110TH CONGRESS
1ST SESSION

S. 1082

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to reauthorize drug and device user fees and ensure the safety of medical products, and for other purposes.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Food and Drug Administration Revitalization Act''.

TITLE I—PRESCRIPTION DRUG USER FEES

SEC. 101. SHORT TITLE; REFERENCES IN TITLE.

(a) SHORT TITLE.—This title may be cited as the ''Prescription Drug User Fee Amendments of 2007''.

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

SEC. 102. DRUG FEES.

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

(1) by striking the section designation and all that follows through ''For purposes of this subchapter:'' and inserting the following:

''SEC. 735. DRUG FEES.

''(a) PURPOSE.—It is the purpose of this part that the fees authorized under this part be dedicated toward expediting the drug development process, the process for the review of human drug applications, and postmarket drug safety, as set forth in the goals identified for purposes of this part in the letters from the Secretary to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Com-

mittee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

''(b) REPORTS.—

''(1) PERFORMANCE REPORT.—For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in subsection (a) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all human drug applications and supplements in the cohort.

''(2) FISCAL REPORT.—For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor,

and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

''(3) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under paragraphs (1) and (2) available to the public on the Internet website of the Food and Drug Administration.

''(c) REAUTHORIZATION.—

''(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of human drug applications for the first 5 fiscal years after fiscal year 2012, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

''(A) the Committee on Energy and Commerce of the House of Representatives;

''(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

''(C) scientific and academic experts;

''(D) health care professionals;

''(E) representatives of patient and consumer advocacy groups; and

''(F) the regulated industry.

''(2) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

''(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;

''(B) publish such recommendations in the Federal Register;

''(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

''(D) hold a meeting at which the public may present its views on such recommendations; and

''(E) after consideration of such public views and comments, revise such recommendations as necessary.

''(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2012, the Secretary shall transmit to Congress the revised recommendations under paragraph (2), a summary of the views and comments received under such paragraph, and

any changes made to the recommendations in response to such views and comments.

''(d) DEFINITIONS.—For purposes of this part:'';

(2) in subsection (d)—

(A) in paragraph (1)—

(i) in subparagraph (A), by striking ''505(b)(1),'' and inserting ''505(b), or'';

(ii) by striking subparagraph (B);

(iii) by redesignating subparagraph (C) as subparagraph (B); and

(iv) in the matter following subparagraph (B), as so redesignated, by striking ''subparagraph (C)'' and inserting ''subparagraph (B)'';

(B) in paragraph (3)(C), by—

(i) striking ''the list'' and inserting ''the list (not including the discontinued section of such list)''; and

(ii) striking ''a list'' and inserting ''a list (not including the discontinued section of such a list)'';

(C) in paragraph (4), by inserting before the period at the end the following: ''(such as capsules, tablets, and lyophilized products before reconstitution)'';

(D) by amending paragraph (6)(F) to read as follows:

''(F) In the case of drugs approved under human drug applications or supplements, postmarket safety activities, including—

''(i) collecting, developing, and reviewing safety information on approved drugs (including adverse event reports);

''(ii) developing and using improved adverse event data collection systems (including information technology systems); and

''(iii) developing and using improved analytical tools to assess potential safety problems (including by accessing external data bases).'';

(E) in paragraph (8)—

(i) by striking ''April of the preceding fiscal year'' and inserting ''October of the preceding fiscal year''; and

(ii) by striking ''April 1997'' and inserting ''October 1996'';

(F) by redesignating paragraph (9) as paragraph (10); and

(G) by inserting after paragraph (8) the following:

''(9) The term 'person' includes an affiliate of such person.''.

SEC. 103. AUTHORITY TO ASSESS AND USE DRUG FEES.

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

(1) in the matter preceding paragraph (1), by striking ''2003'' and inserting ''2008'';

(2) in paragraph (1)—

(A) in subparagraph (D)—

(i) in the heading, by inserting ''OR WITHDRAWN BEFORE FILING'' after ''REFUND OF FEE IF APPLICATION REFUSED FOR FILING''; and

(ii) by inserting before the period at the end the following: ''or withdrawn without a waiver before filing'';

(B) by redesignating subparagraphs (E) and (F) as subparagraphs (F) and (G), respectively; and

(C) by inserting after subparagraph (D) the following:

''(E) FEE FOR APPLICATION PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE

FILING.—An application or supplement that has been refused for filing or that was withdrawn before filing, if filed under protest or resubmitted, shall be subject to the fee under subparagraph (A) (unless an exception under subparagraph (C) or (F) applies or the fee is waived or reduced under subsection (d)), without regard to previous payment of such a fee and the refund of 75 percent of that fee under subparagraph (D).''; and

(3) in paragraph (2)—

(A) in subparagraph (A), by striking ''subparagraph (B)'' and inserting ''subparagraphs (B) and (C)''; and

(B) by adding at the end the following:

''(C) SPECIAL RULES FOR COMPOUNDED POSITRON EMISSION TOMOGRAPHY DRUGS.—

''(i) IN GENERAL.—Except as provided in clause (ii), each person who is named as the applicant in an approved human drug application for a compounded positron emission tomography drug shall be subject under subparagraph (A) to one-fifth of an annual establishment fee with respect to each such establishment identi-

fied in the application as producing compounded positron emission tomography drugs under the approved application.

''(ii) EXCEPTION FROM ANNUAL ESTABLISHMENT FEE.—Each person who is named as the applicant in an application described in clause (i) shall not be assessed an annual establishment fee for a fiscal year if the person certifies to the Secretary, at a time specified by the Secretary and using procedures specified by the Secretary, that—

''(I) the person is a not-for-profit medical center that has only 1 establishment for the production of compounded positron emission tomography drugs; and

''(II) at least 95 percent of the total number of doses of each compounded positron emission tomography drug produced by such establishment during such fiscal year will be used within the medical center.''.

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

''(b) FEE REVENUE AMOUNTS.—Except as provided in subsections (c), (d), (f), and (g), fees under subsection (a) shall be established to generate the following revenue amounts, in each fiscal year beginning with fiscal year 2008 and continuing through fiscal year 2012: $392,783,000, plus an adjustment for workload on $354,893,000 of this amount. Such adjustment shall be made in accordance with the workload adjustment provisions in effect for fiscal year 2007, except that instead of commercial investigational new drug applications submitted to the Secretary, all commercial investigational new drug applications with a submission during the previous 12-month period shall be used in the determination. One-third of the revenue amount shall be derived from application fees, one-third from establishment fees, and one-third from product fees.''.

(c) ADJUSTMENTS TO FEES.—

(1) INFLATION ADJUSTMENT.—Section 736(c)(1) (21 U.S.C. 379h(c)(1)) is amended—

(A) in the matter preceding subparagraph (A) by striking ''The revenues established in subsection (b)'' and inserting ''Beginning with fiscal year 2009, the revenues established in subsection (b)'';

(B) in subparagraph (A) by striking ''or'' at the end;

(C) in subparagraph (B) by striking the period at the end and inserting '', or,'';

(D) by inserting after subparagraph (B) the following:

''(C) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions, for the first 5 fiscal years of the previous 6 fiscal years.''; and

(E) in the matter following subparagraph (C) (as added by this paragraph), by striking ''fiscal year 2003'' and inserting ''fiscal year 2008''.

(2) WORKLOAD ADJUSTMENT.—Section 736(c)(2) (21 U.S.C. 379h(c)(2)) is amended—

(A) in the matter preceding subparagraph (A,) by striking ''2004'' and inserting ''2009'';

(B) in the first sentence of subparagraph (A)—

(i) by striking '', commercial investigational new drug applications'' and in-

serting ''(adjusted for changes in review activities)''; and

(ii) by inserting before the period at the end '', and the change in the number of commercial investigational new drug applications with a submission during the previous 12-month period (adjusted for changes in review activities)'';

(C) in subparagraph (B), by adding at the end the following new sentence: ''Further, any adjustment for changes in review activities made in setting fees and fee revenue amounts for fiscal year 2009 may not result in the total workload adjustment being more than 2 percentage points higher than it would be absent the adjustment for changes in review activities.''; and

(D) by adding at the end the following:

''(C) The Secretary shall contract with an independent accounting firm to study the adjustment for changes in review activities applied in setting fees for fiscal year 2009 and to make recommendations, if warranted, on future changes in the methodology for calculating the adjustment for changes in review activity. After

review of the recommendations by the independent accounting firm, the Secretary shall make appropriate changes to the workload adjustment methodology in setting fees for fiscal years 2010 through 2012. If the study is not conducted, no adjustment for changes in review activities shall be made after fiscal year 2009.''.

(3) RENT AND RENT-RELATED COST ADJUSTMENT.—Section 736(c) (21 U.S.C. 379h(c)) is amended—

(A) by redesignating paragraphs (3), (4), and (5) as paragraphs (4), (5), and (6), respectively; and

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

''(3) RENT AND RENT-RELATED COST ADJUSTMENT.—Beginning with fiscal year 2010, the Secretary shall, before making the adjustments under paragraphs (1) and (2), reduce the fee amounts established in subsection (b), if actual costs paid for rent and rent-related expenses are less than $11,721,000. The reductions made under this paragraph, if any, shall not exceed the amounts by which costs fell below $11,721,000, and shall not exceed $11,721,000 in any fiscal year.''.

(4) FINAL YEAR ADJUSTMENT.—Section 736(c) (21 U.S.C. 379h(c)) is amended—

(A) in paragraph (4), as redesignated by this subsection—

(i) by striking ''2007'' each place it appears and inserting ''2012''; and

(ii) by striking ''2008'' and inserting ''2013''; and

(B) in paragraph (5), as redesignated by this subsection, by striking ''2002'' and inserting ''2007''.

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

(1) in paragraph (1), in the matter preceding subparagraph (A), by—

(A) inserting ''to a person who is named as the applicant'' after ''The Secretary shall grant'';

(B) inserting ''to that person'' after ''a waiver from or a reduction of one or more fees assessed''; and

(C) striking ''finds'' and inserting ''determines'';

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

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

''(2) EVALUATION.—For the purpose of determining whether to grant a waiver or reduction of a fee under paragraph (1), the Secretary shall consider only the circumstances and assets of the applicant and any affiliate of the applicant.''; and

(4) in paragraph (4), as redesignated by this subsection, in subparagraph (A), by inserting before the period at the end '', and that does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce''.

(e) CREDITING AND AVAILABILITY OF FEES.—

(1) AUTHORIZATION OF APPROPRIATIONS.—Section 736(g)(3) (21 U.S.C. 379h(g)(3)) is amended to read as follows:

''(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section such sums as are authorized to be assessed and collected under this section in each of fiscal years 2008 through 2012.''.

(2) OFFSET.—Section 736(g)(4) (21 U.S.C. 379h(g)(4)) is amended to read as follows:

''(4) OFFSET.—If the cumulative amount of fees collected during fiscal years 2008, 2009, and 2010, plus the amount estimated to be collected for fiscal year 2011, exceeds the amount of fees specified in aggregate in appropriation Acts for such fiscal years, the aggregate amount in excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2012.''.

(f) CONFORMING AMENDMENTS.—

(1) Section 736(a) (21 U.S.C. 379h(a)), as amended by this section, is amended—

(A) in paragraph (1)(A), by striking ''subsection (c)(4)'' each place it appears and inserting ''subsection (c)(5)'';

(B) in paragraph (2), by striking ''subsection (c)(4)'' and inserting ''subsection (c)(5)''; and

(C) in paragraph (3), by striking ''subsection (c)(4)'' and inserting ''subsection (c)(5)''.

(2) Section 736A(h)(3), as added by section 104 of this title, is amended by striking ''735(3)'' and inserting ''735(d)(3)''.

SEC. 104. AUTHORITY TO ASSESS AND USE PRESCRIPTION DRUG ADVERTISING FEES.

Chapter VII, subchapter C, part 2 (21 U.S.C. 379g et seq.) is amended by adding after section 736 the following new section:

''SEC. 736A. PROGRAM TO ASSESS AND USE FEES FOR THE ADVISORY REVIEW OF PRESCRIPTION DRUG ADVERTISING.

''(a) TYPES OF DIRECT-TO-CONSUMER TELEVISION ADVERTISEMENT REVIEW FEES.—Beginning with fiscal year 2008, the Secretary shall assess and collect fees in accordance with this section as follows:

''(1) ADVISORY REVIEW FEE.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), each person that on or after October 1, 2007, submits a proposed direct-to-consumer television advertisement for advisory review by the Secretary prior to its initial public dissemination shall be subject to a fee established under subsection (c)(3).

''(B) EXCEPTION FOR REQUIRED SUBMISSIONS.—A direct-to-consumer television adver-

tisement that is required to be submitted to the Secretary prior to initial public dissemination shall not be assessed a fee unless the sponsor designates it as a submission for advisory review.

''(C) PAYMENT.—The fee required by subparagraph (A) shall be due not later than October 1 of the fiscal year in which the direct-to-consumer television advertisement shall be submitted to the Secretary for advisory review.

''(D) MODIFICATION OF ADVISORY REVIEW FEE.—

''(i) LATE PAYMENT.—If, on or before November 1 of the fiscal year in which the fees are due, a person has not paid all fees that were due and payable for advisory reviews identified in response to the Federal Register notice described in subsection (c)(3)(A), the fees shall be regarded as late. Such fees shall be due and payable 20 days before any direct-to-consumer television advertisement is submitted by such person to the Secretary for advisory review. Notwithstanding any other provision of this section, such fees shall be due and

payable for each of those advisory reviews in the amount of 150 percent of the advisory review fee established for that fiscal year pursuant to subsection (c)(3).

"(ii) LATE NOTICE OF SUBMISSION.—If any person submits any direct-to-consumer television advertisements for advisory review that are in excess of the number identified by that person in response to the Federal Register notice described in subsection (c)(3)(A), that person must pay a fee for each of those advisory reviews in the amount of 150 percent of the advisory review fee established for that fiscal year pursuant to subsection (c)(3). Fees under this subparagraph shall be due 20 days before the direct-to-consumer television advertisement is submitted by such person to the Secretary for advisory review.

"(E) LIMITS.—

"(i) IN GENERAL.—The payment of a fee under this paragraph for a fiscal year entitles the person that pays the fee to acceptance for advisory review by the Secretary of 1 direct-to-consumer television

advertisement and acceptance of 1 resubmission for advisory review of the same advertisement. The advertisement shall be submitted for review in the fiscal year for which the fee was assessed, except that a person may carry over no more than 1 paid advisory review submission to the next fiscal year. Resubmissions may be submitted without regard to the fiscal year of the initial advisory review submission.

''(ii) NO REFUND.—Except as provided by subsection (f), fees paid under this paragraph shall not be refunded.

''(iii) NO WAIVER, EXEMPTION, OR REDUCTION.—The Secretary shall not grant a waiver, exemption, or reduction of any fees due or payable under this section.

''(iv) NON-TRANSFERABILITY.—The right to an advisory review is not transferable, except to a successor in interest.

''(2) OPERATING RESERVE FEE.—

''(A) IN GENERAL.—Each person that, on or after October 1, 2007, is assessed an advisory review fee under paragraph (1) shall be subject to an operating reserve fee established

under subsection (d)(2) only in the first fiscal year in which an advisory review fee is assessed.

''(B) PAYMENT.—Except as provided in subparagraph (C), the fee required by subparagraph (A) shall be due not later than October 1 of the first fiscal year in which the person is required to pay an advisory review fee under paragraph (1).

''(C) LATE NOTICE OF SUBMISSION.—If, in the first fiscal year of a person's participation in the Program, that person submits any direct-to-consumer television advertisements for advisory review that are in excess of the number identified by that person in response to the Federal Register notice described in subsection (c)(3)(A), that person must pay an operating reserve fee for each of those advisory reviews equal to the advisory review fee for each submission established under paragraph (1)(D)(ii). Fees required by this subparagraph shall be in addition to the fees required under subparagraph (B), if any. Fees under this subparagraph shall be due 20 days before any direct-to-consumer television advertisement is sub-

mitted by such person to the Secretary for advisory review.

''(b) ADVISORY REVIEW FEE REVENUE AMOUNTS.—Fees under subsection (a)(1) shall be established to generate revenue amounts of $6,250,000 for each of fiscal years 2008 through 2012, as adjusted pursuant to subsection (c).

''(c) ADJUSTMENTS.—

''(1) INFLATION ADJUSTMENT.—Beginning with fiscal year 2009, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the greater of—

''(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average), for the 12-month period ending June 30 preceding the fiscal year for which fees are being established;

''(B) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, as adjusted by any locality-based comparability payment pursuant to section

5304 of such title for Federal employees stationed in the District of Columbia; or

''(C) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions, for the first 5 fiscal years of the previous 6 fiscal years.

The adjustment made each fiscal year by this paragraph shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2008 under this subsection.

''(2) WORKLOAD ADJUSTMENT.—

''(A) IN GENERAL.—Beginning with fiscal year 2009, after the fee revenues established in subsection (b) of this section are adjusted for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall be adjusted further for such fiscal year to reflect changes in the workload of the Secretary with respect to the submission of proposed direct-to-consumer television advertisements for advisory review prior to initial broadcast.

''(B) DETERMINATION OF WORKLOAD ADJUSTMENT.—

''(i) IN GENERAL.—The workload adjustment under this paragraph for a fiscal year shall be determined by the Secretary—

''(I) based upon the number of direct-to-consumer television advertisements identified pursuant to paragraph (3)(A) for that fiscal year, excluding allowable previously paid carry over submissions; and

''(II) by multiplying the number of such advertisements projected for that fiscal year that exceeds 150 by $27,600 (adjusted each year beginning with fiscal year 2009 for inflation in accordance with paragraph (1)).

''(ii) PUBLICATION IN FEDERAL REGISTER.—The Secretary shall publish in the Federal Register, as part of the notice described in paragraph (1), the fee revenues and fees resulting from the adjustment made under this paragraph and the supporting methodologies.

"(C) LIMITATION.—Under no circumstances shall the adjustment made under this paragraph result in fee revenues for a fiscal year that are less than the fee revenues established for the prior fiscal year.

"(3) ANNUAL FEE SETTING.—

"(A) NUMBER OF ADVERTISEMENTS.—The Secretary shall, 120 days before the start of each fiscal year, publish a notice in the Federal Register requesting any person to notify the Secretary within 30 days of the number of direct-to-consumer television advertisements the person intends to submit for advisory review by the Secretary in the next fiscal year. Notification to the Secretary of the number of advertisements a person intends to submit for advisory review prior to initial broadcast shall be a legally binding commitment by that person to pay the annual advisory review fee for that number of submissions on or before October 1 of the fiscal year in which the advertisement is intended to be submitted. A person shall at the same time also notify the Secretary if such person intends to use a paid submission from the previous fiscal year under subsection

(a)(1)(E)(i). If such person does not so notify the Secretary, all submissions for advisory review shall be subject to advisory review fees.

''(B) ANNUAL FEE.—The Secretary shall, 60 days before the start of each fiscal year, establish, for the next fiscal year, the direct-to-consumer television advertisement advisory review fee under subsection (a)(1), based on the revenue amounts established under subsection (b), the adjustments provided under this subsection and the number of direct-to-consumer television advertisements identified pursuant to subparagraph (A), excluding allowable previously paid carry over submissions. The annual advisory review fee shall be established by dividing the fee revenue for a fiscal year (as adjusted pursuant to this subsection) by the number of direct-to-consumer television advertisements identified pursuant to subparagraph (A), excluding allowable previously paid carry over submissions.

''(C) FISCAL YEAR 2008 FEE LIMIT.—Notwithstanding subsection (b), the fee established under subparagraph (B) for fiscal year 2008

may not be more than $83,000 per submission for advisory review.

''(D) ANNUAL FEE LIMIT.—Notwithstanding subsection (b), the fee established under subparagraph (B) for a fiscal year after fiscal year 2008 may not be more than 50 percent more than the fee established for the prior fiscal year.

''(E) LIMIT.—The total amount of fees obligated for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the advisory review of prescription drug advertising.

''(d) OPERATING RESERVES.—

''(1) IN GENERAL.—The Secretary shall establish in the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation a Direct-to-Consumer Advisory Review Operating Reserve, of at least $6,250,000 in fiscal year 2008, to continue the Program in the event the fees collected in any subsequent fiscal year pursuant to subsection (c)(3) do not generate the fee revenue amount established for that fiscal year.

''(2) FEE SETTING.—The Secretary shall establish the operating reserve fee under subsection

(a)(2)(A) for each person required to pay the fee by multiplying the number of direct-to-consumer television advertisements identified by that person pursuant to subsection (c)(3)(A) by the advisory review fee established pursuant to subsection (c)(3) for that fiscal year. In no case shall the operating reserve fee assessed be less than the operating reserve fee assessed if the person had first participated in the Program in fiscal year 2008.

''(3) USE OF OPERATING RESERVE.—The Secretary may use funds from the reserves under this subsection only to the extent necessary in any fiscal year to make up the difference between the fee revenue amount established for that fiscal year under subsection (b) and the amount of fees collected for that fiscal year pursuant to subsection (a), or to pay costs of ending the Program if it is terminated pursuant to subsection (f) or if it is not reauthorized after fiscal year 2012.

''(4) REFUND OF OPERATING RESERVES.—Within 120 days of the end of fiscal year 2012, or if the Program is terminated pursuant to subsection (f), the Secretary, after setting aside sufficient operating reserve amounts to terminate the Program, shall refund all amounts remaining in the operating

reserve on a pro rata basis to each person that paid an operating reserve fee assessment. In no event shall the refund to any person exceed the total amount of operating reserve fees paid by such person pursuant to subsection (a)(2).

''(e) EFFECT OF FAILURE TO PAY FEES.—Notwithstanding any other law or regulation of the Secretary, a submission for advisory review of a direct-to-consumer television advertisement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person under this section have been paid.

''(f) EFFECT OF INADEQUATE FUNDING OF PROGRAM.—

''(1) FIRST FISCAL YEAR.—If on November 1, 2007, or 120 days after enactment of the Prescription Drug User Fee Amendments of 2007, whichever is later, the Secretary has received less than $11,250,000 in advisory review fees and operating reserve fees combined, the Program shall be terminated and all collected fees shall be refunded.

''(2) SUBSEQUENT FISCAL YEARS.—Beginning in fiscal year 2009, if, on November 1 of a fiscal year, the combination of the operating reserves, an-

nual fee revenues from that fiscal year, and unobligated fee revenues from prior fiscal years is less than $9,000,000, adjusted for inflation (in accordance with subsection (c)(1)), the Program shall be terminated, and the Secretary shall notify all participants, retain any money from the unused advisory review fees and the operating reserves needed to terminate the Program, and refund the remainder of the unused fees and operating reserves. To the extent required to terminate the Program, the Secretary shall first use unobligated advisory review fee revenues from prior fiscal years, then the operating reserves, and then unused advisory review fees from the relevant fiscal year.

''(g) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The

sums transferred shall be available solely for the process for the advisory review of prescription drug advertising.

''(2) COLLECTIONS AND APPROPRIATION ACTS.—The fees authorized by this section—

''(A) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year; and

''(B) shall be available for obligation only if appropriated budget authority continues to support at least the total combined number of full-time equivalent employees in the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications, and the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Branch supported in fiscal year 2007.

''(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section not less than $6,250,000 for each of fiscal years 2008, 2009, 2010, 2011, and 2012, as adjusted to reflect adjustments in the total fee

revenues made under this section, plus amounts collected for the reserve fund under subsection (d).

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

''(h) DEFINITIONS.—For purposes of this section:

''(1) The term 'advisory review' means reviewing and providing advisory comments regarding compliance of a proposed advertisement with the requirements of this Act prior to its initial public dissemination.

''(2) The term 'carry over submission' means a submission for an advisory review for which a fee was paid in a fiscal year that is submitted for review in the following fiscal year.

''(3) The term 'direct-to-consumer television advertisement' means an advertisement for a prescription drug product as defined in section 735(3) in-

tended to be displayed on any television channel for less than 2 minutes.

''(4) The term 'person' includes an individual, a partnership, a corporation, and an association, and any affiliate thereof or successor in interest.

''(5) The term 'process for the advisory review of prescription drug advertising' means the activities necessary to review and provide advisory comments on proposed direct-to-consumer television advertisements prior to public dissemination and, to the extent the Secretary has additional staff resources available under the Program that are not necessary for the advisory review of direct-to-consumer television advertisements, the activities necessary to review and provide advisory comments on other proposed advertisements and promotional material prior to public dissemination.

''(6) The term 'Program' means the Program to assess, collect, and use fees for the advisory review of prescription drug advertising established by this section.

''(7) The term 'resources allocated for the process for the advisory review of prescription drug advertising' means the expenses incurred in connection

with the process for the advisory review of prescription drug advertising for—

''(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees, and to contracts with such contractors;

''(B) management of information, and the acquisition, maintenance, and repair of computer resources;

''(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies;

''(D) collection of fees under this section and accounting for resources allocated for the advisory review of prescription drug advertising; and

''(E) terminating the Program under subsection (f)(2), if necessary.

''(8) The term 'resubmission' means a subsequent submission for advisory review of a direct-to-consumer television advertisement that has been re-

vised in response to the Secretary's comments on an original submission. A resubmission may not introduce significant new concepts or creative themes into the television advertisement.

''(9) The term 'submission for advisory review' means an original submission of a direct-to-consumer television advertisement for which the sponsor voluntarily requests advisory comments before the advertisement is publicly disseminated.

''SEC. 736B. SUNSET.

''This part shall cease to be effective on October 1, 2012, except that subsection (b) of section 736 with respect to reports shall cease to be effective on January 31, 2013.''.

SEC. 105. SAVINGS CLAUSE.

Notwithstanding section 509 of the Prescription Drug User Fee Amendments of 2002 (21 U.S.C. 379g note), and notwithstanding the amendments made by this title, part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of enactment of this title, shall continue to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that on or after October 1, 2002, but before October 1, 2007, were accepted by the Food and Drug Administra-

tion for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2008.

SEC. 106. TECHNICAL AMENDMENT.

Section 739 (21 U.S.C. 379j–11) is amended in the matter preceding paragraph (1), by striking ''subchapter'' and inserting ''part''.

SEC. 107. EFFECTIVE DATES.

(a) IN GENERAL.—Except as provided in subsection (b), the amendments made by this title shall take effect October 1, 2007.

(b) EXCEPTION.—The amendment made by section 104 of this title shall take effect on the date of enactment of this title.

TITLE II—DRUG SAFETY

SEC. 200. SHORT TITLE.

This title may be cited as the ''Enhancing Drug Safety and Innovation Act of 2007''.

Subtitle A—Risk Evaluation and Mitigation Strategies

SEC. 201. ROUTINE ACTIVE SURVEILLANCE AND ASSESSMENT.

(a) IN GENERAL.—Subsection (k) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

''(3) ROUTINE ACTIVE SURVEILLANCE AND ASSESSMENT.—

''(A) DEVELOPMENT OF THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—The Secretary shall, not later than 2 years after the date of enactment of the Enhancing Drug Safety and Innovation Act of 2007, act in collaboration with academic institutions and private entities to—

''(i) establish minimum standards for collection and transmission of postmarketing data elements from electronic health data systems; and

''(ii) establish, through partnerships, a validated and integrated postmarket risk identification and analysis system to integrate and analyze safety data from multiple sources, with the goals of including, in aggregate—

''(I) at least 25,000,000 patients by July 1, 2010; and

''(II) at least 100,000,000 patients by July 1, 2012.

''(B) DATA COLLECTION ACTIVITIES.—

"(i) IN GENERAL.—The Secretary shall, not later than 1 year after the establishment of the minimum standards and the identification and analysis system under subparagraph (A), establish and maintain an active surveillance infrastructure—

"(I) to collect and report data for pharmaceutical postmarket risk identification and analysis, in compliance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996; and

"(II) that includes, in addition to the collection and monitoring (in a standardized form) of data on all serious adverse drug experiences (as defined in subsection (o)(2)(C)) required to be submitted to the Secretary under paragraph (1), and those events voluntarily submitted from patients, providers, and drug, when appropriate, procedures to—

"(aa) provide for adverse event surveillance by collecting and monitoring Federal health-related electronic data (such as data from the Medicare program and the health systems of the Department of Veterans Affairs);

"(bb) provide for adverse event surveillance by collecting and monitoring private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data);

"(cc) provide for adverse event surveillance by monitoring standardized electronic health records, as available;

"(dd) provide for adverse event surveillance by collecting and monitoring other information as the Secretary deems necessary to create a robust system to identify adverse events and potential drug safety signals;

"(ee) enable the program to identify certain trends and patterns with respect to data reported to the program;

"(ff) enable the program to provide regular reports to the Secretary concerning adverse event trends, adverse event patterns, incidence and prevalence of adverse events, laboratory data, and other information determined appropriate, which may include data on comparative national adverse event trends; and

"(gg) enable the program to export data in a form appropriate for further aggregation, statistical analysis, and reporting.

"(ii) TIMELINESS OF REPORTING.—The procedures developed under clause (i) shall ensure that such data are collected, monitored, and reported in a timely, routine, and automatic manner, taking into consideration the need for data completeness, coding, cleansing, and transmission.

''(iii) PRIVATE SECTOR RESOURCES.—To ensure the establishment of the active surveillance infrastructure by the date described under clause (i), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

''(iv) COMPLEMENTARY APPROACHES.—To the extent the active surveillance infrastructure established under clause (i) is not sufficient to gather data and information relevant to priority drug safety questions, the Secretary shall develop, support, and participate in complementary approaches to gather and analyze such data and information, including—

''(I) approaches that are complementary with respect to assessing the safety of use of a drug in domestic populations not included in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children); and

''(II) existing approaches such as the Vaccine Adverse Event Reporting System and the Vaccine Safety Datalink or successor databases.

''(v) AUTHORITY FOR CONTRACTS.—The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subparagraph.

''(C) RISK IDENTIFICATION AND ANALYSIS.—

''(i) PURPOSE.—To carry out this paragraph, the Secretary shall establish collaborations with other Government, academic, and private entities, including the Centers for Education and Research on Therapeutics under section 912 of the Public Health Service Act, to provide for the risk identification and analysis of the data collected under subparagraph (B) and data that is publicly available or is provided by the Secretary, in order to—

''(I) improve the quality and efficiency of postmarket drug safety risk-benefit analysis;

"(II) provide the Secretary with routine access to expertise to study advanced drug safety data; and

"(III) enhance the ability of the Secretary to make timely assessments based on drug safety data.

"(ii) PUBLIC PROCESS FOR PRIORITY QUESTIONS.—At least biannually, the Secretary shall seek recommendations from the Drug Safety and Risk Management Advisory Committee (or successor committee) and from other advisory committees, as appropriate, to the Food and Drug Administration on—

"(I) priority drug safety questions; and

"(II) mechanisms for answering such questions, including through—

"(aa) routine active surveillance under subparagraph (B); and

"(bb) when such surveillance is not sufficient, postmarket studies under subsection (o)(4)(B) and postapproval clin-

ical trials under subsection (o)(4)(C).

''(iii) PROCEDURES FOR THE DEVELOPMENT OF DRUG SAFETY COLLABORATIONS.—

''(I) IN GENERAL.—Not later than 180 days after the date of the establishment of the active surveillance infrastructure under subparagraph (B), the Secretary shall establish and implement procedures under which the Secretary may routinely collaborate with a qualified entity to—

''(aa) clean, classify, or aggregate data collected under subparagraph (B) and data that is publicly available or is provided by the Secretary;

''(bb) allow for prompt investigation of priority drug safety questions, including—

''(AA) unresolved safety questions for drugs or classes of drugs; and

"(BB) for a newly-approved drug: safety signals from clinical trials used to approve the drug and other preapproval trials; rare, serious drug side effects; and the safety of use in domestic populations not included in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children);

"(cc) perform advanced research and analysis on identified drug safety risks;

"(dd) convene an expert advisory committee to oversee the establishment of standards for the ethical and scientific uses for, and communication of, post-marketing data collected under subparagraph (B), including advising on the development of ef-

fective research methods for the study of drug safety questions;

''(ee) focus postmarket studies under subsection (o)(4)(B) and postapproval clinical trials under subsection (o)(4)(C) more effectively on cases for which reports under paragraph (1) and other safety signal detection is not sufficient to resolve whether there is an elevated risk of a serious adverse event associated with the use of a drug; and

''(ff) carry out other activities as the Secretary deems necessary to carry out the purposes of this paragraph.

''(II) REQUEST FOR SPECIFIC METHODOLOGY.—The procedures described in subclause (I) shall permit the Secretary to request that a specific methodology be used by the qualified entity. The qualified entity shall work with the Secretary to finalize the methodology to be used.

''(iv) USE OF ANALYSES.—The Secretary shall provide the analyses described under this subparagraph, including the methods and results of such analyses, about a drug to the sponsor or sponsors of such drug.

''(v) QUALIFIED ENTITIES.—

''(I) IN GENERAL.—The Secretary shall enter into contracts with a sufficient number of qualified entities to develop and provide information to the Secretary in a timely manner.

''(II) QUALIFICATION.—The Secretary shall enter into a contract with an entity under subclause (I) only if the Secretary determines that the entity—

''(aa) has the research capability and expertise to conduct and complete the activities under this paragraph;

''(bb) has in place an information technology infrastructure to support adverse event surveil-

lance data and operational standards to provide security for such data;

''(cc) has experience with, and expertise on, the development of drug safety and effectiveness research using electronic population data;

''(dd) has an understanding of drug development and risk/benefit balancing in a clinical setting; and

''(ee) has a significant business presence in the United States.

''(vi) CONTRACT REQUIREMENTS.—Each contract with a qualified entity shall contain the following requirements:

''(I) ENSURING PRIVACY.—The qualified entity shall provide assurances that the entity will not use the data provided by the Secretary in a manner that violates—

''(aa) the regulations promulgated under section 264(c) of

the Health Insurance Portability and Accountability Act of 1996; or

''(bb) sections 552 or 552a of title 5, United States Code, with regard to the privacy of individually-identifiable beneficiary health information.

''(II) COMPONENT OF ANOTHER ORGANIZATION.—If a qualified entity is a component of another organization—

''(aa) the qualified entity shall maintain the data related to the activities carried out under this paragraph separate from the other components of the organization and establish appropriate security measures to maintain the confidentiality and privacy of such data; and

''(bb) the entity shall not make an unauthorized disclosure of such data to the other components of the organization in

breach of such confidentiality and privacy requirement.

''(III) TERMINATION OR NON-RENEWAL.—If a contract with a qualified entity under this subparagraph is terminated or not renewed, the following requirements shall apply:

''(aa) CONFIDENTIALITY AND PRIVACY PROTECTIONS.—The entity shall continue to comply with the confidentiality and privacy requirements under this paragraph with respect to all data disclosed to the entity.

''(bb) DISPOSITION OF DATA.—The entity shall return to the Secretary all data disclosed to the entity or, if returning the data is not practicable, destroy the data.

''(vii) COMPETITIVE PROCEDURES.—The Secretary shall use competitive procedures (as defined in section 4(5) of the Federal Procurement Policy Act) to enter into contracts under clause (v).

''(viii) REVIEW OF CONTRACT IN THE EVEN OF A MERGER OR ACQUISITION.—The Secretary shall review the contract with a qualified entity under this paragraph in the event of a merger or acquisition of the entity in order to ensure that the requirements under this subparagraph will continue to be met.

''(D) COORDINATION.—In carrying out this paragraph, the Secretary shall provide for appropriate communications to the public, scientific, public health, and medical communities, and other key stakeholders, and provide for the coordination of the activities of private entities, professional associations, or other entities that may have sources of surveillance data.''.

(b) AUTHORIZATION OF APPROPRIATIONS.—To carry out activities under the amendment made by this section for which funds are made available under section 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h), there are authorized to be appropriated to carry out the amendment made by this section, in addition to such funds, $25,000,000 for each of fiscal years 2008 through 2012.

SEC. 202. RISK EVALUATION AND MITIGATION STRATEGIES.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

''(o) RISK EVALUATION AND MITIGATION STRATEGY.—

''(1) IN GENERAL.—In the case of any drug subject to subsection (b) or to section 351 of the Public Health Service Act for which a risk evaluation and mitigation strategy is approved as provided for in this subsection, the applicant shall comply with the requirements of such strategy.

''(2) DEFINITIONS.—In this subsection:

''(A) ADVERSE DRUG EXPERIENCE.—The term 'adverse drug experience' means any adverse event associated with the use of a drug in humans, whether or not considered drug related, including—

''(i) an adverse event occurring in the course of the use of the drug in professional practice;

''(ii) an adverse event occurring from an overdose of the drug, whether accidental or intentional;

''(iii) an adverse event occurring from abuse of the drug;

''(iv) an adverse event occurring from withdrawal of the drug; and

''(v) any failure of expected pharmacological action of the drug.

''(B) NEW SAFETY INFORMATION.—The term 'new safety information' with respect to a drug means information about—

''(i) a serious risk or an unexpected serious risk with use of the drug that the Secretary has become aware of since the later of—

''(I) the date of initial approval of the drug under this section or initial licensure of the drug under section 351 of the Public Health Service Act; or

''(II) if applicable, the last assessment of the approved risk evaluation and mitigation strategy for the drug; or

''(ii) the effectiveness of the approved risk evaluation and mitigation strategy for the drug obtained since the later of—

''(I) the approval of such strategy; or

''(II) the last assessment of such strategy.

''(C) SERIOUS ADVERSE DRUG EXPERIENCE.—The term 'serious adverse drug experience' is an adverse drug experience that—

''(i) results in—

''(I) death;

''(II) the placement of the patient at immediate risk of death from the adverse drug experience as it occurred (not including an adverse drug experience that might have caused death had it occurred in a more severe form);

''(III) inpatient hospitalization or prolongation of existing hospitalization;

''(IV) a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; or

''(V) a congenital anomaly or birth defect; or

''(ii) based on appropriate medical judgment, may jeopardize the patient and

may require a medical or surgical intervention to prevent an outcome described under clause (i).

''(D) SERIOUS RISK.—The term 'serious risk' means a risk of a serious adverse drug experience.

''(E) SIGNAL OF A SERIOUS RISK.—The term 'signal of a serious risk' means information related to a serious adverse drug experience derived from—

''(i) a clinical trial;

''(ii) adverse event reports under subsection (k)(1);

''(iii) routine active surveillance under subsection (k)(3);

''(iv) a postapproval study, including a study under paragraph (4)(B); or

''(v) peer-reviewed biomedical literature.

''(F) UNEXPECTED SERIOUS RISK.—The term 'unexpected serious risk' means a serious adverse drug experience that—

''(i) is not listed in the labeling of a drug; or

"(ii) is symptomatically and pathophysiologically related to an adverse drug experience listed in the labeling of the drug, but differs from such adverse drug experience because of greater severity, specificity, or prevalence.

"(3) REQUIRED ELEMENTS OF A RISK EVALUATION AND MITIGATION STRATEGY.—If a risk evaluation and mitigation strategy for a drug is required, such strategy shall include—

"(A) the labeling for the drug for use by health care providers as approved under subsection (c);

"(B) a timetable for submission of assessments of the strategy, that—

"(i) for a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 351 of the Public Health Service Act—

"(I) shall be no less frequently than 18 months and 3 years after the drug is initially approved and at a fre-

quency specified in the strategy for subsequent years; and

"(II) may be eliminated after the first 3 years if the Secretary determines that serious risks of the drug have been adequately identified and assessed and are being adequately managed;

"(ii) for a drug other than a drug described under clause (i), shall occur at a frequency determined by the Secretary; and

"(iii) may be increased or reduced in frequency as necessary as provided for in paragraph (7)(B)(v)(VI).

"(4) ADDITIONAL POTENTIAL EVALUATION ELEMENTS OF A RISK EVALUATION AND MITIGATION STRATEGY.—

"(A) RISK EVALUATION.—If a risk evaluation and mitigation strategy for a drug is required, such strategy may include 1 or more of the additional evaluation elements described in this paragraph, so long as the Secretary makes the determination required with respect to each additional included element.

"(B) POSTAPPROVAL STUDIES.—If the Secretary determines that the reports under subsection (k)(1) and routine active surveillance as available under subsection (k)(3) (including available complementary approaches under subsection (k)(3)(B)(iv)) will not be sufficient to—

"(i) assess a signal of a serious risk with use of a drug; or

"(ii) identify, based on a review of a demonstrated pattern of use of the drug, unexpected serious risks in a domestic population, including older people, people with comorbidities, pregnant women, or children,

the risk evaluation and mitigation strategy for the drug may require that the applicant conduct an appropriate postapproval study, such as a prospective or retrospective observational study, of the drug (which shall include a timeframe specified by the Secretary for completing the study and reporting the results to the Secretary).

"(C) POSTAPPROVAL CLINICAL TRIALS.—If the Secretary determines that the reports under subsection (k)(1), routine active surveillance as

available under subsection (k)(3) (including available complementary approaches under subsection (k)(3)(B)(iv)), and a study or studies under subparagraph (B) will likely be inadequate to assess a signal of a serious risk with use of a drug, and there is no effective approved application for the drug under subsection (j) as of the date that the requirement is first imposed, the risk evaluation and mitigation strategy for the drug may require that the applicant conduct an appropriate postapproval clinical trial of the drug (which shall include a timeframe specified by the Secretary for completing the clinical trial and reporting the results to the Secretary) to be included in the clinical trial registry data bank provided for under subsections (i) and (j) of section 402 of the Public Health Service Act.

''(5) ADDITIONAL POTENTIAL COMMUNICATION ELEMENTS OF A RISK EVALUATION AND MITIGATION STRATEGY.—

''(A) RISK COMMUNICATION.—If a risk evaluation and mitigation strategy for a drug is required, such strategy may include 1 or more of the additional communication elements de-

scribed in this paragraph, so long as the Secretary makes the determination required with respect to each additional included element.

''(B) MEDGUIDE; PATIENT PACKAGE INSERT.—The risk evaluation and mitigation strategy for a drug may require that the applicant develop for distribution to each patient when the drug is dispensed either or both of the following:

''(i) A Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations).

''(ii) A patient package insert, if the Secretary determines that such insert may help mitigate a serious risk listed in the labeling of the drug.

''(C) COMMUNICATION PLAN.—If the Secretary determines that a communication plan to health care providers may support implementation of an element of the risk evaluation and mitigation strategy for a drug, such as a labeling change, the strategy may require that the applicant conduct such a plan, which may include—

''(i) sending letters to health care providers;

''(ii) disseminating information about the elements of the strategy to encourage implementation by health care providers of components that apply to such health care providers, or to explain certain safety protocols (such as medical monitoring by periodic laboratory tests); or

''(iii) disseminating information to health care providers through professional societies about any serious risks of the drug and any protocol to assure safe use.

''(D) PREREVIEW.—

''(i) IN GENERAL.—If the Secretary determines that prereview of advertisements is necessary to ensure the inclusion of a true statement in such advertisements of information in brief summary relating to a serious risk listed in the labeling of a drug, or relating to a protocol to ensure the safe use described in the labeling of the drug, the risk evaluation and mitigation strategy for the drug may require that the applicant submit to the Secretary adver-

tisements of the drug for prereview not later than 45 days before dissemination of the advertisement

''(ii) SPECIFICATION OF ADVERTISEMENTS.—The Secretary may specify the advertisements required to be submitted under clause (i).

''(E) SPECIFIC DISCLOSURES.—

''(i) SERIOUS RISK; SAFETY PROTOCOL.—If the Secretary determines that advertisements lacking a specific disclosure about a serious risk listed in the labeling of a drug or about a protocol to ensure safe use described in the labeling of the drug would be false or misleading, the risk evaluation and mitigation strategy for the drug may require that the applicant include in advertisements of the drug such disclosure.

''(ii) DATE OF APPROVAL.—If the Secretary determines that advertisements lacking a specific disclosure of the date a drug was approved and disclosure of a serious risk would be false or misleading, the risk evaluation and mitigation strategy for

the drug may require that the applicant include in advertisements of the drug such disclosure.

''(iii) SPECIFICATION OF ADVERTISEMENTS.—The Secretary may specify the advertisements required to include a specific disclosure under clause (i) or (ii).

''(iv) REQUIRED SAFETY SURVEILLANCE.—If the approved risk evaluation and mitigation strategy for a drug requires the specific disclosure under clause (ii), the Secretary shall—

''(I) consider identifying and assessing all serious risks of using the drug to be a priority safety question under subsection (k)(3)(B);

''(II) not less frequently than every 3 months, evaluate the reports under subsection (k)(1) and the routine active surveillance as available under subsection (k)(3) with respect to such priority drug safety question to determine whether serious risks that might occur among patients expected to be treated with the drug

have been adequately identified and assessed;

''(III) remove such specific disclosure requirement as an element of such strategy if such serious risks have been adequately identified and assessed; and

''(IV) consider whether a specific disclosure under clause (i) should be required.

