on authoritative statements. This new authority may be used when the Secretary determines that it is not necessary to expedite the review of petitions to make health and nutrient content claims. The conference agreement makes clear that the Secretary should not use this new authority when it is not necessary to expedite the review of a petition to make a health claim, and that the Secretary should consider the health of the patient in making this determination.

Disclosure of irradiation (Sec. 306)

The conference agreement includes a provision intended by the conferees to emphasize that the FDA should not interfere with the practice of medicine. Specifically, the conferees note that the off-label use of a medical device by a physician using his or her best medical judgment and determination is permitted 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 this provision not be construed to affect medical professional liability.

Food contact substances (Sec. 309)

The conference agreement establishes a notification process for the regulation of components of food contact substances, which is intended to expedite the authorization of the marketing of a food contact substance 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 finance the costs of this notification process.

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 without having to be included in the approved labeling of drugs, biological products, and devices. The conference agreement includes a provision intended by the conferees to emphasize that the FDA should not interfere with the practice of medicine. Specifically, the conferees note that the off-label use of a medical device by a physician using his or her best medical judgment and determination is permitted 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 this provision not be construed to affect medical professional liability.

Although the conference intends to ensure that the research is undertaken to get new uses on product labels, the conference also recognizes that there may be limited circumstances under which it may be appropriate for a manufacturer from the requirement to file a supplemental application. In making the determination of whether to grant an exemption, the Secretary may consider, among other factors, whether the new use meets the requirements of section 186(1)(B) of the Social Security Act; that is represented in or recognized by the Council of Medical Specialty Societies (or is a subspecialty of such society) or is recognized by the American Osteopathic Association; or that the new use is consistent with sound medical practice; the new use is described in a recommendation or medical practice guideline of a Federal health agency, including the National Institutes of Health, the Agency for Health Care Policy and Research and the Centers for Disease Control and Prevention of the Department of Health and Human Services; the new use is described in one of three compendia: The U.S. Pharmacopeia-Drug Information, the American Medical Association Drug Information, or the American Hospital Association Formulary Drug Information; the new use involves a combination of products of multiple manufacturers; a marketing application, a biological license application, a device premarket notification, or a device premarket approval application; or the patent status of the product.

The conference recognizes that there may be cases where the size of the patient population may be so small as to be statistically negligible. The conference intends for any determination that a supplemental application should not be filed. However, this is intended to be the exception, rather than the rule. In the case of populations suffering from orphan diseases, this Congress has sought to encourage research into orphan diseases and the approval of innovative drugs for their treatment. The Secretary should examine very carefully whether an exemption from filing a supplemental application might hinder such research and recognize the vital importance of encouraging application for new drugs and new drug uses intended to treat rare disorders.

Expanded access to investigational therapies and diagnostics (Secs. 402)

The conference agreement provides statutory direction to expand access programs and emphasizes that opportunities to participate in expanded access programs are available to eligible individuals with serious or life-threatening conditions, including terminal illness, and that opportunities to participate in expanded access programs are available to eligible individuals who are not enrolled in Medicare or Medicaid who may be affected by the serious or life-threatening conditions.

The conference agreement establishes a new section relating to “serious” conditions, the definition of which is broad language in this section relating to “serious” conditions, without attempting to define them, in order to permit wide flexibility in implementation. Illnesses that do not cause death, but that none theless destroy the lives of both patients and their families. The conference therefore intends that the seriousness of an illness be given due consideration when determining whether to grant an exemption for the Secretary to consider in determining whether to grant an exemption for the Secretary to consider in determining whether to grant an exemption for the Secretary.
patients who have failed existing approved therapies.

Information system (Sec. 407)
The conference intend that the information system shall provide access to the information by clinical centers coordinated by the Secretary, except that access shall not be provided under any particular form of information system to any applicant until appropriate safeguards 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 to conduct clinical research to provide fellowships and training to appropriate undergraduate, post-doctoral, and/or post-doctoral candidates. In the past, FDA's Centers 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 specified authority to conduct and support them. In light of the additional overhead costs, reduced training flexibility, increased paperwork, and hiring delays that have arisen, it is increasingly difficult and impractical for FDA to hire trainees as FTE Service Fellows. As a result, the Intramural Research and Training Authorization Act of 1990 authorized the FDA to conduct and support directly the selection and training of fellows, allow more efficient use of appropriated funds by reducing overhead costs, and other costs, and permit the training of such candidates as non-FTE positions. The conference agreement also provides similar authority for the Centers for Disease Control, the 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 and consult 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 advisory 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 conferees 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 conferees directed the Secretary to 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 conference does not intend this section to preclude judicial review of EISs. The conferences 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 Act authorizes production of limited quantities of Class I and Class II substances for use in medical devices, there will be a continuing, but limited, volume of non-regulatory product information. Therefore, the Act 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 re-captured, recycled or reused consistent with section 600a(3) of the Clean Air Act until such time that Congress conducts oversight hearings into this 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 to help ensure that they are meeting their potential responsibilities so that they can be addressed quickly and effectively. If FDA were to assert routine access to these audits, it would create serious disincentives to conducting appropriate audits and preparing thorough reports of the results. FDA already has a policy of not ordinarily requesting audit reports from operators of OTC drug establishments. 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 conferees 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 believe that early 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 includes 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, they have the ability to make clear that there is no records inspection authority under these provisions for facilities dealing exclusively with cosmetics.

Finally, the conference expects 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 prohibit unsubstantiated claims for nonprescription drugs and cosmetics, and to require corrective advertising. This provision is not intended to preempt the application of these laws under such circumstances.

The Conference Committee intends to make clear that “Little FTC” laws, as they have historically been written and applied, are not preempted. The scope of national uniformity is modified to only apply to state requirements that relate to labeling and packaging 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 pre-empt or prevent States from imposing 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.

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 "Jasmin" Salehi; to the Committee on the Judiciary.