''(6) PROVIDING SAFE ACCESS FOR PATIENTS TO DRUGS WITH KNOWN SERIOUS RISKS THAT WOULD OTHERWISE BE UNAVAILABLE.—

''(A) ALLOWING SAFE ACCESS TO DRUGS WITH KNOWN SERIOUS RISKS.—The Secretary may require that the risk evaluation and mitigation strategy for a drug include such elements as are necessary to assure safe use of the drug, because of its inherent toxicity or potential harmfulness, if the Secretary determines that—

''(i) the drug, which has been shown to be effective, but is associated with a serious adverse drug experience, can be approved only if, or would be withdrawn un-

less, such elements are required as part of such strategy to mitigate a specific serious risk listed in the labeling of the drug; and

''(ii) for a drug initially approved without elements to assure safe use, other elements under paragraphs (3), (4), and (5) are not sufficient to mitigate such serious risk.

''(B) ASSURING ACCESS AND MINIMIZING BURDEN.—Such elements to assure safe use under subparagraph (A) shall—

''(i) be commensurate with the specific serious risk listed in the labeling of the drug;

''(ii) within 30 days of the date on which any element under subparagraph (A) is imposed, be posted publicly by the Secretary with an explanation of how such elements will mitigate the observed safety risk;

''(iii) considering such risk, not be unduly burdensome on patient access to the drug, considering in particular—

''(I) patients with serious or life-threatening diseases or conditions; and

''(II) patients who have difficulty accessing health care (such as patients in rural or medically underserved areas); and

''(iv) to the extent practicable, so as to minimize the burden on the health care delivery system—

''(I) conform with elements to assure safe use for other drugs with similar, serious risks; and

''(II) be designed to be compatible with established distribution, procurement, and dispensing systems for drugs.

''(C) ELEMENTS TO ASSURE SAFE USE.—The elements to assure safe use under subparagraph (A) shall include 1 or more goals to mitigate a specific serious risk listed in the labeling of the drug and, to mitigate such risk, may require that—

''(i) health care providers who prescribe the drug have particular training or

experience, or are specially certified (which training or certification with respect to the drug shall be available to any willing provider from a frontier area in a widely available training or certification method (including an on-line course or via mail) as approved by the Secretary at minimal cost to the provider);

''(ii) pharmacies, practitioners, or health care settings that dispense the drug are specially certified (which certification shall be available to any willing provider from a frontier area);

''(iii) the drug be dispensed to patients only in certain health care settings, such as hospitals;

''(iv) the drug be dispensed to patients with evidence or other documentation of safe-use conditions, such as laboratory test results;

''(v) each patient using the drug be subject to certain monitoring; or

''(vi) each patient using the drug be enrolled in a registry.

''(D) IMPLEMENTATION SYSTEM.—The elements to assure safe use under subparagraph (A) that are described in clauses (ii), (iii), or (iv) of subparagraph (C) may include a system through which the applicant is able to take reasonable steps to—

''(i) monitor and evaluate implementation of such elements by health care providers, pharmacists, and other parties in the health care system who are responsible for implementing such elements; and

''(ii) work to improve implementation of such elements by such persons.

''(E) EVALUATION OF ELEMENTS TO ASSURE SAFE USE.—The Secretary, through the Drug Safety and Risk Management Advisory Committee (or successor committee) of the Food and Drug Administration, shall—

''(i) seek input from patients, physicians, pharmacists, and other health care providers about how elements to assure safe use under this paragraph for 1 or more drugs may be standardized so as not to be—

''(I) unduly burdensome on patient access to the drug; and

''(II) to the extent practicable, minimize the burden on the health care delivery system;

''(ii) at least annually, evaluate, for 1 or more drugs, the elements to assure safe use of such drug to assess whether the elements—

''(I) assure safe use of the drug;

''(II) are not unduly burdensome on patient access to the drug; and

''(III) to the extent practicable, minimize the burden on the health care delivery system; and

''(iii) considering such input and evaluations—

''(I) issue or modify agency guidance about how to implement the requirements of this paragraph; and

''(II) modify elements under this paragraph for 1 or more drugs as appropriate.

''(F) ADDITIONAL MECHANISMS TO ASSURE ACCESS.—The mechanisms under section

561 to provide for expanded access for patients with serious or life-threatening diseases or conditions may be used to provide access for patients with a serious or life-threatening disease or condition, the treatment of which is not an approved use for the drug, to a drug that is subject to elements to assure safe use under this paragraph. The Secretary shall promulgate regulations for how a physician may provide the drug under the mechanisms of section 561.

''(G) WAIVER IN PUBLIC HEALTH EMERGENCIES.—The Secretary may waive any requirement of this paragraph during the period described in section 319(a) of the Public Health Service Act with respect to a qualified countermeasure described under section 319F–1(a)(2) of such Act, to which a requirement under this paragraph has been applied, if the Secretary has—

''(i) declared a public health emergency under such section 319; and

''(ii) determined that such waiver is required to mitigate the effects of, or reduce the severity of, such public health emergency.

''(7) SUBMISSION AND REVIEW OF RISK EVALUATION AND MITIGATION STRATEGY.—

''(A) PROPOSED RISK EVALUATION AND MITIGATION STRATEGY.—

''(i) VOLUNTARY PROPOSAL.—If there is a signal of a serious risk with a drug, an applicant may include a proposed risk evaluation and mitigation strategy for the drug in an application, including in a supplemental application, for the drug under subsection (b) or section 351 of the Public Health Service Act.

''(ii) REQUIRED PROPOSAL.—

''(I) DETERMINATION NECESSARY TO REQUIRE A PROPOSAL.—

''(aa) IN GENERAL.—The Secretary may require that the applicant for a drug submit a proposed risk evaluation and mitigation strategy for a drug if the Secretary (acting through the office responsible for reviewing the drug and the office responsible for postapproval safety with respect to the drug) determines

that, based on a signal of a serious risk with the drug, a risk evaluation and mitigation strategy is necessary to assess such signal or mitigate such serious risk.

''(bb) NON-DELEGATION.—A determination under item (aa) for a drug shall be made by individuals at or above the level of individuals empowered to approve a drug (such as division directors within the Center for Drug Evaluation and Research).

''(II) CIRCUMSTANCES IN WHICH A PROPOSAL MAY BE REQUIRED.—The applicant shall submit a proposed risk evaluation and mitigation strategy for a drug—

''(aa) in response to a letter from the Secretary (acting through the office responsible for reviewing the drug and the office responsible for postapproval safety with respect to the drug) sent

regarding an application, including a supplemental application, for the drug, if the Secretary determines that data or information in the application indicates that an element under paragraph (4), (5), or (6) should be included in a strategy for the drug;

''(bb) within a timeframe specified by the Secretary, not to be less than 45 days, when ordered by the Secretary (acting through such offices), if the Secretary determines that new safety information indicates that—

''(AA) the labeling of the drug should be changed; or

''(BB) an element under paragraph (4) or (5) should be included in a strategy for the drug; or

''(cc) within 90 days when ordered by the Secretary (acting through such offices), if the Sec-

retary determines that new safety information indicates that an element under paragraph (6) should be included in a strategy for the drug.

''(iii) CONTENT OF LETTER.—A letter under clause (ii)(II)(aa) shall describe—

''(I) the data or information in the application that warrants the proposal of a risk evaluation and mitigation strategy for the drug; and

''(II) what elements under paragraphs (4), (5), or (6) should be included in a strategy for the drug.

''(iv) CONTENT OF ORDER.—An order under item (aa) or (bb) of clause (ii)(II) shall describe—

''(I) the new safety information with respect to the drug that warrants the proposal of a risk evaluation and mitigation strategy for the drug; and

''(II) whether and how the labeling of the drug should be changed and what elements under paragraphs (4),

(5), or (6) should be included in a strategy for the drug.

''(v) CONTENT OF PROPOSAL.—A proposed risk evaluation and mitigation strategy—

''(I) shall include a timetable as described under paragraph (3)(B); and

''(II) may also include additional elements as provided for under paragraphs (4), (5), and (6).

''(B) ASSESSMENT AND MODIFICATION OF A RISK EVALUATION AND MITIGATION STRATEGY.—

''(i) VOLUNTARY ASSESSMENTS.—If a risk evaluation and mitigation strategy for a drug is required, the applicant may submit to the Secretary an assessment of, and propose a modification to, such approved strategy for the drug at any time.

''(ii) REQUIRED ASSESSMENTS.—If a risk evaluation and mitigation strategy for a drug is required, the applicant shall submit an assessment of, and may propose a

modification to, such approved strategy for the drug—

"(I) when submitting an application, including a supplemental application, for a new indication under subsection (b) or section 351 of the Public Health Service Act;

"(II) when required by the strategy, as provided for in the timetable under paragraph (3)(B);

"(III) within a timeframe specified by the Secretary, not to be less than 45 days, when ordered by the Secretary (acting through the offices described in subparagraph (A)(ii)(I)), if the Secretary determines that new safety information indicates that an element under paragraph (3) or (4) should be modified or added to the strategy;

"(IV) within 90 days when ordered by the Secretary (acting through such offices), if the Secretary determines that new safety information indicates that an element under

paragraph (6) should be modified or added to the strategy; or

''(V) within 15 days when ordered by the Secretary (acting through such offices), if the Secretary determines that there may be a cause for action by the Secretary under subsection (e).

''(iii) CONTENT OF ORDER.—An order under subclauses (III), (IV), or (V) of clause (ii) shall describe—

''(I) the new safety information with respect to the drug that warrants an assessment of the approved risk evaluation and mitigation strategy for the drug; and

''(II) whether and how such strategy should be modified because of such information.

''(iv) ASSESSMENT.—An assessment of the approved risk evaluation and mitigation strategy for a drug shall include—

''(I) a description of new safety information, if any, with respect to the drug;

''(II) whether and how to modify such strategy because of such information;

''(III) with respect to any post-approval study required under paragraph (4)(B) or otherwise undertaken by the applicant to investigate a safety issue, the status of such study, including whether any difficulties completing the study have been encountered;

''(IV) with respect to any post-approval clinical trial required under paragraph (4)(C) or otherwise undertaken by the applicant to investigate a safety issue, the status of such clinical trial, including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to requirements under subsections (i) and (j) of section 402 of the Public Health Service Act; and

''(V) with respect to any goal under paragraph (6) and considering input and evaluations, if applicable, under paragraph (6)(E), an assessment of how well the elements to assure safe use are meeting the goal of increasing safe access to drugs with known serious risks or whether the goal or such elements should be modified.

''(v) MODIFICATION.—A modification (whether an enhancement or a reduction) to the approved risk evaluation and mitigation strategy for a drug may include the addition or modification of any element under subparagraph (A) or (B) of paragraph (3) or the addition, modification, or removal of any element under paragraph (4), (5), or (6), such as—

''(I) a labeling change, including the addition of a boxed warning;

''(II) adding a postapproval study or clinical trial requirement;

''(III) modifying a postapproval study or clinical trial requirement

(such as a change in trial design due to legitimate difficulties recruiting participants);

''(IV) adding, modifying, or removing an element on advertising under subparagraph (D), (E), or (F) of paragraph (5);

''(V) adding, modifying, or removing an element to assure safe use under paragraph (6); or

''(VI) modifying the timetable for assessments of the strategy under paragraph (3)(B), including to eliminate assessments.

''(C) REVIEW.—The Secretary (acting through the offices described in subparagraph (A)(ii)(I)) shall promptly review the proposed risk evaluation and mitigation strategy for a drug submitted under subparagraph (A), or an assessment of the approved risk evaluation and mitigation strategy for a drug submitted under subparagraph (B).

''(D) DISCUSSION.—The Secretary (acting through the offices described in subparagraph (A)(ii)(I)) shall initiate discussions of the pro-

posed risk evaluation and mitigation strategy for a drug submitted under subparagraph (A), or of an assessment of the approved risk evaluation and mitigation strategy for a drug submitted under subparagraph (B), with the applicant to determine a strategy—

"(i) if the proposed strategy or assessment is submitted as part of an application (including a supplemental application) under subparagraph (A)(i), (A)(ii)(II)(aa), or (B)(ii)(I), by the target date for communication of feedback from the review team to the applicant regarding proposed labeling and postmarketing study commitments, as set forth in the letters described in section 735(a);

"(ii) if the proposed strategy is submitted under subparagraph (A)(ii)(II)(bb) or the assessment is submitted under subclause (II) or (III) of subparagraph (B)(ii), not later than 20 days after such submission;

"(iii) if the proposed strategy is submitted under subparagraph (A)(ii)(II)(cc) or the assessment is submitted under sub-

paragraph (B)(i) or under subparagraph (B)(ii)(IV), not later than 30 days after such submission; or

''(iv) if the assessment is submitted under subparagraph (B)(ii)(V), not later than 10 days after such submission.

''(E) ACTION.—

''(i) IN GENERAL.—Unless the applicant requests the dispute resolution process as described under subparagraph (F) or (G), the Secretary (acting through the offices described in subparagraph (A)(ii)(I)) shall approve and include the risk evaluation and mitigation strategy for a drug, or any modification to the strategy (including a timeframe for implementing such modification), with—

''(I) the action letter on the application, if a proposed strategy is submitted under subparagraph (A)(i) or (A)(ii)(II)(aa) or an assessment of the strategy is submitted under subparagraph (B)(ii)(I); or

''(II) an order, which shall be made public, issued not later than 50

days after the date discussions of such proposed strategy or modification begin under subparagraph (D), if a proposed strategy is submitted under item (bb) or (cc) of subparagraph (A)(ii)(II) or an assessment of the strategy is submitted under subparagraph (B)(i) or under subclause (II), (III), (IV), or (V) of subparagraph (B)(ii).

''(ii) INACTION.—An approved risk evaluation and mitigation strategy shall remain in effect until the Secretary acts, if the Secretary fails to act as provided under clause (i).

''(F) DISPUTE RESOLUTION AT INITIAL APPROVAL.—If a proposed risk evaluation and mitigation strategy is submitted under subparagraph (A)(i) or (A)(ii)(II)(aa) in an application for initial approval of a drug and there is a dispute about the strategy, the applicant shall use the major dispute resolution procedures as set forth in the letters described in section 735(a).

''(G) DISPUTE RESOLUTION IN ALL OTHER CASES.—

"(i) REQUEST FOR REVIEW.—In any case other than a submission under subparagraph (A)(i) or (A)(ii)(II)(aa) in an application for initial approval of a drug if there is a dispute about the strategy, not earlier than 15 days, and not later than 35 days, after discussions under subparagraph (D) have begun, the applicant shall request in writing that the dispute be reviewed by the Drug Safety Oversight Board.

"(ii) SCHEDULING REVIEW.—If the applicant requests review under clause (i), the Secretary—

"(I)(aa) shall schedule the dispute for review at 1 of the next 2 regular meetings of the Drug Safety Oversight Board, whichever meeting date is more practicable; or

"(bb) may convene a special meeting of the Drug Safety Oversight Board to review the matter more promptly, including to meet an action deadline on an application (including a supplemental application);

"(II) shall give advance notice to the public through the Federal Register and on the Internet website of the Food and Drug Administration—

"(aa) that the drug is to be discussed by the Drug Safety Oversight Board; and

"(bb) of the date on which the Drug Safety Oversight Board shall discuss such drug; and

"(III) shall apply section 301(j), section 552 of title 5, and section 1905 of title 18, United States Code, to any request for information about such review.

"(iii) AGREEMENT AFTER DISCUSSION OR ADMINISTRATIVE APPEALS.—

"(I) FURTHER DISCUSSION OR ADMINISTRATIVE APPEALS.—A request for review under clause (i) shall not preclude—

"(aa) further discussions to reach agreement on the risk evaluation and mitigation strategy; or

''(bb) the use of administrative appeals within the Food and Drug Administration to reach agreement on the strategy, including the major dispute resolution procedures as set forth in the letters described in section 735(a).

''(II) AGREEMENT TERMINATES DISPUTE RESOLUTION.—At any time before a decision and order is issued under clause (vi), the Secretary (acting through the offices described in subparagraph (A)(ii)(I)) and the applicant may reach an agreement on the risk evaluation and mitigation strategy through further discussion or administrative appeals, terminating the dispute resolution process, and the Secretary shall issue an action letter or order, as appropriate, that describes the strategy.

''(iv) MEETING OF THE BOARD.—At the meeting of the Drug Safety Oversight

Board described in clause (ii), the Board shall—

"(I) hear from both parties; and

"(II) review the dispute.

"(v) RECOMMENDATION OF THE BOARD.—Not later than 5 days after such meeting of the Drug Safety Oversight Board, the Board shall provide a written recommendation on resolving the dispute to the Secretary.

"(vi) ACTION BY THE SECRETARY.—

"(I) ACTION LETTER.—With respect to a proposed risk evaluation and mitigation strategy submitted under subparagraph (A)(i) or (A)(ii)(II)(aa) or to an assessment of the strategy submitted under subparagraph (B)(ii)(I), the Secretary shall issue an action letter that resolves the dispute not later than the later of—

"(aa) the action deadline for the action letter on the application; or

"(bb) 7 days after receiving the recommendation of the Drug Safety Oversight Board.

"(II) ORDER.—With respect to a proposed risk evaluation and mitigation strategy submitted under item (bb) or (cc) of subparagraph (A)(ii)(II) or an assessment of the risk evaluation and mitigation strategy under subparagraph (B)(i) or under subclause (II), (III), (IV), or (V) of subparagraph (B)(ii), the Secretary shall issue an order, which (with the recommendation of the Drug Safety Oversight Board) shall be made public, that resolves the dispute not later than 7 days after receiving the recommendation of the Drug Safety Oversight Board.

"(vii) INACTION.—An approved risk evaluation and mitigation strategy shall remain in effect until the Secretary acts, if the Secretary fails to act as provided for under clause (vi).

"(viii) EFFECT ON ACTION DEADLINE.—With respect to the application or supplemental application in which a proposed risk evaluation and mitigation strategy is submitted under subparagraph (A)(i) or (A)(ii)(II)(aa) or in which an assessment of the strategy is submitted under subparagraph (B)(ii)(I), the Secretary shall be considered to have met the action deadline for the action letter on such application if the applicant requests the dispute resolution process described in this subparagraph and if the Secretary—

"(I) has initiated the discussions described under subparagraph (D) by the target date referred to in subparagraph (D)(i); and

"(II) has complied with the timing requirements of scheduling review by the Drug Safety Oversight Board, providing a written recommendation, and issuing an action letter under clauses (ii), (v), and (vi), respectively.

"(ix) DISQUALIFICATION.—No individual who is an employee of the Food and

Drug Administration and who reviews a drug or who participated in an administrative appeal under clause (iii)(I) with respect to such drug may serve on the Drug Safety Oversight Board at a meeting under clause (iv) to review a dispute about the risk evaluation and mitigation strategy for such drug.

''(x) ADDITIONAL EXPERTISE.—The Drug Safety Oversight Board may add members with relevant expertise from the Food and Drug Administration, including the Office of Pediatrics, the Office of Women's Health, or the Office of Rare Diseases, or from other Federal public health or health care agencies, for a meeting under clause (iv) of the Drug Safety Oversight Board.

''(H) USE OF ADVISORY COMMITTEES.—The Secretary (acting through the offices described in subparagraph (A)(ii)(I)) may convene a meeting of 1 or more advisory committees of the Food and Drug Administration to—

''(i) review a concern about the safety of a drug or class of drugs, including be-

fore an assessment of the risk evaluation and mitigation strategy or strategies of such drug or drugs is required to be submitted under subclause (II), (III), (IV), or (V) of subparagraph (B)(ii);

''(ii) review the risk evaluation and mitigation strategy or strategies of a drug or group of drugs; or

''(iii) with the consent of the applicant, review a dispute under subparagraph (G).

''(I) PROCESS FOR ADDRESSING DRUG CLASS EFFECTS.—

''(i) IN GENERAL.—When a concern about a serious risk of a drug may be related to the pharmacological class of the drug, the Secretary (acting through the offices described in subparagraph (A)(ii)(I)) may defer assessments of the approved risk evaluation and mitigation strategies for such drugs until the Secretary has—

''(I) convened, after appropriate public notice, 1 or more public meetings to consider possible responses to such concern; or

''(II) gathered additional information or data about such concern.

''(ii) PUBLIC MEETINGS.—Such public meetings may include—

''(I) 1 or more meetings of the applicants for such drugs;

''(II) 1 or more meetings of 1 or more advisory committees of the Food and Drug Administration, as provided for under subparagraph (H); or

''(III) 1 or more workshops of scientific experts and other stakeholders.

''(iii) ACTION.—After considering the discussions from any meetings under clause (ii), the Secretary may—

''(I) announce in the Federal Register a planned regulatory action, including a modification to each risk evaluation and mitigation strategy, for drugs in the pharmacological class;

''(II) seek public comment about such action; and

''(III) after seeking such comment, issue an order addressing such regulatory action.

''(J) INTERNATIONAL COORDINATION.—The Secretary (acting through the offices described in subparagraph (A)(ii)(I)) may coordinate the timetable for submission of assessments under paragraph (3)(B), a study under paragraph (4)(B), or a clinical trial under paragraph (4)(C), with efforts to identify and assess the serious risks of such drug by the marketing authorities of other countries whose drug approval and risk management processes the Secretary deems comparable to the drug approval and risk management processes of the United States.

''(K) EFFECT.—Use of the processes described in subparagraphs (I) and (J) shall not delay action on an application or a supplement to an application for a drug.

''(L) NO EFFECT ON LABELING CHANGES THAT DO NOT REQUIRE PREAPPROVAL.—In the case of a labeling change to which section 314.70 of title 21, Code of Federal Regulations (or any successor regulation), applies for which

the submission of a supplemental application is not required or for which distribution of the drug involved may commence upon the receipt by the Secretary of a supplemental application for the change, the submission of an assessment of the approved risk evaluation and mitigation strategy for the drug under this subsection is not required.

''(8) DRUG SAFETY OVERSIGHT BOARD.—

''(A) IN GENERAL.—There is established a Drug Safety Oversight Board.

''(B) COMPOSITION; MEETINGS.—The Drug Safety Oversight Board shall—

''(i) be composed of scientists and health care practitioners appointed by the Secretary, each of whom is an employee of the Federal Government;

''(ii) include representatives from offices throughout the Food and Drug Administration (including the offices responsible for postapproval safety of drugs);

''(iii) include at least 1 representative each from the National Institutes of Health, the Department of Health and Human Services (other than the Food and

Drug Administration), and the Veterans Health Administration; and

''(iv) meet at least monthly to provide oversight and advice to the Secretary on the management of important drug safety issues.

''(9) CIVIL MONETARY PENALTY.—Notwithstanding any other provision of this Act, an applicant (as such term is defined for purposes of this section) that knowingly fails to comply with a requirement of an approved risk evaluation and mitigation strategy under this subsection shall be subject to a civil money penalty of $250,000 for the first 30-day period that the applicant is in noncompliance, and such amount shall double for every 30-day period thereafter that the requirement is not complied with, not to exceed $2,000,000.''.

SEC. 203. ENFORCEMENT.

(a) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(x) If it is a drug subject to an approved risk evaluation and mitigation strategy under section 505(o) and the applicant for such drug fails to—

''(1) make a labeling change required by such strategy after the Secretary has approved such strategy or completed review of, and acted on, an assessment of such strategy under paragraph (7) of such section; or

''(2) comply with a requirement of such strategy with respect to advertising as provided for under subparagraph (D), (E), or (F) of paragraph (5) of such section.''.

(b) CIVIL PENALTIES.—Section 303(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)) is amended—

(1) by redesignating paragraphs (3), (4), and (5) as paragraphs (4), (5), and (6), respectively;

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

''(3) An applicant (as such term is used in section 505(o)) who knowingly fails to comply with a requirement of an approved risk evaluation and mitigation strategy under such section 505(o) shall be subject to a civil money penalty of not less than $15,000 and not more than $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.'';

(3) in paragraph (2)(C), by striking ''paragraph (3)(A)'' and inserting ''paragraph (4)(A)'';

(4) in paragraph (4), as so redesignated, by striking ''paragraph (1) or (2)'' each place it appears and inserting ''paragraph (1), (2), or (3)''; and

(5) in paragraph (6), as so redesignated, by striking ''paragraph (4)'' each place it appears and inserting ''paragraph (5)''.

SEC. 204. REGULATION OF DRUGS THAT ARE BIOLOGICAL PRODUCTS.

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

(1) in subsection (a)(2), by adding at the end the following:

''(D) RISK EVALUATION AND MITIGATION STRATEGY.—A person that submits an application for a license for a drug under this paragraph may submit to the Secretary as part of the application a proposed risk evaluation and mitigation strategy as described under section 505(o) of the Federal Food, Drug, and Cosmetic Act.''; and

(2) in subsection (j), by inserting '', including the requirements under section 505(o) of such Act,'' after '', and Cosmetic Act''.

SEC. 205. NO EFFECT ON WITHDRAWAL OR SUSPENSION OF APPROVAL.

Section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) is amended by adding at the end the following: ''The Secretary may withdraw the approval of an application submitted under this section, or suspend the approval of such an application, as provided under this subsection, without first ordering the applicant to submit an assessment of the approved risk evaluation and mitigation strategy for the drug under subsection (o)(7)(B)(ii)(V).''.

SEC. 206. DRUGS SUBJECT TO AN ABBREVIATED NEW DRUG APPLICATION.

Section 505(j)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)) is amended by adding at the end the following:

''(E) RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENT.—

''(i) IN GENERAL.—A drug that is the subject of an abbreviated new drug application under this subsection shall be subject to only the following elements of the approved risk evaluation and mitigation strategy if required under subsection (o) for the applicable listed drug:

''(I) Labeling, as required under subsection (o)(3)(A) for the applicable listed drug.

''(II) A Medication Guide or patient package insert, if required under subsection (o)(5)(B) for the applicable listed drug.

''(III) Prereview of advertising, if required under subsection (o)(5)(D) for the applicable listed drug.

''(IV) Specific disclosures in advertising, if required under subsection (o)(5)(E) for the applicable listed drug.

''(V) Elements to assure safe use, if required under subsection (o)(6) for the applicable listed drug, except that such drug may use a different, comparable aspect of such elements as are necessary to assure safe use of such drug if—

''(aa) the corresponding aspect of the elements to assure safe use for the applicable listed drug is claimed by a patent that has not expired or is a method or process that as a trade secret is entitled to protection; and

''(bb) the applicant certifies that it has sought a license for use of such aspect of the elements to assure safe use for the applicable listed drug.

''(ii) ACTION BY SECRETARY.—For an applicable listed drug for which a drug is approved under this subsection, the Secretary—

''(I) shall undertake any communication plan to health care providers required under section (o)(5)(C) for the applicable listed drug;

''(II) shall conduct, or contract for, any postapproval study required under subsection (o)(4)(B) for the applicable listed drug;

''(III) shall inform the applicant for a drug approved under this subsection if the approved risk evaluation and mitigation strategy for the applicable listed drug is modified; and

''(IV) in order to minimize the burden on the health care delivery system of different elements to assure safe use for the drug approved under this subsection and the applicable listed drug, may seek to negotiate a voluntary agreement with the owner of the patent, method, or process for a license under which the applicant for such drug may use an aspect of the elements to assure safe use, if required under subsection (o)(6) for the applicable listed drug, that is claimed by a patent that has not expired

or is a method or process that as a trade secret is entitled to protection.''.

SEC. 207. RESOURCES.

(a) USER FEES.—Subparagraph (F) of section 735(d)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(d)(6)), as amended by section 103, is amended—

(1) in clause (ii), by striking ''systems); and'' and inserting ''systems);''

(2) in clause (iii), by striking ''bases).'' and inserting ''bases); and''; and

(3) by adding at the end the following:

''(iv) reviewing, implementing, and ensuring compliance with risk evaluation and mitigation strategies.''.

(b) ADDITIONAL FEE REVENUES FOR DRUG SAFETY.—Section 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h), as amended by section 103, is amended by—

(1) striking the subsection designation and all that follows through ''.—Except'' and inserting the following:

''(b) FEE REVENUE AMOUNTS.—

''(1) IN GENERAL.—Except''; and

(2) adding at the end the following:

''(2) ADDITIONAL FEE REVENUES FOR DRUG SAFETY.—

''(A) IN GENERAL.—Subject to subparagraph (C), in each of fiscal years 2008 through 2012, paragraph (1) shall be applied by substituting the amount determined under subparagraph (B) for '$392,783,000'.

''(B) AMOUNT DETERMINED.—For any fiscal year 2008 through 2012, the amount determined under this subparagraph is the sum of—

''(i) $392,783,000; plus

''(ii) the amount equal to—

''(I)(aa) for fiscal year 2008, $25,000,000;

''(bb) for fiscal year 2009, $35,000,000;

''(cc) for fiscal year 2010, $45,000,000;

''(dd) for fiscal year 2011, $55,000,000; and

''(ee) for fiscal year 2012, $65,000,000; minus

''(II) the amount equal to one-fifth of the excess amount in item (bb), provided that—

''(aa) the amount of the total appropriation for the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) exceeds the amount of the total appropriation for the Food and Drug Administration for fiscal year 2007 (excluding the amount of fees appropriated for such fiscal year), adjusted as provided under subsection (c)(1); and

''(bb) the amount of the total appropriations for the process of human drug review at the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) exceeds the amount of appropriations for the process of human drug review at the Food and Drug Administration for fiscal year 2007 (excluding the amount of fees appropriated for such fiscal year), adjusted as provided under subsection (c)(1).

In making the adjustment under subclause (II) for any fiscal year 2008 through 2012, subsection (c)(1) shall be applied by substituting '2007' for '2008.'

''(C) LIMITATION.—This paragraph shall not apply for any fiscal year if the amount described under subparagraph (B)(ii) is less than 0.''.

(c) STRATEGIC PLAN FOR INFORMATION TECHNOLOGY.—Not later than 1 year after the date of enactment of this title, the Secretary of Health and Human Services (referred to in this title as the ''Secretary'') shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a strategic plan on information technology that includes—

(1) an assessment of the information technology infrastructure, including systems for data collection, access to data in external health care databases, data mining capabilities, personnel, and personnel training programs, needed by the Food and Drug Administration to—

(A) comply with the requirements of this subtitle (and the amendments made by this subtitle);

(B) achieve interoperability within and among the centers of the Food and Drug Administration and between the Food and Drug Administration and product application sponsors;

(C) utilize electronic health records;

(D) implement routine active surveillance under section 505(k)(3) (including complementary approaches under subsection (c) of such section) of the Federal Food, Drug, and Cosmetic Act, as added by section 201 of this Act; and

(E) communicate drug safety information to physicians and other health care providers;

(2) an assessment of the extent to which the current information technology assets of the Food and Drug Administration are sufficient to meet the needs assessments under paragraph (1);

(3) a plan for enhancing the information technology assets of the Food and Drug Administration toward meeting the needs assessments under paragraph (1); and

(4) an assessment of additional resources needed to so enhance the information technology assets of the Food and Drug Administration.

SEC. 208. SAFETY LABELING CHANGES.

(a) IN GENERAL.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506C the following:

"SEC. 506D. SAFETY LABELING CHANGES.

''(a) NEW SAFETY INFORMATION.—

''(1) NOTIFICATION.—The holder of an approved application under section 505 of this Act or a license under section 351 of the Public Health Service Act (referred to in this section as a 'holder') shall promptly notify the Secretary if the holder becomes aware of new safety information that the holder believes should be included in the labeling of the drug. The Secretary shall promptly notify the holder if the Secretary becomes aware of new safety information that the Secretary believes should be included in the labeling of the drug.

''(2) DISCUSSION REGARDING LABELING CHANGES.—Following notification pursuant to paragraph (1), the Secretary and holder shall initiate discussions of the new safety information in order to

reach agreement on whether the labeling for the drug should be modified to reflect the new safety information and, if so, on the contents of such labeling changes.

''(3) SUPPLEMENT.—If the Secretary determines that there is reasonable scientific evidence that an adverse event is associated with use of the drug, the Secretary may request the holder to submit a supplement to an application under section 505 of this Act or to a license under section 351 of the Public Health Service Act (referred to in this section as a 'supplement') proposing changes to the approved labeling to reflect the new safety information, including changes to boxed warnings, contraindications, warnings, precautions, or adverse reactions (referred to in this section as a 'safety labeling change'). If the Secretary determines that no safety labeling change is necessary or appropriate based upon the new safety information, the Secretary shall notify the holder of this determination in writing.

''(b) LABELING SUPPLEMENTS.—

''(1) IN GENERAL.—The holder shall submit a supplement whenever the holder seeks, either at the holder's own initiative or at the request of the Secretary, to make a safety labeling change.

''(2) NONACCELERATED PROCESS.—Unless the accelerated labeling review process described in subsection (c) is initiated, any supplement proposing a safety labeling change shall be reviewed and acted upon by the Secretary not later than 30 days after the date the Secretary receives the supplement. Until the Secretary acts on such a supplement proposing a safety labeling change, the existing approved labeling shall remain in effect and be distributed by the holder without change.

''(3) NEW SAFETY INFORMATION.—Nothing in this section shall prohibit the Secretary from informing health care professionals or the public about new safety information prior to approval of a supplement proposing a safety labeling change.

''(c) ACCELERATED LABELING REVIEW PROCESS.—An accelerated labeling review process shall be available to resolve disagreements in a timely manner between the Secretary and a holder about the need for, or content of, a safety labeling change, as follows:

''(1) REQUEST TO INITIATE ACCELERATED PROCESS.—The accelerated labeling review process shall be initiated upon the written request of either the Secretary or the holder. Such request may be made at any time after the notification described in

subsection (a)(1), including during the Secretary's review of a supplement proposing a safety labeling change.

''(2) SCIENTIFIC DISCUSSION AND MEETINGS.—

''(A) IN GENERAL.—Following initiation of the accelerated labeling review process, the Secretary and holder shall immediately initiate discussions to review and assess the new safety information and to reach agreement on whether safety labeling changes are necessary and appropriate and, if so, the content of such safety labeling changes.

''(B) TIME PERIOD.—The discussions under this paragraph shall not extend for more than 45 calendar days after the initiation of the accelerated labeling review process.

''(C) DISPUTE PROCEEDINGS.—If the Secretary and holder do not reach an agreement regarding the safety labeling changes by not later than 25 calendar days after the initiation of the accelerated labeling review process, the dispute automatically shall be referred to the director of the drug evaluation office responsible for the drug under consideration, who

shall be required to take an active role in such discussions.

''(3) REQUEST FOR SAFETY LABELING CHANGE AND FAILURE TO AGREE.—If the Secretary and holder fail to reach an agreement on appropriate safety labeling changes by not later than 45 calendar days after the initiation of the accelerated labeling review process—

''(A) on the next calendar day (other than a weekend or Federal holiday) after such period, the Secretary shall—

''(i) request in writing that the holder make any safety labeling change that the Secretary determines to be necessary and appropriate based upon the new safety information; or

''(ii) notify the holder in writing that the Secretary has determined that no safety labeling change is necessary or appropriate; and

''(B) if the Secretary fails to act within the specified time, or if the holder does not agree to make a safety labeling change requested by the Secretary or does not agree with the Secretary's determination that no labeling change

is necessary or appropriate, the Secretary (on his own initiative or upon request by the holder) shall refer the matter for expedited review to the Drug Safety Oversight Board.

''(4) ACTION BY THE DRUG SAFETY OVERSIGHT BOARD.—Not later than 45 days after receiving a referral under paragraph (3)(B), the Drug Safety Oversight Board shall—

''(A) review the new safety information;

''(B) review all written material submitted by the Secretary and the holder;

''(C) convene a meeting to hear oral presentations and arguments from the Secretary and holder; and

''(D) make a written recommendation to the Secretary—

''(i) concerning appropriate safety labeling changes, if any; or

''(ii) stating that no safety labeling changes are necessary or appropriate based upon the new safety information.

''(5) CONSIDERATION OF RECOMMENDATIONS.—

''(A) ACTION BY THE SECRETARY.—The Secretary shall consider the recommendation of

the Drug Safety Oversight Board made under paragraph (4)(D) and, not later than 20 days after receiving the recommendation—

"(i) issue an order requiring the holder to make any safety labeling change that the Secretary determines to be necessary and appropriate; or

"(ii) if the Secretary determines that no safety labeling change is necessary or appropriate, the Secretary shall notify the holder of this determination in writing.

"(B) FAILURE TO ACT.—If the Secretary fails to act by not later than 20 days after receiving the recommendation of the Drug Safety Oversight Board, the written recommendation of the Drug Safety Oversight Board shall be considered the order of the Secretary under this paragraph.

"(C) NONDELEGATION.—The Secretary's authority under this paragraph shall not be redelegated to an individual below the level of the Director of the Center for Drug Evaluation and Research, or the Director of the Center for Biologics Evaluation and Research, of the Food and Drug Administration.

''(6) MISBRANDING.—If the holder, not later than 10 days after receiving an order under subparagraph (A) or (B) of paragraph (5), does not agree to make a safety labeling change ordered by the Secretary, the Secretary may deem the drug that is the subject of the request to be misbranded.

''(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to change the standards in existence on the date of enactment of this section for determining whether safety labeling changes are necessary or appropriate.''.

(b) CONFORMING AMENDMENT.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352 et seq.), as amended by section 203, is further amended by adding at the end the following:

''(y) If it is a drug and the holder does not agree to make a safety labeling change ordered by the Secretary under section 506D(c) within 10 days after issuance of such an order.''.

SEC. 209. POSTMARKET DRUG SAFETY INFORMATION FOR PATIENTS AND PROVIDERS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by section 251, is amended by adding at the end the following:

''(r) POSTMARKET DRUG SAFETY INFORMATION FOR PATIENTS AND PROVIDERS.—

''(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of the Enhancing Drug Safety and Innovation Act of 2007, the Secretary shall improve the transparency of pharmaceutical data and allow patients and health care providers better access to pharmaceutical data by developing and maintaining an Internet website that—

''(A) provides comprehensive drug safety information for prescription drugs that are approved by the Secretary under this section or licensed under section 351 of the Public Health Service Act; and

''(B) improves communication of drug safety information to patients and providers.

''(2) INTERNET WEBSITE.—The Secretary shall carry out paragraph (1) by—

''(A) developing and maintaining an accessible, consolidated Internet website with easily searchable drug safety information, including the information found on United States Government Internet websites, such as the United States National Library of Medicine's Daily Med and Medline Plus websites, in addition to

other such websites maintained by the Secretary;

''(B) ensuring that the information provided on the Internet website is comprehensive and includes, when available and appropriate—

''(i) patient labeling and patient packaging inserts;

''(ii) a link to a list of each drug, whether approved under this section or licensed under such section 351, for which a Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations), is required;

''(iii) a link to the clinical trial registry data bank provided for under subsections (i) and (j) of section 402 of the Public Health Service Act;

''(iv) the most recent safety information and alerts issued by the Food and Drug Administration for drugs approved by the Secretary under this section, such as product recalls, warning letters, and import alerts;

''(v) publicly available information about implemented RiskMAPs and risk evaluation and mitigation strategies under subsection (o);

''(vi) guidance documents and regulations related to drug safety; and

''(vii) other material determined appropriate by the Secretary;

''(C) including links to non-Food and Drug Administration Internet resources that provide access to relevant drug safety information, such as medical journals and studies;

''(D) providing access to summaries of the assessed and aggregated data collected from the active surveillance infrastructure under subsection (k)(3) to provide information of known and serious side-effects for drugs approved by the Secretary under this section or licensed under such section 351;

''(E) enabling patients, providers, and drug sponsors to submit adverse event reports through the Internet website;

''(F) providing educational materials for patients and providers about the appropriate

means of disposing of expired, damaged, or unusable medications; and

"(G) supporting initiatives that the Secretary determines to be useful to fulfill the purposes of the Internet website.

"(3) POSTING OF DRUG LABELING.—The Secretary shall post on the Internet website established under paragraph (1) the approved professional labeling and any required patient labeling of a drug approved under this section or licensed under such section 351 not later than 21 days after the date the drug is approved or licensed, including in a supplemental application with respect to a labeling change.

"(4) PRIVATE SECTOR RESOURCES.—To ensure development of the Internet website by the date described in paragraph (1), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

"(5) AUTHORITY FOR CONTRACTS.—The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subsection.

"(6) REVIEW.—The Advisory Committee on Risk Communication under section 566 shall, on a regular basis, perform a comprehensive review and

evaluation of the types of risk communication information provided on the Internet website established under paragraph (1) and, through other means, shall identify, clarify, and define the purposes and types of information available to facilitate the efficient flow of information to patients and providers, and shall recommend ways for the Food and Drug Administration to work with outside entities to help facilitate the dispensing of risk communication information to patients and providers.''.

SEC. 210. ACTION PACKAGE FOR APPROVAL.

Section 505(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(l)) is amended by—

(1) redesignating paragraphs (1), (2), (3), (4), and (5) as subparagraphs (A), (B), (C), (D), and (E), respectively;

(2) striking ''(l) Safety and'' and inserting ''(l)(1) Safety and''; and

(3) adding at the end the following:

''(2) ACTION PACKAGE FOR APPROVAL.—

''(A) ACTION PACKAGE.—The Secretary shall publish the action package for approval of an application under subsection (b) or section 351 of the Public Health Service Act on the Internet website of the Food and Drug Administration—

''(i) not later than 30 days after the date of approval of such application for a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 351 of the Public Health Service Act; and

''(ii) not later than 30 days after the third request for such action package for approval received under section 552 of title 5, United States Code, for any other drug.

''(B) IMMEDIATE PUBLICATION OF SUMMARY REVIEW.—Notwithstanding subparagraph (A), the Secretary shall publish, on the Internet website of the Food and Drug Administration, the materials described in subparagraph (C)(iv) not later than 48 hours after the date of approval of the drug, except where such materials require redaction by the Secretary.

''(C) CONTENTS.—An action package for approval of an application under subparagraph (A) shall be dated and shall include the following:

''(i) Documents generated by the Food and Drug Administration related to review of the application.

''(ii) Documents pertaining to the format and content of the application generated during drug development.

''(iii) Labeling submitted by the applicant.

''(iv) A summary review that documents conclusions from all reviewing disciplines about the drug, noting any critical issues and disagreements with the applicant and how they were resolved, recommendation for action, and an explanation of any nonconcurrence with review conclusions.

''(v) If applicable, a separate review from a supervisor who does not concur with the summary review.

''(vi) Identification by name of each officer or employee of the Food and Drug Administration who—

''(I) participated in the decision to approve the application; and

''(II) consents to have his or her name included in the package.

''(D) DISAGREEMENTS.—A scientific review of an application is considered the work of the reviewer and shall not be altered by management or the reviewer once final. Disagreements by team leaders,

division directors, or office directors with any or all of the major conclusions of a reviewer shall be document in a separate review or in an addendum to the review.

''(E) CONFIDENTIAL INFORMATION.—This paragraph does not authorize the disclosure of any trade secret or confidential commercial or financial information described in section 552(b)(4) of title 5, United States Code, unless the Secretary declares an emergency under section 319 of the Public Health Service Act and such disclosure is necessary to mitigate the effects of such emergency.''.

SEC. 211. RISK COMMUNICATION.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

''SEC. 566. RISK COMMUNICATION.

''(a) ADVISORY COMMITTEE ON RISK COMMUNICATION.—

''(1) IN GENERAL.—The Secretary shall establish an advisory committee to be known as the 'Advisory Committee on Risk Communication' (referred to in this section as the 'Committee').

''(2) DUTIES OF COMMITTEE.—The Committee shall advise the Commissioner on methods to effec-

tively communicate risks associated with the products regulated by the Food and Drug Administration.

''(3) MEMBERS.—The Secretary shall ensure that the Committee is composed of experts on risk communication, experts on the risks described in subsection (b), and representatives of patient, consumer, and health professional organizations.

''(4) PERMANENCE OF COMMITTEE.—Section 14 of the Federal Advisory Committee Act shall not apply to the Committee established under this subsection.

''(b) PARTNERSHIPS FOR RISK COMMUNICATION.—

''(1) IN GENERAL.—The Secretary shall partner with professional medical societies, medical schools, academic medical centers, and other stakeholders to develop robust and multi-faceted systems for communication to health care providers about emerging postmarket drug risks.

''(2) PARTNERSHIPS.—The systems developed under paragraph (1) shall—

''(A) account for the diversity among physicians in terms of practice, affinity for technology, and focus; and

''(B) include the use of existing communication channels, including electronic communications, in place at the Food and Drug Administration.''.

SEC. 212. REFERRAL TO ADVISORY COMMITTEE.

Section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by section 202, is further amended by adding at the end the following:

''(p) REFERRAL TO ADVISORY COMMITTEE.—

''(1) IN GENERAL.—Prior to the approval of a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 351 of the Public Health Service Act, the Secretary shall refer such drug to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee.

''(2) EXCEPTION.—Notwithstanding paragraph (1), an advisory committee review of a drug described under such paragraph may occur within 1 year after approval of such a drug if—

''(A) the clinical trial that formed the primary basis of the safety and efficacy determination was halted by a drug safety monitoring board or an Institutional Review Board before

its scheduled completion due to early unanticipated therapeutic results; or

''(B) the Secretary determines that it would be beneficial to the public health.''.

SEC. 213. RESPONSE TO THE INSTITUTE OF MEDICINE.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this title, the Secretary shall issue a report responding to the 2006 report of the Institute of Medicine entitled ''The Future of Drug Safety—Promoting and Protecting the Health of the Public''.

(b) CONTENT OF REPORT.—The report issued by the Secretary under subsection (a) shall include—

(1) an update on the implementation by the Food and Drug Administration of its plan to respond to the Institute of Medicine report described under such subsection; and

(2) an assessment of how the Food and Drug Administration has implemented—

(A) the recommendations described in such Institute of Medicine report; and

(B) the requirement under paragraph (7) of section 505(o) of the Federal Food, Drug, and Cosmetic Act (as added by this title), that the appropriate office responsible for reviewing a drug and the office responsible for post-

approval safety with respect to the drug act together to assess, implement, and ensure compliance with the requirements of such section 505(o).

SEC. 214. EFFECTIVE DATE AND APPLICABILITY.

(a) EFFECTIVE DATES.—

(1) IN GENERAL.—Except as provided in paragraph (2), this subtitle shall take effect 180 days after the date of enactment of this title.

(2) USER FEES.—The amendments made by subsections (a) through (c) of section 207 shall take effect on October 1, 2007.

(b) DRUGS DEEMED TO HAVE RISK EVALUATION AND MITIGATION STRATEGIES.—

(1) IN GENERAL.—A drug that was approved before the effective date of this subtitle shall be deemed to have an approved risk evaluation and mitigation strategy under section 505(o) of the Federal Food, Drug, and Cosmetic Act (as added by this subtitle) if there are in effect on the effective date of this subtitle restrictions on distribution or use—

(A) required under section 314.520 or section 601.42 of title 21, Code of Federal Regulations; or

(B) otherwise agreed to by the applicant and the Secretary for such drug.

(2) RISK EVALUATION AND MITIGATION STRATEGY.—The approved risk evaluation and mitigation strategy deemed in effect for a drug under paragraph (1) shall consist of the elements described in subparagraphs (A) and (B) of paragraph (3) of such section 505(o) and any other additional elements under paragraphs (4), (5), and (6) in effect for such drug on the effective date of this subtitle.

(3) NOTIFICATION.—Not later than 30 days after the effective date of this subtitle, the Secretary shall notify the applicant for each drug described in paragraph (1)—

(A) that such drug is deemed to have an approved risk evaluation and mitigation strategy pursuant to such paragraph; and

(B) of the date, which, unless a safety issue with the drug arises, shall be no earlier than 6 months after the applicant is so notified, by which the applicant shall submit to the Secretary an assessment of such approved strategy under paragraph (7)(B) of such section 505(o), except with respect to the drug Mifeprex (mifepristone), such assessment shall be sub-

mitted 6 months after the applicant is so notified.

(4) ENFORCEMENT ONLY AFTER ASSESSMENT AND REVIEW.—Neither the Secretary nor the Attorney General may seek to enforce a requirement of a risk evaluation and mitigation strategy deemed in effect under paragraph (1) before the Secretary has completed review of, and acted on, the first assessment of such strategy under such section 505(o).

(c) NO EFFECT ON VETERINARY MEDICINE.—This subtitle, and the amendments made by this subtitle, shall have no effect on the use of drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act by, or on the lawful written or oral order of, a licensed veterinarian within the context of a veterinarian-client-patient relationship, as provided for under section 512(a)(5) of such Act.

Subtitle B—Reagan-Udall Foundation for the Food and Drug Administration

SEC. 221. THE REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION.

(a) IN GENERAL.—Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

"Subchapter I—Reagan-Udall Foundation for the Food and Drug Administration

"SEC. 770. ESTABLISHMENT AND FUNCTIONS OF THE FOUNDATION.

''(a) IN GENERAL.—A nonprofit corporation to be known as the Reagan-Udall Foundation for the Food and Drug Administration (referred to in this subchapter as the 'Foundation') shall be established in accordance with this section. The Foundation shall be headed by an Executive Director, appointed by the members of the Board of Directors under subsection (e). The Foundation shall not be an agency or instrumentality of the United States Government.

''(b) PURPOSE OF FOUNDATION.—The purpose of the Foundation is to advance the mission of the Food and Drug Administration to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety.

''(c) DUTIES OF THE FOUNDATION.—The Foundation shall—

''(1) taking into consideration the Critical Path reports and priorities published by the Food and Drug Administration, identify unmet needs in the development, manufacture, and evaluation of the safety and effectiveness, including postapproval, of

devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics;

''(2) establish goals and priorities in order to meet the unmet needs identified in paragraph (1);

''(3) in consultation with the Secretary, identify existing and proposed Federal intramural and extramural research and development programs relating to the goals and priorities established under paragraph (2), coordinate Foundation activities with such programs, and minimize Foundation duplication of existing efforts;

''(4) award grants to, or enter into contracts, memoranda of understanding, or cooperative agreements with, scientists and entities, which may include the Food and Drug Administration, university consortia, public-private partnerships, institutions of higher education, entities described in section 501(c)(3) of the Internal Revenue Code (and exempt from tax under section 501(a) of such Code), and industry, to efficiently and effectively advance the goals and priorities established under paragraph (2);

''(5) recruit meeting participants and hold or sponsor (in whole or in part) meetings as appro-

priate to further the goals and priorities established under paragraph (2);

''(6) release and publish information and data and, to the extent practicable, license, distribute, and release material, reagents, and techniques to maximize, promote, and coordinate the availability of such material, reagents, and techniques for use by the Food and Drug Administration, nonprofit organizations, and academic and industrial researchers to further the goals and priorities established under paragraph (2);

''(7) ensure that—

''(A) action is taken as necessary to obtain patents for inventions developed by the Foundation or with funds from the Foundation;

''(B) action is taken as necessary to enable the licensing of inventions developed by the Foundation or with funds from the Foundation; and

''(C) executed licenses, memoranda of understanding, material transfer agreements, contracts, and other such instruments, promote, to the maximum extent practicable, the broadest conversion to commercial and noncommercial applications of licensed and patented inventions

of the Foundation to further the goals and priorities established under paragraph (2);

''(8) provide objective clinical and scientific information to the Food and Drug Administration and, upon request, to other Federal agencies to assist in agency determinations of how to ensure that regulatory policy accommodates scientific advances and meets the agency's public health mission;

''(9) conduct annual assessments of the unmet needs identified in paragraph (1); and

''(10) carry out such other activities consistent with the purposes of the Foundation as the Board determines appropriate.

''(d) BOARD OF DIRECTORS.—

''(1) ESTABLISHMENT.—

''(A) IN GENERAL.—The Foundation shall have a Board of Directors (referred to in this subchapter as the 'Board'), which shall be composed of ex officio and appointed members in accordance with this subsection. All appointed members of the Board shall be voting members.

''(B) EX OFFICIO MEMBERS.—The ex officio members of the Board shall be the following individuals or their designees:

''(i) The Commissioner.

''(ii) The Director of the National Institutes of Health.

''(iii) The Director of the Centers for Disease Control and Prevention.

''(iv) The Director of the Agency for Healthcare Research and Quality.

''(C) APPOINTED MEMBERS.—

''(i) IN GENERAL.—The ex officio members of the Board under subparagraph (B) shall, by majority vote, appoint to the Board 12 individuals, from a list of candidates to be provided by the National Academy of Sciences. Of such appointed members—

''(I) 4 shall be representatives of the general pharmaceutical, device, food, cosmetic, and biotechnology industries;

''(II) 3 shall be representatives of academic research organizations;

''(III) 2 shall be representatives of Government agencies, including the Food and Drug Administration and the National Institutes of Health;

''(IV) 2 shall be representatives of patient or consumer advocacy organizations; and

''(V) 1 shall be a representative of health care providers.

''(ii) REQUIREMENT.—The ex officio members shall ensure the Board membership includes individuals with expertise in areas including the sciences of developing, manufacturing, and evaluating the safety and effectiveness of devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics.

''(D) INITIAL MEETING.—

''(i) IN GENERAL.—Not later than 30 days after the date of the enactment of the Enhancing Drug Safety and Innovation Act of 2007, the Secretary shall convene a meeting of the ex officio members of the Board to—

''(I) incorporate the Foundation; and

''(II) appoint the members of the Board in accordance with subparagraph (C).

''(ii) SERVICE OF EX OFFICIO MEMBERS.—Upon the appointment of the members of the Board under clause (i)(II), the terms of service of the ex officio members of the Board as members of the Board shall terminate.

''(iii) CHAIR.—The ex officio members of the Board under subparagraph (B) shall designate an appointed member of the Board to serve as the Chair of the Board.

''(2) DUTIES OF BOARD.—The Board shall—

''(A) establish bylaws for the Foundation that—

''(i) are published in the Federal Register and available for public comment;

''(ii) establish policies for the selection of the officers, employees, agents, and contractors of the Foundation;

''(iii) establish policies, including ethical standards, for the acceptance, solicitation, and disposition of donations and grants to the Foundation and for the dis-

position of the assets of the Foundation, including appropriate limits on the ability of donors to designate, by stipulation or restriction, the use or recipient of donated funds;

''(iv) establish policies that would subject all employees, fellows, and trainees of the Foundation to the conflict of interest standards under section 208 of title 18, United States Code;

''(v) establish licensing, distribution, and publication policies that support the widest and least restrictive use by the public of information and inventions developed by the Foundation or with Foundation funds to carry out the duties described in paragraphs (6) and (7) of subsection (c), and may include charging cost-based fees for published material produced by the Foundation;

''(vi) specify principles for the review of proposals and awarding of grants and contracts that include peer review and that are consistent with those of the Foundation for the National Institutes of Health,

to the extent determined practicable and appropriate by the Board;

''(vii) specify a cap on administrative expenses for recipients of a grant, contract, or cooperative agreement from the Foundation;

''(viii) establish policies for the execution of memoranda of understanding and cooperative agreements between the Foundation and other entities, including the Food and Drug Administration;

''(ix) establish policies for funding training fellowships, whether at the Foundation, academic or scientific institutions, or the Food and Drug Administration, for scientists, doctors, and other professionals who are not employees of regulated industry, to foster greater understanding of and expertise in new scientific tools, diagnostics, manufacturing techniques, and potential barriers to translating basic research into clinical and regulatory practice;

''(x) specify a process for annual Board review of the operations of the Foundation; and

''(xi) establish specific duties of the Executive Director;

''(B) prioritize and provide overall direction to the activities of the Foundation;

''(C) evaluate the performance of the Executive Director; and

''(D) carry out any other necessary activities regarding the functioning of the Foundation.

''(3) TERMS AND VACANCIES.—

''(A) TERM.—The term of office of each member of the Board appointed under paragraph (1)(C) shall be 4 years, except that the terms of offices for the initial appointed members of the Board shall expire on a staggered basis as determined by the ex officio members.

''(B) VACANCY.—Any vacancy in the membership of the Board—

''(i) shall not affect the power of the remaining members to execute the duties of the Board; and

''(ii) shall be filled by appointment by the appointed members described in paragraph (1)(C) by majority vote.

''(C) PARTIAL TERM.—If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed under subparagraph (B) to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

''(D) SERVING PAST TERM.—A member of the Board may continue to serve after the expiration of the term of the member until a successor is appointed.

''(4) COMPENSATION.—Members of the Board may not receive compensation for service on the Board. Such members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board, as set forth in the bylaws issued by the Board.

''(e) INCORPORATION.—The ex officio members of the Board shall serve as incorporators and shall take whatever actions necessary to incorporate the Foundation.

''(f) NONPROFIT STATUS.—The Foundation shall be considered to be a corporation under section 501(c) of the Internal Revenue Code of 1986, and shall be subject to the provisions of such section.

''(g) EXECUTIVE DIRECTOR.—

''(1) IN GENERAL.—The Board shall appoint an Executive Director who shall serve at the pleasure of the Board. The Executive Director shall be responsible for the day-to-day operations of the Foundation and shall have such specific duties and responsibilities as the Board shall prescribe.

''(2) COMPENSATION.—The compensation of the Executive Director shall be fixed by the Board but shall not be greater than the compensation of the Commissioner.

''(h) ADMINISTRATIVE POWERS.—In carrying out this subchapter, the Board, acting through the Executive Director, may—

''(1) adopt, alter, and use a corporate seal, which shall be judicially noticed;

''(2) hire, promote, compensate, and discharge 1 or more officers, employees, and agents, as may be necessary, and define their duties;

''(3) prescribe the manner in which—

''(A) real or personal property of the Foundation is acquired, held, and transferred;

''(B) general operations of the Foundation are to be conducted; and

''(C) the privileges granted to the Board by law are exercised and enjoyed;

''(4) with the consent of the applicable executive department or independent agency, use the information, services, and facilities of such department or agencies in carrying out this section;

''(5) enter into contracts with public and private organizations for the writing, editing, printing, and publishing of books and other material;

''(6) hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Foundation under subsection (i);

''(7) enter into such other contracts, leases, cooperative agreements, and other transactions as the Board considers appropriate to conduct the activities of the Foundation;

''(8) modify or consent to the modification of any contract or agreement to which it is a party or in which it has an interest under this subchapter;

''(9) take such action as may be necessary to obtain patents and licenses for devices and procedures developed by the Foundation and its employees;

''(10) sue and be sued in its corporate name, and complain and defend in courts of competent jurisdiction;

''(11) appoint other groups of advisors as may be determined necessary to carry out the functions of the Foundation; and

''(12) exercise other powers as set forth in this section, and such other incidental powers as are necessary to carry out its powers, duties, and functions in accordance with this subchapter.

''(i) ACCEPTANCE OF FUNDS FROM OTHER SOURCES.—The Executive Director may solicit and accept on behalf of the Foundation, any funds, gifts, grants, devises, or bequests of real or personal property made to the Foundation, including from private entities, for the purposes of carrying out the duties of the Foundation.

''(j) SERVICE OF FEDERAL EMPLOYEES.—Federal Government employees may serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying out its functions, so long as such employees do not direct or control Foundation activities.

''(k) DETAIL OF GOVERNMENT EMPLOYEES; FELLOWSHIPS.—

''(1) DETAIL FROM FEDERAL AGENCIES.—Federal Government employees may be detailed from Federal agencies with or without reimbursement to those agencies to the Foundation at any time, and

such detail shall be without interruption or loss of civil service status or privilege. Each such employee shall abide by the statutory, regulatory, ethical, and procedural standards applicable to the employees of the agency from which such employee is detailed and those of the Foundation.

''(2) VOLUNTARY SERVICE; ACCEPTANCE OF FEDERAL EMPLOYEES.—

''(A) FOUNDATION.—The Executive Director of the Foundation may accept the services of employees detailed from Federal agencies with or without reimbursement to those agencies.

''(B) FOOD AND DRUG ADMINISTRATION.—The Commissioner may accept the uncompensated services of Foundation fellows or trainees. Such services shall be considered to be undertaking an activity under contract with the Secretary as described in section 708.

''(l) ANNUAL REPORTS.—

''(1) REPORTS TO FOUNDATION.—Any recipient of a grant, contract, fellowship, memorandum of understanding, or cooperative agreement from the Foundation under this section shall submit to the Foundation a report on an annual basis for the du-

ration of such grant, contract, fellowship, memorandum of understanding, or cooperative agreement, that describes the activities carried out under such grant, contract, fellowship, memorandum of understanding, or cooperative agreement.

''(2) REPORT TO CONGRESS AND THE FDA.—Beginning with fiscal year 2009, the Executive Director shall submit to Congress and the Commissioner an annual report that—

''(A) describes the activities of the Foundation and the progress of the Foundation in furthering the goals and priorities established under subsection (c)(2), including the practical impact of the Foundation on regulated product development;

''(B) provides a specific accounting of the source and use of all funds used by the Foundation to carry out such activities; and

''(C) provides information on how the results of Foundation activities could be incorporated into the regulatory and product review activities of the Food and Drug Administration.

''(m) SEPARATION OF FUNDS.—The Executive Director shall ensure that the funds received from the Treas-

ury are held in separate accounts from funds received from entities under subsection (i).

''(n) FUNDING.—From amounts appropriated to the Food and Drug Administration for each fiscal year, the Commissioner shall transfer not less than $500,000 and not more than $1,250,000, to the Foundation to carry out subsections (a), (b), and (d) through (m).''.

(b) OTHER FOUNDATION PROVISIONS.—Chapter VII (21 U.S.C. 371 et seq.) (as amended by subsection (a)) is amended by adding at the end the following:

''SEC. 771. LOCATION OF FOUNDATION.

''The Foundation shall, if practicable, be located not more than 20 miles from the District of Columbia.

''SEC. 772. ACTIVITIES OF THE FOOD AND DRUG ADMINISTRATION.

''(a) IN GENERAL.—The Commissioner shall receive and assess the report submitted to the Commissioner by the Executive Director of the Foundation under section 770(l)(2).

''(b) REPORT TO CONGRESS.—Beginning with fiscal year 2009, the Commissioner shall submit to Congress an annual report summarizing the incorporation of the information provided by the Foundation in the report described under section 770(l)(2) and by other recipients of grants, contracts, memoranda of understanding, or cooperative

agreements into regulatory and product review activities of the Food and Drug Administration.

''(c) EXTRAMURAL GRANTS.—The provisions of this subchapter shall have no effect on any grant, contract, memorandum of understanding, or cooperative agreement between the Food and Drug Administration and any other entity entered into before, on, or after the date of enactment of the Enhancing Drug Safety and Innovation Act of 2007.''.

(c) CONFORMING AMENDMENT.—Section 742(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379l(b)) is amended by adding at the end the following: ''Any such fellowships and training programs under this section or under section 770(d)(2)(A)(ix) may include provision by such scientists and physicians of services on a voluntary and uncompensated basis, as the Secretary determines appropriate. Such scientists and physicians shall be subject to all legal and ethical requirements otherwise applicable to officers or employees of the Department of Health and Human Services.''.

SEC. 222. OFFICE OF THE CHIEF SCIENTIST.

Chapter IX of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

"SEC. 910. OFFICE OF THE CHIEF SCIENTIST.

''(a) ESTABLISHMENT; APPOINTMENT.—The Secretary shall establish within the Office of the Commissioner an office to be known as the Office of the Chief Scientist. The Secretary shall appoint a Chief Scientist to lead such Office.

''(b) DUTIES OF THE OFFICE.—The Office of the Chief Scientist shall—

''(1) oversee, coordinate, and ensure quality and regulatory focus of the intramural research programs of the Food and Drug Administration;

''(2) track and, to the extent necessary, coordinate intramural research awards made by each center of the Administration or science-based office within the Office of the Commissioner, and ensure that there is no duplication of research efforts supported by the Reagan-Udall Foundation for the Food and Drug Administration;

''(3) develop and advocate for a budget to support intramural research;

''(4) develop a peer review process by which intramural research can be evaluated; and

''(5) identify and solicit intramural research proposals from across the Food and Drug Administration through an advisory board composed of employees of the Administration that shall include—

''(A) representatives of each of the centers and the science-based offices within the Office of the Commissioner; and

''(B) experts on trial design, epidemiology, demographics, pharmacovigilance, basic science, and public health.''.

Subtitle C—Clinical Trials

SEC. 231. EXPANDED CLINICAL TRIAL REGISTRY DATA BANK.

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

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

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

''(j) EXPANDED CLINICAL TRIAL REGISTRY DATA BANK.—

''(1) DEFINITIONS; REQUIREMENT.—

''(A) DEFINITIONS.—In this subsection:

''(i) APPLICABLE DEVICE CLINICAL TRIAL.—The term 'applicable device clinical trial' means—

''(I) a prospective study of health outcomes comparing an intervention against a control in human subjects intended to support an application

under section 515 or 520(m), or a report under section 510(k), of the Federal Food, Drug, and Cosmetic Act (other than a limited study to gather essential information used to refine the device or design a pivotal trial and that is not intended to determine safety and effectiveness of a device); and

''(II) a pediatric postmarket surveillance as required under section 522 of the Federal Food, Drug, and Cosmetic Act.

''(ii) APPLICABLE DRUG CLINICAL TRIAL.—

''(I) IN GENERAL.—The term 'applicable drug clinical trial' means a controlled clinical investigation, other than a phase I clinical investigation, of a product subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act.

''(II) CLINICAL INVESTIGATION.—For purposes of subclause (I), the term 'clinical investigation' has

the meaning given that term in section 312.3 of title 21, Code of Federal Regulations.

"(III) PHASE I.—The term 'phase I' has the meaning given that term in section 312.21 of title 21, Code of Federal Regulations.

"(iii) CLINICAL TRIAL INFORMATION.—The term 'clinical trial information' means those data elements that are necessary to complete an entry in the clinical trial registry data bank under paragraph (2).

"(iv) COMPLETION DATE.—The term 'completion date' means, with respect to an applicable drug clinical trial or an applicable device clinical trial, the date on which the last patient enrolled in the clinical trial has completed his or her last medical visit of the clinical trial, whether the clinical trial concluded according to the prespecified protocol plan or was terminated.

"(v) DEVICE.—The term 'device' means a device as defined in section

201(h) of the Federal Food, Drug, and Cosmetic Act.

''(vi) DRUG.—The term 'drug' means a drug as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act or a biological product as defined in section 351 of this Act.

''(vii) RESPONSIBLE PARTY.—The term 'responsible party', with respect to a clinical trial of a drug or device, means—

''(I) the sponsor of the clinical trial (as defined in section 50.3 of title 21, Code of Federal Regulations (or any successor regulations)) or the principal investigator of such clinical trial if so designated by such sponsor; or

''(II) if no sponsor exists, the grantee, contractor, or awardee for a trial funded by a Federal agency or the principal investigator of such clinical trial if so designated by such grantee, contractor, or awardee.

''(B) REQUIREMENT.—The Secretary shall develop a mechanism by which—

''(i) the responsible party for each applicable drug clinical trial and applicable device clinical trial shall submit the identity and contact information of such responsible party to the Secretary at the time of submission of clinical trial information under paragraph (2); and

''(ii) other Federal agencies may identify the responsible party for an applicable drug clinical trial or applicable device clinical trial.

''(2) EXPANSION OF CLINICAL TRIAL REGISTRY DATA BANK WITH RESPECT TO CLINICAL TRIAL INFORMATION.—

''(A) IN GENERAL.—

''(i) EXPANSION OF DATA BANK.—To enhance patient enrollment and provide a mechanism to track subsequent progress of clinical trials, the Secretary, acting through the Director of NIH, shall expand, in accordance with this subsection, the clinical trials registry of the data bank described under subsection (i)(3)(A) (referred to in this subsection as the 'registry data bank'). The Director of NIH shall en-

sure that the registry data bank is made publicly available through the Internet.

''(ii) CONTENT.—Not later than 18 months after the date of enactment of the Enhancing Drug Safety and Innovation Act of 2007, and after notice and comment, the Secretary shall promulgate regulations to expand the registry data bank to require the submission to the registry data bank of clinical trial information for applicable drug clinical trials and applicable device clinical trials that—

''(I) conforms to the International Clinical Trials Registry Platform trial registration data set of the World Health Organization;

''(II) includes the city, State, and zip code for each clinical trial location, or a toll-free number through which such location information may be accessed;

''(III) if the drug is not approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act,

specifies whether or not there is expanded access to the drug under section 561 of the Federal Food, Drug, and Cosmetic Act for those who do not qualify for enrollment in the clinical trial and how to obtain information about such access;

''(IV) requires the inclusion of such other data elements to the registry data bank as appropriate; and

''(V) becomes effective 90 days after issuance of the final rule.

''(B) FORMAT AND STRUCTURE.—

''(i) SEARCHABLE CATEGORIES.—The Director of NIH shall ensure that the public may search the entries in the registry data bank by 1 or more of the following criteria:

''(I) The disease or condition being studied in the clinical trial, using Medical Subject Headers (MeSH) descriptors.

''(II) The treatment being studied in the clinical trial.

''(III) The location of the clinical trial.

''(IV) The age group studied in the clinical trial, including pediatric subpopulations.

''(V) The study phase of the clinical trial.

''(VI) The source of support for the clinical trial, which may be the National Institutes of Health or other Federal agency, a private industry source, or a university or other organization.

''(VII) The recruitment status of the clinical trial.

''(VIII) The National Clinical Trial number or other study identification for the clinical trial.

''(ii) FORMAT.—The Director of the NIH shall ensure that the registry data bank is easily used by the public, and that entries are easily compared.

''(C) DATA SUBMISSION.—The responsible party for an applicable drug clinical trial shall submit to the Director of NIH for inclusion in

the registry data bank the clinical trial information described in subparagraph (A)(ii).

''(D) TRUTHFUL CLINICAL TRIAL INFORMATION.—

''(i) IN GENERAL.—The clinical trial information submitted by a responsible party under this paragraph shall not be false or misleading in any particular.

''(ii) EFFECT.—Clause (i) shall not have the effect of requiring clinical trial information with respect to an applicable drug clinical trial or an applicable device clinical trial to include information from any source other than such clinical trial involved.

''(E) CHANGES IN CLINICAL TRIAL STATUS.—

''(i) ENROLLMENT.—The responsible party for an applicable drug clinical trial or an applicable device clinical trial shall update the enrollment status not later than 30 days after the enrollment status of such clinical trial changes.

''(ii) COMPLETION.—The responsible party for an applicable drug clinical trial

or applicable device clinical trial shall report to the Director of NIH that such clinical trial is complete not later than 30 days after the completion date of the clinical trial.

''(F) TIMING OF SUBMISSION.—The clinical trial information for an applicable drug clinical trial or an applicable device clinical trial required to be submitted under this paragraph shall be submitted not later than 21 days after the first patient is enrolled in such clinical trial.

''(G) POSTING OF DATA.—

''(i) APPLICABLE DRUG CLINICAL TRIAL.—The Director of NIH shall ensure that clinical trial information for an applicable drug clinical trial submitted in accordance with this paragraph is posted publicly within 30 days of such submission.

''(ii) APPLICABLE DEVICE CLINICAL TRIAL.—The Director of NIH shall ensure that clinical trial information for an applicable device clinical trial submitted in accordance with this paragraph is posted publicly within 30 days of clearance under section 510(k) of the Federal Food, Drug,

and Cosmetic Act, or approval under section 515 or section 520(m) of such Act, as applicable.

''(H) VOLUNTARY SUBMISSIONS.—A responsible party for a clinical trial that is not an applicable drug clinical trial or an applicable device clinical trial may submit clinical trial information to the registry data bank in accordance with this subsection.

''(3) EXPANSION OF REGISTRY DATA BANK TO INCLUDE RESULTS OF CLINICAL TRIALS.—

''(A) LINKING REGISTRY DATA BANK TO EXISTING RESULTS.—

''(i) IN GENERAL.—Beginning not later than 90 days after the date of enactment of the Enhancing Drug Safety and Innovation Act of 2007, for those clinical trials that form the primary basis of an efficacy claim or are conducted after the drug involved is approved or after the device involved is cleared or approved, the Secretary shall ensure that the registry data bank includes links to results information for such clinical trial—

"(I) not earlier than 30 days after the date of the approval of the drug involved or clearance or approval of the device involved; or

"(II) not later than 30 days after such information becomes publicly available, as applicable.

"(ii) REQUIRED INFORMATION.—

"(I) FDA INFORMATION.—The Secretary shall ensure that the registry data bank includes links to the following information:

"(aa) If an advisory committee considered at a meeting an applicable drug clinical trial or an applicable device clinical trial, any posted Food and Drug Administration summary document regarding such applicable drug clinical trial or applicable clinical device trial.

"(bb) If an applicable drug clinical trial was conducted under section 505A or 505B of the Federal Food, Drug, and Cos-

metic Act, a link to the posted Food and Drug Administration assessment of the results of such trial.

''(cc) Food and Drug Administration public health advisories regarding the drug or device that is the subject of the applicable drug clinical trial or applicable device clinical trial, respectively, if any.

''(dd) For an applicable drug clinical trial, the Food and Drug Administration action package for approval document required under section 505(l)(2) of the Food Drug and Cosmetic Act.

''(ee) For an applicable device clinical trial, in the case of a premarket application, the detailed summary of information respecting the safety and effectiveness of the device required under section 520(h)(1) of the

Federal Food, Drug, and Cosmetic Act, or, in the case of a report under section 510(k) of such Act, the section 510(k) summary of the safety and effectiveness data required under section 807.95(d) of title 21, Code of Federal Regulations (or any successor regulations).

''(II) NIH INFORMATION.—The Secretary shall ensure that the registry data bank includes links to the following information:

''(aa) Medline citations to any publications regarding each applicable drug clinical trial and applicable device clinical trial.

''(bb) The entry for the drug that is the subject of an applicable drug clinical trial in the National Library of Medicine database of structured product labels, if available.

''(iii) RESULTS FOR EXISTING DATA BANK ENTRIES.—The Secretary may in-

clude the links described in clause (ii) for data bank entries for clinical trials submitted to the data bank prior to enactment of the Enhancing Drug Safety and Innovation Act of 2007, as available.

''(B) FEASIBILITY STUDY.—The Director of NIH shall—

''(i) conduct a study to determine the best, validated methods of making the results of clinical trials publicly available after the approval of the drug that is the subject of an applicable drug clinical trial; and

''(ii) not later than 18 months after initiating such study, submit to the Secretary any findings and recommendations of such study.

''(C) NEGOTIATED RULEMAKING.—

''(i) IN GENERAL.—The Secretary shall establish a negotiated rulemaking process pursuant to subchapter IV of chapter 5 of title 5, United States Code, to determine, for applicable drug clinical trials—

''(I) how to ensure quality and validate methods of expanding the registry data bank to include clinical trial results information for trials not within the scope of this Act;

''(II) the clinical trials of which the results information is appropriate for adding to the expanded registry data bank; and

''(III) the appropriate timing of the posting of such results information.

''(ii) TIME REQUIREMENT.—The process described in paragraph (1) shall be conducted in a timely manner to ensure that—

''(I) any recommendation for a proposed rule—

''(aa) is provided to the Secretary not later than 21 months after the date of the enactment of the Enhancing Drug Safety and Innovation Act of 2007; and

''(bb) includes an assessment of the benefits and costs of the recommendation; and

''(II) a final rule is promulgated not later than 30 months after the date of the enactment of the Enhancing Drug Safety and Innovation Act of 2007, taking into account the recommendations under subclause (I) and the results of the feasibility study conducted under subparagraph (B).

''(iii) REPRESENTATION ON NEGOTIATED RULEMAKING COMMITTEE.—The negotiated rulemaking committee established by the Secretary pursuant to clause (i) shall include members representing—

''(I) the Food and Drug Administration;

''(II) the National Institutes of Health;

''(III) other Federal agencies as the Secretary determines appropriate;

''(IV) patient advocacy and health care provider groups;

''(V) the pharmaceutical industry;

''(VI) contract clinical research organizations;

''(VII) the International Committee of Medical Journal Editors; and

''(VIII) other interested parties, including experts in privacy protection, pediatrics, health information technology, health literacy, communication, clinical trial design and implementation, and health care ethics.

''(iv) CONTENT OF REGULATIONS.—The regulations promulgated pursuant to clause (i) shall establish—

''(I) procedures to determine which clinical trials results information data elements shall be included in the registry data bank, taking into account the needs of different populations of users of the registry data bank;

"(II) a standard format for the submission of clinical trials results to the registry data bank;

"(III) a standard procedure for the submission of clinical trial results information, including the timing of submission and the timing of posting of results information, to the registry data bank, taking into account the possible impacts on publication of manuscripts based on the clinical trial;

"(IV) a standard procedure for the verification of clinical trial results information, including ensuring that free text data elements are non-promotional; and

"(V) an implementation plan for the prompt inclusion of clinical trials results information in the registry data bank.

"(D) CONSIDERATION OF WORLD HEALTH ORGANIZATION DATA SET.—The Secretary shall consider the status of the consensus data elements set for reporting clinical trial results of

the World Health Organization when promulgating the regulations under subparagraph (C).

''(E) TRUTHFUL CLINICAL TRIAL INFORMATION.—

''(i) IN GENERAL.—The clinical trial information submitted by a responsible party under this paragraph shall not be false or misleading in any particular.

''(ii) EFFECT.—Clause (i) shall not have the effect of requiring clinical trial information with respect to an applicable drug clinical trial or an applicable device clinical trial to include information from any source other than such clinical trial involved.

''(F) WAIVERS REGARDING CERTAIN CLINICAL TRIAL RESULTS.—The Secretary may waive any applicable requirements of this paragraph for an applicable drug clinical trial or an applicable device clinical trial, upon a written request from the responsible person, if the Secretary determines that extraordinary circumstances justify the waiver and that providing the waiver is in the public interest, consistent with the protection of public health, or

in the interest of national security. Not later than 30 days after any part of a waiver is granted, the Secretary shall notify, in writing, the appropriate committees of Congress of the waiver and provide an explanation for why the waiver was granted.

''(4) COORDINATION AND COMPLIANCE.—

''(A) CLINICAL TRIALS SUPPORTED BY GRANTS FROM FEDERAL AGENCIES.—

''(i) IN GENERAL.—No Federal agency may release funds under a research grant to an awardee who has not complied with paragraph (2) for any applicable drug clinical trial or applicable device clinical trial for which such person is the responsible party.

''(ii) GRANTS FROM CERTAIN FEDERAL AGENCIES.—If an applicable drug clinical trial or applicable device clinical trial is funded in whole or in part by a grant from the Food and Drug Administration, National Institutes of Health, the Agency for Healthcare Research and Quality, or the Department of Veterans Affairs, any grant or progress report forms re-

quired under such grant shall include a certification that the responsible party has made all required submissions to the Director of NIH under paragraph (2).

''(iii) VERIFICATION BY FEDERAL AGENCIES.—The heads of the agencies referred to in clause (ii), as applicable, shall verify that the clinical trial information for each applicable drug clinical trial or applicable device clinical trial for which a grantee is the responsible party has been submitted under paragraph (2) before releasing any remaining funding for a grant or funding for a future grant to such grantee.

''(iv) NOTICE AND OPPORTUNITY TO REMEDY.—If the head of an agency referred to in clause (ii), as applicable, verifies that a grantee has not submitted clinical trial information as described in clause (iii), such agency head shall provide notice to such grantee of such non-compliance and allow such grantee 30 days to correct such non-compliance and submit the required clinical trial information.

"(v) CONSULTATION WITH OTHER FEDERAL AGENCIES.—The Secretary shall—

"(I) consult with other agencies that conduct research involving human subjects in accordance with any section of part 46 of title 45, Code of Federal Regulations (or any successor regulations), to determine if any such research is an applicable drug clinical trial or an applicable device clinical trial under paragraph (1); and

"(II) develop with such agencies procedures comparable to those described in clauses (ii), (iii), and (iv) to ensure that clinical trial information for such applicable drug clinical trials and applicable device clinical trial is submitted under paragraph (2).

"(B) CERTIFICATION TO ACCOMPANY DRUG, BIOLOGICAL PRODUCT, AND DEVICE SUBMISSIONS.—At the time of submission of an application under section 505 of the Federal Food, Drug, and Cosmetic Act, section 515 of

such Act, section 520(m) of such Act, or section 351 of this Act, or submission of a report under section 510(k) of such Act, such application or submission shall be accompanied by a certification that all applicable requirements of this subsection have been met. Where available, such certification shall include the appropriate National Clinical Trial control numbers.

''(C) VERIFICATION OF SUBMISSION PRIOR TO POSTING.—In the case of clinical trial information that is submitted under paragraph (2), but is not made publicly available pending regulatory approval or clearance, as applicable, the Director of NIH shall respond to inquiries from other Federal agencies and peer-reviewed scientific journals to confirm that such clinical trial information has been submitted but has not yet been posted.

''(5) LIMITATION ON DISCLOSURE OF CLINICAL TRIAL INFORMATION.—

''(A) IN GENERAL.—Nothing in this subsection (or under section 552 of title 5, United States Code) shall require the Secretary to publicly disclose, from any record or source other than the registry data bank expanded under

this subsection, information described in subparagraph (B).

''(B) INFORMATION DESCRIBED.—Information described in this subparagraph is—

''(i) information submitted to the Director of NIH under this subsection, or information of the same general nature as (or integrally associated with) the information so submitted; and

''(ii) not otherwise publicly available, including because it is protected from disclosure under section 552 of title 5, United States Code.

''(6) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection $10,000,000 for each fiscal year.''.

(b) CONFORMING AMENDMENTS.—

(1) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(jj)(1) The failure to submit the certification required by section 402(j)(4)(B) of the Public Health Service Act, or knowingly submitting a false certification under such section.

''(2) The submission of clinical trial information under subsection (i) or (j) of section 402 of the Public Health Service Act that is promotional or false or misleading in any particular under paragraph (2) or (3) of such subsection (j).''.

(2) CIVIL MONEY PENALTIES.—Section 303(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)), as amended by section 203, is further amended by—

(A) redesignating paragraphs (4), (5), and (6) as paragraphs (5), (6), and (7), respectively;

(B) inserting after paragraph (3) the following:

''(4) Any person who violates section 301(jj) shall be subject to a civil monetary penalty of not more than $10,000 for the first violation, and not more than $20,000 for each subsequent violation.'';

(C) in paragraph (2)(C), by striking ''paragraph (4)(A)'' and inserting ''paragraph (5)(A)'';

(D) in paragraph (5), as so redesignated, by striking ''paragraph (1), (2), or (3)'' each place it appears and inserting ''paragraph (1), (2), (3), or (4)''; and

(E) in paragraph (7), as so redesignated, by striking ''paragraph (5)'' each place it appears and inserting ''paragraph (6)''.

(3) NEW DRUGS AND DEVICES.—

(A) INVESTIGATIONAL NEW DRUGS.—Section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) is amended in paragraph (4), by adding at the end the following: ''The Secretary shall update such regulations to require inclusion in the informed consent form a statement that clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to subsections (i) and (j) of section 402 of the Public Health Service Act.''.

(B) NEW DRUG APPLICATIONS.—Section 505(b) of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended by adding at the end the following:

''(6) An application submitted under this subsection shall be accompanied by the certification required under section 402(j)(4)(B) of the Public Health Service Act. Such certification shall not be considered an element of such application.''.

(C) DEVICE REPORTS UNDER SECTION 510(k).—Section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) is amended by adding at the end the following:

''A notification submitted under this subsection that contains clinical trial data for an applicable device clinical trial (as defined in section 402(j)(1) of the Public Health Service Act) shall be accompanied by the certification required under section 402(j)(4)(B) of such Act. Such certification shall not be considered an element of such notification.''.

(D) DEVICE PREMARKET APPROVAL APPLICATION.—Section 515(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is amended—

(i) in subparagraph (F), by striking ''; and'' and inserting a semicolon;

(ii) by redesignating subparagraph (G) as subparagraph (H); and

(iii) by inserting after subparagraph (F) the following:

''(G) the certification required under section 402(j)(4)(B) of the Public Health Service Act (which shall not be considered an element of such application); and''.

(E) HUMANITARIAN DEVICE EXEMPTION.—Section 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is amended in the first sentence in the matter following subparagraph (C), by inserting at the end before the period ''and such application shall include the certification required under section 402(j)(4)(B) of the Public Health Service Act (which shall not be considered an element of such application)''.

(c) PREEMPTION.—

(1) IN GENERAL.—No State or political subdivision of a State may establish or continue in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database.

(2) RULE OF CONSTRUCTION.—The fact of submission of clinical trial information, if submitted in compliance with subsection (i) and (j) of section 402 of the Public Health Service Act (as amended by this section), that relates to a use of a drug or device not included in the official labeling of the approved drug or device shall not be construed by the Secretary or in any administrative or judicial proceeding, as evidence of a new intended use of the

drug or device that is different from the intended use of the drug or device set forth in the official labeling of the drug or device. The availability of clinical trial information through the data bank under such subsections (i) and (j), if submitted in compliance with such subsections, shall not be considered as labeling, adulteration, or misbranding of the drug or device under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(d) TRANSITION RULE; EFFECTIVE DATE OF FUNDING RESTRICTIONS.—

(1) TRANSITION RULE FOR CLINICAL TRIALS INITIATED PRIOR TO EXPANSION OF REGISTRY DATA BANK.—The responsible party (as defined in paragraph (1) of section 402(j) of the Public Health Service Act (as added by this section)) for an applicable drug clinical trial or applicable device clinical trial (as defined under such paragraph (1)) that is initiated after the date of enactment of this subtitle and before the effective date of the regulations promulgated under paragraph (2) of such section 402(j), shall submit required clinical trial information under such section not later than 120 days after such effective date.

(2) FUNDING RESTRICTIONS.—Subparagraph (A) of paragraph (4) of such section 402(j) shall take effect 210 days after the effective date of the regulations promulgated under paragraph (2) of such section 402(j).

(e) EFFECTIVE DATE.—

(1) IN GENERAL.—Beginning 90 days after the date of enactment of this title, the responsible party for an applicable drug clinical trial or an applicable device clinical trial (as that term is defined in such section 402(j)) that is initiated after the date of enactment of this title and before the effective date of the regulations issued under subparagraph (A) of paragraph (2) of such subsection, shall submit clinical trial information under such paragraph (2).

(2) RULEMAKING.—

(A) IN GENERAL.—Except as provided in subparagraph (B), subsection (c)(1) shall become effective on the date on which the regulation promulgated pursuant to section 402(j)(3)(C)(i) of the Public Health Service Act, as added by this section, becomes effective.

(B) EXCEPTION.—Subsection (c)(1) shall apply with respect to any clinical trial for which the registry data bank includes links to results

information, as provided for under section 402(j)(3)(A) of such Act, as added by this section.

Subtitle D—Conflicts of Interest

SEC. 241. CONFLICTS OF INTEREST.

(a) IN GENERAL.—Subchapter A of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by inserting at the end the following:

"SEC. 712. CONFLICTS OF INTEREST.

"(a) DEFINITIONS.—For purposes of this section:

"(1) ADVISORY COMMITTEE.—The term 'advisory committee' means an advisory committee under the Federal Advisory Committee Act that provides advice or recommendations to the Secretary regarding activities of the Food and Drug Administration.

"(2) FINANCIAL INTEREST.—The term 'financial interest' means a financial interest under section 208(a) of title 18, United States Code.

"(b) APPOINTMENTS TO ADVISORY COMMITTEES.—

"(1) RECRUITMENT.—

"(A) IN GENERAL.—Given the importance of advisory committees to the review process at the Food and Drug Administration, the Secretary shall carry out informational and recruitment activities for purposes of recruiting indi-

viduals to serve as advisory committee members. The Secretary shall seek input from professional medical and scientific societies to determine the most effective informational and recruitment activities. The Secretary shall also take into account the advisory committees with the greatest number of vacancies.

''(B) RECRUITMENT ACTIVITIES.—The recruitment activities under subparagraph (A) may include—

''(i) advertising the process for becoming an advisory committee member at medical and scientific society conferences;

''(ii) making widely available, including by using existing electronic communications channels, the contact information for the Food and Drug Administration point of contact regarding advisory committee nominations; and

''(iii) developing a method through which an entity receiving National Institutes of Health funding can identify a person who the Food and Drug Administration can contact regarding the nomination

of individuals to serve on advisory committees.

''(2) EVALUATION AND CRITERIA.—When considering a term appointment to an advisory committee, the Secretary shall review the expertise of the individual and the financial disclosure report filed by the individual pursuant to the Ethics in Government Act of 1978 for each individual under consideration for the appointment, so as to reduce the likelihood that an appointed individual will later require a written determination as referred to in section 208(b)(1) of title 18, United States Code, a written certification as referred to in section 208(b)(3) of title 18, United States Code, or a waiver as referred to in subsection (c)(3) of this section for service on the committee at a meeting of the committee.

''(c) GRANTING AND DISCLOSURE OF WAIVERS.—

''(1) IN GENERAL.—Prior to a meeting of an advisory committee regarding a 'particular matter' (as that term is used in section 208 of title 18, United States Code), each member of the committee who is a full-time Government employee or special Government employee shall disclose to the Secretary

financial interests in accordance with subsection (b) of such section 208.

''(2) FINANCIAL INTEREST OF ADVISORY COMMITTEE MEMBER OR FAMILY MEMBER.—No member of an advisory committee may vote with respect to any matter considered by the advisory committee if such member (or an immediate family member of such member) has a financial interest that could be affected by the advice given to the Secretary with respect to such matter, excluding interests exempted in regulations issued by the Director of the Office of Government Ethics as too remote or inconsequential to affect the integrity of the services of the Government officers or employees to which such regulations apply.

''(3) WAIVER.—The Secretary may grant a waiver of the prohibition in paragraph (2) if such waiver is necessary to afford the advisory committee essential expertise.

''(4) LIMITATION.—The Secretary may not grant a waiver under paragraph (3) for a member of an advisory committee when the member's own scientific work is involved.

"(5) DISCLOSURE OF WAIVER.—Notwithstanding section 107(a)(2) of the Ethics in Government Act (5 U.S.C. App.), the following shall apply:

"(A) 15 OR MORE DAYS IN ADVANCE.—As soon as practicable, but in no case later than 15 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18, United States Code, a written certification as referred to in section 208(b)(3) of title 18, United States Code, or a waiver as referred to in paragraph (3) applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 of title 5, United States Code, and section 552a of title 5, United States Code (popularly known as the Freedom of Information Act and the Privacy Act of 1974, respectively)) on the Internet website of the Food and Drug Administration—

"(i) the type, nature, and magnitude of the financial interests of the advisory committee member to which such determination, certification, or waiver applies; and

"(ii) the reasons of the Secretary for such determination, certification, or waiver.

"(B) LESS THAN 30 DAYS IN ADVANCE.—In the case of a financial interest that becomes known to the Secretary less than 30 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18, United States Code, a written certification as referred to in section 208(b)(3) of title 18, United States Code, or a waiver as referred to in paragraph (3) applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 of title 5, United States Code, and section 552a of title 5, United States Code) on the Internet website of the Food and Drug Administration, the information described in clauses (i) and (ii) of subparagraph (A) as soon as practicable after the Secretary makes such determination, certification, or waiver, but in no case later than the date of such meeting.

"(d) PUBLIC RECORD.—The Secretary shall ensure that the public record and transcript of each meeting of an advisory committee includes the disclosure required

under subsection (c)(5) (other than information exempted from disclosure under section 552 of title 5, United States Code, and section 552a of title 5, United States Code).

''(e) ANNUAL REPORT.—Not later than February 1 of each year, the Secretary shall submit to the Inspector General of the Department of Health and Human Services, the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives, a report that describes—

''(1) with respect to the fiscal year that ended on September 30 of the previous year, the number of vacancies on each advisory committee, the number of nominees received for each committee, and the number of such nominees willing to serve;

''(2) with respect to such year, the aggregate number of disclosures required under subsection (c)(5) for each meeting of each advisory committee and the percentage of individuals to whom such disclosures did not apply who served on such committee for each such meeting;

''(3) with respect to such year, the number of times the disclosures required under subsection

(c)(5) occurred under subparagraph (B) of such subsection; and

''(4) how the Secretary plans to reduce the number of vacancies reported under paragraph (1) during the fiscal year following such year, and mechanisms to encourage the nomination of individuals for service on an advisory committee, including those who are classified by the Food and Drug Administration as academicians or practitioners.

''(f) PERIODIC REVIEW OF GUIDANCE.—Not less than once every 5 years, the Secretary shall review guidance of the Food and Drug Administration regarding conflict of interest waiver determinations with respect to advisory committees and update such guidance as necessary.''.

(b) CONFORMING AMENDMENT.—Section 505(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(n)) is amended by—

(1) striking paragraph (4); and

(2) redesignating paragraphs (5), (6), (7), and (8) as paragraphs (4), (5), (6), and (7), respectively.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on October 1, 2007.

Subtitle E—Other Drug Safety Provisions

SEC. 251. DATABASE FOR AUTHORIZED GENERIC DRUGS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by this title, is further amended by adding at the end the following:

''(q) DATABASE FOR AUTHORIZED GENERIC DRUGS.—

''(1) IN GENERAL.—

''(A) PUBLICATION.—The Commissioner shall—

''(i) not later than 9 months after the date of enactment of the Enhancing Drug Safety and Innovation Act of 2007, publish a complete list on the Internet website of the Food and Drug Administration of all authorized generic drugs (including drug trade name, brand company manufacturer, and the date the authorized generic drug entered the market); and

''(ii) update the list quarterly to include each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug during the preceding 3-month period.

"(B) NOTIFICATION.—The Commissioner shall notify relevant Federal agencies, including the Centers for Medicare & Medicaid Services and the Federal Trade Commission, any time the Commissioner updates the information described in subparagraph (A).

"(2) INCLUSION.—The Commissioner shall include in the list described in paragraph (1) each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug after January 1, 1999.

"(3) AUTHORIZED GENERIC DRUG.—In this section, the term 'authorized generic drug' means a listed drug (as that term is used in subsection (j)) that—

"(A) has been approved under subsection (c); and

"(B) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the listed drug.".

SEC. 252. MEDICAL MARIJUANA.

The Secretary shall require that State-legalized medical marijuana be subject to the full regulatory requirements of the Food and Drug Administration, including a risk evaluation and mitigation strategy and all other requirements and penalties of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) regarding safe and effective reviews, approval, sale, marketing, and use of pharmaceuticals.

Subtitle F—Antibiotic Access and Innovation

SEC. 261. INCENTIVES FOR THE DEVELOPMENT OF, AND ACCESS TO, CERTAIN ANTIBIOTICS.

(a) IN GENERAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by this Act, is further amended by adding at the end the following:

''(s) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997.—

''(1) ANTIBIOTIC DRUGS APPROVED BEFORE NOVEMBER 21, 1997.—

''(A) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph

(B)(i) shall be eligible for, with respect to the drug, the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable.

''(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

''(i) APPLICATION.—An application described in this clause is an application for marketing submitted under this section after the date of enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

''(ii) ANTIBIOTIC DRUG.—An antibiotic drug described in this clause is an antibiotic drug that was the subject of an application approved by the Secretary under section 507 of this Act (as in effect before November 21, 1997).

''(2) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997, BUT NOT APPROVED.—

''(A) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration

Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) may elect to be eligible for, with respect to the drug—

"(i)(I) the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; and

"(II) the 5-year exclusivity period referred to under clause (ii) of subsection (c)(3)(E) and under clause (ii) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; or

"(ii) a patent term extension under section 156 of title 35, United States Code, subject to the requirements of such section.

"(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

"(i) APPLICATION.—An application described in this clause is an application for marketing submitted under this section

after the date of enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

''(ii) ANTIBIOTIC DRUG.—An antibiotic drug described in this clause is an antibiotic drug that was the subject of 1 or more applications received by the Secretary under section 507 of this Act (as in effect before November 21, 1997), none of which was approved by the Secretary under such section.

''(3) LIMITATIONS.—

''(A) EXCLUSIVITIES AND EXTENSIONS.—Paragraphs (1)(A) and (2)(A) shall not be construed to entitle a drug that is the subject of an approved application described in subparagraphs (1)(B)(i) or (2)(B)(i), as applicable, to any market exclusivities or patent extensions other than those exclusivities or extensions described in paragraph (1)(A) or (2)(A).

''(B) CONDITIONS OF USE.—Paragraphs (1)(A) and (2)(A)(i) shall not apply to any condition of use for which the drug referred to in subparagraph (1)(B)(i) or (2)(B)(i), as applica-

ble, was approved before the date of enactment of this subsection.

''(4) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding section 125, or any other provision, of the Food and Drug Administration Modernization Act of 1997, or any other provision of law, and subject to the limitations in paragraphs (1), (2), and (3), the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 shall apply to any drug subject to paragraph (1) or any drug with respect to which an election is made under paragraph (2)(A).''.

(b) TRANSITION RULE.—With respect to a patent issued on or before the date of enactment of this Act, any patent information required to be filed with the Secretary under subsection (b)(1) or (c)(2) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) to be listed on a drug to which subsection (s)(1) of such section 505 (as added by this section) applies shall be filed with such Secretary not later than 60 days after the date of enactment of this Act.

SEC. 262. ANTIBIOTICS AS ORPHAN PRODUCTS.

(a) PUBLIC MEETING.—The Commissioner of Food and Drugs shall convene a public meeting and, if appropriate, issue guidance, regarding which serious and life-

threatening infectious diseases, such as diseases due to gram-negative bacteria and other diseases due to antibiotic-resistant bacteria, potentially qualify for available grants and contracts under subsection (a) of section 5 of the Orphan Drug Act (21 U.S.C. 360ee(a)) or other incentives for development.

(b) GRANTS AND CONTRACTS FOR THE DEVELOPMENT OF ORPHAN DRUGS.—Subsection (c) of section 5 of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amended to read as follows:

''(c) For grants and contracts under subsection (a) there are authorized to be appropriated—

''(1) such sums as already have been appropriated for fiscal year 2007; and

''(2) $35,000,000 for each of fiscal years 2008 through 2012.''.

SEC. 263. IDENTIFICATION OF CLINICALLY SUSCEPTIBLE CONCENTRATIONS OF ANTIMICROBIALS.

(a) DEFINITION.—In this section, the term ''clinically susceptible concentrations'' means specific values which characterize bacteria as clinically susceptible, intermediate, or resistant to the drug (or drugs) tested.

(b) IDENTIFICATION.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), through the Commissioner of Food and Drugs,

shall identify and periodically update clinically susceptible concentrations.

(c) PUBLIC AVAILABILITY.—The Secretary, through the Commissioner of Food and Drugs, shall make such clinically susceptible concentrations publicly available within 30 days of the date of identification and any update under this section.

(d) EFFECT.—Nothing in this section shall be construed to restrict, in any manner, the prescribing of antibiotics by physicians, or to limit the practice of medicine, including for diseases such as Lyme and tick-borne diseases.

SEC. 264. EXCLUSIVITY OF CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S. C. 355), as amended by this subtitle, is amended by adding at the end the following:

''(t) CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.—

''(1) IN GENERAL.—For purposes of subsections (c)(3)(E)(ii) and (j)(5)(F)(ii), if an application is submitted under subsection (b) for a non-racemic drug containing as an active ingredient a single enantiomer that is contained in a racemic drug approved in another application under subsection

(b), the applicant may, in the application for such non-racemic drug, elect to have the single enantiomer not be considered the same active ingredient as that contained in the approved racemic drug, if—

''(A)(i) the single enantiomer has not been previously approved except in the approved racemic drug; and

''(ii) the application submitted under subsection (b) for such non-racemic drug—

''(I) includes full reports of new clinical investigations (other than bioavailability studies)—

''(aa) necessary for the approval of the application under subsections (c) and (d); and

''(bb) conducted or sponsored by the applicant; and

''(II) does not rely on any investigations that are part of an application submitted under subsection (b) for approval of the approved racemic drug; and

''(B) the application submitted under subsection (b) for such non-racemic drug is not submitted for approval of a condition of use—

"(i) in a therapeutic category in which the approved racemic drug has been approved; or

"(ii) for which any other enantiomer of the racemic drug has been approved.

"(2) LIMITATION.—

"(A) NO APPROVAL IN CERTAIN THERAPEUTIC CATEGORIES.—Until the date that is 10 years after the date of approval of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph, the Secretary shall not approve such non-racemic drug for any condition of use in the therapeutic category in which the racemic drug has been approved.

"(B) LABELING.—If applicable, the labeling of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph shall include a statement that the non-racemic drug is not approved, and has not been shown to be safe and effective, for any condition of use of the racemic drug.

"(3) DEFINITION.—

"(A) IN GENERAL.—For purposes of this subsection, the term 'therapeutic category' means a therapeutic category identified in the list developed by the United States Pharmacopeia pursuant to section 1860D–4(b)(3)(C)(ii) of the Social Security Act and as in effect on the date of enactment of this subsection.

"(B) PUBLICATION BY SECRETARY.—The Secretary shall publish the list described in subparagraph (A) and may amend such list by regulation.

"(4) AVAILABILITY.—The election referred to in paragraph (1) may be made only in an application that is submitted to the Secretary after the date of enactment of this subsection and before October 1, 2012.".

SEC. 265. REPORT.

Not later than January 1, 2012, the Comptroller General of the United States shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that examines whether and how this subtitle has—

(1) encouraged the development of new antibiotics and other drugs; and

(2) prevented or delayed timely generic drug entry into the market.

TITLE III—MEDICAL DEVICES

SEC. 300. REFERENCES.

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

Subtitle A—Device User Fees

SEC. 301. SHORT TITLE.

This subtitle may be cited as the ''Medical Device User Fee Amendments of 2007''.

SEC. 302. DEVICE FEES.

Section 737 (21 U.S.C. 379i) is amended—

(1) by striking the section designation and all that follows through ''For purposes of this subchapter'' and inserting the following:

''SEC. 737. DEVICE FEES.

''(a) PURPOSE.—It is the purpose of this part that the fees authorized under this part be dedicated toward expediting the process for the review of device applications

and for assuring the safety and effectiveness of devices, as set forth in the goals identified for purposes of this part in the letters from the Secretary to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

''(b) REPORTS.—

''(1) PERFORMANCE REPORT.—For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in subsection (a) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all device premarket applications, supplements, and premarket notifications in the cohort.

''(2) FISCAL REPORT.—For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

''(3) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under paragraphs (1) and (2) available to the public on the Internet website of the Food and Drug Administration.

''(c) REAUTHORIZATION.—

''(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of device applications for the first 5 fiscal years after fiscal year 2012, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

''(A) the Committee on Energy and Commerce of the House of Representatives;

''(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

''(C) scientific and academic experts;

''(D) health care professionals;

''(E) representatives of patient and consumer advocacy groups; and

''(F) the regulated industry.

''(2) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

''(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;

''(B) publish such recommendations in the Federal Register;

''(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

''(D) hold a meeting at which the public may present its views on such recommendations; and

''(E) after consideration of such public views and comments, revise such recommendations as necessary.

''(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2012, the Secretary shall transmit to Congress the revised recommendations under paragraph (2), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

''(d) DEFINITIONS.—For purposes of this part:'';

(2) by redesignating paragraphs (5), (6), (7), and (8), as paragraphs (7), (8), (9), and (11), respectively;

(3) in paragraph (4)—

(A) in subparagraph (A), by striking ''or an efficacy supplement,'' and inserting ''an efficacy supplement, or a 30-day notice,''; and

(B) by adding at the end the following:

''(F) The term '30-day notice' means a supplement to an approved premarket application or premarket report under section 515 that is limited to a request to make modifications to manufacturing procedures or methods of manufacture affecting the safety and effectiveness of the device.'';

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

''(5) The term 'request for classification information' means a request made under section 513(g) for information respecting the class in which a device has been classified or the requirements applicable to a device.

''(6) The term 'annual fee for periodic reporting concerning a class III device' means the fee associated with reports imposed by a premarket application approval order (as described in section 814.82(a)(7) of title 21, Code of Federal Regulations), usually referred to as 'annual reports.' '';

(5) in paragraph (9), as redesignated by paragraph (2)—

(A) by striking ''April of'' and inserting ''October of''; and

(B) by striking ''April 2002'' and inserting ''October 2001'';

(6) by inserting after paragraph (9), as redesignated by paragraph (2), the following:

''(10) The term 'person' includes an affiliate of such person.''; and

(7) by adding at the end the following:

''(12) The term 'establishment subject to a registration fee' means an establishment required to register with the Secretary under section 510 at which any of the following types of activities are conducted:

''(A) MANUFACTURER.—An establishment that makes by any means any article that is a device including an establishment that sterilizes or otherwise makes such article for or on behalf of a specification developer or any other person.

''(B) SINGLE-USE DEVICE REPROCESSOR.—An establishment that performs manufacturing operations on a single-use device that has previously been used on a patient.

''(C) SPECIFICATION DEVELOPER.—An establishment that develops specifications for a device that is distributed under the establishment's name but that performs no manufacturing, including establishments that, in addition to developing specifications, arrange for the manufacturing of devices labeled with another establishment's name by a contract manufacturer.

''(13) The term 'establishment registration fee' means a fee assessed under section 738(a)(3) for the

registration of an establishment subject to a registration fee.

''(e) SUNSET.—This part shall cease to be effective on October 1, 2012, except that subsection (b) with respect to reports shall cease to be effective January 31, 2013.''.

SEC. 303. AUTHORITY TO ASSESS AND USE DEVICE FEES.

Section 738 (21 U.S.C. 379j) is amended—

(1) in subsection (a)—

(A) in paragraph (2)—

(i) in the header, by inserting '', AND ANNUAL FEE FOR PERIODIC REPORTING CONCERNING A CLASS III DEVICE'' after ''FEE'';

(ii) in subparagraph (A)—

(I) in clause (iii), by inserting ''75 percent of'' after ''a fee equal to'';

(II) in clause (iv), by striking ''21.5'' and inserting ''15'';

(III) in clause (v), by striking ''7.2'' and inserting ''7'';

(IV) by redesignating clauses (vi) and (vii) as clauses (vii) and (viii), respectively;

(V) by inserting after clause (v) the following:

''(vi) For a 30-day notice, a fee equal to 1.6 percent of the fee that applies under clause (i).'';

(VI) in clause (viii), as redesignated by subclause (IV)—

(aa) by striking ''1.42'' and inserting ''1.84''; and

(bb) by striking '', subject to any adjustment under subsection (e)(2)(C)(ii)''; and

(VII) by adding at the end the following:

''(ix) For a request for classification information, a fee equal to 1.35 percent of the fee that applies under clause (i).

''(x) For periodic reporting concerning a class III device, the annual fee shall be equal to 3.5 percent of the fee that applies under clause (i).'';

(iii) in subparagraph (C)—

(I) in the first sentence—

(aa) by striking ''or''; and

(bb) by striking ''except that'' and all that follows through the period and inserting '', 30-day notice, request for classification information, or periodic report concerning a class III device.''; and

(II) by striking the third sentence; and

(iv) in subparagraph (D)—

(I) in clause (iii), by striking the last two sentences; and

(II) by adding at the end the following:

''(iv) MODULAR APPLICATION WITHDRAWN BEFORE FIRST ACTION.—The Secretary shall refund 75 percent of the application fee paid for a modular application submitted under section 515(c)(4) that is withdrawn before a second module is submitted and before a first action on the first module. If the modular application is withdrawn after a second or subsequent module is submitted but before any first action, the Secretary may return a portion of the

fee. The amount of refund, if any, shall be based on the level of effort already expended on the review of the modules submitted.

''(v) SOLE DISCRETION TO REFUND.—The Secretary shall have sole discretion to refund a fee or portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.''; and

(B) by adding at the end the following:

''(3) ANNUAL ESTABLISHMENT REGISTRATION FEE.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), each establishment subject to a registration fee shall be subject to a fee for each initial or annual registration beginning with its registration for fiscal year 2008.

''(B) EXCEPTION FOR FEDERAL OR STATE GOVERNMENT ESTABLISHMENT.—No fee shall be required under subparagraph (A) for an establishment operated by a Federal or State government entity unless a device manufactured by the establishment is to be distributed commercially.

"(C) PAYMENT.—The annual establishment registration fee shall be due once each fiscal year, upon the initial registration of the establishment or upon the annual registration under section 510.";

(2) by striking subsection (b) and inserting the following:

"(b) FEE AMOUNTS.—Except as provided in subsections (c), (d), and (e), the fees under subsection (a) shall be based on the following fee amounts:

Fee Type	Fiscal Year 2008	Fiscal Year 2009	Fiscal Year 2010	Fiscal Year 2011	Fiscal Year 2012
Premarket Application	$185,000	$200,725	$217,787	$236,298	$256,384 .....
Establishment Registration Fee	$1,706	$1,851	$2,008	$2,179	$2,364";

(3) in subsection (c)—

(A) in the heading, by striking "Annual Fee Setting.—" and inserting "ANNUAL FEE SETTING.—";

(B) in paragraph (1), by striking the second sentence;

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

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

''(2) ADJUSTMENT OF ANNUAL ESTABLISHMENT REGISTRATION FEE.—

''(A) IN GENERAL.—When setting the fees for fiscal year 2010, the Secretary may increase the establishment registration fee specified in subsection (b) only if the Secretary estimates that the number of establishments submitting fees for fiscal year 2009 is less than 12,250. The percent increase shall be the percent by which the estimate of establishments submitting fees in fiscal year 2009 is less than 12,750, but in no case shall the percent increase be more than 8.5 percent over the amount for such fee specified in subsection (b) for fiscal year 2010. If the Secretary makes any adjustment to the establishment registration fee for fiscal year 2010, then the establishment registration fee for fiscal years 2011 and 2012 under subsection (b) shall be adjusted as follows: the fee for fiscal year 2011 shall be equal to the adjusted fee for fiscal year 2010, increased by 8.5 percent, and the fee for fiscal year 2012 shall

be equal to the adjusted fee for fiscal year 2011, increased by 8.5 percent.

''(B) PUBLICATION IN THE FEDERAL REGISTER.—The Secretary shall publish any determination with respect to any establishment registration fee adjustment made under subparagraph (A), and the rationale for such determination, in the Federal Register.''; and

(E) in paragraph (4)(A), as so redesignated—

(i) by striking ''For fiscal years 2006 and 2007, the'' and inserting ''The''; and

(ii) by striking ''of fiscal year 2008'' and inserting ''of the next fiscal year'';

(4) in subsection (d)—

(A) in paragraph (1), by striking '', partners, and parent firms'';

(B) in paragraph (2)—

(i) in subparagraph (A), by striking '', partners, and parent firms'';

(ii) in subparagraph (B)—

(I) by striking ''An applicant shall'' and inserting the following:

''(i) IN GENERAL.—An applicant shall'';

(II) by striking ''The applicant shall support'' and inserting the following:

''(ii) FIRMS SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support'';

(III) by striking '', partners, and parent firms'' both places the term appears;

(IV) by striking ''partners, or parent firms, the'' and inserting ''the'';

(V) by striking '', partners, or parent firms, respectively''; and

(VI) by adding at the end the following:

''(iii) FIRMS NOT SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of the following:

''(I) A signed certification, in such form as the Secretary may direct

through a notice published in the Federal Register, that the applicant meets the criteria for a small business.

''(II) A certification, in English, from the national taxing authority of the country in which it is headquartered. Such certification shall provide the applicant's gross receipts and sales for the most recent year, in both the local currency and in United States dollars, the exchange rate used in making this conversion to dollars, and the dates during which these receipts and sales were collected, and it shall bear the official seal of the national taxing authority.

''(III) Identical certifications shall be provided for each of the applicant's affiliates.

''(IV) A statement signed by the head of the applicant or its chief financial officer that it has submitted certifications for all of its affiliates, or that it had no affiliates, whichever is applicable.''; and

(iii) in subparagraph (C)—

(I) by striking ''reduced rate of'' and inserting ''reduced rate of—''; and

(II) by striking ''38 percent'' and all that follows through the period and inserting the following:

''(i) 25 percent of the fee established under such subsection for a premarket application, a premarket report, a supplement, or a periodic report concerning a class III device; and

''(ii) 50 percent of the fee established under such subsection for a 30-day notice or a request for classification information.'';

(5) in subsection (e)—

(A) in paragraph (1), by striking ''2004'' and inserting ''2008''; and

(B) in paragraph (2)—

(i) in subparagraph (A), by striking '', partners, and parent firms'';

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

''(B) EVIDENCE OF QUALIFICATION.—

''(i) IN GENERAL.—An applicant shall pay the higher fees established by the Secretary each year unless the applicant submits evidence that it qualifies for the lower fee rate.

''(ii) FIRMS SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of such returns of its affiliates, which show an amount of gross sales or receipts that is less than the maximum established in subparagraph (A). The applicant, and each of such affiliates, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted for affiliates, the applicant shall certify that the applicant has no affiliates.

''(iii) FIRMS NOT SUBMITTING TAX RETURNS TO THE UNITED STATES INTER-

NAL REVENUE SERVICE.—The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of the following:

"(I) A signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant meets the criteria for a small business.

"(II) A certification, in English, from the national taxing authority of the country in which it is headquartered. Such certification shall provide the applicant's gross receipts and sales for the most recent year, in both the local currency and in United States dollars, and the exchange rate used in making such conversion to dollars, and the dates during which such receipts and sales were collected, and it shall bear the official seal of the national taxing authority.

"(III) Identical certifications shall be provided for each of the applicant's affiliates.

''(IV) A statement signed by the head of the applicant or its chief financial officer that it has submitted certifications for all of its affiliates, or that it had no affiliates, whichever is applicable.''; and

(iii) by striking subparagraph (C) and inserting the following:

''(C) REDUCED FEES.—For fiscal year 2008 and each subsequent fiscal year, where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fee for a premarket notification submission may be paid at 50 percent of the fee that applies under subsection (a)(2)(A)(viii) and as established under subsection (c)(1).'';

(6) by striking subsection (f) and inserting the following:

''(f) EFFECT OF FAILURE TO PAY FEES.—

''(1) IN GENERAL.—A premarket application, premarket report, supplement, or premarket notification submission, 30-day notice, request for classification information, or periodic report concerning a class III device submitted by a person subject to fees under paragraphs (2) and (3) of subsection (a) shall

be considered incomplete and shall not be accepted by the Secretary until all fees owed by such person have been paid.

''(2) REGISTRATION INFORMATION.—Registration information submitted by an establishment subject to a registration fee under subsection (a)(3) shall be considered incomplete and shall not be accepted by the Secretary until the registration fee owed for the establishment has been paid. Until the fee is paid and the registration is complete, the establishment shall be deemed to have failed to register in accordance with section 510.'';

(7) in subsection (g)—

(A) by striking paragraph (1) and inserting the following:

''(1) PERFORMANCE GOALS; TERMINATION OF PROGRAM.—With respect to the amount that, under the salaries and expenses account of the Food and Drug Administration, is appropriated for a fiscal year for devices and radiological products, fees may not be assessed under subsection (a) for the fiscal year, and the Secretary is not expected to meet any performance goals identified for the fiscal year, if—

''(A) the amount so appropriated for the fiscal year, excluding the amount of fees appro-

priated for the fiscal year, is more than 1 percent less than $205,720,000 multiplied by the adjustment factor applicable to such fiscal year; or

''(B) fees were not assessed under subsection (a) for the previous fiscal year.''; and

(B) in paragraph (2), by striking ''and premarket notification submissions, and'' and inserting ''premarket notification submissions, 30-day notices, requests for classification information, periodic reports concerning a class III device, and establishment registrations''; and

(8) in subsection (h), by striking paragraphs (3) and (4) and inserting the following:

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

''(A) $48,431,000 for fiscal year 2008;

''(B) $52,547,000 for fiscal year 2009;

''(C) $57,014,000 for fiscal year 2010;

''(D) $61,860,000 for fiscal year 2011; and

''(E) $67,118,000 for fiscal year 2012.

''(4) OFFSET.—If the cumulative amount of fees collected during fiscal years 2008, 2009, and

2010, added to the amount estimated to be collected for fiscal year 2011 (which estimate shall be based upon the amount of fees received by the Secretary through June 30, 2011), exceeds the amount of fees specified in aggregate in paragraph (3) for such 4 fiscal years, the aggregate amount in excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2012.''.

SEC. 304. SAVINGS CLAUSE.

Notwithstanding section 107 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250), and notwithstanding the amendments made by this subtitle, part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of enactment of this subtitle, shall continue to be in effect with respect to premarket applications, premarket reports, premarket notification submissions, and supplements (as defined in such part as of such day) that on or after October 1, 2002, but before October 1, 2007, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any

fee required by such part for a fiscal year prior to fiscal year 2008.

SEC. 305. EFFECTIVE DATE.

The amendments made by this subtitle shall take effect on October 1, 2007.

Subtitle B—Amendments Regarding Regulation of Medical Devices

SEC. 311. INSPECTIONS BY ACCREDITED PERSONS.

Section 704(g) (21 U.S.C. 374(g)) is amended—

(1) in paragraph (1), by striking ''Not later than one year after the date of enactment of this subsection, the Secretary'' and inserting ''The Secretary'';

(2) in paragraph (2), by—

(A) striking ''Not later than 180 days after the date of enactment of this subsection, the'' and inserting ''The Secretary''; and

(B) striking the fifth sentence;

(3) in paragraph (3), by adding at the end the following:

''(F) Such person shall notify the Secretary of any withdrawal, suspension, restriction, or expiration of certificate of conformance with the quality systems standard referred to in

paragraph (7) for any device establishment that such person inspects under this subsection not later than 30 days after such withdrawal, suspension, restriction, or expiration.

''(G) Such person may conduct audits to establish conformance with the quality systems standard referred to in paragraph (7).'';

(4) by amending paragraph (6) to read as follows:

''(6)(A) Subject to subparagraphs (B) and (C), a device establishment is eligible for inspection by persons accredited under paragraph (2) if the following conditions are met:

''(i) The Secretary classified the results of the most recent inspection of the establishment as 'no action indicated' or 'voluntary action indicated'.

''(ii) With respect to inspections of the establishment to be conducted by an accredited person, the owner or operator of the establishment submits to the Secretary a notice that—

''(I) provides the date of the last inspection of the establishment by the Secretary and the classification of that inspection;

''(II) states the intention of the owner or operator to use an accredited person to conduct inspections of the establishment;

''(III) identifies the particular accredited person the owner or operator intends to select to conduct such inspections; and

''(IV) includes a certification that, with respect to the devices that are manufactured, prepared, propagated, compounded, or processed in the establishment—

''(aa) at least 1 of such devices is marketed in the United States; and

''(bb) at least 1 of such devices is marketed, or is intended to be marketed, in 1 or more foreign countries, 1 of which countries certifies, accredits, or otherwise recognizes the person accredited under paragraph (2) and identified under subclause (III) as a person authorized to conduct inspections of device establishments.

''(B)(i) Except with respect to the requirement of subparagraph (A)(i), a device establishment is deemed to have clearance to participate in the program and to use the accredited person identified in the notice under subparagraph (A)(ii) for inspections of the establishment un-

less the Secretary, not later than 30 days after receiving such notice, issues a response that—

''(I) denies clearance to participate as provided under subparagraph (C); or

''(II) makes a request under clause (ii).

''(ii) The Secretary may request from the owner or operator of a device establishment in response to the notice under subparagraph (A)(ii) with respect to the establishment, or from the particular accredited person identified in such notice—

''(I) compliance data for the establishment in accordance with clause (iii)(I); or

''(II) information concerning the relationship between the owner or operator of the establishment and the accredited person identified in such notice in accordance with clause (iii)(II).

The owner or operator of the establishment, or such accredited person, as the case may be, shall respond to such a request not later than 60 days after receiving such request.

''(iii)(I) The compliance data to be submitted by the owner or operation of a device establishment in response to a request under clause (ii)(I) are data describing whether the quality controls of the establishment have been sufficient for ensuring consistent compliance with current

good manufacturing practice within the meaning of section 501(h) and with other applicable provisions of this Act. Such data shall include complete reports of inspectional findings regarding good manufacturing practice or other quality control audits that, during the preceding 2-year period, were conducted at the establishment by persons other than the owner or operator of the establishment, together with all other compliance data the Secretary deems necessary. Data under the preceding sentence shall demonstrate to the Secretary whether the establishment has facilitated consistent compliance by promptly correcting any compliance problems identified in such inspections.

''(II) A request to an accredited person under clause (ii)(II) may not seek any information that is not required to be maintained by such person in records under subsection (f)(1).

''(iv) A device establishment is deemed to have clearance to participate in the program and to use the accredited person identified in the notice under subparagraph (A)(ii) for inspections of the establishment unless the Secretary, not later than 60 days after receiving the information requested under clause (ii), issues a response that denies clearance to participate as provided under subparagraph (C).

''(C)(i) The Secretary may deny clearance to a device establishment if the Secretary has evidence that the certification under subparagraph (A)(ii)(IV) is untrue and the Secretary provides to the owner or operator of the establishment a statement summarizing such evidence.

''(ii) The Secretary may deny clearance to a device establishment if the Secretary determines that the establishment has failed to demonstrate consistent compliance for purposes of subparagraph (B)(iii)(I) and the Secretary provides to the owner or operator of the establishment a statement of the reasons for such determination.

''(iii)(I) The Secretary may reject the selection of the accredited person identified in the notice under subparagraph (A)(ii) if the Secretary provides to the owner or operator of the establishment a statement of the reasons for such rejection. Reasons for the rejection may include that the establishment or the accredited person, as the case may be, has failed to fully respond to the request, or that the Secretary has concerns regarding the relationship between the establishment and such accredited person.

''(II) If the Secretary rejects the selection of an accredited person by the owner or operator of a device establishment, the owner or operator may make an additional selection of an accredited person by submitting to the Secretary a notice that identifies the additional selection.

Clauses (i) and (ii) of subparagraph (B), and subclause (I) of this clause, apply to the selection of an accredited person through a notice under the preceding sentence in the same manner and to the same extent as such provisions apply to a selection of an accredited person through a notice under subparagraph (A)(ii).

''(iv) In the case of a device establishment that is denied clearance under clause (i) or (ii) or with respect to which the selection of the accredited person is rejected under clause (iii), the Secretary shall designate a person to review the statement of reasons, or statement summarizing such evidence, as the case may be, of the Secretary under such clause if, during the 30-day period beginning on the date on which the owner or operator of the establishment receives such statement, the owner or operator requests the review. The review shall commence not later than 30 days after the owner or operator requests the review, unless the Secretary and the owner or operator otherwise agree.'';

(5) in paragraph (7)—

(A) by amending subparagraph (A) to read as follows:

''(A) Persons accredited under paragraph (2) to conduct inspections shall record in writing their inspection observations and shall

present the observations to the device establishment's designated representative and describe each observation. Additionally, such accredited person shall prepare an inspection report in a form and manner designated by the Secretary to conduct inspections, taking into consideration the goals of international harmonization of quality systems standards. Any official classification of the inspection shall be determined by the Secretary.''; and

(B) by adding at the end the following:

''(F) For the purpose of setting risk-based inspectional priorities, the Secretary shall accept voluntary submissions of reports of audits assessing conformance with appropriate quality systems standards set by the International Organization for Standardization (ISO) and identified by the Secretary in public notice. If the owner or operator of an establishment elects to submit audit reports under this subparagraph, the owner or operator shall submit all such audit reports with respect to the establishment during the preceding 2-year periods.''; and

(6) in paragraphs (10)(C)(iii), by striking ''based'' and inserting ''base''.

SEC. 312. EXTENSION OF AUTHORITY FOR THIRD PARTY REVIEW OF PREMARKET NOTIFICATION.

Section 523(c) (21 U.S.C. 360m(c)) is amended by striking ''2007'' and inserting ''2012''.

SEC. 313. REGISTRATION.

(a) ANNUAL REGISTRATION OF PRODUCERS OF DRUGS AND DEVICES.—Section 510(b) (21 U.S.C. 359(b)) is amended—

(1) by redesignating the existing text as paragraph (1), and indenting and relocating it appropriately;

(2) in paragraph (1), as so redesignated, by striking ''or a device or devices''; and

(3) by adding at the end the following new paragraph:

''(2) Between October 1 and December 31 of each year every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a device or devices shall register with the Secretary his name, places of business, and all such establishments.''.

(b) REGISTRATION OF FOREIGN ESTABLISHMENTS.—Section 510(i)(1) (21 U.S.C. 359(i)(1)) is amended—

(1) by redesignating the existing text as subparagraph (A), and indenting and relocating it appropriately;

(2) in subparagraph (A), as so redesignated—

(A) by striking ''processing of a drug or a device that is imported'' and inserting ''processing of a drug that is imported''; and

(B) by striking ''or device'' each place it appears; and

(3) by adding after such subparagraph (A) the following new subparagraph:

''(B) Between October 1 and December 31 of each year, any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States shall, through electronic means in accordance with the criteria of the Secretary, register with the Secretary the name and place of business of the establishment, the name of the United States agent for the establishment, the name of each importer of such device in the United States that is known to the establishment, and the name of each person who imports or offers for import such de-

vice to the United States for purposes of importation.''.

SEC. 314. FILING OF LISTS OF DRUGS AND DEVICES MANUFACTURED PREPARED, PROPAGATED AND COMPOUNDED BY REGISTRANTS; STATEMENTS; ACCOMPANYING DISCLOSURES.

Section 510(j)(2) (21 U.S.C. 360(j)(2) is amended, in the matter preceding subparagraph (A), to read as follows:

''(2) Each person who registers with the Secretary under this section shall report to the Secretary (i) with regard to drugs, once during the month of June of each year and once during the month of December of each year, and (ii) with regard to devices, once each year between October 1 and December 31, the following information:''.

SEC. 315. ELECTRONIC REGISTRATION AND LISTING.

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

''(p)(1) With regard to any establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a drug, registrations under subsections (b), (c), (d), and (i) of this section (including the submission of updated information) shall be submitted to the Secretary by electronic means, upon a finding by the Sec-

retary that the electronic receipt of such registrations is feasible, unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting such waiver.

''(2) With regard to any establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device, the registration and listing information required by this section shall be submitted to the Secretary by electronic means, unless the Secretary grants a waiver because electronic registration and listing is not reasonable for the person requesting such waiver.''.

TITLE IV—PEDIATRIC MEDICAL PRODUCTS

Subtitle A—Best Pharmaceuticals for Children

SEC. 401. SHORT TITLE.

This subtitle may be cited as the ''Best Pharmaceuticals for Children Amendments of 2007''.

SEC. 402. PEDIATRIC STUDIES OF DRUGS.

(a) IN GENERAL.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(1) in subsection (a), by inserting before the period at the end the following: '', and, at the discre-

tion of the Secretary, may include preclinical studies'';

(2) in subsection (b)—

(A) in paragraph (1)(A)(i), by striking ''(D)'' both places it appears and inserting ''(E)'';

(B) in paragraph (1)(A)(ii), by striking ''(D)'' and inserting ''(E)'';

(C) by striking ''(1)(A)(i)'' and inserting ''(A)(i)(I)'';

(D) by striking ''(ii) the'' and inserting ''(II) the'';

(E) by striking ''(B) if the drug is designated'' and inserting ''(ii) if the drug is designated'';

(F) by striking ''(2)(A)'' and inserting ''(B)(i)'';

(G) by striking ''(i) a listed patent'' and inserting ''(I) a listed patent'';

(H) by striking ''(ii) a listed patent'' and inserting ''(II) a listed patent'';

(I) by striking ''(B) if the drug is the subject'' and inserting ''(ii) if the drug is the subject'';

(J) by striking ''If'' and all that follows through ''subsection (d)(3)'' and inserting the following:

''(1) IN GENERAL.—Except as provided in paragraph (2), if, prior to approval of an application that is submitted under section 505(b)(1), the Secretary determines that information relating to the use of a 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 a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with subsection (d)(3), and if the Secretary determines that labeling changes are appropriate, such changes are made within the timeframe requested by the Secretary—''; and

(K) by adding at the end the following:

''(2) EXCEPTION.—The Secretary shall not extend a period referred to in paragraph (1)(A) or in paragraph (1)(B) if the determination made under

subsection (d)(3) is made less than 9 months prior to the expiration of such period.'';

(3) in subsection (c)—

(A) in paragraph (1)(A)(i), by striking ''(D)'' both places it appears and inserting ''(E)'';

(B) in paragraph (1)(A)(ii), by striking ''(D)'' and inserting ''(E)'';

(C) by striking ''(1)(A)(i)'' and inserting ''(A)(i)(I)'';

(D) by striking ''(ii) the'' and inserting ''(II) the'';

(E) by striking ''(B) if the drug is designated'' and inserting ''(ii) if the drug is designated'';

(F) by striking ''(2)(A)'' and inserting ''(B)(i)'';

(G) by striking ''(i) a listed patent'' and inserting ''(I) a listed patent'';

(H) by striking ''(ii) a listed patent'' and inserting ''(II) a listed patent'';

(I) by striking ''(B) if the drug is the subject'' and inserting ''(ii) if the drug is the subject'';

(J) by striking ''If'' and all that follows through ''subsection (d)(3)'' and inserting the following:

''(1) IN GENERAL.—Except as provided in paragraph (2), if the Secretary determines that information relating to the use of an approved drug in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under section 505(b)(1) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with subsection (d)(3), and if the Secretary determines that labeling changes are appropriate, such changes are made within the timeframe requested by the Secretary—''; and

(K) by adding at the end the following:

''(2) EXCEPTION.—The Secretary shall not extend a period referred to in paragraph (1)(A) or in paragraph (1)(B) if the determination made under

subsection (d)(3) is made less than 9 months prior to the expiration of such period.'';

(4) by striking subsection (d) and inserting the following:

''(d) CONDUCT OF PEDIATRIC STUDIES.—

''(1) REQUEST FOR STUDIES.—

''(A) IN GENERAL.—The Secretary may, after consultation with the sponsor of an application for an investigational new drug under section 505(i), the sponsor of an application for a new drug under section 505(b)(1), or the holder of an approved application for a drug under section 505(b)(1), issue to the sponsor or holder a written request for the conduct of pediatric studies for such drug. In issuing such request, the Secretary shall take into account adequate representation of children of ethnic and racial minorities. Such request to conduct pediatric studies shall be in writing and shall include a timeframe for such studies and a request to the sponsor or holder to propose pediatric labeling resulting from such studies.

''(B) SINGLE WRITTEN REQUEST.—A single written request—

"(i) may relate to more than 1 use of a drug; and

"(ii) may include uses that are both approved and unapproved.

"(2) WRITTEN REQUEST FOR PEDIATRIC STUDIES.—

"(A) REQUEST AND RESPONSE.—

"(i) IN GENERAL.—If the Secretary makes a written request for pediatric studies (including neonates, as appropriate) under subsection (b) or (c), the applicant or holder, not later than 180 days after receiving the written request, shall respond to the Secretary as to the intention of the applicant or holder to act on the request by—

"(I) indicating when the pediatric studies will be initiated, if the applicant or holder agrees to the request; or

"(II) indicating that the applicant or holder does not agree to the request and the reasons for declining the request.

"(ii) DISAGREE WITH REQUEST.—If, on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the applicant or holder does not agree to the request on the grounds that it is not possible to develop the appropriate pediatric formulation, the applicant or holder shall submit to the Secretary the reasons such pediatric formulation cannot be developed.

"(B) ADVERSE EVENT REPORTS.—An applicant or holder that, on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, agrees to the request for such studies shall provide the Secretary, at the same time as submission of the reports of such studies, with all postmarket adverse event reports regarding the drug that is the subject of such studies and are available prior to submission of such reports.

"(3) MEETING THE STUDIES REQUIREMENT.—Not later than 180 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accept-

ing or rejecting the reports shall be to determine, within the 180 days, whether the studies fairly respond to the written request, have been conducted in accordance with commonly accepted scientific principles and protocols, and have been reported in accordance with the requirements of the Secretary for filing.

''(4) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.'';

(5) by striking subsections (e) and (f) and inserting the following:

''(e) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—

''(1) IN GENERAL.—The Secretary shall publish a notice of any determination, made on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, that the requirements of subsection (d) have been met and that submissions and approvals under subsection (b)(2) or (j) of section 505 for a drug will be subject to the provisions of this section. Such notice shall be published not later than 30 days after the date of the Secretary's determination regarding market exclu-

sivity and shall include a copy of the written request made under subsection (b) or (c).

''(2) IDENTIFICATION OF CERTAIN DRUGS.—The Secretary shall publish a notice identifying any drug for which, on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, a pediatric formulation was developed, studied, and found to be safe and effective in the pediatric population (or specified subpopulation) if the pediatric formulation for such drug is not introduced onto the market within 1 year of the date that the Secretary publishes the notice described in paragraph (1). Such notice identifying such drug shall be published not later than 30 days after the date of the expiration of such 1 year period.

''(f) INTERNAL REVIEW OF WRITTEN REQUESTS AND PEDIATRIC STUDIES.—

''(1) INTERNAL REVIEW.—

''(A) IN GENERAL.—The Secretary shall create an internal review committee to review all written requests issued and all reports submitted on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, in accordance with paragraphs (2) and (3).

''(B) MEMBERS.—The committee under subparagraph (A) shall include individuals, each of whom is an employee of the Food and Drug Administration, with the following expertise:

''(i) Pediatrics.

''(ii) Biopharmacology.

''(iii) Statistics.

''(iv) Drugs and drug formulations.

''(v) Legal issues.

''(vi) Appropriate expertise, such as expertise in child and adolescent psychiatry, pertaining to the pediatric product under review.

''(vii) One or more experts from the Office of Pediatric Therapeutics, which may include an expert in pediatric ethics.

''(viii) Other individuals as designated by the Secretary.

''(C) ACTION BY COMMITTEE.—The committee established under this paragraph may perform a function under this section using appropriate members of the committee under subparagraph (B) and need not convene all members of the committee under subparagraph (B)

in order to perform a function under this section.

''(D) DOCUMENTATION OF COMMITTEE ACTION.—The committee established under this paragraph shall document for each function under paragraphs (2) and (3), which members of the committee participated in such function.

''(2) REVIEW OF WRITTEN REQUESTS.—All written requests under this section shall be reviewed and approved by the committee established under paragraph (1) prior to being issued.

''(3) REVIEW OF PEDIATRIC STUDIES.—The committee established under paragraph (1) shall review all studies conducted pursuant to this section to make a recommendation to the Secretary whether to accept or reject such reports under subsection (d)(3).

''(4) TRACKING PEDIATRIC STUDIES AND LABELING CHANGES.—The committee established under paragraph (1) shall be responsible for tracking and making available to the public, in an easily accessible manner, including through posting on the website of the Food and Drug Administration—

''(A) the number of studies conducted under this section;

''(B) the specific drugs and drug uses, including labeled and off-labeled indications, studied under this section;

''(C) the types of studies conducted under this section, including trial design, the number of pediatric patients studied, and the number of centers and countries involved;

''(D) the number of pediatric formulations developed and the number of pediatric formulations not developed and the reasons such formulations were not developed;

''(E) the labeling changes made as a result of studies conducted under this section;

''(F) an annual summary of labeling changes made as a result of studies conducted under this section for distribution pursuant to subsection (k)(2);

''(G) information regarding reports submitted on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007; and

''(H) the number of times the committee established under paragraph (1) made a recommendation to the Secretary under paragraph (3), the number of times the Secretary did not

follow such a recommendation to accept reports under subsection (d)(3), and the number of times the Secretary did not follow such a recommendation to reject such reports under section (d)(3).

''(5) COMMITTEE.—The committee established under paragraph (1) is the committee established under section 505B(f)(1).'';

(6) in subsection (g)—

(A) in paragraph (1)—

(i) by striking ''(c)(1)(A)(ii)'' and inserting ''(c)(1)(A)(i)(II)''; and

(ii) by striking ''(c)(2)'' and inserting ''(c)(1)(B)'';

(B) in paragraph (2), by striking ''(c)(1)(B)'' and inserting ''(c)(1)(A)(ii)'';

(C) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively;

(D) by striking ''LIMITATIONS.—A drug'' and inserting ''LIMITATIONS.—

''(1) IN GENERAL.—Notwithstanding subsection (c)(2), a drug''; and

(E) by adding at the end the following:

''(2) EXCLUSIVITY ADJUSTMENT.—

''(A) ADJUSTMENT.—

''(i) IN GENERAL.—With respect to any drug, if the organization designated under subparagraph (B) notifies the Secretary that the combined annual gross sales for all drugs with the same active moiety exceeded $1,000,000,000 in any calendar year prior to the time the sponsor or holder agrees to the initial written request pursuant to subsection (d)(2), then each period of market exclusivity deemed or extended under subsection (b) or (c) shall be reduced by 3 months for such drug.

''(ii) DETERMINATION.—The determination under clause (i) of the combined annual gross sales shall be determined—

''(I) taking into account only those sales within the United States; and

''(II) taking into account only the sales of all drugs with the same active moiety of the sponsor or holder and its affiliates.

''(B) DESIGNATION.—The Secretary shall designate an organization other than the Food

and Drug Administration to evaluate whether the combined annual gross sales for all drugs with the same active moiety exceeded $1,000,000,000 in a calendar year as described in subparagraph (A). Prior to designating such organization, the Secretary shall determine that such organization is independent and is qualified to evaluate the sales of pharmaceutical products. The Secretary shall re-evaluate the designation of such organization once every 3 years.

''(C) NOTIFICATION.—Once a year at a time designated by the Secretary, the organization designated under subparagraph (B) shall notify the Food and Drug Administration of all drugs with the same active moiety with combined annual gross sales that exceed $1,000,000,000 during the previous calendar year.'';

(7) in subsection (i)—

(A) in the heading, by striking ''SUPPLEMENTS'' and inserting ''CHANGES'';

(B) in paragraph (1)—

(i) in the heading, by inserting ''APPLICATIONS AND'' after ''PEDIATRIC'';

(ii) by inserting ''application or'' after ''Any'';

(iii) by striking ''change pursuant to a report on a pediatric study under'' and inserting ''change as a result of any pediatric study conducted pursuant to''; and

(iv) by inserting ''application or'' after ''to be a priority''; and

(C) in paragraph (2)(A), by—

(i) striking ''If the Commissioner'' and inserting ''If, on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the Commissioner''; and

(ii) striking ''an application with'' and all that follows through ''on appropriate'' and inserting ''the sponsor and the Commissioner have been unable to reach agreement on appropriate'';

(8) by striking subsection (m);

(9) by redesignating subsections (j), (k), (l), and (n), as subsections (k), (m), (o), and (p), respectively;

(10) by inserting after subsection (i) the following:

''(j) OTHER LABELING CHANGES.—If, on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the Secretary determines that a pediatric study conducted under this section does or does not demonstrate that the drug that is the subject of the study is safe and effective, including whether such study results are inconclusive, in pediatric populations or subpopulations, the Secretary shall order the labeling of such product to include information about the results of the study and a statement of the Secretary's determination.'';

(11) in subsection (k), as redesignated by paragraph (9)—

(A) in paragraph (1)—

(i) by striking ''a summary of the medical and'' and inserting ''the medical, statistical, and''; and

(ii) by striking ''for the supplement'' and all that follows through the period and inserting ''under subsection (b) or (c).'';

(B) by redesignating paragraph (2) as paragraph (3); and

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

''(2) DISSEMINATION OF INFORMATION REGARDING LABELING CHANGES.—Beginning on the

date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the Secretary shall require that the sponsors of the studies that result in labeling changes that are reflected in the annual summary developed pursuant to subsection (f)(4)(F) distribute, at least annually (or more frequently if the Secretary determines that it would be beneficial to the public health), such information to physicians and other health care providers.'';

(12) by inserting after subsection (k), as redesignated by paragraph (9), the following:

''(l) ADVERSE EVENT REPORTING.—

''(1) REPORTING IN YEAR ONE.—Beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, during the 1-year period beginning on the date a labeling change is made pursuant to subsection (i), the Secretary shall ensure that all adverse event reports that have been received for such drug (regardless of when such report was received) are referred to the Office of Pediatric Therapeutics established under section 6 of the Best Pharmaceuticals for Children Act (Public Law 107–109). In considering such reports, the Director of such Office shall provide for the review of the report by the Pediatric Advisory Committee, including

obtaining any recommendations of such Committee regarding whether the Secretary should take action under this section in response to such reports.

''(2) REPORTING IN SUBSEQUENT YEARS.—Following the 1-year period described in paragraph (1), the Secretary shall, as appropriate, refer to the Office of Pediatric Therapeutics all pediatric adverse event reports for a drug for which a pediatric study was conducted under this section. In considering such reports, the Director of such Office may provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendation of such Committee regarding whether the Secretary should take action in response to such reports.

''(3) EFFECT.—The requirements of this subsection shall supplement, not supplant, other review of such adverse event reports by the Secretary.'';

(13) by inserting after subsection (m), as redesignated by paragraph (9), the following:

''(n) REFERRAL IF PEDIATRIC STUDIES NOT COMPLETED.—

''(1) IN GENERAL.—Beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, if pediatric studies of a drug

have not been completed under subsection (d) and if the Secretary, through the committee established under subsection (f), determines that there is a continuing need for information relating to the use of the drug in the pediatric population (including neonates, as appropriate), the Secretary shall carry out the following:

''(A) For a drug for which a listed patent has not expired, make a determination regarding whether an assessment shall be required to be submitted under section 505B. Prior to making such determination, the Secretary may take not more than 60 days to certify whether the Foundation for the National Institutes of Health has sufficient funding at the time of such certification to initiate 1 or more of the pediatric studies of such drug referred to in the sentence preceding this paragraph and fund 1 or more of such studies in their entirety. Only if the Secretary makes such certification in the affirmative, the Secretary shall refer such pediatric study or studies to the Foundation for the National Institutes of Health for the conduct of such study or studies.

''(B) For a drug that has no listed patents or has 1 or more listed patents that have expired, the Secretary shall refer the drug for inclusion on the list established under section 409I of the Public Health Service Act for the conduct of studies.

''(2) PUBLIC NOTICE.—The Secretary shall give the public notice of—

''(A) a decision under paragraph (1)(A) not to require an assessment under section 505B and the basis for such decision; and

''(B) any referral under paragraph (1)(B) of a drug for inclusion on the list established under section 409I of the Public Health Service Act.

''(3) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.''; and

(14) in subsection (p), as redesignated by paragraph (9)—

(A) striking ''6-month period'' and inserting ''3-month or 6-month period'';

(B) by striking ''subsection (a)'' and inserting ''subsection (b)''; and

(C) by striking ''2007'' both places it appears and inserting ''2012''.

(b) EFFECTIVE DATE.—Except as otherwise provided in the amendments made by subsection (a), such amendments shall apply to written requests under section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) made after the date of enactment of this subtitle.

SEC. 403. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.

Section 409I of the Public Health Service Act (42 U.S.C. 284m) is amended—

(1) by striking subsections (a) and (b) and inserting the following:

''(a) LIST OF PRIORITY ISSUES IN PEDIATRIC THERAPEUTICS.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs and experts in pediatric research, shall develop and publish a priority list of needs in pediatric therapeutics, including drugs or indications that require study. The list shall be revised every 3 years.

''(2) CONSIDERATION OF AVAILABLE INFORMATION.—In developing and prioritizing the list under paragraph (1), the Secretary shall consider—

''(A) therapeutic gaps in pediatrics that may include developmental pharmacology, pharmacogenetic determinants of drug response, metabolism of drugs and biologics in children, and pediatric clinical trials;

''(B) particular pediatric diseases, disorders or conditions where more complete knowledge and testing of therapeutics, including drugs and biologics, may be beneficial in pediatric populations; and

''(C) the adequacy of necessary infrastructure to conduct pediatric pharmacological research, including research networks and trained pediatric investigators.

''(b) PEDIATRIC STUDIES AND RESEARCH.—The Secretary, acting through the National Institutes of Health, shall award funds to entities that have the expertise to conduct pediatric clinical trials or other research (including qualified universities, hospitals, laboratories, contract research organizations, practice groups, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals)

to enable the entities to conduct the drug studies or other research on the issues described in subsection (a). The Secretary may use contracts, grants, or other appropriate funding mechanisms to award funds under this subsection.'';

(2) in subsection (c)—

(A) in the heading, by striking ''CONTRACTS'' and inserting ''PROPOSED PEDIATRIC STUDY REQUESTS'';

(B) by striking paragraphs (4) and (12);

(C) by redesignating paragraphs (1), (2), and (3), as paragraphs (2), (3), and (4);

(D) by inserting before paragraph (2), as redesignated by subparagraph (C), the following:

''(1) SUBMISSION OF PROPOSED PEDIATRIC STUDY REQUEST.—The Director of the National Institutes of Health shall, as appropriate, submit proposed pediatric study requests for consideration by the Commissioner of Food and Drugs for pediatric studies of a specific pediatric indication identified under subsection (a). Such a proposed pediatric study request shall be made in a manner equivalent to a written request made under subsection (b) or (c) of section 505A of the Federal Food, Drug, and

Cosmetic Act, including with respect to the information provided on the pediatric studies to be conducted pursuant to the request. The Director of the National Institutes of Health may submit a proposed pediatric study request for a drug for which—

''(A)(i) there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act; or

''(ii) there is a submitted application that could be approved under the criteria of section 505(j) of the Federal Food, Drug, and Cosmetic Act;

''(B) there is no patent protection or market exclusivity protection for at least 1 form of the drug under the Federal Food, Drug, and Cosmetic Act; and

''(C) additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.'';

(E) in paragraph (2), as redesignated by subparagraph (C)—

(i) by inserting ''based on the proposed pediatric study request for the indication or indications submitted pursuant to

paragraph (1)'' after ''issue a written request'';

(ii) by striking ''in the list described in subsection (a)(1)(A) (except clause (iv))'' and inserting ''under subsection (a)''; and

(iii) by inserting ''and using appropriate formulations for each age group for which the study is requested'' before the period at the end;

(F) in paragraph (3), as redesignated by subparagraph (C)—

(i) in the heading, by striking ''CONTRACT'';

(ii) by striking ''paragraph (1)'' and inserting ''paragraph (2)'';

(iii) by striking ''or if a referral described in subsection (a)(1)(A)(iv) is made,'';

(iv) by striking ''for contract proposals'' and inserting ''for proposals''; and

(v) by inserting ''in accordance with subsection (b)'' before the period at the end;

(G) in paragraph (4), as redesignated by subparagraph (C)—

(i) by striking ''contract''; and

(ii) by striking ''paragraph (2)'' and inserting ''paragraph (3)'';

(H) in paragraph (5)—

(i) by striking the heading and inserting ''CONTRACTS, GRANTS, OR OTHER FUNDING MECHANISMS''; and

(ii) by striking ''A contract'' and all that follows through ''is submitted'' and inserting ''A contract, grant, or other funding may be awarded under this section only if a proposal is submitted'';

(I) in paragraph (6)(A)—

(i) by striking ''a contract awarded'' and inserting ''an award''; and

(ii) by inserting '', including a written request if issued'' after ''with the study''; and

(3) by inserting after subsection (c) the following:

''(d) DISSEMINATION OF PEDIATRIC INFORMATION.—Not later than 1 year after the date of enactment of the Best Pharmaceuticals for Children Amendments of

2007, the Secretary, acting through the Director of the National Institutes of Health, shall study the feasibility of establishing a compilation of information on pediatric drug use and report the findings to Congress.''

''(e) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—There are authorized to be appropriated to carry out this section—

''(A) $200,000,000 for fiscal year 2008; and

''(B) such sums as are necessary for each of the 4 succeeding fiscal years.

''(2) AVAILABILITY.—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.''.

SEC. 404. REPORTS AND STUDIES.

(a) GAO REPORT.—Not later than January 31, 2011, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, shall submit to Congress a report that addresses the effectiveness of section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) in ensuring that medicines used by children are tested and properly labeled, including—

(1) the number and importance of drugs for children that are being tested as a result of the

amendments made by this subtitle and the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;

(2) the number and importance of drugs for children that are not being tested for their use notwithstanding the provisions of this subtitle and the amendments made by this subtitle, and possible reasons for the lack of testing, including whether the number of written requests declined by sponsors or holders of drugs subject to section 505A(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(g)(2)), has increased or decreased as a result of the amendments made by this subtitle;

(3) the number of drugs for which testing is being done and labeling changes required, including the date labeling changes are made and which labeling changes required the use of the dispute resolution process established pursuant to the amendments made by this subtitle, together with a description of the outcomes of such process, including a description of the disputes and the recommendations of the Pediatric Advisory Committee;

(4) any recommendations for modifications to the programs established under section 505A of the

Federal Food, Drug and Cosmetic Act (21 U.S.C. 355a) and section 409I of the Public Health Service Act (42 U.S.C. 284m) that the Secretary determines to be appropriate, including a detailed rationale for each recommendation; and

(5)(A) the efforts made by the Secretary to increase the number of studies conducted in the neonate population; and

(B) the results of those efforts, including efforts made to encourage the conduct of appropriate studies in neonates by companies with products that have sufficient safety and other information to make the conduct of the studies ethical and safe.

(b) IOM STUDY.—Not later than 3 years after the date of enactment of this subtitle, the Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine to conduct a study and report to Congress regarding the written requests made and the studies conducted pursuant to section 505A of the Federal Food, Drug, and Cosmetic Act. The Institute of Medicine may devise an appropriate mechanism to review a representative sample of requests made and studies conducted pursuant to such section in order to conduct such study. Such study shall—

(1) review such representative written requests issued by the Secretary since 1997 under subsections (b) and (c) of such section 505A;

(2) review and assess such representative pediatric studies conducted under such subsections (b) and (c) since 1997 and labeling changes made as a result of such studies; and

(3) review the use of extrapolation for pediatric subpopulations, the use of alternative endpoints for pediatric populations, neonatal assessment tools, and ethical issues in pediatric clinical trials.

SEC. 405. TRAINING OF PEDIATRIC PHARMACOLOGISTS.

(a) INVESTMENT IN TOMORROW'S PEDIATRIC RESEARCHERS.—Section 452G(2) of the Public Health Service Act (42 U.S.C. 285g–10(2)) is amended by adding before the period at the end the following: ", including pediatric pharmacological research".

(b) PEDIATRIC RESEARCH LOAN REPAYMENT PROGRAM.—Section 487F(a)(1) of the Public Health Service Act (42 U.S.C. 288–6(a)(1)) is amended by inserting "including pediatric pharmacological research," after "pediatric research,".

SEC. 406. FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH.

Section 499(c)(1)(C) of the Public Health Service Act (42 U.S.C. 290b(c)(1)(C)) is amended by striking ''and studies listed by the Secretary pursuant to section 409I(a)(1)(A) of the is Act and referred under section 505A(d)(4)(C) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(a)(d)(4)(C)'' and inserting ''and studies for which the Secretary issues a certification under section 505A(n)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(n)(1)(A))''.

SEC. 407. CONTINUATION OF OPERATION OF COMMITTEE.

Section 14 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended by adding at the end the following:

''(d) CONTINUATION OF OPERATION OF COMMITTEE.—Notwithstanding section 14 of the Federal Advisory Committee Act (5 U.S.C. App.), the advisory committee shall continue to operate during the 5-year period beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007.''.

SEC. 408. PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC DRUGS ADVISORY COMMITTEE.

Section 15 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph (B), by striking ''and'' after the semicolon;

(ii) in subparagraph (C), by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end the following:

''(D) provide recommendations to the internal review committee created under section 505A(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(f)) regarding the implementation of amendments to sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a and 355c) with respect to the treatment of pediatric cancers.''; and

(B) by adding at the end the following:

''(3) CONTINUATION OF OPERATION OF SUBCOMMITTEE.—Notwithstanding section 14 of the Federal Advisory Committee Act (5 U.S.C. App.), the Subcommittee shall continue to operate during the 5-year period beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007.''; and

(2) in subsection (d), by striking ''2003'' and inserting ''2009''.

SEC. 409. EFFECTIVE DATE AND LIMITATION FOR RULE RELATING TO TOLL-FREE NUMBER FOR ADVERSE EVENTS ON LABELING FOR HUMAN DRUG PRODUCTS.

(a) IN GENERAL.—Notwithstanding subchapter II of chapter 5, and chapter 7, of title 5, United States Code (commonly known as the ''Administrative Procedure Act'') and any other provision of law, the proposed rule issued by the Commissioner of Food and Drugs entitled ''Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products'', 69 Fed. Reg. 21778, (April 22, 2004) shall take effect on January 1, 2008, unless such Commissioner issues the final rule before such date.

(b) LIMITATION.—The proposed rule that takes effect under subsection (a), or the final rule described under subsection (a), shall, notwithstanding section 17(a) of the Best Pharmaceuticals for Children Act (21 U.S.C. 355b(a)), not apply to a drug—

(1) for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355);

(2) that is not described under section 503(b)(1) of such Act (21 U.S.C. 353(b)(1)); and

(3) the packaging of which includes a toll-free number through which consumers can report complaints to the manufacturer or distributor of the drug.

Subtitle B—Pediatric Research Improvement

SEC. 411. SHORT TITLE.

This subtitle may be cited as the ''Pediatric Research Improvement Act''.

SEC. 412. PEDIATRIC FORMULATIONS, EXTRAPOLATIONS, AND DEFERRALS.

Section 505B(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)) is amended—

(1) in paragraph (4)(C), by adding at the end the following: ''An applicant seeking either a partial or full waiver on this ground shall submit to the Secretary documentation detailing why a pediatric formulation cannot be developed, and, if the waiver is granted, the applicant's submission shall promptly be made available to the public in an easily accessible manner, including through posting on the website of the Food and Drug Administration'';

(2) in paragraph (2)(B), by adding at the end the following:

''(iii) INFORMATION ON EXTRAPOLATION.—A brief documentation of the scientific data supporting the conclusion under clauses (i) and (ii) shall be included in any pertinent reviews for the application under section 505 or section 351 of the Public Health Service Act.''; and

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

''(3) DEFERRAL.—

''(A) IN GENERAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may defer submission of some or all assessments required under paragraph (1) until a specified date after approval of the drug or issuance of the license for a biological product if—

''(i) the Secretary finds that—

''(I) the drug or biological product is ready for approval for use in adults before pediatric studies are complete;

''(II) pediatric studies should be delayed until additional safety or ef-

fectiveness data have been collected; or

''(III) there is another appropriate reason for deferral; and

''(ii) the applicant submits to the Secretary—

''(I) certification of the grounds for deferring the assessments;

''(II) a description of the planned or ongoing studies;

''(III) evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time; and

''(IV) a timeline for the completion of such studies.

''(B) ANNUAL REVIEW.—

''(i) IN GENERAL.—On an annual basis following the approval of a deferral under subparagraph (A), the applicant shall submit to the Secretary the following information:

''(I) Information detailing the progress made in conducting pediatric studies.

''(II) If no progress has been made in conducting such studies, evidence and documentation that such studies will be conducted with due diligence and at the earliest possible time.

''(ii) PUBLIC AVAILABILITY.—The information submitted through the annual review under clause (i) shall promptly be made available to the public in an easily accessible manner, including through the website of the Food and Drug Administration.''.

SEC. 413. IMPROVING AVAILABILITY OF PEDIATRIC DATA FOR ALREADY MARKETED PRODUCTS.

Section 505B(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(b)) is amended—

(1) by striking paragraph (1) and inserting the following:

''(1) IN GENERAL.—After providing notice in the form of a written request under section 505A that was declined by the sponsor or holder, or a letter referencing such declined written request, and an opportunity for written response and a meeting, which may include an advisory committee meeting,

the Secretary may (by order in the form of a letter) require the sponsor or holder of an approved application for a drug under section 505 or the holder of a license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262) to submit by a specified date the assessments described in subsection (a)(2) and the written request, as appropriate, for the labeled indication or indications, if the Secretary finds that—

''(A)(i) the drug or biological product is used for a substantial number of pediatric patients for the labeled indications; and

''(ii) adequate pediatric labeling could confer a benefit on pediatric patients;

''(B) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients for 1 or more of the claimed indications; or

''(C) the absence of adequate pediatric labeling could pose a risk to pediatric patients.'';

(2) in paragraph (2)(C), by adding at the end the following: ''An applicant seeking either a partial or full waiver shall submit to the Secretary documentation detailing why a pediatric formulation can-

not be developed, and, if the waiver is granted, the applicant's submission shall promptly be made available to the public in an easily accessible manner, including through posting on the website of the Food and Drug Administration.''; and

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

''(3) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.''.

SEC. 414. SUNSET; REVIEW OF PEDIATRIC ASSESSMENTS; ADVERSE EVENT REPORTING; LABELING CHANGES; AND PEDIATRIC ASSESSMENTS.

Section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended—

(1) redesignating subsection (h) as subsection (j);

(2) in subsection (j), as so redesignated, by striking ''505A(n)'' and inserting ''505A(p)'';

(3) by redesignating subsection (f) as subsection (k);

(4) by redesignating subsection (g) as subsection (l); and

(5) by inserting after subsection (e) the following:

''(f) REVIEW OF PEDIATRIC ASSESSMENT REQUESTS, PEDIATRIC ASSESSMENTS, DEFERRALS, AND WAIVERS.—

''(1) REVIEW.—The Secretary shall create an internal committee to review all pediatric assessment requests issued under this section, all pediatric assessments conducted under this section, and all deferral and waiver requests made pursuant to this section. Such internal committee shall include individuals, each of whom is an employee of the Food and Drug Administration, with the following expertise:

''(A) Pediatrics.

''(B) Biopharmacology.

''(C) Statistics.

''(D) Drugs and drug formulations.

''(E) Pediatric ethics.

''(F) Legal issues.

''(G) Appropriate expertise, such as expertise in child and adolescent psychiatry, pertaining to the pediatric product under review.

''(H) 1 or more experts from the Office of Pediatric Therapeutics.

''(I) Other individuals as designated by the Secretary.

''(2) ACTION BY THE COMMITTEE.—The committee established under paragraph (1) may perform a function under this section using appropriate members of the committee under paragraph (1) and need not convene all members of the committee under paragraph (1) in order to perform a function under this section.

''(3) DOCUMENTATION OF COMMITTEE ACTION.—For each drug or biological product, the committee established under this paragraph shall document for each function under paragraph (4) or (5), which members of the committee participated in such function.

''(4) REVIEW OF REQUESTS FOR PEDIATRIC ASSESSMENTS, DEFERRALS, AND WAIVERS.—All written requests for a pediatric assessment issued pursuant to this section and all requests for deferrals and waivers from the requirement to conduct a pediatric assessment under this section shall be reviewed and approved by the committee established under paragraph (1).

''(5) REVIEW OF ASSESSMENTS.—The committee established under paragraph (1) shall review

all assessments conducted under this section to determine whether such assessments meet the requirements of this section.

''(6) TRACKING OF ASSESSMENTS AND LABELING CHANGES.—The committee established under paragraph (1) is responsible for tracking and making public in an easily accessible manner, including through posting on the website of the Food and Drug Administration—

''(A) the number of assessments conducted under this section;

''(B) the specific drugs and drug uses assessed under this section;

''(C) the types of assessments conducted under this section, including trial design, the number of pediatric patients studied, and the number of centers and countries involved;

''(D) the total number of deferrals requested and granted under this section, and, if granted, the reasons for such deferrals, the timeline for completion, and the number completed and pending by the specified date, as outlined in subsection (a)(3);

''(E) the number of waivers requested and granted under this section, and, if granted, the reasons for the waivers;

''(F) the number of pediatric formulations developed and the number of pediatric formulations not developed and the reasons any such formulations were not developed;

''(G) the labeling changes made as a result of assessments conducted under this section;

''(H) an annual summary of labeling changes made as a result of assessments conducted under this section for distribution pursuant to subsection (i)(2); and

''(I) an annual summary of the information submitted pursuant to subsection (a)(3)(B).

''(7) COMMITTEE.—The committee established under paragraph (1) is the committee established under section 505A(f)(1).

''(g) LABELING CHANGES.—

''(1) PRIORITY STATUS FOR PEDIATRIC SUPPLEMENT.—Any supplement to an application under section 505 and section 351 of the Public Health Service Act proposing a labeling change as a result

of any pediatric assessments conducted pursuant to this section—

''(A) shall be considered a priority supplement; and

''(B) shall be subject to the performance goals established by the Commissioner for priority drugs.

''(2) DISPUTE RESOLUTION.—

''(A) REQUEST FOR LABELING CHANGE AND FAILURE TO AGREE.—If the Commissioner determines that a sponsor and the Commissioner have been unable to reach agreement on appropriate changes to the labeling for the drug that is the subject of the application or supplement, not later than 180 days after the date of the submission of the application or supplement—

''(i) the Commissioner shall request that the sponsor make any labeling change that the Commissioner determines to be appropriate; and

''(ii) if the sponsor does not agree to make a labeling change requested by the Commissioner, the Commissioner shall

refer the matter to the Pediatric Advisory Committee.

''(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under subparagraph (A)(ii), the Pediatric Advisory Committee shall—

''(i) review the pediatric study reports; and

''(ii) make a recommendation to the Commissioner concerning appropriate labeling changes, if any.

''(C) CONSIDERATION OF RECOMMENDATIONS.—The Commissioner shall consider the recommendations of the Pediatric Advisory Committee and, if appropriate, not later than 30 days after receiving the recommendation, make a request to the sponsor of the application or supplement to make any labeling changes that the Commissioner determines to be appropriate.

''(D) MISBRANDING.—If the sponsor, within 30 days after receiving a request under subparagraph (C), does not agree to make a labeling change requested by the Commissioner, the Commissioner may deem the drug that is the

subject of the application or supplement to be misbranded.

''(E) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under this Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.

''(3) OTHER LABELING CHANGES.—If the Secretary makes a determination that a pediatric assessment conducted under this section does or does not demonstrate that the drug that is the subject of such assessment is safe and effective, including whether such assessment results are inconclusive, in pediatric populations or subpopulations, the Secretary shall order the labeling of such product to include information about the results of the assessment and a statement of the Secretary's determination.

''(h) DISSEMINATION OF PEDIATRIC INFORMATION.—

''(1) IN GENERAL.—Not later than 180 days after the date of submission of a pediatric assessment under this section, the Secretary shall make available to the public in an easily accessible manner the medical, statistical, and clinical pharmacology reviews of such pediatric assessments and shall post such assessments on the website of the Food and Drug Administration.

''(2) DISSEMINATION OF INFORMATION REGARDING LABELING CHANGES.—The Secretary shall require that the sponsors of the assessments that result in labeling changes that are reflected in the annual summary developed pursuant to subsection (f)(4)(H) distribute such information to physicians and other health care providers.

''(3) EFFECT OF SUBSECTION.—Nothing in this subsection shall alter or amend section 301(j) of this Act or section 552 of title 5, United States Code, or section 1905 of title 18, United States Code.

''(i) ADVERSE EVENT REPORTING.—

''(1) REPORTING IN YEAR 1.—During the 1-year period beginning on the date a labeling change is made pursuant to subsection (g), the Secretary shall ensure that all adverse event reports that have been received for such drug (regardless of when such

report was received) are referred to the Office of Pediatric Therapeutics. In considering such reports, the Director of such Office shall provide for the review of the report by the Pediatric Advisory Committee, including obtaining any recommendations of such committee regarding whether the Secretary should take action under this Act in response to such report.

''(2) REPORTING IN SUBSEQUENT YEARS.—Following the 1-year period described in paragraph (1), the Secretary shall, as appropriate, refer to the Office of Pediatric Therapeutics with all pediatric adverse event reports for a drug for which a pediatric study was conducted under this section. In considering such reports, the Director of such Office may provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendation of such Committee regarding whether the Secretary should take action in response to such report.

''(3) EFFECT.—The requirements of this subsection shall supplement, not supplant, other review of such adverse event reports by the Secretary.''.

SEC. 415. MEANINGFUL THERAPEUTIC BENEFIT.

Section 505B(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended—

(1) by striking ''estimates'' and inserting ''determines''; and

(2) by striking ''would'' and inserting ''could''.

SEC. 416. REPORTS.

(a) INSTITUTE OF MEDICINE STUDY.—

(1) IN GENERAL.—Not later than 3 years after the date of enactment of this subtitle, the Secretary shall contract with the Institute of Medicine to conduct a study and report to Congress regarding the pediatric studies conducted pursuant to section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) since 1997.

(2) CONTENT OF STUDY.—The study under paragraph (1) shall review and assess—

(A) pediatric studies conducted pursuant to section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) since 1997 and labeling changes made as a result of such studies; and

(B) the use of extrapolation for pediatric subpopulations, the use of alternative endpoints for pediatric populations, neonatal assessment tools, number and type of pediatric adverse

events, and ethical issues in pediatric clinical trials.

(3) REPRESENTATIVE SAMPLE.—The Institute of Medicine may devise an appropriate mechanism to review a representative sample of studies conducted pursuant to section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) from each review division within the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research in order to make the required assessment.

(b) GAO REPORT.—Not later than September 1, 2010, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, shall submit to Congress a report that addresses the effectiveness of section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) in ensuring that medicines used by children are tested and properly labeled, including—

(1) the number and importance of drugs for children that are being tested as a result of this provision and the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;

(2) the number and importance of drugs for children that are not being tested for their use notwithstanding the provisions of such section 505B, and possible reasons for the lack of testing; and

(3) the number of drugs for which testing is being done and labeling changes required, including the date labeling changes are made and which labeling changes required the use of the dispute resolution process established under such section 505B, together with a description of the outcomes of such process, including a description of the disputes and the recommendations of the Pediatric Advisory Committee.

SEC. 417. TECHNICAL CORRECTIONS.

Section 505B(a)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)(2)(B)(ii)) is amended by striking ''one'' and inserting ''1''.

Subtitle C—Pediatric Medical Devices

SEC. 421. SHORT TITLE.

This subtitle may be cited as the ''Pediatric Medical Device Safety and Improvement Act of 2007''.

SEC. 422. TRACKING PEDIATRIC DEVICE APPROVALS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 515 the following:

"SEC. 515A. PEDIATRIC USES OF DEVICES.

''(a) NEW DEVICES.—

''(1) IN GENERAL.—A person that submits to the Secretary an application under section 520(m), or an application (or supplement to an application) or a product development protocol under section 515, shall include in the application or protocol the information described in paragraph (2).

''(2) REQUIRED INFORMATION.—The application or protocol described in paragraph (1) shall include, with respect to the device for which approval is sought and if readily available—

''(A) a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and

''(B) the number of affected pediatric patients.

''(3) ANNUAL REPORT.—Not later than 18 months after the date of enactment of this section, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and

Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes—

"(A) the number of devices approved in the year preceding the year in which the report is submitted, for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure;

"(B) the number of devices approved in the year preceding the year in which the report is submitted, labeled for use in pediatric patients;

"(C) the number of pediatric devices approved in the year preceding the year in which the report is submitted, exempted from a fee pursuant to section 738(a)(2)(B)(v); and

"(D) the review time for each device described in subparagraphs (A), (B), and (C).

"(b) DETERMINATION OF PEDIATRIC EFFECTIVENESS BASED ON SIMILAR COURSE OF DISEASE OR CONDITION OR SIMILAR EFFECT OF DEVICE ON ADULTS.—

"(1) IN GENERAL.—If the course of the disease or condition and the effects of the device are sufficiently similar in adults and pediatric patients, the

Secretary may conclude that adult data may be used to support a determination of a reasonable assurance of effectiveness in pediatric populations, as appropriate.

''(2) EXTRAPOLATION BETWEEN SUBPOPULATIONS.—A study may not be needed in each pediatric subpopulation if data from one subpopulation can be extrapolated to another subpopulation.

''(c) PEDIATRIC SUBPOPULATION.—In this section, the term 'pediatric subpopulation' has the meaning given the term in section 520(m)(6)(E)(ii).''.

SEC. 423. MODIFICATION TO HUMANITARIAN DEVICE EXEMPTION.

(a) IN GENERAL.—Section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (3), by striking ''No'' and inserting ''Except as provided in paragraph (6), no'';

(2) in paragraph (5)—

(A) by inserting '', if the Secretary has reason to believe that the requirements of paragraph (6) are no longer met,'' after ''public health''; and

(B) by adding at the end the following: ''If the person granted an exemption under para-

graph (2) fails to demonstrate continued compliance with the requirements of this subsection, the Secretary may suspend or withdraw the 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.'';

(3) by striking paragraph (6) and inserting the following:

''(6)(A) Except as provided in subparagraph (D), the prohibition in paragraph (3) shall not apply with respect to a person granted an exemption under paragraph (2) if each of the following conditions apply:

''(i)(I) The device with respect to which the exemption is granted is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs.

''(II) The device was not previously approved under this subsection for the pediatric patients or the pediatric subpopulation described in subclause (I) prior to the date of enactment of the Pediatric

Medical Device Safety and Improvement Act of 2007.

''(ii) During any calendar year, the number of such devices distributed during that year does not exceed the annual distribution number specified by the Secretary when the Secretary grants such exemption. The annual distribution number shall be based on the number of individuals affected by the disease or condition that such device is intended to treat, diagnose, or cure, and of that number, the number of individuals likely to use the device, and the number of devices reasonably necessary to treat such individuals. In no case shall the annual distribution number exceed the number identified in paragraph (2)(A).

''(iii) Such person immediately notifies the Secretary if the number of such devices distributed during any calendar year exceeds the annual distribution number referred to in clause (ii).

''(iv) The request for such exemption is submitted on or before October 1, 2012.

''(B) The Secretary may inspect the records relating to the number of devices distributed during any calendar year of a person granted an exemption under paragraph

(2) for which the prohibition in paragraph (3) does not apply.

''(C) A person may petition the Secretary to modify the annual distribution number specified by the Secretary under subparagraph (A)(ii) with respect to a device if additional information on the number of individuals affected by the disease or condition arises, and the Secretary may modify such number but in no case shall the annual distribution number exceed the number identified in paragraph (2)(A).

''(D) If a person notifies the Secretary, or the Secretary determines through an inspection under subparagraph (B), that the number of devices distributed during any calendar year exceeds the annual distribution number, as required under subparagraph (A)(iii), and modified under subparagraph (C), if applicable, then the prohibition in paragraph (3) shall apply with respect to such person for such device for any sales of such device after such notification.

''(E)(i) In this subsection, the term 'pediatric patients' means patients who are 21 years of age or younger at the time of the diagnosis or treatment.

''(ii) In this subsection, the term 'pediatric subpopulation' means 1 of the following populations:

''(I) Neonates.

''(II) Infants.

''(III) Children.

''(IV) Adolescents.''; and

(4) by adding at the end the following:

''(7) The Secretary shall refer any report of an adverse event regarding a device for which the prohibition under paragraph (3) does not apply pursuant to paragraph (6)(A) that the Secretary receives to the Office of Pediatric Therapeutics, established under section 6 of the Best Pharmaceuticals for Children Act (Public Law 107–109)). In considering the report, the Director of the Office of Pediatric Therapeutics, in consultation with experts in the Center for Devices and Radiological Health, shall provide for periodic review of the report by the Pediatric Advisory Committee, including obtaining any recommendations of such committee regarding whether the Secretary should take action under this Act in response to the report.''.

(b) REPORT.—Not later than January 1, 2012, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the impact of allowing persons granted an exemption under section 520(m)(2) of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 360j(m)(2)) with respect to a device to profit from such device pursuant to section 520(m)(6) of such Act (21 U.S.C. 360j(m)(6)) (as amended by subsection (a)), including—

(1) an assessment of whether such section 520(m)(6) (as amended by subsection (a)) has increased the availability of pediatric devices for conditions that occur in small numbers of children, including any increase or decrease in the number of—

(A) exemptions granted under such section 520(m)(2) for pediatric devices; and

(B) applications approved under section 515 of such Act (21 U.S.C. 360e) for devices intended to treat, diagnose, or cure conditions that occur in pediatric patients or for devices labeled for use in a pediatric population;

(2) the conditions or diseases the pediatric devices were intended to treat or diagnose and the estimated size of the pediatric patient population for each condition or disease;

(3) the costs of the pediatric devices, based on a survey of children's hospitals;

(4) the extent to which the costs of such devices are covered by health insurance;

(5) the impact, if any, of allowing profit on access to such devices for patients;

(6) the profits made by manufacturers for each device that receives an exemption;

(7) an estimate of the extent of the use of the pediatric devices by both adults and pediatric populations for a condition or disease other than the condition or disease on the label of such devices;

(8) recommendations of the Comptroller General of the United States regarding the effectiveness of such section 520(m)(6) (as amended by subsection (a)) and whether any modifications to such section 520(m)(6) (as amended by subsection (a)) should be made;

(9) existing obstacles to pediatric device development; and

(10) an evaluation of the demonstration grants described in section 425, which shall include an evaluation of the number of pediatric medical devices—

(A) that have been or are being studied in children; and

(B) that have been submitted to the Food and Drug Administration for approval, clearance, or review under such section 520(m) (as

amended by this Act) and any regulatory actions taken.

(c) GUIDANCE.—Not later than 180 days after the date of enactment of this subtitle, the Commissioner of Food and Drugs shall issue guidance for institutional review committees on how to evaluate requests for approval for devices for which a humanitarian device exemption under section 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)) has been granted.

SEC. 424. CONTACT POINT FOR AVAILABLE FUNDING.

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

(1) in paragraph (21), by striking ''and'' after the semicolon at the end;

(2) in paragraph (22), by striking the period at the end and inserting ''; and''; and

(3) by inserting after paragraph (22) the following:

''(23) shall designate a contact point or office to help innovators and physicians identify sources of funding available for pediatric medical device development.''.

SEC. 425. DEMONSTRATION GRANTS FOR IMPROVING PEDIATRIC DEVICE AVAILABILITY.

(a) IN GENERAL.—

(1) REQUEST FOR PROPOSALS.—Not later than 90 days after the date of enactment of this subtitle, the Secretary of Health and Human Services shall issue a request for proposals for 1 or more grants or contracts to nonprofit consortia for demonstration projects to promote pediatric device development.

(2) DETERMINATION ON GRANTS OR CONTRACTS.—Not later than 180 days after the date the Secretary of Health and Human Services issues a request for proposals under paragraph (1), the Secretary shall make a determination on the grants or contracts under this section.

(b) APPLICATION.—A nonprofit consortium that desires to receive a grant or contract under this section shall submit an application to the Secretary of Health and Human Services at such time, in such manner, and containing such information as the Secretary may require.

(c) USE OF FUNDS.—A nonprofit consortium that receives a grant or contract under this section shall facilitate the development, production, and distribution of pediatric medical devices by—

(1) encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers;

(2) mentoring and managing pediatric device projects through the development process, including product identification, prototype design, device development, and marketing;

(3) connecting innovators and physicians to existing Federal and non-Federal resources, including resources from the Food and Drug Administration, the National Institutes of Health, the Small Business Administration, the Department of Energy, the Department of Education, the National Science Foundation, the Department of Veterans Affairs, the Agency for Healthcare Research and Quality, and the National Institute of Standards and Technology;

(4) assessing the scientific and medical merit of proposed pediatric device projects; and

(5) providing assistance and advice as needed on business development, personnel training, prototype development, postmarket needs, and other activities consistent with the purposes of this section.

(d) COORDINATION.—

(1) NATIONAL INSTITUTES OF HEALTH.—Each consortium that receives a grant or contract under this section shall—

(A) coordinate with the National Institutes of Health's pediatric device contact point or office, designated under section 424; and

(B) provide to the National Institutes of Health any identified pediatric device needs that the consortium lacks sufficient capacity to address or those needs in which the consortium has been unable to stimulate manufacturer interest.

(2) FOOD AND DRUG ADMINISTRATION.—Each consortium that receives a grant or contract under this section shall coordinate with the Commissioner of Food and Drugs and device companies to facilitate the application for approval or clearance of devices labeled for pediatric use.

(3) EFFECTIVENESS AND OUTCOMES.—Each consortium that receives a grant or contract under this section shall annually report to the Secretary of Health and Human Services on—

(A) the effectiveness of activities conducted under subsection (c);

(B) the impact of activities conducted under subsection (c) on pediatric device development; and

(C) the status of pediatric device development that has been facilitated by the consortium.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $6,000,000 for each of fiscal years 2008 through 2012.

SEC. 426. AMENDMENTS TO OFFICE OF PEDIATRIC THERAPEUTICS AND PEDIATRIC ADVISORY COMMITTEE.

(a) IN GENERAL.—

(1) OFFICE OF PEDIATRIC THERAPEUTICS.—Section 6(b) of the Best Pharmaceuticals for Children Act (21 U.S.C. 393a(b)) is amended by inserting ", including increasing pediatric access to medical devices" after "pediatric issues".

(2) PLAN FOR PEDIATRIC MEDICAL DEVICE RESEARCH.—

(A) IN GENERAL.—Not later than 270 days after the date of enactment of this subtitle, the Office of Pediatric Therapeutics, in collaboration with the Director of the National Institutes of Health and the Director of the Agency for Healthcare Research and Quality, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and

the Committee on Energy and Commerce of the House of Representatives a plan for expanding pediatric medical device research and development. In developing such plan, the Commissioner of Food and Drugs shall consult with individuals and organizations with appropriate expertise in pediatric medical devices.

(B) CONTENTS.—The plan under subparagraph (A) shall include—

(i) the current status of federally funded pediatric medical device research;

(ii) any gaps in such research, which may include a survey of pediatric medical providers regarding unmet pediatric medical device needs, as needed; and

(iii) a research agenda for improving pediatric medical device development and Food and Drug Administration clearance or approval of pediatric medical devices, and for evaluating the short- and long-term safety and effectiveness of pediatric medical devices.

(b) PEDIATRIC ADVISORY COMMITTEE.—Section 14 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended—

(1) in subsection (a), by inserting ''(including drugs and biological products) and medical devices'' after ''therapeutics''; and

(2) in subsection (b)—

(A) in paragraph (1), by inserting ''(including drugs and biological products) and medical devices'' after ''therapeutics''; and

(B) in paragraph (2)—

(i) in subparagraph (A), by striking ''and 505B'' and inserting ''505B, 510(k), 515, and 520(m)'';

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

''(B) identification of research priorities related to therapeutics (including drugs and biological products) and medical devices for pediatric populations and the need for additional diagnostics and treatments for specific pediatric diseases or conditions; and''; and

(iii) in subparagraph (C), by inserting ''(including drugs and biological products) and medical devices'' after ''therapeutics''.

SEC. 427. POSTMARKET SURVEILLANCE.

(a) POSTMARKET SURVEILLANCE.—Section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l) is amended—

(1) by striking subsection (a) and inserting the following:

''(a) POSTMARKET SURVEILLANCE.—

''(1) IN GENERAL.—

''(A) CONDUCT.—The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer that is a class II or class III device—

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

''(ii) that is expected to have significant use in pediatric populations; or

''(iii) that is intended to be—

''(I) implanted in the human body for more than 1 year; or

''(II) a life-sustaining or life-supporting device used outside a device user facility.

''(B) CONDITION.—The Secretary may order a postmarket surveillance under subpara-

graph (A) as a condition to approval or clearance of a device described in subparagraph (A)(ii).

''(2) RULE OF CONSTRUCTION.—The provisions of paragraph (1) shall have no effect on authorities otherwise provided under the Act or regulations issued under this Act.''; and

(2) in subsection (b)—

(A) by striking ''(b) SURVEILLANCE APPROVAL.—Each'' and inserting the following:

''(b) SURVEILLANCE APPROVAL.—

''(1) IN GENERAL.—Each'';

(B) by striking ''The Secretary, in consultation'' and inserting ''Except as provided in paragraph (2), the Secretary, in consultation'';

(C) by striking ''Any determination'' and inserting ''Except as provided in paragraph (2), any determination''; and

(D) by adding at the end the following:

''(2) LONGER SURVEILLANCES FOR PEDIATRIC DEVICES.—The Secretary may by order require a prospective surveillance period of more than 36 months with respect to a device that is expected to have significant use in pediatric populations if such period of more than 36 months is necessary in order

to assess the impact of the device on growth and development, or the effects of growth, development, activity level, or other factors on the safety of the device.''.

TITLE V—OTHER PROVISIONS

SEC. 501. POLICY ON THE REVIEW AND CLEARANCE OF SCIENTIFIC ARTICLES PUBLISHED BY FDA EMPLOYEES.

Subchapter A of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.), as amended by section 241, is further amended by adding at the end the following:

''SEC. 713. POLICY ON THE REVIEW AND CLEARANCE OF SCIENTIFIC ARTICLES PUBLISHED BY FDA EMPLOYEES.

''(a) DEFINITION.—In this section, the term 'article' means a paper, poster, abstract, book, book chapter, or other published writing.

''(b) POLICIES.—The Secretary, through the Commissioner of Food and Drugs, shall establish and make publicly available clear written policies to implement this section and govern the timely submission, review, clearance, and disclaimer requirements for articles.

''(c) TIMING OF SUBMISSION FOR REVIEW.—If an officer or employee, including a Staff Fellow and a con-

tractor who performs staff work, of the Food and Drug Administration is required by the policies established under subsection (b) to submit an article to the supervisor of such officer or employee, or to some other official of the Food and Drug Administration, for review and clearance before such officer or employee may seek to publish or present such an article at a conference, such officer or employee shall submit such article for such review and clearance not less than 30 days before submitting the article for publication or presentation.

''(d) TIMING FOR REVIEW AND CLEARANCE.—The supervisor or other reviewing official shall review such article and provide written clearance, or written clearance on the condition of specified changes being made, to such officer or employee not later than 30 days after such officer or employee submitted such article for review.

''(e) NON-TIMELY REVIEW.—If, 31 days after such submission under subsection (c), the supervisor or other reviewing official has not cleared or has not reviewed such article and provided written clearance, such officer or employee may consider such article not to have been cleared and may submit the article for publication or presentation with an appropriate disclaimer as specified in the policies established under subsection (b).''.

SEC. 502. TECHNICAL AMENDMENTS.

The Public Health Service Act (42 U.S.C. 201 et seq.) is amended—

(1) in section 319C–2(j)(3)(B), by striking ''section 319C–1(h)'' and inserting ''section 319C–1(i)'';

(2) in section 402(b)(4), by inserting ''minority and other'' after ''reducing'';

(3) in section 403(a)(4)(C)(iv)(III), by inserting ''and post doctoral training funded through investigator-initiated research grant awards'' before the semicolon; and

(4) in section 403C(a)—

(A) in the matter preceding paragraph (1), by inserting ''graduate students supported by NIH for'' after ''with respect to'';

(B) in paragraph (1), by inserting ''such'' after ''percentage of''; and

(C) in paragraph (2), by inserting ''(not including any leaves of absence)'' after ''average time''.

SEC. 503. SEVERABILITY CLAUSE.

If any provision of this Act, an amendment made this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made

by this Act, and the application of the provisions of such to any person or circumstances shall not be affected thereby.

SEC. 504. SENSE OF THE SENATE WITH RESPECT TO FOLLOW-ON BIOLOGICS.

(a) FINDINGS.—The Senate finds the following:

(1) The Food and Drug Administration has stated that it requires legislative authority to review follow-on biologics.

(2) Business, consumer, and government purchasers require competition and choice to ensure more affordable prescription drug options.

(3) Well-constructed policies that balance the needs of innovation and affordability have broad bipartisan support.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that legislation should be enacted to—

(1) provide the Food and Drug Administration with the authority and flexibility to approve biopharmaceuticals subject to an abbreviated approval pathway;

(2) ensure that patient safety remains paramount in the system;

(3) establish a regulatory pathway that is efficient, effective, and scientifically-grounded and that

also includes measures to ensure timely resolution of patent disputes; and

(4) provide appropriate incentives to facilitate the research and development of innovative biopharmaceuticals.

SEC. 505. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"SEC. 524. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.

''(a) DEFINITIONS.—In this section:

''(1) AIDS.—The term 'AIDS' means the acquired immune deficiency syndrome.

''(2) AIDS DRUG.—The term 'AIDS drug' means a drug indicated for treating HIV.

''(3) HIV.—The term 'HIV' means the human immunodeficiency virus, the pathogen that causes AIDS.

''(4) NEGLECTED OR TROPICAL DISEASE.—The term 'neglected or tropical disease' means—

''(A) HIV, malaria, tuberculosis, and related diseases; or

"(B) any other infectious disease that disproportionately affects poor and marginalized populations, including those diseases targeted by the Special Programme for Research and Training in Tropical Diseases cosponsored by the United Nations Development Program, UNICEF, the World Bank, and the World Health Organization.

"(5) PRIORITY REVIEW.—The term 'priority review', with respect to a new drug application described in paragraph (6), means review and action by the Secretary on such application not later than 180 days after receipt by the Secretary of such application, pursuant to the Manual of Policies and Procedures of the Food and Drug Administration.

"(6) PRIORITY REVIEW VOUCHER.—The term 'priority review voucher' means a voucher issued by the Secretary to the sponsor of a tropical disease product that entitles such sponsor, or a person described under subsection (b)(2), to priority review of a new drug application submitted under section 505(b)(1) after the date of approval of the tropical disease product.

"(7) TROPICAL DISEASE PRODUCT.—The term 'tropical disease product' means a product that—

''(A) is a new drug, antibiotic drug, biological product, vaccine, device, diagnostic, or other tool for treatment of a neglected or tropical disease; and

''(B) is approved by the Secretary for use in the treatment of a neglected or tropical disease.

''(b) PRIORITY REVIEW VOUCHER.—

''(1) IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of a tropical disease product upon approval by the Secretary of such tropical disease product.

''(2) TRANSFERABILITY.—The sponsor of a tropical disease product that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher to a sponsor of a new drug for which an application under section 505(b)(1) will be submitted after the date of the approval of the tropical disease product.

''(3) LIMITATION.—A sponsor of a tropical disease product may not receive a priority review voucher under this section if the tropical disease product was approved by the Secretary prior to the date of enactment of this section.

''(c) PRIORITY REVIEW USER FEE.—

''(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a drug that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

''(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the anticipated costs to the Secretary of implementing this section.

''(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2007, for that fiscal year, the amount of the priority review user fee.

''(4) PAYMENT.—

''(A) IN GENERAL.—The fee required by this subsection shall be due upon the filing of the new drug application under section 505(b)(1) for which the voucher is used.

''(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if

the fee required by this subsection is not included in such application.

''(5) OFFSETTING COLLECTIONS.—Fees collected pursuant to this subsection for any fiscal year—

''(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

''(B) shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.''.

SEC. 506. CITIZENS PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by this Act, is amended by adding at the end the following:

''(s) CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.—

''(1) IN GENERAL.—

''(A) NO DELAY OF CONSIDERATION OR APPROVAL.—

''(i) IN GENERAL.—With respect to a pending application submitted under subsection (b)(2) or (j), if a petition is sub-

mitted to the Secretary that seeks to have the Secretary take, or refrain from taking, any form of action relating to the approval of the application, including a delay in the effective date of the application, clauses (ii) and (iii) shall apply.

''(ii) NO DELAY OF CONSIDERATION OR APPROVAL.—Except as provided in clause (iii), the receipt and consideration of a petition described in clause (i) shall not delay consideration or approval of an application submitted under subsection (b)(2) or (j).

''(iii) NO DELAY OF APPROVAL WITHOUT DETERMINATION.—The Secretary shall not delay approval of an application submitted under subsection (b)(2) or (j) while a petition described in clause (i) is reviewed and considered unless the Secretary determines, not later than 25 business days after the submission of the petition, that a delay is necessary to protect the public health.

''(B) DETERMINATION OF DELAY.—With respect to a determination by the Secretary

under subparagraph (A)(iii) that a delay is necessary to protect the public health the following shall apply:

''(i) Not later than 5 days after making such determination, the Secretary shall publish on the Internet website of the Food and Drug Administration a detailed statement providing the reasons underlying the determination. The detailed statement shall include a summary of the petition and comments and supplements, the specific substantive issues that the petition raises which need to be considered prior to approving a pending application submitted under subsection (b)(2) or (j), and any clarifications and additional data that is needed by the Secretary to promptly review the petition.

''(ii) Not later than 10 days after making such determination, the Secretary shall provide notice to the sponsor of the pending application submitted under subsection (b)(2) or (j) and provide an opportunity for a meeting with appropriate staff

as determined by the Commissioner to discuss the determination.

''(2) TIMING OF FINAL AGENCY ACTION ON PETITIONS.—

''(A) IN GENERAL.—Notwithstanding a determination made by the Secretary under paragraph (1)(A)(iii), the Secretary shall take final agency action with respect to a petition not later than 180 days of submission of that petition unless the Secretary determines, prior to the date that is 180 days after the date of submission of the petition, that a delay is necessary to protect the public health.

''(B) DETERMINATION OF DELAY.—With respect to a determination by the Secretary under subparagraph (A) that a delay is necessary to protect the public health the following shall apply:

''(i) Not later than 5 days after making the determination under subparagraph (A), the Secretary shall publish on the Internet website of the Food and Drug Administration a detailed statement providing the reasons underlying the determination. The detailed statement should include the

state of the review of the petition, the specific outstanding issues that still need to be resolved, a proposed timeframe to resolve the issues, and any additional information that has been requested by the Secretary of the petitioner or needed by the Secretary in order to resolve the petition and not further delay an application filed under subsection (b)(2) or (j).

''(ii) Not later than 10 days after making the determination under subparagraph (A), the Secretary shall provide notice to the sponsor of the pending application submitted under subsection (b)(2) or (j) and provide an opportunity for a meeting with appropriate staff as determined by the Commissioner to discuss the determination.

''(3) VERIFICATIONS.—

''(A) PETITIONS FOR REVIEW.—The Secretary shall not accept a petition for review unless it is signed and contains the following verification: 'I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition re-

lies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) information upon which I have based the action requested herein first became known to the party on whose behalf this petition is filed on or about _____. I received or expect to receive payments, including cash and other forms of consideration, from the following persons or organizations to file this petition: _____. I verify under penalty of perjury that the foregoing is true and correct.', with the date of the filing of such petition and the signature of the petitioner inserted in the first and second blank space, respectively.

''(B) SUPPLEMENTAL INFORMATION.—The Secretary shall not accept for review any supplemental information or comments on a petition unless the party submitting such information or comments does so in written form and that the subject document is signed and contains the following verification: 'I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information

upon which I have based the action requested herein first became known to me on or about _____. I received or expect to receive payments, including cash and other forms of consideration, from the following persons or organizations to submit this information or its contents: _____. I verify under penalty of perjury that the foregoing is true and correct.', with the date of the submission of such document and the signature of the petitioner inserted in the first and second blank space, respectively.

''(4) ANNUAL REPORT ON DELAYS IN APPROVALS PER PETITION.—The Secretary shall annually submit to the Congress a report that specifies—

''(A) the number of applications under subsection (b)(2) and (j) that were approved during the preceding 1-year period;

''(B) the number of petitions that were submitted during such period;

''(C) the number of applications whose effective dates were delayed by petitions during such period and the number of days by which the applications were so delayed; and

''(D) the number of petitions that were filed under this subsection that were deemed by the Secretary under paragraph (1)(A)(iii) to require delaying an application under subsection (b)(2) or (j) and the number of days by which the applications were so delayed.

''(5) EXCEPTION.—This subsection does not apply to a petition that is made by the sponsor of the application under subsection (b)(2) or (j) and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

''(6) REPORT BY INSPECTOR GENERAL.—The Office of Inspector General of the Department of Health and Human Services shall issue a report not later than 2 years after the date of enactment of this subsection evaluating evidence of the compliance of the Food and Drug Administration with the requirement that the consideration by the Secretary of petitions that do not raise public health concerns remain separate and apart from the review and approval of an application submitted under subsection (b)(2) or (j).

''(7) DEFINITION.—For purposes of this subsection, the term 'petition' includes any request for

an action described in paragraph (1)(A)(i) to the Secretary, without regard to whether the request is characterized as a petition.''.

SEC. 507. PUBLICATION OF ANNUAL REPORTS.

(a) IN GENERAL.—The Commissioner on Food and Drugs shall annually submit to Congress and publish on the Internet website of the Food and Drug Administration, a report concerning the results of the Administration's pesticide residue monitoring program, that includes—

(1) information and analysis similar to that contained in the report entitled ''Food and Drug Administration Pesticide Program Residue Monitoring 2003'' as released in June of 2005;

(2) based on an analysis of previous samples, an identification of products or countries (for imports) that require special attention and additional study based on a comparison with equivalent products manufactured, distributed, or sold in the United States (including details on the plans for such additional studies), including in the initial report (and subsequent reports as determined necessary) the results and analysis of the Ginseng Dietary Supplements Special Survey as described on page 13 of the

report entitled ''Food and Drug Administration Pesticide Program Residue Monitoring 2003'';

(3) information on the relative number of interstate and imported shipments of each tested commodity that were sampled, including recommendations on whether sampling is statistically significant, provides confidence intervals or other related statistical information, and whether the number of samples should be increased and the details of any plans to provide for such increase; and

(4) a description of whether certain commodities are being improperly imported as another commodity, including a description of additional steps that are being planned to prevent such smuggling.

(b) INITIAL REPORTS.—Annual reports under subsection (a) for fiscal years 2004 through 2006 may be combined into a single report, by not later than June 1, 2008, for purposes of publication under subsection (a). Thereafter such reports shall be completed by June 1 of each year for the data collected for the year that was 2-years prior to the year in which the report is published.

(c) MEMORANDUM OF UNDERSTANDING.—The Commissioner of Food and Drugs, the Administrator of the Food Safety and Inspection Service, the Department of Commerce, and the head of the Agricultural Marketing

Service shall enter into a memorandum of understanding to permit inclusion of data in the reports under subsection (a) relating to testing carried out by the Food Safety and Inspection Service and the Agricultural Marketing Service on meat, poultry, eggs, and certain raw agricultural products, respectively.

SEC. 508. HEAD START ACT AMENDMENT IMPOSING PARENTAL CONSENT REQUIREMENT FOR NONEMERGENCY INTRUSIVE PHYSICAL EXAMINATIONS.

The Head Start Act (42 U.S.C. 9831 et seq.) is amended by adding at the end the following:

"SEC. 657A. PARENTAL CONSENT REQUIREMENT FOR NONEMERGENCY INTRUSIVE PHYSICAL EXAMINATIONS.

''(a) IN GENERAL.—A Head Start agency shall obtain written parental consent before administration of any nonemergency intrusive physical examination of a child in connection with participation in a program under this subchapter.

''(b) DEFINITION.—The term 'nonemergency intrusive physical examination' means, with respect to a child, a physical examination that—

''(1) is not immediately necessary to protect the health or safety of the child involved or the health or safety of another individual; and

''(2) requires incision or is otherwise invasive, or involves exposure of private body parts.

''(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit agencies from using established methods, for handling cases of suspected or known child abuse and neglect, that are in compliance with applicable Federal, State, or tribal law.''.

SEC. 509. SAFETY OF FOOD ADDITIVES.

Not later than 90 days after the date of enactment of this Act, the Food and Drug Administration shall issue a report on the question of whether substances used to preserve the appearance of fresh meat may create any health risks, or mislead consumers.

SEC. 510. IMPROVING GENETIC TEST SAFETY AND QUALITY.

Not later than 30 days after the date of enactment of this Act, the Secretary shall enter into a contract with the Institute of Medicine to conduct a study to assess the overall safety and quality of genetic tests and prepare a report that includes recommendations to improve Federal oversight and regulation of genetic tests. Such study shall take into consideration relevant reports by the Secretary's Advisory Committee on Genetic Testing and other groups

and shall be completed not later than 1 year after the date on which the Secretary entered into such contract.

SEC. 511. ORPHAN DISEASE TREATMENT IN CHILDREN.

(a) FINDING.—The Senate finds that parents of children suffering from rare genetic diseases known as orphan diseases face multiple obstacles in obtaining safe and effective treatment for their children due mainly to the fact that many Food and Drug Administration-approved drugs used in the treatment of orphan diseases in children may not be approved for pediatric indications.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that the Food and Drug Administration should enter into a contract with the Institute of Medicine for the conduct of a study concerning measures that may be taken to improve the likelihood that Food and Drug Administration-approved drugs that are safe and effective in treating children with orphan diseases are made available and affordable for pediatric indications.

SEC. 512. COLOR CERTIFICATION REPORTS.

Section 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e) is amended by adding at the end the following:

''(g) COLOR CERTIFICATION REPORTS.—Not later than—

''(1) 90 days after the close of a fiscal year in which color certification fees are collected, the Secretary shall submit to Congress a performance report for such fiscal year on the number of batches of color additives approved, the average turn around time for approval, and quantifiable goals for improving laboratory efficiencies; and

''(2) 120 days after the close of a fiscal year in which color certification fees are collected, the Secretary shall submit to Congress a financial report for such fiscal year that includes all fees and expenses of the color certification program, the balance remaining in the fund at the end of the fiscal year, and anticipated costs during the next fiscal year for equipment needs and laboratory improvements of such program.''.

SEC. 513. PROHIBITION ON IMPORTATION FROM A FOREIGN FOOD FACILITY THAT DENIES ACCESS TO FOOD INSPECTORS.

Notwithstanding any other provision of law, no food product may be imported into the United States that is the product of a foreign facility registered under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d) that refuses to permit United States inspec-

tors, upon request, to inspect such facility or that unduly delays access to United States inspectors.

SEC. 514. COUNTERFEIT-RESISTANT TECHNOLOGIES.

Notwithstanding any other provision of this Act, the requirement that the Secretary of Health and Human Services certify that the implementation of the title of this Act relating to the Importation of Prescription Drugs will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of covered products to the American consumer shall not apply to the requirement that the Secretary require that the packaging of any prescription drug incorporates—

(1) not later than 18 months after the date of enactment of this Act, a standardized numerical identifier (which, to the extent practicable, shall be harmonized with international consensus standards for such an identifier) unique to each package of such drug, applied at the point of manufacturing and repackaging (in which case the numerical identifier shall be linked to the numerical identifier applied at the point of manufacturing); and

(2) not later than 24 months after the date of enactment of this Act for the 50 prescription drugs with the highest dollar volume of sales in the United States, based on the calendar year that ends of De-

cember 31, 2007, and, not later than 30 months after the date of enactment of this Act for all other prescription drugs—

(A) overt optically variable counterfeit-resistant technologies that—

(i) are visible to the naked eye, providing for visual identification of product authenticity without the need for readers, microscopes, lighting devices, or scanners;

(ii) are similar to that used by the Bureau of Engraving and Printing to secure United States currency;

(iii) are manufactured and distributed in a highly secure, tightly controlled environment; and

(iv) incorporate additional layers of nonvisible convert security features up to and including forensic capability; or

(B) technologies that have a function of security comparable to that described in subparagraph (A), as determined by the Secretary.

SEC. 515. ENHANCED AQUACULTURE AND SEAFOOD INSPECTION.

(a) FINDINGS.—Congress finds the following:

(1) In 2007, there has been an overwhelming increase in the volume of aquaculture and seafood that has been found to contain substances that are not approved for use in food in the United States.

(2) As of May 2007, inspection programs are not able to satisfactorily accomplish the goals of ensuring the food safety of the United States.

(3) To protect the health and safety of consumers in the United States, the ability of the Secretary of Health and Human Services to perform inspection functions must be enhanced.

(b) HEIGHTENED INSPECTIONS.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') is authorized to, by regulation, enhance, as necessary, the inspection regime of the Food and Drug Administration for aquaculture and seafood, consistent with obligations of the United States under international agreements and United States law.

(c) REPORT TO CONGRESS.—Not later than 90 days after the date of enactment of this Act, the Secretary shall submit to Congress a report that—

(1) describes the specifics of the aquaculture and seafood inspection program;

(2) describes the feasibility of developing a traceability system for all catfish and seafood prod-

ucts, both domestic and imported, for the purpose of identifying the processing plant of origin of such products; and

(3) provides for an assessment of the risks associated with particular contaminants and banned substances.

(d) PARTNERSHIPS WITH STATES.—Upon the request by any State, the Secretary may enter into partnership agreements, as soon as practicable after the request is made, to implement inspection programs regarding the importation of aquaculture and seafood.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

SEC. 516. SENSE OF THE SENATE REGARDING CERTAIN PATENT INFRINGEMENTS.

(a) FINDINGS.—The Senate makes the following findings:

(1) Innovation in developing life-saving prescription drugs saves millions of lives around the world each year.

(2) The responsible protection of intellectual property is vital to the continued development of new and life-saving drugs and future growth of the United States economy.

(3) In order to maintain the global competitiveness of the United States, the United States Trade Representative's Office of Intellectual Property and Innovation develops and implements trade policy in support of vital American innovations, including innovation in the pharmaceutical and medical technology industries.

(4) The United States Trade Representative also provides trade policy leadership and expertise across the full range of interagency initiatives to enhance protection and enforcement of intellectual property rights.

(5) Strong and fair intellectual property protection, including patent, copyright, trademark, and data protection plays an integral role in fostering economic growth and development and ensuring patient access to the most effective medicines around the world.

(6) There are concerns that certain countries have engaged in unfair price manipulation and abuse of compulsory licensing. Americans bear the majority of research and development costs for the world, which could undermine the value of existing United States pharmaceutical patents and could impede access to important therapies.

(7) There is a growing global threat of counterfeit medicines and increased need for the United States Trade Representative and other United States agencies to use available trade policy measures to strengthen laws and enforcement abroad to prevent harm to United States patients and patients around the world.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that—

(1) the United States Trade Representative should use all the tools at the disposal of the Trade Representative to address violations and other concerns with intellectual property, including through—

(A) bilateral engagement with United States trading partners;

(B) transparency and balance of the annual ''Special 301'' review and reviews of compliance with the intellectual property requirements of countries with respect to which the United States grants trade preferences;

(C) negotiation of responsible and fair intellectual property provisions as part of bilateral and regional trade agreements; and

(D) multilateral engagement through the World Trade Organization (WTO); and

(2) the United States Trade Representative should develop and submit to Congress a strategic plan to address the problem of countries that infringe upon American pharmaceutical intellectual property rights and the problem of countries that engage in price manipulation.

SEC. 517. CONSULTATION REGARDING GENETICALLY ENGINEERED SEAFOOD PRODUCTS.

The Commissioner of Food and Drugs shall consult with the Assistant Administrator of the National Marine Fisheries Service of the National Oceanic and Atmospheric Administration to produce a report on any environmental risks associated with genetically engineered seafood products, including the impact on wild fish stocks.

SEC. 518. REPORT ON THE MARKETING OF CERTAIN CRUSTACEANS.

Not later than 30 days after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with the Secretary of Commerce, shall submit to the Health, Education, Labor, and Pensions Committee and the Committee on Commerce, Science, and Transportation of the Senate, a report on the differences between taxonomy of species of lobster in the subfamily Nephropinae, and species of langostino, specifically from the infraorder Caridea or Anomura. This report shall also

describe the differences in consumer perception of such species, including such factors as taste, quality, and value of the species.

SEC. 519. CIVIL PENALTIES; DIRECT-TO-CONSUMER ADVERTISEMENT.

(a) CIVIL PENALTIES.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

''(g)(1) Any applicant (as such term is used in section 505(o)) who disseminates a direct-to-consumer advertisement for a prescription drug that is false or misleading and a violation of section 502(n) shall be liable to the United States for a civil penalty in an amount not to exceed $150,000 for the first such violation in any 3-year period, and not to exceed $300,000 for each subsequent violation committed after the applicant has been penalized under this paragraph any time in the preceding 3-year period. For the purposes of this paragraph, repeated dissemination of the same or similar advertisement prior to the receipt of the written notice referred to in paragraph (2) for such advertisements shall be considered as 1 violation.

''(2) A civil penalty under paragraph (1) shall be assessed by the Secretary by an order made on the record after providing written notice to the applicant to be as-

sessed a civil penalty and an opportunity for a hearing in accordance with this paragraph and section 554 of title 5, United States Code. If upon receipt of the written notice, the applicant to be assessed a civil penalty objects and requests a hearing, then in the course of any investigation related to such hearing, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation, including information pertaining to the factors described in paragraph (3).

''(3) Upon the request of the applicant to be assessed a civil penalty, the Secretary, in determining the amount of a civil penalty, shall take into account the nature, circumstances, extent, and gravity of the violation or violations, including the following factors:

''(A) Whether the applicant submitted the advertisement or a similar advertisement for review under section 736A.

''(B) Whether the applicant submitted the advertisement for prereview if required under section 505(o)(5)(D).

''(C) Whether, after submission of the advertisement as described in subparagraph (A) or (B), the applicant disseminated the advertisement before the end of the 45-day comment period.

''(D) Whether the applicant failed to incorporate any comments made by the Secretary with regard to the advertisement or a similar advertisement into the advertisement prior to its dissemination.

''(E) Whether the applicant ceased distribution of the advertisement upon receipt of the written notice referred to in paragraph (2) for such advertisement.

''(F) Whether the applicant had the advertisement reviewed by qualified medical, regulatory, and legal reviewers prior to its dissemination.

''(G) Whether the violations were material.

''(H) Whether the applicant who created the advertisement acted in good faith.

''(I) Whether the applicant who created the advertisement has been assessed a civil penalty under this provision within the previous 1-year period.

''(J) The scope and extent of any voluntary, subsequent remedial action by the applicant.

''(K) Such other matters, as justice may require.

''(4)(A) Subject to subparagraph (B), no applicant shall be required to pay a civil penalty under paragraph (1) if the applicant submitted the advertisement to the

Secretary and disseminated such advertisement after incorporating any comment received from the Secretary.

''(B) The Secretary may retract or modify any prior comments the Secretary has provided to an advertisement submitted to the Secretary based on new information or changed circumstances, so long as the Secretary provides written notice to the applicant of the new views of the Secretary on the advertisement and provides a reasonable time for modification or correction of the advertisement prior to seeking any civil penalty under paragraph (1).

''(5) The Secretary may compromise, modify, remit, with or without conditions, any civil penalty which may be assessed under paragraph (1). The amount of such penalty, when finally determined, or the amount charged upon in compromise, may be deducted from any sums owned by the United States to the applicant charged.

''(6) Any applicant who requested, in accordance with paragraph (2), a hearing with respect to the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty, may file a petition for de novo judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such applicant resides or transacts business. Such a petition may only be filed within the 60-day

period beginning on the date the order making such assessments was issued.

''(7) If any applicant fails to pay an assessment of a civil penalty—

''(A) after the order making the assessment becomes final, and if such applicant does not file a petition for judicial review of the order in accordance with paragraph (6); or

''(B) after a court in an action brought under paragraph (6) has entered a final judgment in favor of the Secretary,

the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (6) or date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.''.

(b) DIRECT-TO-CONSUMER ADVERTISEMENT.—

(1) IN GENERAL.—Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) is amended by inserting after the first sentence the following: ''In the case of an advertisement for a prescription drug presented directly to con-

sumers in television or radio format that states the name of the drug and its conditions of use, the major statement relating to side effects, contraindications, and effectiveness referred to in the previous sentence shall be stated in a clear and conspicuous (neutral) manner.''.

(2) REGULATIONS TO DETERMINE NEUTRAL MANNER.—The Secretary of Health and Human Services shall by regulation establish standards for determining whether a major statement, relating to side effects, contraindications, and effectiveness of a drug, described in section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) (as amended by paragraph (1)) is presented in the manner required under such section.

SEC. 520. REPORT BY THE FOOD AND DRUG ADMINISTRATION REGARDING LABELING INFORMATION ON THE RELATIONSHIP BETWEEN THE USE OF INDOOR TANNING DEVICES AND DEVELOPMENT OF SKIN CANCER OR OTHER SKIN DAMAGE.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall determine—

(1) whether the labeling requirements for indoor tanning devices, including the positioning requirements, provide sufficient information to consumers regarding the risks that the use of such devices pose for the development of irreversible damage to the eyes and skin, including skin cancer; and

(2)(A) whether modifying the warning label required on tanning beds to read, ''Ultraviolet radiation can cause skin cancer'', or any other additional warning, would communicate the risks of indoor tanning more effectively; or

(B) whether there is no warning that would be capable of adequately communicating such risks.

(b) CONSUMER TESTING.—In making the determinations under subsection (a), the Secretary shall conduct appropriate consumer testing, using the best available methods for determining consumer understanding of label warnings.

(c) PUBLIC HEARINGS; PUBLIC COMMENT.—The Secretary shall hold public hearings and solicit comments from the public in making the determinations under subsection (a).

(d) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit to the Congress a report that provides the determinations

under subsection (a). In addition, the Secretary shall include in the report the measures being implemented by the Secretary to significantly reduce the risks associated with indoor tanning devices.

TITLE VI—FOOD SAFETY

SEC. 601. FINDINGS.

(a) FINDINGS.—Congress finds that—

(1) the safety and integrity of the United States food supply is vital to the public health, to public confidence in the food supply, and to the success of the food sector of the Nation's economy;

(2) illnesses and deaths of individuals and companion animals caused by contaminated food—

(A) have contributed to a loss of public confidence in food safety; and

(B) have caused significant economic losses to manufacturers and producers not responsible for contaminated food items;

(3) the task of preserving the safety of the food supply of the United States faces tremendous pressures with regard to—

(A) emerging pathogens and other contaminants and the ability to detect all forms of contamination; and

(B) an increasing volume of imported food from a wide variety of countries; and

(C) a shortage of adequate resources for monitoring and inspection;

(4) the United States is increasing the amount of food that it imports such that—

(A) from 2003 to the present, the value of food imports has increased from $45,600,000,000 to $64,000,000,000; and

(B) imported food accounts for 13 percent of the average Americans diet including 31 percent of fruits, juices, and nuts, 9.5 percent of red meat and 78.6 percent of fish and shellfish; and

(5) the number of full time equivalent Food and Drug Administration employees conducting inspections has decreased from 2003 to 2007.

SEC. 602. ENSURING THE SAFETY OF PET FOOD.

(a) PROCESSING AND INGREDIENT STANDARDS.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this title as the ''Secretary''), in consultation with the Association of American Feed Control Officials, and other relevant stakeholder groups, including veterinary medical associations, animal health organizations,

and pet food manufacturers, shall by regulation establish—

(1) processing and ingredient standards with respect to pet food, animal waste, and ingredient definitions; and

(2) updated standards for the labeling of pet food that includes nutritional information and ingredient information.

(b) EARLY WARNING SURVEILLANCE SYSTEMS AND NOTIFICATION DURING PET FOOD RECALLS.—Not later than 180 days after the date of enactment of this Act, the Secretary shall by regulation establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food. In establishing such system, the Secretary shall—

(1) use surveillance and monitoring mechanisms similar to, or in coordination with, those mechanisms used by the Centers for Disease Control and Prevention to monitor human health, such as the Foodborne Diseases Active Surveillance Network (FoodNet) and PulseNet;

(2) consult with relevant professional associations and private sector veterinary hospitals; and

(3) work with the Health Alert Network and other notification networks to inform veterinarians and relevant stakeholders during any recall of pet food.

SEC. 603. ENSURING EFFICIENT AND EFFECTIVE COMMUNICATIONS DURING A RECALL.

The Secretary shall, during an ongoing recall of human or pet food—

(1) work with companies, relevant professional associations, and other organizations to collect and aggregate information pertaining to the recall;

(2) use existing networks of communication including electronic forms of information dissemination to enhance the quality and speed of communication with the public; and

(3) post information regarding recalled products on the Internet website of the Food and Drug Administration in a consolidated, searchable form that is easily accessed and understood by the public.

SEC. 604. STATE AND FEDERAL COOPERATION.

(a) IN GENERAL.—The Secretary shall work with the States in undertaking activities and programs that assist in improving the safety of fresh and processed produce so that State food safety programs involving the safety of fresh and processed produce and activities conducted

by the Secretaries function in a coordinated and cost-effective manner. With the assistance provided under subsection (b), the Secretary shall encourage States to—

(1) establish, continue, or strengthen State food safety programs, especially with respect to the regulation of retail commercial food establishments; and

(2) establish procedures and requirements for ensuring that processed produce under the jurisdiction of the State food safety programs is not unsafe for human consumption.

(b) ASSISTANCE.—The Secretary may provide to a State, for planning, developing, and implementing such a food safety program—

(1) advisory assistance;

(2) technical assistance, training, and laboratory assistance (including necessary materials and equipment); and

(3) financial and other assistance.

(c) SERVICE AGREEMENTS.—The Secretary may, under an agreement entered into with a Federal, State, or local agency, use, on a reimbursable basis or otherwise, the personnel, services, and facilities of the agency to carry out the responsibilities of the agency under this section. An agreement entered into with a State agency under this subsection may provide for training of State employees.

SEC. 605. ADULTERATED FOOD REGISTRY.

(a) FINDINGS.—Congress makes the following findings:

(1) In 1994, Congress passed the Dietary Supplement Health and Education Act (P.L. 103–417) to provide the Food and Drug Administration with the legal framework to ensure that dietary supplements are safe and properly labeled foods.

(2) In 2006, Congress passed the Dietary Supplement and Nonprescription Drug Consumer Protection Act (P.L. 109–462) to establish a mandatory reporting system of serious adverse events for nonprescription drugs and dietary supplements sold and consumed in the United States.

(3) The adverse event reporting system created under the Dietary Supplement and Nonprescription Drug Consumer Protection Act will serve as the early warning system for any potential public health issues associated with the use of these food products.

(4) A reliable mechanism to track patterns of adulteration in food would support efforts by the Food and Drug Administration to effectively target limited inspection resources to protect the public health.

(b) IN GENERAL.—Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

"SEC. 417. ADULTERATED FOOD REGISTRY.

"(a) DEFINITIONS.—In this section:

"(1) IMPORTER.—The term 'importer', with respect to an article of food, means the person who submitted the notice with respect to such article of food under section 801(m).

"(2) RESPONSIBLE PARTY.—The term 'responsible party', with respect to an article of food, means any registered food facility under section 415(a), including those responsible for the manufacturing, processing, packaging or holding of such food for consumption in the United States.

"(3) REPORTABLE ADULTERATED FOOD.—The term 'reportable adulterated food' for purposes of this section means a food that is adulterated or—

"(A) presents a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death as defined in section 7.3(m)(1) of title, Code of Federal Regulations (or any successor regulations); or

''(B) meets the threshold established in section 304(h).

''(b) ESTABLISHMENT.—

''(1) IN GENERAL.—Not later than 180 days after the date of enactment of this section, the Secretary shall establish within the Food and Drug Administration an Adulterated Food Registry to which instances of reportable adulterated food may be submitted by the Food and Drug Administration after receipt of reports of adulteration, via an electronic portal, from—

''(A) Federal, State, and local public health officials;

''(B) an importer;

''(C) a responsible party; or

''(D) a consumer or other individual.

''(2) REVIEW BY SECRETARY.—The Secretary shall review and determine the validity of the information submitted under paragraph (1) for the purposes of identifying adulterated food, submitting entries to the Adulterated Food Registry, acting under subsection (c), and exercising other existing food safety authorities under the Act to protect the public health.

''(c) ISSUANCE OF AN ALERT BY THE SECRETARY.—

''(1) IN GENERAL.—The Secretary shall issue an alert with respect to an adulterated food if the Adulterated Food Registry shows that the food—

''(A) has been associated with repeated and separate outbreaks of illness or has been repeatedly determined to be adulterated; or

''(B) is a reportable adulterated food.

''(2) SCOPE OF ALERT.—An alert under paragraph (1) may apply to a particular food or to food from a particular producer, manufacturer, shipper, growing area, or country, to the extent that elements in subparagraph (A) or (B) of paragraph (1) are associated with the particular food, producer, manufacturer, shipper, growing area, or country.

''(d) SUBMISSION BY A CONSUMER OR OTHER INDIVIDUAL.—A consumer or other individual may submit a report to the Food and Drug Administration using the electronic portal data elements described in subsection (e). Such reports shall be evaluated by the Secretary as specified in subsection (b)(2).

''(e) NOTIFICATION AND REPORTING OF ADULTERATION.—

''(1) DETERMINATION BY RESPONSIBLE PARTY OR IMPORTER.—If a responsible party or importer determines that an article of food it produced, proc-

essed, manufactured, distributed, or otherwise handled is a reportable adulterated food, the responsible party shall provide the notifications described under paragraph (2).

''(2) NOTIFICATION OF ADULTERATION.—

''(A) IN GENERAL.—Not later than 5 days after a responsible party or importer receives a notification, the responsible party or importer, as applicable, shall review whether the food referenced in the report described in paragraph (1) is a reportable adulterated food.

''(B) NOTIFICATION.—If a determination is made by such responsible party or importer that the food is a reportable adulterated food, such responsible party or importer shall, no later than 2 days after such determination is made, notify other responsible parties directly linked in the supply chain to which and from which the article of reportable adulterated food was transferred.

''(3) SUBMISSION OF REPORTS TO THE FOOD AND DRUG ADMINISTRATION BY A RESPONSIBLE PARTY OR IMPORTER.—The responsible party or importer, as applicable, shall submit a report to the Food and Drug Administration through the elec-

tronic portal using the data elements described in subsection (f) not later than 2 days after a responsible party or importer—

''(A) makes a notification under paragraph (2)(B); or

''(B) determines that an article of food it produced, processed, manufactured, distributed, imported, or otherwise handled is a reportable adulterated food, except that if such adulteration was initiated with such responsible party or importer, was detected prior to any transfer of such article of food, and was destroyed, no report is necessary.

''(f) DATA ELEMENTS IN THE REGISTRY.—A report submitted to the Food and Drug Administration electronic portal under subsection (e) shall include the following data elements:

''(1) Contact information for the individual or entity submitting the report.

''(2) The date on which an article of food was determined to be adulterated or suspected of being adulterated.

''(3) A description of the article of food including the quantity or amount.

''(4) The extent and nature of the adulteration.

''(5) The disposition of the article.

''(6) Product information typically found on packaging including product codes, use by dates, and names of manufactures or distributors.

''(7) Information about the place of purchase or process by which the consumer or other individual acquired the article of adulterated food.

''(8) In the case of a responsible party or an importer, the elements required for the registration of food facilities under section 415(a).

''(9) The contact information for parties directly linked in the supply chain and notified under subsection (e)(2).

''(10) In the case of an importer, the elements required for the prior notice of imported food shipments under section 801(m).

''(g) MAINTENANCE AND INSPECTION OF RECORDS.—The responsible person or importer shall maintain records related to each report received, notification made, and report submitted to the Food and Drug Administration under this section and permit inspection of such records as provided for in section 414. Such records shall also be made available during an inspection under section 704.

''(h) REQUEST FOR INFORMATION.—Section 552 of title 5, United States Code, shall apply to any request for information regarding a record in the Adulterated Food Registry.

''(i) HOMELAND SECURITY NOTIFICATION.—If, after receiving a report under subsection (e), the Secretary suspects such food may have been deliberately adulterated, the Secretary shall immediately notify the Secretary of Homeland Security. The Secretary shall make the data in the Adulterated Imported Food Registry available to the Secretary of Homeland Security.''.

(c) DEFINITION.—Section 201(ff) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff)) is amended by striking ''section 201(g)'' and inserting ''sections 201(g) and 417''.

(d) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by this Act, is further amended by adding at the end the following:

''(kk) The failure to provide a report as required under section 417(e)(3).

''(ll) The falsification a report as required under section 417(e)(3).''.

(e) SUSPECTED FOOD ADULTERATION REGULATIONS.—The Secretary shall, within 180 days of enact-

ment of this Act, promulgate regulations that establish standards and thresholds by which importers and responsible parties shall be required and consumers may be able to, under section 417 of the Federal Food, Drug, and Cosmetic Act (as added by this section)—

(1) report instances of suspected reportable adulteration of food to the Food and Drug Administration for possible inclusion in the Adulterated Food Registry after evaluation of such report; and

(2) notify, in keeping with subsection (e)(2) of such section 417, other responsible parties directly linked in the supply chain, including establishments as defined in section 415(b) of such Act.

(f) EFFECTIVE DATE.—The requirements of section 417(e) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall become effective 180 days after the date of enactment of this Act.

SEC. 606. SENSE OF THE SENATE.

It is the sense of the Senate that—

(1) it is vital for Congress to provide the Food and Drug Administration with additional resources, authorities, and direction with respect to ensuring the safety of the food supply of the United States;

(2) additional inspectors are required to improve the Food and Drug Administration's ability to safeguard the food supply of the United States;

(3) because of the increasing volume of international trade in food products the Secretary of Health and Human Services should make it a priority to enter into agreements with the trading partners of the United States with respect to food safety; and

(4) the Senate should work to develop a comprehensive response to the issue of food safety.

SEC. 607. ANNUAL REPORT TO CONGRESS.

The Secretary shall, on an annual basis, submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report that includes, with respect to the preceding 1-year period—

(1) the number and amount of food products regulated by the Food and Drug Administration imported into the United States, aggregated by country and type of food;

(2) a listing of the number of Food and Drug Administration inspectors of imported food products

referenced in paragraph (1) and the number of Food and Drug Administration inspections performed on such products; and

(3) aggregated data on the findings of such inspections, including data related to violations of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 et seq.), and enforcement actions used to follow-up on such findings and violations.

SEC. 608. RULE OF CONSTRUCTION.

Nothing in this title (or an amendment made by this title) shall be construed to affect—

(1) the regulation of dietary supplements under the Dietary Supplement Health and Education Act; or

(2) the adverse event reporting system for dietary supplements created under the Dietary Supplement and Nonprescription Drug Consumer Protection Act.

SEC. 609. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to carry out this title (and the amendments made by this title) such sums as may be necessary.

TITLE VII—DOMESTIC PET TURTLE MARKET ACCESS

SEC. 701. SHORT TITLE.

This title may be cited as the ''Domestic Pet Turtle Market Access Act of 2007''.

SEC. 702. FINDINGS.

Congress makes the following findings:

(1) Pet turtles less than 10.2 centimeters in diameter have been banned for sale in the United States by the Food and Drug Administration since 1975 due to health concerns.

(2) The Food and Drug Administration does not ban the sale of iguanas or other lizards, snakes, frogs, or other amphibians or reptiles that are sold as pets in the United States that also carry salmonella bacteria. The Food and Drug Administration also does not require that these animals be treated for salmonella bacteria before being sold as pets.

(3) The technology to treat turtles for salmonella, and make them safe for sale, has greatly advanced since 1975. Treatments exist that can nearly eradicate salmonella from turtles, and individuals are more aware of the causes of salmonella, how

to treat salmonella poisoning, and the seriousness associated with salmonella poisoning.

(4) University research has shown that these turtles can be treated in such a way that they can be raised, shipped, and distributed without having a recolonization of salmonella.

(5) University research has also shown that pet owners can be equipped with a treatment regiment that allows the turtle to be maintained safe from salmonella.

(6) The Food and Drug Administration should allow the sale of turtles less than 10.2 centimeters in diameter as pets as long as the sellers are required to use proven methods to treat these turtles for salmonella.

SEC. 703. SALE OF BABY TURTLES.

Notwithstanding any other provision of law, the Food and Drug Administration shall not restrict the sale by a turtle farmer, wholesaler, or commercial retail seller of a turtle that is less than 10.2 centimeters in diameter as a pet if—

(1) the State or territory in which such farmer is located has developed a regulatory process by which pet turtle farmers are required to have a State license to breed, hatch, propagate, raise, grow,

receive, ship, transport, export, or sell pet turtles or pet turtle eggs;

(2) such State or territory requires certification of sanitization that is signed by a veterinarian who is licensed in the State or territory, and approved by the State or territory agency in charge of regulating the sale of pet turtles;

(3) the certification of sanitization requires each turtle to be sanitized or treated for diseases, including salmonella, and is dependant upon using the Siebeling method, or other such proven non-antibiotic method, to make the turtle salmonella-free; and

(4) the turtle farmer or commercial retail seller includes, with the sale of such a turtle, a disclosure to the buyer that includes—

(A) information regarding—

(i) the possibility that salmonella can re-colonize in turtles;

(ii) the dangers, including possible severe illness or death, especially for at-risk people who may be susceptible to salmonella poisoning, such as children, pregnant women, and others who may have weak immune systems, that could result if

the turtle is not properly handled and safely maintained;

(iii) the proper handling of the turtle, including an explanation of proper hygiene such as handwashing after handling a turtle; and

(iv) the proven methods of treatment that, if properly applied, keep the turtle safe from salmonella;

(B) a detailed explanation of how to properly treat the turtle to keep it safe from salmonella, using the proven methods of treatment referred to under subparagraph (A), and how the buyer can continue to purchase the tools, treatments, or any other required item to continually treat the turtle; and

(C) a statement that buyers of pet turtles should not abandon the turtle or abandon it outside, as the turtle may become an invasive species to the local community, but should instead return them to a commercial retail pet seller or other organization that would accept turtles no longer wanted as pets.

SEC. 704. FDA REVIEW OF STATE PROTECTIONS.

The Commissioner of Food and Drugs may, after providing an opportunity for the affected State to respond, restrict the sale of a turtle only if the Secretary of Health and Human Services determines that the actual implementation of State health protections described in this title are insufficient to protect consumers against infectious diseases acquired from such turtle at the time of sale.

TITLE VIII—IMPORTATION OF PRESCRIPTION DRUGS

SEC. 801. SHORT TITLE.

This title may be cited as the ''Pharmaceutical Market Access and Drug Safety Act of 2007''.

SEC. 802. FINDINGS.

Congress finds that—

(1) Americans unjustly pay up to 5 times more to fill their prescriptions than consumers in other countries;

(2) the United States is the largest market for pharmaceuticals in the world, yet American consumers pay the highest prices for brand pharmaceuticals in the world;

(3) a prescription drug is neither safe nor effective to an individual who cannot afford it;

(4) allowing and structuring the importation of prescription drugs to ensure access to safe and af-

fordable drugs approved by the Food and Drug Administration will provide a level of safety to American consumers that they do not currently enjoy;

(5) American spend more than $200,000,000,000 on prescription drugs every year;

(6) the Congressional Budget Office has found that the cost of prescription drugs are between 35 to 55 percent less in other highly-developed countries than in the United States; and

(7) promoting competitive market pricing would both contribute to health care savings and allow greater access to therapy, improving health and saving lives.

SEC. 803. REPEAL OF CERTAIN SECTION REGARDING IMPORTATION OF PRESCRIPTION DRUGS.

Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by striking section 804.

SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS; WAIVER OF CERTAIN IMPORT RESTRICTIONS.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.), as amended by section 803, is further amended by inserting after section 803 the following:

"SEC. 804. COMMERCIAL AND PERSONAL IMPORTATION OF PRESCRIPTION DRUGS.

''(a) IMPORTATION OF PRESCRIPTION DRUGS.—

''(1) IN GENERAL.—In the case of qualifying drugs imported or offered for import into the United States from registered exporters or by registered importers—

''(A) the limitation on importation that is established in section 801(d)(1) is waived; and

''(B) the standards referred to in section 801(a) regarding admission of the drugs are subject to subsection (g) of this section (including with respect to qualifying drugs to which section 801(d)(1) does not apply).

''(2) IMPORTERS.—A qualifying drug may not be imported under paragraph (1) unless—

''(A) the drug is imported by a pharmacy, group of pharmacies, or a wholesaler that is a registered importer; or

''(B) the drug is imported by an individual for personal use or for the use of a family member of the individual (not for resale) from a registered exporter.

''(3) RULE OF CONSTRUCTION.—This section shall apply only with respect to a drug that is im-

ported or offered for import into the United States—

"(A) by a registered importer; or

"(B) from a registered exporter to an individual.

"(4) DEFINITIONS.—

"(A) REGISTERED EXPORTER; REGISTERED IMPORTER.—For purposes of this section:

"(i) The term 'registered exporter' means an exporter for which a registration under subsection (b) has been approved and is in effect.

"(ii) The term 'registered importer' means a pharmacy, group of pharmacies, or a wholesaler for which a registration under subsection (b) has been approved and is in effect.

"(iii) The term 'registration condition' means a condition that must exist for a registration under subsection (b) to be approved.

"(B) QUALIFYING DRUG.—For purposes of this section, the term 'qualifying drug' means a

drug for which there is a corresponding U.S. label drug.

''(C) U.S. LABEL DRUG.—For purposes of this section, the term 'U.S. label drug' means a prescription drug that—

''(i) with respect to a qualifying drug, has the same active ingredient or ingredients, route of administration, dosage form, and strength as the qualifying drug;

''(ii) with respect to the qualifying drug, is manufactured by or for the person that manufactures the qualifying drug;

''(iii) is approved under section 505(c); and

''(iv) is not—

''(I) a controlled substance, as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802);

''(II) a biological product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262), including—

''(aa) a therapeutic DNA plasmid product;

''(bb) a therapeutic synthetic peptide product;

''(cc) a monoclonal antibody product for in vivo use; and

''(dd) a therapeutic recombinant DNA-derived product;

''(III) an infused drug, including a peritoneal dialysis solution;

''(IV) an injected drug;

''(V) a drug that is inhaled during surgery;

''(VI) a drug that is the listed drug referred to in 2 or more abbreviated new drug applications under which the drug is commercially marketed; or

''(VII) a sterile opthlamic drug intended for topical use on or in the eye.

''(D) OTHER DEFINITIONS.—For purposes of this section:

''(i)(I) The term 'exporter' means a person that is in the business of exporting a drug to individuals in the United States from Canada or from a permitted country

designated by the Secretary under subclause (II), or that, pursuant to submitting a registration under subsection (b), seeks to be in such business.

''(II) The Secretary shall designate a permitted country under subparagraph (E) (other than Canada) as a country from which an exporter may export a drug to individuals in the United States if the Secretary determines that—

''(aa) the country has statutory or regulatory standards that are equivalent to the standards in the United States and Canada with respect to—

''(AA) the training of pharmacists;

''(BB) the practice of pharmacy; and

''(CC) the protection of the privacy of personal medical information; and

''(bb) the importation of drugs to individuals in the United States from

the country will not adversely affect public health.

''(ii) The term 'importer' means a pharmacy, a group of pharmacies, or a wholesaler that is in the business of importing a drug into the United States or that, pursuant to submitting a registration under subsection (b), seeks to be in such business.

''(iii) The term 'pharmacist' means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

''(iv) The term 'pharmacy' means a person that—

''(I) is licensed by a State to engage in the business of selling prescription drugs at retail; and

''(II) employs 1 or more pharmacists.

''(v) The term 'prescription drug' means a drug that is described in section 503(b)(1).

''(vi) The term 'wholesaler'—

"(I) means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A); and

"(II) does not include a person authorized to import drugs under section 801(d)(1).

"(E) PERMITTED COUNTRY.—The term 'permitted country' means—

"(i) Australia;

"(ii) Canada;

"(iii) a member country of the European Union, but does not include a member country with respect to which—

"(I) the country's Annex to the Treaty of Accession to the European Union 2003 includes a transitional measure for the regulation of human pharmaceutical products that has not expired; or

"(II) the Secretary determines that the requirements described in subclauses (I) and (II) of clause (vii) will not be met by the date on which such transitional measure for the reg-

ulation of human pharmaceutical products expires;

''(iv) Japan;

''(v) New Zealand;

''(vi) Switzerland; and

''(vii) a country in which the Secretary determines the following requirements are met:

''(I) The country has statutory or regulatory requirements—

''(aa) that require the review of drugs for safety and effectiveness by an entity of the government of the country;

''(bb) that authorize the approval of only those drugs that have been determined to be safe and effective by experts employed by or acting on behalf of such entity and qualified by scientific training and experience to evaluate the safety and effectiveness of drugs on the basis of adequate and well-controlled investigations, including clinical investigations,

conducted by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs;

''(cc) that require the methods used in, and the facilities and controls used for the manufacture, processing, and packing of drugs in the country to be adequate to preserve their identity, quality, purity, and strength;

''(dd) for the reporting of adverse reactions to drugs and procedures to withdraw approval and remove drugs found not to be safe or effective; and

''(ee) that require the labeling and promotion of drugs to be in accordance with the approval of the drug.

''(II) The valid marketing authorization system in the country is equivalent to the systems in the countries described in clauses (i) through (vi).

''(III) The importation of drugs to the United States from the country will not adversely affect public health.

''(b) REGISTRATION OF IMPORTERS AND EXPORTERS.—

''(1) REGISTRATION OF IMPORTERS AND EXPORTERS.—A registration condition is that the importer or exporter involved (referred to in this subsection as a 'registrant') submits to the Secretary a registration containing the following:

''(A)(i) In the case of an exporter, the name of the exporter and an identification of all places of business of the exporter that relate to qualifying drugs, including each warehouse or other facility owned or controlled by, or operated for, the exporter.

''(ii) In the case of an importer, the name of the importer and an identification of the places of business of the importer at which the importer initially receives a qualifying drug after importation (which shall not exceed 3 places of business except by permission of the Secretary).

''(B) Such information as the Secretary determines to be necessary to demonstrate that

the registrant is in compliance with registration conditions under—

"(i) in the case of an importer, subsections (c), (d), (e), (g), and (j) (relating to the sources of imported qualifying drugs; the inspection of facilities of the importer; the payment of fees; compliance with the standards referred to in section 801(a); and maintenance of records and samples); or

"(ii) in the case of an exporter, subsections (c), (d), (f), (g), (h), (i), and (j) (relating to the sources of exported qualifying drugs; the inspection of facilities of the exporter and the marking of compliant shipments; the payment of fees; and compliance with the standards referred to in section 801(a); being licensed as a pharmacist; conditions for individual importation; and maintenance of records and samples).

"(C) An agreement by the registrant that the registrant will not under subsection (a) import or export any drug that is not a qualifying drug.

''(D) An agreement by the registrant to—

''(i) notify the Secretary of a recall or withdrawal of a qualifying drug distributed in a permitted country that the registrant has exported or imported, or intends to export or import, to the United States under subsection (a);

''(ii) provide for the return to the registrant of such drug; and

''(iii) cease, or not begin, the exportation or importation of such drug unless the Secretary has notified the registrant that exportation or importation of such drug may proceed.

''(E) An agreement by the registrant to ensure and monitor compliance with each registration condition, to promptly correct any noncompliance with such a condition, and to promptly report to the Secretary any such noncompliance.

''(F) A plan describing the manner in which the registrant will comply with the agreement under subparagraph (E).

''(G) An agreement by the registrant to enforce a contract under subsection (c)(3)(B)

against a party in the chain of custody of a qualifying drug with respect to the authority of the Secretary under clauses (ii) and (iii) of that subsection.

''(H) An agreement by the registrant to notify the Secretary not more than 30 days before the registrant intends to make the change, of—

''(i) any change that the registrant intends to make regarding information provided under subparagraph (A) or (B); and

''(ii) any change that the registrant intends to make in the compliance plan under subparagraph (F).

''(I) In the case of an exporter—

''(i) An agreement by the exporter that a qualifying drug will not under subsection (a) be exported to any individual not authorized pursuant to subsection (a)(2)(B) to be an importer of such drug.

''(ii) An agreement to post a bond, payable to the Treasury of the United States that is equal in value to the lesser of—

''(I) the value of drugs exported by the exporter to the United States in a typical 4-week period over the course of a year under this section; or

''(II) $1,000,000;

''(iii) An agreement by the exporter to comply with applicable provisions of Canadian law, or the law of the permitted country designated under subsection (a)(4)(D)(i)(II) in which the exporter is located, that protect the privacy of personal information with respect to each individual importing a prescription drug from the exporter under subsection (a)(2)(B).

''(iv) An agreement by the exporter to report to the Secretary—

''(I) not later than August 1 of each fiscal year, the total price and the total volume of drugs exported to the United States by the exporter during the 6-month period from January 1 through June 30 of that year; and

''(II) not later than January 1 of each fiscal year, the total price and the total volume of drugs exported to

the United States by the exporter during the previous fiscal year.

''(J) In the case of an importer, an agreement by the importer to report to the Secretary—

''(i) not later than August 1 of each fiscal year, the total price and the total volume of drugs imported to the United States by the importer during the 6-month period from January 1 through June 30 of that fiscal year; and

''(ii) not later than January 1 of each fiscal year, the total price and the total volume of drugs imported to the United States by the importer during the previous fiscal year.

''(K) Such other provisions as the Secretary may require by regulation to protect the public health while permitting—

''(i) the importation by pharmacies, groups of pharmacies, and wholesalers as registered importers of qualifying drugs under subsection (a); and

''(ii) importation by individuals of qualifying drugs under subsection (a).

''(2) APPROVAL OR DISAPPROVAL OF REGISTRATION.—

''(A) IN GENERAL.—Not later than 90 days after the date on which a registrant submits to the Secretary a registration under paragraph (1), the Secretary shall notify the registrant whether the registration is approved or is disapproved. The Secretary shall disapprove a registration if there is reason to believe that the registrant is not in compliance with one or more registration conditions, and shall notify the registrant of such reason. In the case of a disapproved registration, the Secretary shall subsequently notify the registrant that the registration is approved if the Secretary determines that the registrant is in compliance with such conditions.

''(B) CHANGES IN REGISTRATION INFORMATION.—Not later than 30 days after receiving a notice under paragraph (1)(H) from a registrant, the Secretary shall determine whether the change involved affects the approval of the registration of the registrant under paragraph (1), and shall inform the registrant of the determination.

''(3) PUBLICATION OF CONTACT INFORMATION FOR REGISTERED EXPORTERS.—Through the Internet website of the Food and Drug Administration and a toll-free telephone number, the Secretary shall make readily available to the public a list of registered exporters, including contact information for the exporters. Promptly after the approval of a registration submitted under paragraph (1), the Secretary shall update the Internet website and the information provided through the toll-free telephone number accordingly.

''(4) SUSPENSION AND TERMINATION.—

''(A) SUSPENSION.—With respect to the effectiveness of a registration submitted under paragraph (1):

''(i) Subject to clause (ii), the Secretary may suspend the registration if the Secretary determines, after notice and opportunity for a hearing, that the registrant has failed to maintain substantial compliance with a registration condition.

''(ii) If the Secretary determines that, under color of the registration, the exporter has exported a drug or the importer has imported a drug that is not a quali-

fying drug, or a drug that does not comply with subsection (g)(2)(A) or (g)(4), or has exported a qualifying drug to an individual in violation of subsection (i)(2)(F), the Secretary shall immediately suspend the registration. A suspension under the preceding sentence is not subject to the provision by the Secretary of prior notice, and the Secretary shall provide to the registrant an opportunity for a hearing not later than 10 days after the date on which the registration is suspended.

''(iii) The Secretary may reinstate the registration, whether suspended under clause (i) or (ii), if the Secretary determines that the registrant has demonstrated that further violations of registration conditions will not occur.

''(B) TERMINATION.—The Secretary, after notice and opportunity for a hearing, may terminate the registration under paragraph (1) of a registrant if the Secretary determines that the registrant has engaged in a pattern or practice of violating 1 or more registration conditions, or if on 1 or more occasions the Secretary

has under subparagraph (A)(ii) suspended the registration of the registrant. The Secretary may make the termination permanent, or for a fixed period of not less than 1 year. During the period in which the registration is terminated, any registration submitted under paragraph (1) by the registrant, or a person that is a partner in the export or import enterprise, or a principal officer in such enterprise, and any registration prepared with the assistance of the registrant or such a person, has no legal effect under this section.

''(5) DEFAULT OF BOND.—A bond required to be posted by an exporter under paragraph (1)(I)(ii) shall be defaulted and paid to the Treasury of the United States if, after opportunity for an informal hearing, the Secretary determines that the exporter has—

''(A) exported a drug to the United States that is not a qualifying drug or that is not in compliance with subsection (g)(2)(A), (g)(4), or (i); or

''(B) failed to permit the Secretary to conduct an inspection described under subsection (d).

''(c) SOURCES OF QUALIFYING DRUGS.—A registration condition is that the exporter or importer involved agrees that a qualifying drug will under subsection (a) be exported or imported into the United States only if there is compliance with the following:

''(1) The drug was manufactured in an establishment—

''(A) required to register under subsection (h) or (i) of section 510; and

''(B)(i) inspected by the Secretary; or

''(ii) for which the Secretary has elected to rely on a satisfactory report of a good manufacturing practice inspection of the establishment from a permitted country whose regulatory system the Secretary recognizes as equivalent under a mutual recognition agreement, as provided for under section 510(i)(3), section 803, or part 26 of title 21, Code of Federal Regulations (or any corresponding successor rule or regulation).

''(2) The establishment is located in any country, and the establishment manufactured the drug for distribution in the United States or for distribution in 1 or more of the permitted countries (without regard to whether in addition the drug is manufac-

tured for distribution in a foreign country that is not a permitted country).

''(3) The exporter or importer obtained the drug—

''(A) directly from the establishment; or

''(B) directly from an entity that, by contract with the exporter or importer—

''(i) provides to the exporter or importer a statement (in such form and containing such information as the Secretary may require) that, for the chain of custody from the establishment, identifies each prior sale, purchase, or trade of the drug (including the date of the transaction and the names and addresses of all parties to the transaction);

''(ii) agrees to permit the Secretary to inspect such statements and related records to determine their accuracy;

''(iii) agrees, with respect to the qualifying drugs involved, to permit the Secretary to inspect warehouses and other facilities, including records, of the entity for purposes of determining whether the facilities are in compliance with any standards

under this Act that are applicable to facilities of that type in the United States; and

''(iv) has ensured, through such contractual relationships as may be necessary, that the Secretary has the same authority regarding other parties in the chain of custody from the establishment that the Secretary has under clauses (ii) and (iii) regarding such entity.

''(4)(A) The foreign country from which the importer will import the drug is a permitted country; or

''(B) The foreign country from which the exporter will export the drug is the permitted country in which the exporter is located.

''(5) During any period in which the drug was not in the control of the manufacturer of the drug, the drug did not enter any country that is not a permitted country.

''(6) The exporter or importer retains a sample of each lot of the drug for testing by the Secretary.

''(d) INSPECTION OF FACILITIES; MARKING OF SHIPMENTS.—

''(1) INSPECTION OF FACILITIES.—A registration condition is that, for the purpose of assisting

the Secretary in determining whether the exporter involved is in compliance with all other registration conditions—

''(A) the exporter agrees to permit the Secretary—

''(i) to conduct onsite inspections, including monitoring on a day-to-day basis, of places of business of the exporter that relate to qualifying drugs, including each warehouse or other facility owned or controlled by, or operated for, the exporter;

''(ii) to have access, including on a day-to-day basis, to—

''(I) records of the exporter that relate to the export of such drugs, including financial records; and

''(II) samples of such drugs;

''(iii) to carry out the duties described in paragraph (3); and

''(iv) to carry out any other functions determined by the Secretary to be necessary regarding the compliance of the exporter; and

''(B) the Secretary has assigned 1 or more employees of the Secretary to carry out the

functions described in this subsection for the Secretary randomly, but not less than 12 times annually, on the premises of places of businesses referred to in subparagraph (A)(i), and such an assignment remains in effect on a continuous basis.

''(2) MARKING OF COMPLIANT SHIPMENTS.—A registration condition is that the exporter involved agrees to affix to each shipping container of qualifying drugs exported under subsection (a) such markings as the Secretary determines to be necessary to identify the shipment as being in compliance with all registration conditions. Markings under the preceding sentence shall—

''(A) be designed to prevent affixation of the markings to any shipping container that is not authorized to bear the markings; and

''(B) include anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies.

''(3) CERTAIN DUTIES RELATING TO EXPORTERS.—Duties of the Secretary with respect to an exporter include the following:

''(A) Inspecting, randomly, but not less than 12 times annually, the places of business of the exporter at which qualifying drugs are stored and from which qualifying drugs are shipped.

''(B) During the inspections under subparagraph (A), verifying the chain of custody of a statistically significant sample of qualifying drugs from the establishment in which the drug was manufactured to the exporter, which shall be accomplished or supplemented by the use of anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies, except that a drug that lacks such technologies from the point of manufacture shall not for that reason be excluded from importation by an exporter.

''(C) Randomly reviewing records of exports to individuals for the purpose of determining whether the drugs are being imported by the individuals in accordance with the conditions under subsection (i). Such reviews shall be conducted in a manner that will result in a sta-

tistically significant determination of compliance with all such conditions.

''(D) Monitoring the affixing of markings under paragraph (2).

''(E) Inspecting as the Secretary determines is necessary the warehouses and other facilities, including records, of other parties in the chain of custody of qualifying drugs.

''(F) Determining whether the exporter is in compliance with all other registration conditions.

''(4) PRIOR NOTICE OF SHIPMENTS.—A registration condition is that, not less than 8 hours and not more than 5 days in advance of the time of the importation of a shipment of qualifying drugs, the importer involved agrees to submit to the Secretary a notice with respect to the shipment of drugs to be imported or offered for import into the United States under subsection (a). A notice under the preceding sentence shall include—

''(A) the name and complete contact information of the person submitting the notice;

''(B) the name and complete contact information of the importer involved;

''(C) the identity of the drug, including the established name of the drug, the quantity of the drug, and the lot number assigned by the manufacturer;

''(D) the identity of the manufacturer of the drug, including the identity of the establishment at which the drug was manufactured;

''(E) the country from which the drug is shipped;

''(F) the name and complete contact information for the shipper of the drug;

''(G) anticipated arrival information, including the port of arrival and crossing location within that port, and the date and time;

''(H) a summary of the chain of custody of the drug from the establishment in which the drug was manufactured to the importer;

''(I) a declaration as to whether the Secretary has ordered that importation of the drug from the permitted country cease under subsection (g)(2)(C) or (D); and

''(J) such other information as the Secretary may require by regulation.

''(5) MARKING OF COMPLIANT SHIPMENTS.—A registration condition is that the importer involved

agrees, before wholesale distribution (as defined in section 503(e)) of a qualifying drug that has been imported under subsection (a), to affix to each container of such drug such markings or other technology as the Secretary determines necessary to identify the shipment as being in compliance with all registration conditions, except that the markings or other technology shall not be required on a drug that bears comparable, compatible markings or technology from the manufacturer of the drug. Markings or other technology under the preceding sentence shall—

''(A) be designed to prevent affixation of the markings or other technology to any container that is not authorized to bear the markings; and

''(B) shall include anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of such technologies.

''(6) CERTAIN DUTIES RELATING TO IMPORTERS.—Duties of the Secretary with respect to an importer include the following:

''(A) Inspecting, randomly, but not less than 12 times annually, the places of business

of the importer at which a qualifying drug is initially received after importation.

''(B) During the inspections under subparagraph (A), verifying the chain of custody of a statistically significant sample of qualifying drugs from the establishment in which the drug was manufactured to the importer, which shall be accomplished or supplemented by the use of anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies, except that a drug that lacks such technologies from the point of manufacture shall not for that reason be excluded from importation by an importer.

''(C) Reviewing notices under paragraph (4).

''(D) Inspecting as the Secretary determines is necessary the warehouses and other facilities, including records of other parties in the chain of custody of qualifying drugs.

''(E) Determining whether the importer is in compliance with all other registration conditions.

''(e) IMPORTER FEES.—

''(1) REGISTRATION FEE.—A registration condition is that the importer involved pays to the Secretary a fee of $10,000 due on the date on which the importer first submits the registration to the Secretary under subsection (b).

''(2) INSPECTION FEE.—A registration condition is that the importer involved pays a fee to the Secretary in accordance with this subsection. Such fee shall be paid not later than October 1 and April 1 of each fiscal year in the amount provided for under paragraph (3).

''(3) AMOUNT OF INSPECTION FEE.—

''(A) AGGREGATE TOTAL OF FEES.—Not later than 30 days before the start of each fiscal year, the Secretary, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, shall establish an aggregate total of fees to be collected under paragraph (2) for importers for that fiscal year that is sufficient, and not more than necessary, to pay the costs for that fiscal year of administering this section with respect to registered importers, including the costs associated with—

''(i) inspecting the facilities of registered importers, and of other entities in

the chain of custody of a qualifying drug as necessary, under subsection (d)(6);

''(ii) developing, implementing, and operating under such subsection an electronic system for submission and review of the notices required under subsection (d)(4) with respect to shipments of qualifying drugs under subsection (a) to assess compliance with all registration conditions when such shipments are offered for import into the United States; and

''(iii) inspecting such shipments as necessary, when offered for import into the United States to determine if such a shipment should be refused admission under subsection (g)(5).

''(B) LIMITATION.—Subject to subparagraph (C), the aggregate total of fees collected under paragraph (2) for a fiscal year shall not exceed 2.5 percent of the total price of qualifying drugs imported during that fiscal year into the United States by registered importers under subsection (a).

''(C) TOTAL PRICE OF DRUGS.—

"(i) ESTIMATE.—For the purposes of complying with the limitation described in subparagraph (B) when establishing under subparagraph (A) the aggregate total of fees to be collected under paragraph (2) for a fiscal year, the Secretary shall estimate the total price of qualifying drugs imported into the United States by registered importers during that fiscal year by adding the total price of qualifying drugs imported by each registered importer during the 6-month period from January 1 through June 30 of the previous fiscal year, as reported to the Secretary by each registered importer under subsection (b)(1)(J).

"(ii) CALCULATION.—Not later than March 1 of the fiscal year that follows the fiscal year for which the estimate under clause (i) is made, the Secretary shall calculate the total price of qualifying drugs imported into the United States by registered importers during that fiscal year by adding the total price of qualifying drugs imported by each registered importer during that fiscal year, as reported to the Sec-

retary by each registered importer under subsection (b)(1)(J).

''(iii) ADJUSTMENT.—If the total price of qualifying drugs imported into the United States by registered importers during a fiscal year as calculated under clause (ii) is less than the aggregate total of fees collected under paragraph (2) for that fiscal year, the Secretary shall provide for a pro-rata reduction in the fee due from each registered importer on April 1 of the subsequent fiscal year so that the limitation described in subparagraph (B) is observed.

''(D) INDIVIDUAL IMPORTER FEE.—Subject to the limitation described in subparagraph (B), the fee under paragraph (2) to be paid on October 1 and April 1 by an importer shall be an amount that is proportional to a reasonable estimate by the Secretary of the semiannual share of the importer of the volume of qualifying drugs imported by importers under subsection (a).

''(4) USE OF FEES.—

''(A) IN GENERAL.—Subject to appropriations Acts, fees collected by the Secretary under

paragraphs (1) and (2) shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration until expended (without fiscal year limitation), and the Secretary may, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, transfer some proportion of such fees to the appropriation account for salaries and expenses of the Bureau of Customs and Border Protection until expended (without fiscal year limitation).

''(B) SOLE PURPOSE.—Fees collected by the Secretary under paragraphs (1) and (2) are only available to the Secretary and, if transferred, to the Secretary of Homeland Security, and are for the sole purpose of paying the costs referred to in paragraph (3)(A).

''(5) COLLECTION OF FEES.—In any case where the Secretary does not receive payment of a fee assessed under paragraph (1) or (2) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(f) EXPORTER FEES.—

''(1) REGISTRATION FEE.—A registration condition is that the exporter involved pays to the Secretary a fee of $10,000 due on the date on which the exporter first submits that registration to the Secretary under subsection (b).

''(2) INSPECTION FEE.—A registration condition is that the exporter involved pays a fee to the Secretary in accordance with this subsection. Such fee shall be paid not later than October 1 and April 1 of each fiscal year in the amount provided for under paragraph (3).

''(3) AMOUNT OF INSPECTION FEE.—

''(A) AGGREGATE TOTAL OF FEES.—Not later than 30 days before the start of each fiscal year, the Secretary, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, shall establish an aggregate total of fees to be collected under paragraph (2) for exporters for that fiscal year that is sufficient, and not more than necessary, to pay the costs for that fiscal year of administering this section with respect to registered exporters, including the costs associated with—

''(i) inspecting the facilities of registered exporters, and of other entities in

the chain of custody of a qualifying drug as necessary, under subsection (d)(3);

''(ii) developing, implementing, and operating under such subsection a system to screen marks on shipments of qualifying drugs under subsection (a) that indicate compliance with all registration conditions, when such shipments are offered for import into the United States; and

''(iii) screening such markings, and inspecting such shipments as necessary, when offered for import into the United States to determine if such a shipment should be refused admission under subsection (g)(5).

''(B) LIMITATION.—Subject to subparagraph (C), the aggregate total of fees collected under paragraph (2) for a fiscal year shall not exceed 2.5 percent of the total price of qualifying drugs imported during that fiscal year into the United States by registered exporters under subsection (a).

''(C) TOTAL PRICE OF DRUGS.—

''(i) ESTIMATE.—For the purposes of complying with the limitation described in

subparagraph (B) when establishing under subparagraph (A) the aggregate total of fees to be collected under paragraph (2) for a fiscal year, the Secretary shall estimate the total price of qualifying drugs imported into the United States by registered exporters during that fiscal year by adding the total price of qualifying drugs exported by each registered exporter during the 6-month period from January 1 through June 30 of the previous fiscal year, as reported to the Secretary by each registered exporter under subsection (b)(1)(I)(iv).

''(ii) CALCULATION.—Not later than March 1 of the fiscal year that follows the fiscal year for which the estimate under clause (i) is made, the Secretary shall calculate the total price of qualifying drugs imported into the United States by registered exporters during that fiscal year by adding the total price of qualifying drugs exported by each registered exporter during that fiscal year, as reported to the Secretary by each registered exporter under subsection (b)(1)(I)(iv).

"(iii) ADJUSTMENT.—If the total price of qualifying drugs imported into the United States by registered exporters during a fiscal year as calculated under clause (ii) is less than the aggregate total of fees collected under paragraph (2) for that fiscal year, the Secretary shall provide for a pro-rata reduction in the fee due from each registered exporter on April 1 of the subsequent fiscal year so that the limitation described in subparagraph (B) is observed.

"(D) INDIVIDUAL EXPORTER FEE.—Subject to the limitation described in subparagraph (B), the fee under paragraph (2) to be paid on October 1 and April 1 by an exporter shall be an amount that is proportional to a reasonable estimate by the Secretary of the semiannual share of the exporter of the volume of qualifying drugs exported by exporters under subsection (a).

"(4) USE OF FEES.—

"(A) IN GENERAL.—Subject to appropriations Acts, fees collected by the Secretary under paragraphs (1) and (2) shall be credited to the appropriation account for salaries and expenses

of the Food and Drug Administration until expended (without fiscal year limitation), and the Secretary may, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, transfer some proportion of such fees to the appropriation account for salaries and expenses of the Bureau of Customs and Border Protection until expended (without fiscal year limitation).

''(B) SOLE PURPOSE.—Fees collected by the Secretary under paragraphs (1) and (2) are only available to the Secretary and, if transferred, to the Secretary of Homeland Security, and are for the sole purpose of paying the costs referred to in paragraph (3)(A).

''(5) COLLECTION OF FEES.—In any case where the Secretary does not receive payment of a fee assessed under paragraph (1) or (2) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(g) COMPLIANCE WITH SECTION 801(a).—

''(1) IN GENERAL.—A registration condition is that each qualifying drug exported under subsection

(a) by the registered exporter involved or imported under subsection (a) by the registered importer involved is in compliance with the standards referred to in section 801(a) regarding admission of the drug into the United States, subject to paragraphs (2), (3), and (4).

''(2) SECTION 505; APPROVAL STATUS.—

''(A) IN GENERAL.—A qualifying drug that is imported or offered for import under subsection (a) shall comply with the conditions established in the approved application under section 505(b) for the U.S. label drug as described under this subsection.

''(B) NOTICE BY MANUFACTURER; GENERAL PROVISIONS.—

''(i) IN GENERAL.—The person that manufactures a qualifying drug that is, or will be, introduced for commercial distribution in a permitted country shall in accordance with this paragraph submit to the Secretary a notice that—

''(I) includes each difference in the qualifying drug from a condition established in the approved application for the U.S. label drug beyond—

"(aa) the variations provided for in the application; and

"(bb) any difference in labeling (except ingredient labeling); or

"(II) states that there is no difference in the qualifying drug from a condition established in the approved application for the U.S. label drug beyond—

"(aa) the variations provided for in the application; and

"(bb) any difference in labeling (except ingredient labeling).

"(ii) INFORMATION IN NOTICE.—A notice under clause (i)(I) shall include the information that the Secretary may require under section 506A, any additional information the Secretary may require (which may include data on bioequivalence if such data are not required under section 506A), and, with respect to the permitted country that approved the qualifying drug for commercial distribution, or with respect to

which such approval is sought, include the following:

''(I) The date on which the qualifying drug with such difference was, or will be, introduced for commercial distribution in the permitted country.

''(II) Information demonstrating that the person submitting the notice has also notified the government of the permitted country in writing that the person is submitting to the Secretary a notice under clause (i)(I), which notice describes the difference in the qualifying drug from a condition established in the approved application for the U.S. label drug.

''(III) The information that the person submitted or will submit to the government of the permitted country for purposes of obtaining approval for commercial distribution of the drug in the country which, if in a language other than English, shall be accompanied by an English translation verified to be complete and accurate,

with the name, address, and a brief statement of the qualifications of the person that made the translation.

''(iii) CERTIFICATIONS.—The chief executive officer and the chief medical officer of the manufacturer involved shall each certify in the notice under clause (i) that—

''(I) the information provided in the notice is complete and true; and

''(II) a copy of the notice has been provided to the Federal Trade Commission and to the State attorneys general.

''(iv) FEE.—If a notice submitted under clause (i) includes a difference that would, under section 506A, require the submission of a supplemental application if made as a change to the U.S. label drug, the person that submits the notice shall pay to the Secretary a fee in the same amount as would apply if the person were paying a fee pursuant to section 736(a)(1)(A)(ii). Subject to appropriations Acts, fees collected by the Secretary under the preceding sentence are available only to

the Secretary and are for the sole purpose of paying the costs of reviewing notices submitted under clause (i).

''(v) TIMING OF SUBMISSION OF NOTICES.—

''(I) PRIOR APPROVAL NOTICES.—A notice under clause (i) to which subparagraph (C) applies shall be submitted to the Secretary not later than 120 days before the qualifying drug with the difference is introduced for commercial distribution in a permitted country, unless the country requires that distribution of the qualifying drug with the difference begin less than 120 days after the country requires the difference.

''(II) OTHER APPROVAL NOTICES.—A notice under clause (i) to which subparagraph (D) applies shall be submitted to the Secretary not later than the day on which the qualifying drug with the difference is introduced for commercial distribution in a permitted country.

''(III) OTHER NOTICES.—A notice under clause (i) to which subparagraph (E) applies shall be submitted to the Secretary on the date that the qualifying drug is first introduced for commercial distribution in a permitted country and annually thereafter.

''(vi) REVIEW BY SECRETARY.—

''(I) IN GENERAL.—In this paragraph, the difference in a qualifying drug that is submitted in a notice under clause (i) from the U.S. label drug shall be treated by the Secretary as if it were a manufacturing change to the U.S. label drug under section 506A.

''(II) STANDARD OF REVIEW.—Except as provided in subclause (III), the Secretary shall review and approve or disapprove the difference in a notice submitted under clause (i), if required under section 506A, using the safe and effective standard for approving or disapproving a manufacturing change under section 506A.

''(III) BIOEQUIVALENCE.—If the Secretary would approve the difference in a notice submitted under clause (i) using the safe and effective standard under section 506A and if the Secretary determines that the qualifying drug is not bioequivalent to the U.S. label drug, the Secretary shall—

''(aa) include in the labeling provided under paragraph (3) a prominent advisory that the qualifying drug is safe and effective but is not bioequivalent to the U.S. label drug if the Secretary determines that such an advisory is necessary for health care practitioners and patients to use the qualifying drug safely and effectively; or

''(bb) decline to approve the difference if the Secretary determines that the availability of both the qualifying drug and the

U.S. label drug would pose a threat to the public health.

''(IV) REVIEW BY THE SECRETARY.—The Secretary shall review and approve or disapprove the difference in a notice submitted under clause (i), if required under section 506A, not later than 120 days after the date on which the notice is submitted.

''(V) ESTABLISHMENT INSPECTION.—If review of such difference would require an inspection of the establishment in which the qualifying drug is manufactured—

''(aa) such inspection by the Secretary shall be authorized; and

''(bb) the Secretary may rely on a satisfactory report of a good manufacturing practice inspection of the establishment from a permitted country whose regulatory system the Secretary recognizes as equivalent under a

mutual recognition agreement, as provided under section 510(i)(3), section 803, or part 26 of title 21, Code of Federal Regulations (or any corresponding successor rule or regulation).

''(vii) PUBLICATION OF INFORMATION ON NOTICES.—

''(I) IN GENERAL.—Through the Internet website of the Food and Drug Administration and a toll-free telephone number, the Secretary shall readily make available to the public a list of notices submitted under clause (i).

''(II) CONTENTS.—The list under subclause (I) shall include the date on which a notice is submitted and whether—

''(aa) a notice is under review;

''(bb) the Secretary has ordered that importation of the qualifying drug from a permitted country cease; or

''(cc) the importation of the drug is permitted under subsection (a).

''(III) UPDATE.—The Secretary shall promptly update the Internet website with any changes to the list.

''(C) NOTICE; DRUG DIFFERENCE REQUIRING PRIOR APPROVAL.—In the case of a notice under subparagraph (B)(i) that includes a difference that would, under section 506A(c) or (d)(3)(B)(i), require the approval of a supplemental application before the difference could be made to the U.S. label drug the following shall occur:

''(i) Promptly after the notice is submitted, the Secretary shall notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general that the notice has been submitted with respect to the qualifying drug involved.

''(ii) If the Secretary has not made a determination whether such a supplemental application regarding the U.S. label drug would be approved or disapproved by

the date on which the qualifying drug involved is to be introduced for commercial distribution in a permitted country, the Secretary shall—

''(I) order that the importation of the qualifying drug involved from the permitted country not begin until the Secretary completes review of the notice; and

''(II) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the order.

''(iii) If the Secretary determines that such a supplemental application regarding the U.S. label drug would not be approved, the Secretary shall—

''(I) order that the importation of the qualifying drug involved from the permitted country cease, or provide that an order under clause (ii), if any, remains in effect;

''(II) notify the permitted country that approved the qualifying drug

for commercial distribution of the determination; and

''(III) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the determination.

''(iv) If the Secretary determines that such a supplemental application regarding the U.S. label drug would be approved, the Secretary shall—

''(I) vacate the order under clause (ii), if any;

''(II) consider the difference to be a variation provided for in the approved application for the U.S. label drug;

''(III) permit importation of the qualifying drug under subsection (a); and

''(IV) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the determination.

''(D) NOTICE; DRUG DIFFERENCE NOT REQUIRING PRIOR APPROVAL.—In the case of a notice under subparagraph (B)(i) that includes a difference that would, under section 506A(d)(3)(B)(ii), not require the approval of a supplemental application before the difference could be made to the U.S. label drug the following shall occur:

''(i) During the period in which the notice is being reviewed by the Secretary, the authority under this subsection to import the qualifying drug involved continues in effect.

''(ii) If the Secretary determines that such a supplemental application regarding the U.S. label drug would not be approved, the Secretary shall—

''(I) order that the importation of the qualifying drug involved from the permitted country cease;

''(II) notify the permitted country that approved the qualifying drug for commercial distribution of the determination; and

''(III) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the determination.

''(iii) If the Secretary determines that such a supplemental application regarding the U.S. label drug would be approved, the difference shall be considered to be a variation provided for in the approved application for the U.S. label drug.

''(E) NOTICE; DRUG DIFFERENCE NOT REQUIRING APPROVAL; NO DIFFERENCE.—In the case of a notice under subparagraph (B)(i) that includes a difference for which, under section 506A(d)(1)(A), a supplemental application would not be required for the difference to be made to the U.S. label drug, or that states that there is no difference, the Secretary—

''(i) shall consider such difference to be a variation provided for in the approved application for the U.S. label drug;

''(ii) may not order that the importation of the qualifying drug involved cease; and

''(iii) shall promptly notify registered exporters and registered importers.

''(F) DIFFERENCES IN ACTIVE INGREDIENT, ROUTE OF ADMINISTRATION, DOSAGE FORM, OR STRENGTH.—

''(i) IN GENERAL.—A person who manufactures a drug approved under section 505(b) shall submit an application under section 505(b) for approval of another drug that is manufactured for distribution in a permitted country by or for the person that manufactures the drug approved under section 505(b) if—

''(I) there is no qualifying drug in commercial distribution in permitted countries whose combined population represents at least 50 percent of the total population of all permitted countries with the same active ingredient or ingredients, route of administration, dosage form, and strength as the drug approved under section 505(b); and

''(II) each active ingredient of the other drug is related to an active

ingredient of the drug approved under section 505(b), as defined in clause (v).

''(ii) APPLICATION UNDER SECTION 505(b).—The application under section 505(b) required under clause (i) shall—

''(I) request approval of the other drug for the indication or indications for which the drug approved under section 505(b) is labeled;

''(II) include the information that the person submitted to the government of the permitted country for purposes of obtaining approval for commercial distribution of the other drug in that country, which if in a language other than English, shall be accompanied by an English translation verified to be complete and accurate, with the name, address, and a brief statement of the qualifications of the person that made the translation;

''(III) include a right of reference to the application for the drug approved under section 505(b); and

''(IV) include such additional information as the Secretary may require.

''(iii) TIMING OF SUBMISSION OF APPLICATION.—An application under section 505(b) required under clause (i) shall be submitted to the Secretary not later than the day on which the information referred to in clause (ii)(II) is submitted to the government of the permitted country.

''(iv) NOTICE OF DECISION ON APPLICATION.—The Secretary shall promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of a determination to approve or to disapprove an application under section 505(b) required under clause (i).

''(v) RELATED ACTIVE INGREDIENTS.—For purposes of clause (i)(II), 2 active ingredients are related if they are—

''(I) the same; or

''(II) different salts, esters, or complexes of the same moiety.

''(3) SECTION 502; LABELING.—

''(A) IMPORTATION BY REGISTERED IMPORTER.—

''(i) IN GENERAL.—In the case of a qualifying drug that is imported or offered for import by a registered importer, such drug shall be considered to be in compliance with section 502 and the labeling requirements under the approved application for the U.S. label drug if the qualifying drug bears—

''(I) a copy of the labeling approved for the U.S. label drug under section 505, without regard to whether the copy bears any trademark involved;

''(II) the name of the manufacturer and location of the manufacturer;

''(III) the lot number assigned by the manufacturer;

''(IV) the name, location, and registration number of the importer; and

"(V) the National Drug Code number assigned to the qualifying drug by the Secretary.

"(ii) REQUEST FOR COPY OF THE LABELING.—The Secretary shall provide such copy to the registered importer involved, upon request of the importer.

"(iii) REQUESTED LABELING.—The labeling provided by the Secretary under clause (ii) shall—

"(I) include the established name, as defined in section 502(e)(3), for each active ingredient in the qualifying drug;

"(II) not include the proprietary name of the U.S. label drug or any active ingredient thereof;

"(III) if required under paragraph (2)(B)(vi)(III), a prominent advisory that the qualifying drug is safe and effective but not bioequivalent to the U.S. label drug; and

"(IV) if the inactive ingredients of the qualifying drug are different

from the inactive ingredients for the U.S. label drug, include—

"(aa) a prominent notice that the ingredients of the qualifying drug differ from the ingredients of the U.S. label drug and that the qualifying drug must be dispensed with an advisory to people with allergies about this difference and a list of ingredients; and

"(bb) a list of the ingredients of the qualifying drug as would be required under section 502(e).

"(B) IMPORTATION BY INDIVIDUAL.—

"(i) IN GENERAL.—In the case of a qualifying drug that is imported or offered for import by a registered exporter to an individual, such drug shall be considered to be in compliance with section 502 and the labeling requirements under the approved application for the U.S. label drug if the packaging and labeling of the qualifying drug complies with all applicable regula-

tions promulgated under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.) and the labeling of the qualifying drug includes—

"(I) directions for use by the consumer;

"(II) the lot number assigned by the manufacturer;

"(III) the name and registration number of the exporter;

"(IV) if required under paragraph (2)(B)(vi)(III), a prominent advisory that the drug is safe and effective but not bioequivalent to the U.S. label drug;

"(V) if the inactive ingredients of the drug are different from the inactive ingredients for the U.S. label drug—

"(aa) a prominent advisory that persons with an allergy should check the ingredient list of the drug because the ingredients of the drug differ from the

ingredients of the U.S. label drug; and

''(bb) a list of the ingredients of the drug as would be required under section 502(e); and

''(VI) a copy of any special labeling that would be required by the Secretary had the U.S. label drug been dispensed by a pharmacist in the United States, without regard to whether the special labeling bears any trademark involved.

''(ii) PACKAGING.—A qualifying drug offered for import to an individual by an exporter under this section that is packaged in a unit-of-use container (as those items are defined in the United States Pharmacopeia and National Formulary) shall not be repackaged, provided that—

''(I) the packaging complies with all applicable regulations under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.); or

''(II) the consumer consents to waive the requirements of such Act, after being informed that the packaging does not comply with such Act and that the exporter will provide the drug in packaging that is compliant at no additional cost.

''(iii) REQUEST FOR COPY OF SPECIAL LABELING AND INGREDIENT LIST.—The Secretary shall provide to the registered exporter involved a copy of the special labeling, the advisory, and the ingredient list described under clause (i), upon request of the exporter.

''(iv) REQUESTED LABELING AND INGREDIENT LIST.—The labeling and ingredient list provided by the Secretary under clause (iii) shall—

''(I) include the established name, as defined in section 502(e)(3), for each active ingredient in the drug; and

''(II) not include the proprietary name of the U.S. label drug or any active ingredient thereof.

''(4) SECTION 501; ADULTERATION.—A qualifying drug that is imported or offered for import under subsection (a) shall be considered to be in compliance with section 501 if the drug is in compliance with subsection (c).

''(5) STANDARDS FOR REFUSING ADMISSION.—A drug exported under subsection (a) from a registered exporter or imported by a registered importer may be refused admission into the United States if 1 or more of the following applies:

''(A) The drug is not a qualifying drug.

''(B) A notice for the drug required under paragraph (2)(B) has not been submitted to the Secretary.

''(C) The Secretary has ordered that importation of the drug from the permitted country cease under paragraph (2) (C) or (D).

''(D) The drug does not comply with paragraph (3) or (4).

''(E) The shipping container appears damaged in a way that may affect the strength, quality, or purity of the drug.

''(F) The Secretary becomes aware that—

''(i) the drug may be counterfeit;

''(ii) the drug may have been prepared, packed, or held under insanitary conditions; or

''(iii) the methods used in, or the facilities or controls used for, the manufacturing, processing, packing, or holding of the drug do not conform to good manufacturing practice.

''(G) The Secretary has obtained an injunction under section 302 that prohibits the distribution of the drug in interstate commerce.

''(H) The Secretary has under section 505(e) withdrawn approval of the drug.

''(I) The manufacturer of the drug has instituted a recall of the drug.

''(J) If the drug is imported or offered for import by a registered importer without submission of a notice in accordance with subsection (d)(4).

''(K) If the drug is imported or offered for import from a registered exporter to an individual and 1 or more of the following applies:

''(i) The shipping container for such drug does not bear the markings required under subsection (d)(2).

''(ii) The markings on the shipping container appear to be counterfeit.

''(iii) The shipping container or markings appear to have been tampered with.

''(h) EXPORTER LICENSURE IN PERMITTED COUNTRY.—A registration condition is that the exporter involved agrees that a qualifying drug will be exported to an individual only if the Secretary has verified that—

''(1) the exporter is authorized under the law of the permitted country in which the exporter is located to dispense prescription drugs; and

''(2) the exporter employs persons that are licensed under the law of the permitted country in which the exporter is located to dispense prescription drugs in sufficient number to dispense safely the drugs exported by the exporter to individuals, and the exporter assigns to those persons responsibility for dispensing such drugs to individuals.

''(i) INDIVIDUALS; CONDITIONS FOR IMPORTATION.—

''(1) IN GENERAL.—For purposes of subsection (a)(2)(B), the importation of a qualifying drug by an individual is in accordance with this subsection if the following conditions are met:

''(A) The drug is accompanied by a copy of a prescription for the drug, which prescription—

''(i) is valid under applicable Federal and State laws; and

''(ii) was issued by a practitioner who, under the law of a State of which the individual is a resident, or in which the individual receives care from the practitioner who issues the prescription, is authorized to administer prescription drugs.

''(B) The drug is accompanied by a copy of the documentation that was required under the law or regulations of the permitted country in which the exporter is located, as a condition of dispensing the drug to the individual.

''(C) The copies referred to in subparagraphs (A)(i) and (B) are marked in a manner sufficient—

''(i) to indicate that the prescription, and the equivalent document in the permitted country in which the exporter is located, have been filled; and

''(ii) to prevent a duplicative filling by another pharmacist.

''(D) The individual has provided to the registered exporter a complete list of all drugs used by the individual for review by the individuals who dispense the drug.

''(E) The quantity of the drug does not exceed a 90-day supply.

''(F) The drug is not an ineligible subpart H drug. For purposes of this section, a prescription drug is an 'ineligible subpart H drug' if the drug was approved by the Secretary under subpart H of part 314 of title 21, Code of Federal Regulations (relating to accelerated approval), with restrictions under section 520 of such part to assure safe use, and the Secretary has published in the Federal Register a notice that the Secretary has determined that good cause exists to prohibit the drug from being imported pursuant to this subsection.

''(2) NOTICE REGARDING DRUG REFUSED ADMISSION.—If a registered exporter ships a drug to an individual pursuant to subsection (a)(2)(B) and the drug is refused admission to the United States, a written notice shall be sent to the individual and to the exporter that informs the individual and the

exporter of such refusal and the reason for the refusal.

''(j) MAINTENANCE OF RECORDS AND SAMPLES.—

''(1) IN GENERAL.—A registration condition is that the importer or exporter involved shall—

''(A) maintain records required under this section for not less than 2 years; and

''(B) maintain samples of each lot of a qualifying drug required under this section for not more than 2 years.

''(2) PLACE OF RECORD MAINTENANCE.—The records described under paragraph (1) shall be maintained—

''(A) in the case of an importer, at the place of business of the importer at which the importer initially receives the qualifying drug after importation; or

''(B) in the case of an exporter, at the facility from which the exporter ships the qualifying drug to the United States.

''(k) DRUG RECALLS.—

''(1) MANUFACTURERS.—A person that manufactures a qualifying drug imported from a permitted country under this section shall promptly inform the Secretary—

''(A) if the drug is recalled or withdrawn from the market in a permitted country;

''(B) how the drug may be identified, including lot number; and

''(C) the reason for the recall or withdrawal.

''(2) SECRETARY.—With respect to each permitted country, the Secretary shall—

''(A) enter into an agreement with the government of the country to receive information about recalls and withdrawals of qualifying drugs in the country; or

''(B) monitor recalls and withdrawals of qualifying drugs in the country using any information that is available to the public in any media.

''(3) NOTICE.—The Secretary may notify, as appropriate, registered exporters, registered importers, wholesalers, pharmacies, or the public of a recall or withdrawal of a qualifying drug in a permitted country.

''(l) DRUG LABELING AND PACKAGING.—

''(1) IN GENERAL.—When a qualifying drug that is imported into the United States by an importer under subsection (a) is dispensed by a phar-

macist to an individual, the pharmacist shall provide that the packaging and labeling of the drug complies with all applicable regulations promulgated under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.) and shall include with any other labeling provided to the individual the following:

''(A) The lot number assigned by the manufacturer.

''(B) The name and registration number of the importer.

''(C) If required under paragraph (2)(B)(vi)(III) of subsection (g), a prominent advisory that the drug is safe and effective but not bioequivalent to the U.S. label drug.

''(D) If the inactive ingredients of the drug are different from the inactive ingredients for the U.S. label drug—

''(i) a prominent advisory that persons with allergies should check the ingredient list of the drug because the ingredients of the drug differ from the ingredients of the U.S. label drug; and

"(ii) a list of the ingredients of the drug as would be required under section 502(e).

"(2) PACKAGING.—A qualifying drug that is packaged in a unit-of-use container (as those terms are defined in the United States Pharmacopeia and National Formulary) shall not be repackaged, provided that—

"(A) the packaging complies with all applicable regulations under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.); or

"(B) the consumer consents to waive the requirements of such Act, after being informed that the packaging does not comply with such Act and that the pharmacist will provide the drug in packaging that is compliant at no additional cost.

"(m) CHARITABLE CONTRIBUTIONS.—Notwithstanding any other provision of this section, this section does not authorize the importation into the United States of a qualifying drug donated or otherwise supplied for free or at nominal cost by the manufacturer of the drug to a charitable or humanitarian organization, including the

United Nations and affiliates, or to a government of a foreign country.

''(n) UNFAIR AND DISCRIMINATORY ACTS AND PRACTICES.—

''(1) IN GENERAL.—It is unlawful for a manufacturer, directly or indirectly (including by being a party to a licensing agreement or other agreement), to—

''(A) discriminate by charging a higher price for a prescription drug sold to a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section than the price that is charged, inclusive of rebates or other incentives to the permitted country or other person, to another person that is in the same country and that does not export a qualifying drug into the United States under this section;

''(B) discriminate by charging a higher price for a prescription drug sold to a registered importer or other person that distributes, sells, or uses a qualifying drug imported into the United States under this section than the price that is charged to another person in the United States that does not import a qualifying drug

under this section, or that does not distribute, sell, or use such a drug;

''(C) discriminate by denying, restricting, or delaying supplies of a prescription drug to a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section or to a registered importer or other person that distributes, sells, or uses a qualifying drug imported into the United States under this section;

''(D) discriminate by publicly, privately, or otherwise refusing to do business with a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section or with a registered importer or other person that distributes, sells, or uses a qualifying drug imported into the United States under this section;

''(E) knowingly fail to submit a notice under subsection (g)(2)(B)(i), knowingly fail to submit such a notice on or before the date specified in subsection (g)(2)(B)(v) or as otherwise required under subsection (e) (3), (4), and (5) of section 4 of the Pharmaceutical Market Access and Drug Safety Act of 2007, knowingly

submit such a notice that makes a materially false, fictitious, or fraudulent statement, or knowingly fail to provide promptly any information requested by the Secretary to review such a notice;

''(F) knowingly fail to submit an application required under subsection (g)(2)(F), knowingly fail to submit such an application on or before the date specified in subsection (g)(2)(F)(ii), knowingly submit such an application that makes a materially false, fictitious, or fraudulent statement, or knowingly fail to provide promptly any information requested by the Secretary to review such an application;

''(G) cause there to be a difference (including a difference in active ingredient, route of administration, dosage form, strength, formulation, manufacturing establishment, manufacturing process, or person that manufactures the drug) between a prescription drug for distribution in the United States and the drug for distribution in a permitted country;

''(H) refuse to allow an inspection authorized under this section of an establishment that manufactures a qualifying drug that is, or will

be, introduced for commercial distribution in a permitted country;

''(I) fail to conform to the methods used in, or the facilities used for, the manufacturing, processing, packing, or holding of a qualifying drug that is, or will be, introduced for commercial distribution in a permitted country to good manufacturing practice under this Act;

''(J) become a party to a licensing agreement or other agreement related to a qualifying drug that fails to provide for compliance with all requirements of this section with respect to such drug;

''(K) enter into a contract that restricts, prohibits, or delays the importation of a qualifying drug under this section;

''(L) engage in any other action to restrict, prohibit, or delay the importation of a qualifying drug under this section; or

''(M) engage in any other action that the Federal Trade Commission determines to discriminate against a person that engages or attempts to engage in the importation of a qualifying drug under this section.

''(2) REFERRAL OF POTENTIAL VIOLATIONS.—The Secretary shall promptly refer to the Federal Trade Commission each potential violation of subparagraph (E), (F), (G), (H), or (I) of paragraph (1) that becomes known to the Secretary.

''(3) AFFIRMATIVE DEFENSE.—

''(A) DISCRIMINATION.—It shall be an affirmative defense to a charge that a manufacturer has discriminated under subparagraph (A), (B), (C), (D), or (M) of paragraph (1) that the higher price charged for a prescription drug sold to a person, the denial, restriction, or delay of supplies of a prescription drug to a person, the refusal to do business with a person, or other discriminatory activity against a person, is not based, in whole or in part, on—

''(i) the person exporting or importing a qualifying drug into the United States under this section; or

''(ii) the person distributing, selling, or using a qualifying drug imported into the United States under this section.

''(B) DRUG DIFFERENCES.—It shall be an affirmative defense to a charge that a manufacturer has caused there to be a difference de-

scribed in subparagraph (G) of paragraph (1) that—

''(i) the difference was required by the country in which the drug is distributed;

''(ii) the Secretary has determined that the difference was necessary to improve the safety or effectiveness of the drug;

''(iii) the person manufacturing the drug for distribution in the United States has given notice to the Secretary under subsection (g)(2)(B)(i) that the drug for distribution in the United States is not different from a drug for distribution in permitted countries whose combined population represents at least 50 percent of the total population of all permitted countries; or

''(iv) the difference was not caused, in whole or in part, for the purpose of restricting importation of the drug into the United States under this section.

''(4) EFFECT OF SUBSECTION.—

''(A) SALES IN OTHER COUNTRIES.—This subsection applies only to the sale or distribu-

tion of a prescription drug in a country if the manufacturer of the drug chooses to sell or distribute the drug in the country. Nothing in this subsection shall be construed to compel the manufacturer of a drug to distribute or sell the drug in a country.

''(B) DISCOUNTS TO INSURERS, HEALTH PLANS, PHARMACY BENEFIT MANAGERS, AND COVERED ENTITIES.—Nothing in this subsection shall be construed to—

''(i) prevent or restrict a manufacturer of a prescription drug from providing discounts to an insurer, health plan, pharmacy benefit manager in the United States, or covered entity in the drug discount program under section 340B of the Public Health Service Act (42 U.S.C. 256b) in return for inclusion of the drug on a formulary;

''(ii) require that such discounts be made available to other purchasers of the prescription drug; or

''(iii) prevent or restrict any other measures taken by an insurer, health plan,

or pharmacy benefit manager to encourage consumption of such prescription drug.

''(C) CHARITABLE CONTRIBUTIONS.—Nothing in this subsection shall be construed to—

''(i) prevent a manufacturer from donating a prescription drug, or supplying a prescription drug at nominal cost, to a charitable or humanitarian organization, including the United Nations and affiliates, or to a government of a foreign country; or

''(ii) apply to such donations or supplying of a prescription drug.

''(5) ENFORCEMENT.—

''(A) UNFAIR OR DECEPTIVE ACT OR PRACTICE.—A violation of this subsection shall be treated as a violation of a rule defining an unfair or deceptive act or practice prescribed under section 18(a)(1)(B) of the Federal Trade Commission Act (15 U.S.C. 57a(a)(1)(B)).

''(B) ACTIONS BY THE COMMISSION.—The Federal Trade Commission—

''(i) shall enforce this subsection in the same manner, by the same means, and

with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of this section; and

''(ii) may seek monetary relief threefold the damages sustained, in addition to any other remedy available to the Federal Trade Commission under the Federal Trade Commission Act (15 U.S.C. 41 et seq.).

''(6) ACTIONS BY STATES.—

''(A) IN GENERAL.—

''(i) CIVIL ACTIONS.—In any case in which the attorney general of a State has reason to believe that an interest of the residents of that State have been adversely affected by any manufacturer that violates paragraph (1), the attorney general of a State may bring a civil action on behalf of the residents of the State, and persons doing business in the State, in a district court of the United States of appropriate jurisdiction to—

''(I) enjoin that practice;

''(II) enforce compliance with this subsection;

''(III) obtain damages, restitution, or other compensation on behalf of residents of the State and persons doing business in the State, including threefold the damages; or

''(IV) obtain such other relief as the court may consider to be appropriate.

''(ii) NOTICE.—

''(I) IN GENERAL.—Before filing an action under clause (i), the attorney general of the State involved shall provide to the Federal Trade Commission—

''(aa) written notice of that action; and

''(bb) a copy of the complaint for that action.

''(II) EXEMPTION.—Subclause (I) shall not apply with respect to the filing of an action by an attorney general of a State under this paragraph,

if the attorney general determines that it is not feasible to provide the notice described in that subclause before filing of the action. In such case, the attorney general of a State shall provide notice and a copy of the complaint to the Federal Trade Commission at the same time as the attorney general files the action.

''(B) INTERVENTION.—

''(i) IN GENERAL.—On receiving notice under subparagraph (A)(ii), the Federal Trade Commission shall have the right to intervene in the action that is the subject of the notice.

''(ii) EFFECT OF INTERVENTION.—If the Federal Trade Commission intervenes in an action under subparagraph (A), it shall have the right—

''(I) to be heard with respect to any matter that arises in that action; and

''(II) to file a petition for appeal.

''(C) CONSTRUCTION.—For purposes of bringing any civil action under subparagraph

(A), nothing in this subsection shall be construed to prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of that State to—

''(i) conduct investigations;

''(ii) administer oaths or affirmations; or

''(iii) compel the attendance of witnesses or the production of documentary and other evidence.

''(D) ACTIONS BY THE COMMISSION.—In any case in which an action is instituted by or on behalf of the Federal Trade Commission for a violation of paragraph (1), a State may not, during the pendency of that action, institute an action under subparagraph (A) for the same violation against any defendant named in the complaint in that action.

''(E) VENUE.—Any action brought under subparagraph (A) may be brought in the district court of the United States that meets applicable requirements relating to venue under section 1391 of title 28, United States Code.

''(F) SERVICE OF PROCESS.—In an action brought under subparagraph (A), process may

be served in any district in which the defendant—

"(i) is an inhabitant; or

"(ii) may be found.

"(G) MEASUREMENT OF DAMAGES.—In any action under this paragraph to enforce a cause of action under this subsection in which there has been a determination that a defendant has violated a provision of this subsection, damages may be proved and assessed in the aggregate by statistical or sampling methods, by the computation of illegal overcharges or by such other reasonable system of estimating aggregate damages as the court in its discretion may permit without the necessity of separately proving the individual claim of, or amount of damage to, persons on whose behalf the suit was brought.

"(H) EXCLUSION ON DUPLICATIVE RELIEF.—The district court shall exclude from the amount of monetary relief awarded in an action under this paragraph brought by the attorney general of a State any amount of monetary relief which duplicates amounts which have been awarded for the same injury.

''(7) EFFECT ON ANTITRUST LAWS.—Nothing in this subsection shall be construed to modify, impair, or supersede the operation of the antitrust laws. For the purpose of this subsection, the term 'antitrust laws' has the meaning given it in the first section of the Clayton Act, except that it includes section 5 of the Federal Trade Commission Act to the extent that such section 5 applies to unfair methods of competition.

''(8) MANUFACTURER.—In this subsection, the term 'manufacturer' means any entity, including any affiliate or licensee of that entity, that is engaged in—

''(A) the production, preparation, propagation, compounding, conversion, or processing of a prescription drug, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

''(B) the packaging, repackaging, labeling, relabeling, or distribution of a prescription drug.''.

(b) PROHIBITED ACTS.—The Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 301 (21 U.S.C. 331), by striking paragraph (aa) and inserting the following:

''(aa)(1) The sale or trade by a pharmacist, or by a business organization of which the pharmacist is a part, of a qualifying drug that under section 804(a)(2)(A) was imported by the pharmacist, other than—

''(A) a sale at retail made pursuant to dispensing the drug to a customer of the pharmacist or organization; or

''(B) a sale or trade of the drug to a pharmacy or a wholesaler registered to import drugs under section 804.

''(2) The sale or trade by an individual of a qualifying drug that under section 804(a)(2)(B) was imported by the individual.

''(3) The making of a materially false, fictitious, or fraudulent statement or representation, or a material omission, in a notice under clause (i) of section 804(g)(2)(B) or in an application required under section 804(g)(2)(F), or the failure to submit such a notice or application.

''(4) The importation of a drug in violation of a registration condition or other requirement under section 804, the falsification of any record required to be maintained, or provided to the Secretary, under such section,

or the violation of any registration condition or other requirement under such section.''; and

(2) in section 303(a) (21 U.S.C. 333(a)), by striking paragraph (6) and inserting the following:

''(6) Notwithstanding subsection (a), any person that knowingly violates section 301(i) (2) or (3) or section 301(aa)(4) shall be imprisoned not more than 10 years, or fined in accordance with title 18, United States Code, or both.''.

(c) AMENDMENT OF CERTAIN PROVISIONS.—

(1) IN GENERAL.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by striking subsection (g) and inserting the following:

''(g) With respect to a prescription drug that is imported or offered for import into the United States by an individual who is not in the business of such importation, that is not shipped by a registered exporter under section 804, and that is refused admission under subsection (a), the Secretary shall notify the individual that—

''(1) the drug has been refused admission because the drug was not a lawful import under section 804;

''(2) the drug is not otherwise subject to a waiver of the requirements of subsection (a);

''(3) the individual may under section 804 lawfully import certain prescription drugs from exporters registered with the Secretary under section 804; and

''(4) the individual can find information about such importation, including a list of registered exporters, on the Internet website of the Food and Drug Administration or through a toll-free telephone number required under section 804.''.

(2) ESTABLISHMENT REGISTRATION.—Section 510(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(i)) is amended in paragraph (1) by inserting after ''import into the United States'' the following: '', including a drug that is, or may be, imported or offered for import into the United States under section 804,''.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the date that is 90 days after the date of enactment of this title.

(d) EXHAUSTION.—

(1) IN GENERAL.—Section 271 of title 35, United States Code, is amended—

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

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

''(h) It shall not be an act of infringement to use, offer to sell, or sell within the United States or to import into the United States any patented invention under section 804 of the Federal Food, Drug, and Cosmetic Act that was first sold abroad by or under authority of the owner or licensee of such patent.''.

(2) RULE OF CONSTRUCTION.—Nothing in the amendment made by paragraph (1) shall be construed to affect the ability of a patent owner or licensee to enforce their patent, subject to such amendment.

(e) EFFECT OF SECTION 804.—

(1) IN GENERAL.—Section 804 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall permit the importation of qualifying drugs (as defined in such section 804) into the United States without regard to the status of the issuance of implementing regulations—

(A) from exporters registered under such section 804 on the date that is 90 days after the date of enactment of this title; and

(B) from permitted countries, as defined in such section 804, by importers registered under

such section 804 on the date that is 1 year after the date of enactment of this title.

(2) REVIEW OF REGISTRATION BY CERTAIN EXPORTERS.—

(A) REVIEW PRIORITY.—In the review of registrations submitted under subsection (b) of such section 804, registrations submitted by entities in Canada that are significant exporters of prescription drugs to individuals in the United States as of the date of enactment of this title will have priority during the 90 day period that begins on such date of enactment.

(B) PERIOD FOR REVIEW.—During such 90-day period, the reference in subsection (b)(2)(A) of such section 804 to 90 days (relating to approval or disapproval of registrations) is, as applied to such entities, deemed to be 30 days.

(C) LIMITATION.—That an exporter in Canada exports, or has exported, prescription drugs to individuals in the United States on or before the date that is 90 days after the date of enactment of this title shall not serve as a basis, in whole or in part, for disapproving a

registration under such section 804 from the exporter.

(D) FIRST YEAR LIMIT ON NUMBER OF EXPORTERS.—During the 1-year period beginning on the date of enactment of this title, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') may limit the number of registered exporters under such section 804 to not less than 50, so long as the Secretary gives priority to those exporters with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States.

(E) SECOND YEAR LIMIT ON NUMBER OF EXPORTERS.—During the 1-year period beginning on the date that is 1 year after the date of enactment of this title, the Secretary may limit the number of registered exporters under such section 804 to not less than 100, so long as the Secretary gives priority to those exporters with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States.

(F) FURTHER LIMIT ON NUMBER OF EXPORTERS.—During any 1-year period beginning

on a date that is 2 or more years after the date of enactment of this title, the Secretary may limit the number of registered exporters under such section 804 to not less than 25 more than the number of such exporters during the previous 1-year period, so long as the Secretary gives priority to those exporters with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States.

(3) LIMITS ON NUMBER OF IMPORTERS.—

(A) FIRST YEAR LIMIT ON NUMBER OF IMPORTERS.—During the 1-year period beginning on the date that is 1 year after the date of enactment of this title, the Secretary may limit the number of registered importers under such section 804 to not less than 100 (of which at least a significant number shall be groups of pharmacies, to the extent feasible given the applications submitted by such groups), so long as the Secretary gives priority to those importers with demonstrated ability to process a high volume of shipments of drugs imported into the United States.

(B) SECOND YEAR LIMIT ON NUMBER OF IMPORTERS.—During the 1-year period beginning on the date that is 2 years after the date of enactment of this title, the Secretary may limit the number of registered importers under such section 804 to not less than 200 (of which at least a significant number shall be groups of pharmacies, to the extent feasible given the applications submitted by such groups), so long as the Secretary gives priority to those importers with demonstrated ability to process a high volume of shipments of drugs into the United States.

(C) FURTHER LIMIT ON NUMBER OF IMPORTERS.—During any 1-year period beginning on a date that is 3 or more years after the date of enactment of this title, the Secretary may limit the number of registered importers under such section 804 to not less than 50 more (of which at least a significant number shall be groups of pharmacies, to the extent feasible given the applications submitted by such groups) than the number of such importers during the previous 1-year period, so long as the Secretary gives priority to those importers

with demonstrated ability to process a high volume of shipments of drugs to the United States.

(4) NOTICES FOR DRUGS FOR IMPORT FROM CANADA.—The notice with respect to a qualifying drug introduced for commercial distribution in Canada as of the date of enactment of this title that is required under subsection (g)(2)(B)(i) of such section 804 shall be submitted to the Secretary not later than 30 days after the date of enactment of this title if—

(A) the U.S. label drug (as defined in such section 804) for the qualifying drug is 1 of the 100 prescription drugs with the highest dollar volume of sales in the United States based on the 12 calendar month period most recently completed before the date of enactment of this Act; or

(B) the notice is a notice under subsection (g)(2)(B)(i)(II) of such section 804.

(5) NOTICE FOR DRUGS FOR IMPORT FROM OTHER COUNTRIES.—The notice with respect to a qualifying drug introduced for commercial distribution in a permitted country other than Canada as of the date of enactment of this title that is required

under subsection (g)(2)(B)(i) of such section 804 shall be submitted to the Secretary not later than 180 days after the date of enactment of this title if—

(A) the U.S. label drug for the qualifying drug is 1 of the 100 prescription drugs with the highest dollar volume of sales in the United States based on the 12 calendar month period that is first completed on the date that is 120 days after the date of enactment of this title; or

(B) the notice is a notice under subsection (g)(2)(B)(i)(II) of such section 804.

(6) NOTICE FOR OTHER DRUGS FOR IMPORT.—

(A) GUIDANCE ON SUBMISSION DATES.—The Secretary shall by guidance establish a series of submission dates for the notices under subsection (g)(2)(B)(i) of such section 804 with respect to qualifying drugs introduced for commercial distribution as of the date of enactment of this title and that are not required to be submitted under paragraph (4) or (5).

(B) CONSISTENT AND EFFICIENT USE OF RESOURCES.—The Secretary shall establish the dates described under subparagraph (A) so that such notices described under subparagraph (A)

are submitted and reviewed at a rate that allows consistent and efficient use of the resources and staff available to the Secretary for such reviews. The Secretary may condition the requirement to submit such a notice, and the review of such a notice, on the submission by a registered exporter or a registered importer to the Secretary of a notice that such exporter or importer intends to import such qualifying drug to the United States under such section 804.

(C) PRIORITY FOR DRUGS WITH HIGHER SALES.—The Secretary shall establish the dates described under subparagraph (A) so that the Secretary reviews the notices described under such subparagraph with respect to qualifying drugs with higher dollar volume of sales in the United States before the notices with respect to drugs with lower sales in the United States.

(7) NOTICES FOR DRUGS APPROVED AFTER EFFECTIVE DATE.—The notice required under subsection (g)(2)(B)(i) of such section 804 for a qualifying drug first introduced for commercial distribution in a permitted country (as defined in such section 804) after the date of enactment of this title shall be submitted to and reviewed by the Secretary

as provided under subsection (g)(2)(B) of such section 804, without regard to paragraph (4), (5), or (6).

(8) REPORT.—Beginning with the first full fiscal year after the date of enactment of this title, not later than 90 days after the end of each fiscal year during which the Secretary reviews a notice referred to in paragraph (4), (5), or (6), the Secretary shall submit a report to Congress concerning the progress of the Food and Drug Administration in reviewing the notices referred to in paragraphs (4), (5), and (6).

(9) USER FEES.—

(A) EXPORTERS.—When establishing an aggregate total of fees to be collected from exporters under subsection (f)(2) of such section 804, the Secretary shall, under subsection (f)(3)(C)(i) of such section 804, estimate the total price of drugs imported under subsection (a) of such section 804 into the United States by registered exporters during the first fiscal year in which this title takes effect to be an amount equal to the amount which bears the same ratio to $1,000,000,000 as the number of

days in such fiscal year during which this title is effective bears to 365.

(B) IMPORTERS.—When establishing an aggregate total of fees to be collected from importers under subsection (e)(2) of such section 804, the Secretary shall, under subsection (e)(3)(C)(i) of such section 804, estimate the total price of drugs imported under subsection (a) of such section 804 into the United States by registered importers during—

(i) the first fiscal year in which this title takes effect to be an amount equal to the amount which bears the same ratio to $1,000,000,000 as the number of days in such fiscal year during which this title is effective bears to 365; and

(ii) the second fiscal year in which this title is in effect to be $3,000,000,000.

(C) SECOND YEAR ADJUSTMENT.—

(i) REPORTS.—Not later than February 20 of the second fiscal year in which this title is in effect, registered importers shall report to the Secretary the total price and the total volume of drugs imported to the United States by the importer during

the 4-month period from October 1 through January 31 of such fiscal year.

(ii) REESTIMATE.—Notwithstanding subsection (e)(3)(C)(ii) of such section 804 or subparagraph (B), the Secretary shall reestimate the total price of qualifying drugs imported under subsection (a) of such section 804 into the United States by registered importers during the second fiscal year in which this title is in effect. Such reestimate shall be equal to—

(I) the total price of qualifying drugs imported by each importer as reported under clause (i); multiplied by

(II) 3.

(iii) ADJUSTMENT.—The Secretary shall adjust the fee due on April 1 of the second fiscal year in which this title is in effect, from each importer so that the aggregate total of fees collected under subsection (e)(2) for such fiscal year does not exceed the total price of qualifying drugs imported under subsection (a) of such section 804 into the United States by reg-

istered importers during such fiscal year as reestimated under clause (ii).

(D) FAILURE TO PAY FEES.—Notwithstanding any other provision of this section, the Secretary may prohibit a registered importer or exporter that is required to pay user fees under subsection (e) or (f) of such section 804 and that fails to pay such fees within 30 days after the date on which it is due, from importing or offering for importation a qualifying drug under such section 804 until such fee is paid.

(E) ANNUAL REPORT.—

(i) FOOD AND DRUG ADMINISTRATION.—Not later than 180 days after the end of each fiscal year during which fees are collected under subsection (e), (f), or (g)(2)(B)(iv) of such section 804, the Secretary shall prepare and submit to the House of Representatives and the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for the fiscal year for which the report is made

and credited to the Food and Drug Administration.

(ii) CUSTOMS AND BORDER CONTROL.—Not later than 180 days after the end of each fiscal year during which fees are collected under subsection (e) or (f) of such section 804, the Secretary of Homeland Security, in consultation with the Secretary of the Treasury, shall prepare and submit to the House of Representatives and the Senate a report on the use, by the Bureau of Customs and Border Protection, of the fees, if any, transferred by the Secretary to the Bureau of Customs and Border Protection for the fiscal year for which the report is made.

(10) SPECIAL RULE REGARDING IMPORTATION BY INDIVIDUALS.—

(A) IN GENERAL.—Notwithstanding any provision of this title (or an amendment made by this title), the Secretary shall expedite the designation of any additional countries from which an individual may import a qualifying drug into the United States under such section 804 if any action implemented by the Govern-

ment of Canada has the effect of limiting or prohibiting the importation of qualifying drugs into the United States from Canada.

(B) TIMING AND CRITERIA.—The Secretary shall designate such additional countries under subparagraph (A)—

(i) not later than 6 months after the date of the action by the Government of Canada described under such subparagraph; and

(ii) using the criteria described under subsection (a)(4)(D)(i)(II) of such section 804.

(f) IMPLEMENTATION OF SECTION 804.—

(1) INTERIM RULE.—The Secretary may promulgate an interim rule for implementing section 804 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a) of this section.

(2) NO NOTICE OF PROPOSED RULEMAKING.—The interim rule described under paragraph (1) may be developed and promulgated by the Secretary without providing general notice of proposed rulemaking.

(3) FINAL RULE.—Not later than 1 year after the date on which the Secretary promulgates an interim rule under paragraph (1), the Secretary shall,

in accordance with procedures under section 553 of title 5, United States Code, promulgate a final rule for implementing such section 804, which may incorporate by reference provisions of the interim rule provided for under paragraph (1), to the extent that such provisions are not modified.

(g) CONSUMER EDUCATION.—The Secretary shall carry out activities that educate consumers—

(1) with regard to the availability of qualifying drugs for import for personal use from an exporter registered with and approved by the Food and Drug Administration under section 804 of the Federal Food, Drug, and Cosmetic Act, as added by this section, including information on how to verify whether an exporter is registered and approved by use of the Internet website of the Food and Drug Administration and the toll-free telephone number required by this title;

(2) that drugs that consumers attempt to import from an exporter that is not registered with and approved by the Food and Drug Administration can be seized by the United States Customs Service and destroyed, and that such drugs may be counterfeit, unapproved, unsafe, or ineffective;

(3) with regard to the suspension and termination of any registration of a registered importer or exporter under such section 804; and

(4) with regard to the availability at domestic retail pharmacies of qualifying drugs imported under such section 804 by domestic wholesalers and pharmacies registered with and approved by the Food and Drug Administration.

(h) EFFECT ON ADMINISTRATION PRACTICES.—Notwithstanding any provision of this title (and the amendments made by this title), the practices and policies of the Food and Drug Administration and Bureau of Customs and Border Protection, in effect on January 1, 2004, with respect to the importation of prescription drugs into the United States by an individual, on the person of such individual, for personal use, shall remain in effect.

(i) REPORT TO CONGRESS.—The Federal Trade Commission shall, on an annual basis, submit to Congress a report that describes any action taken during the period for which the report is being prepared to enforce the provisions of section 804(n) of the Federal Food, Drug, and Cosmetic Act (as added by this title), including any pending investigations or civil actions under such section.

SEC. 805. DISPOSITION OF CERTAIN DRUGS DENIED ADMISSION INTO UNITED STATES.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.), as amended by section 804, is further amended by adding at the end the following section:

"SEC. 805. DISPOSITION OF CERTAIN DRUGS DENIED ADMISSION.

''(a) IN GENERAL.—The Secretary of Homeland Security shall deliver to the Secretary a shipment of drugs that is imported or offered for import into the United States if—

''(1) the shipment has a declared value of less than $10,000; and

''(2)(A) the shipping container for such drugs does not bear the markings required under section 804(d)(2); or

''(B) the Secretary has requested delivery of such shipment of drugs.

''(b) NO BOND OR EXPORT.—Section 801(b) does not authorize the delivery to the owner or consignee of drugs delivered to the Secretary under subsection (a) pursuant to the execution of a bond, and such drugs may not be exported.

''(c) DESTRUCTION OF VIOLATIVE SHIPMENT.—The Secretary shall destroy a shipment of drugs delivered by

the Secretary of Homeland Security to the Secretary under subsection (a) if—

''(1) in the case of drugs that are imported or offered for import from a registered exporter under section 804, the drugs are in violation of any standard described in section 804(g)(5); or

''(2) in the case of drugs that are not imported or offered for import from a registered exporter under section 804, the drugs are in violation of a standard referred to in section 801(a) or 801(d)(1).

''(d) CERTAIN PROCEDURES.—

''(1) IN GENERAL.—The delivery and destruction of drugs under this section may be carried out without notice to the importer, owner, or consignee of the drugs except as required by section 801(g) or section 804(i)(2). The issuance of receipts for the drugs, and recordkeeping activities regarding the drugs, may be carried out on a summary basis.

''(2) OBJECTIVE OF PROCEDURES.—Procedures promulgated under paragraph (1) shall be designed toward the objective of ensuring that, with respect to efficiently utilizing Federal resources available for carrying out this section, a substantial majority of shipments of drugs subject to described in subsection (c) are identified and destroyed.

''(e) EVIDENCE EXCEPTION.—Drugs may not be destroyed under subsection (c) to the extent that the Attorney General of the United States determines that the drugs should be preserved as evidence or potential evidence with respect to an offense against the United States.

''(f) RULE OF CONSTRUCTION.—This section may not be construed as having any legal effect on applicable law with respect to a shipment of drugs that is imported or offered for import into the United States and has a declared value equal to or greater than $10,000.''.

(b) PROCEDURES.—Procedures for carrying out section 805 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall be established not later than 90 days after the date of the enactment of this title.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date that is 90 days after the date of enactment of this title.

SEC. 806. WHOLESALE DISTRIBUTION OF DRUGS; STATEMENTS REGARDING PRIOR SALE, PURCHASE, OR TRADE.

(a) STRIKING OF EXEMPTIONS; APPLICABILITY TO REGISTERED EXPORTERS.—Section 503(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is amended—

(1) in paragraph (1)—

(A) by striking ''and who is not the manufacturer or an authorized distributor of record of such drug'';

(B) by striking ''to an authorized distributor of record or''; and

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

''(B) The fact that a drug subject to subsection (b) is exported from the United States does not with respect to such drug exempt any person that is engaged in the business of the wholesale distribution of the drug from providing the statement described in subparagraph (A) to the person that receives the drug pursuant to the export of the drug.

''(C)(i) The Secretary shall by regulation establish requirements that supersede subparagraph (A) (referred to in this subparagraph as 'alternative requirements') to identify the chain of custody of a drug subject to subsection (b) from the manufacturer of the drug throughout the wholesale distribution of the drug to a pharmacist who intends to sell the drug at retail if the Secretary determines that the alternative requirements, which may include standardized anti-counterfeiting or track-and-trace technologies, will identify such chain of custody or the identity of the discrete package of the drug from which

the drug is dispensed with equal or greater certainty to the requirements of subparagraph (A), and that the alternative requirements are economically and technically feasible.

''(ii) When the Secretary promulgates a final rule to establish such alternative requirements, the final rule in addition shall, with respect to the registration condition established in clause (i) of section 804(c)(3)(B), establish a condition equivalent to the alternative requirements, and such equivalent condition may be met in lieu of the registration condition established in such clause (i).'';

(2) in paragraph (2)(A), by adding at the end the following: ''The preceding sentence may not be construed as having any applicability with respect to a registered exporter under section 804.''; and

(3) in paragraph (3), by striking ''and subsection (d)—'' in the matter preceding subparagraph (A) and all that follows through ''the term 'wholesale distribution' means'' in subparagraph (B) and inserting the following: ''and subsection (d), the term 'wholesale distribution' means''.

(b) CONFORMING AMENDMENT.—Section 503(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(d)) is amended by adding at the end the following:

''(4) Each manufacturer of a drug subject to subsection (b) shall maintain at its corporate offices a current list of the authorized distributors of record of such drug.

''(5) For purposes of this subsection, the term 'authorized distributors of record' means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products.''.

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by paragraphs (1) and (3) of subsection (a) and by subsection (b) shall take effect on January 1, 2010.

(2) DRUGS IMPORTED BY REGISTERED IMPORTERS UNDER SECTION 804.—Notwithstanding paragraph (1), the amendments made by paragraphs (1) and (3) of subsection (a) and by subsection (b) shall take effect on the date that is 90 days after the date of enactment of this title with respect to qualifying drugs imported under section 804 of the Federal Food, Drug, and Cosmetic Act, as added by section 804.

(3) EFFECT WITH RESPECT TO REGISTERED EXPORTERS.—The amendment made by subsection (a)(2) shall take effect on the date that is 90 days after the date of enactment of this title.

(4) ALTERNATIVE REQUIREMENTS.—The Secretary shall issue regulations to establish the alternative requirements, referred to in the amendment made by subsection (a)(1), that take effect not later than January 1, 2010.

(5) INTERMEDIATE REQUIREMENTS.—The Secretary shall by regulation require the use of standardized anti-counterfeiting or track-and-trace technologies on prescription drugs at the case and pallet level effective not later than 1 year after the date of enactment of this title.

(6) ADDITIONAL REQUIREMENTS.—

(A) IN GENERAL.—Notwithstanding any other provision of this section, the Secretary shall, not later than 18 months after the date of enactment of this title, require that the packaging of any prescription drug incorporates—

(i) a standardized numerical identifier unique to each package of such drug, applied at the point of manufacturing and repackaging (in which case the numerical identifier shall be linked to the numerical identifier applied at the point of manufacturing); and

(ii)(I) overt optically variable counterfeit-resistant technologies that—

(aa) are visible to the naked eye, providing for visual identification of product authenticity without the need for readers, microscopes, lighting devices, or scanners;

(bb) are similar to that used by the Bureau of Engraving and Printing to secure United States currency;

(cc) are manufactured and distributed in a highly secure, tightly controlled environment; and

(dd) incorporate additional layers of nonvisible convert security features up to and including forensic capability, as described in subparagraph (B); or

(II) technologies that have a function of security comparable to that described in subclause (I), as determined by the Secretary.

(B) STANDARDS FOR PACKAGING.—For the purpose of making it more difficult to counterfeit the packaging of drugs subject to this

paragraph, the manufacturers of such drugs shall incorporate the technologies described in subparagraph (A) into at least 1 additional element of the physical packaging of the drugs, including blister packs, shrink wrap, package labels, package seals, bottles, and boxes.

SEC. 807. INTERNET SALES OF PRESCRIPTION DRUGS.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 503A the following:

"SEC. 503B. INTERNET SALES OF PRESCRIPTION DRUGS.

"(a) REQUIREMENTS REGARDING INFORMATION ON INTERNET SITE.—

"(1) IN GENERAL.—A person may not dispense a prescription drug pursuant to a sale of the drug by such person if—

"(A) the purchaser of the drug submitted the purchase order for the drug, or conducted any other part of the sales transaction for the drug, through an Internet site;

"(B) the person dispenses the drug to the purchaser by mailing or shipping the drug to the purchaser; and

"(C) such site, or any other Internet site used by such person for purposes of sales of a

prescription drug, fails to meet each of the requirements specified in paragraph (2), other than a site or pages on a site that—

''(i) are not intended to be accessed by purchasers or prospective purchasers; or

''(ii) provide an Internet information location tool within the meaning of section 231(e)(5) of the Communications Act of 1934 (47 U.S.C. 231(e)(5)).

''(2) REQUIREMENTS.—With respect to an Internet site, the requirements referred to in subparagraph (C) of paragraph (1) for a person to whom such paragraph applies are as follows:

''(A) Each page of the site shall include either the following information or a link to a page that provides the following information:

''(i) The name of such person.

''(ii) Each State in which the person is authorized by law to dispense prescription drugs.

''(iii) The address and telephone number of each place of business of the person with respect to sales of prescription drugs through the Internet, other than a place of

business that does not mail or ship prescription drugs to purchasers.

''(iv) The name of each individual who serves as a pharmacist for prescription drugs that are mailed or shipped pursuant to the site, and each State in which the individual is authorized by law to dispense prescription drugs.

''(v) If the person provides for medical consultations through the site for purposes of providing prescriptions, the name of each individual who provides such consultations; each State in which the individual is licensed or otherwise authorized by law to provide such consultations or practice medicine; and the type or types of health professions for which the individual holds such licenses or other authorizations.

''(B) A link to which paragraph (1) applies shall be displayed in a clear and prominent place and manner, and shall include in the caption for the link the words 'licensing and contact information'.

''(b) INTERNET SALES WITHOUT APPROPRIATE MEDICAL RELATIONSHIPS.—

''(1) IN GENERAL.—Except as provided in paragraph (2), a person may not dispense a prescription drug, or sell such a drug, if—

''(A) for purposes of such dispensing or sale, the purchaser communicated with the person through the Internet;

''(B) the patient for whom the drug was dispensed or purchased did not, when such communications began, have a prescription for the drug that is valid in the United States;

''(C) pursuant to such communications, the person provided for the involvement of a practitioner, or an individual represented by the person as a practitioner, and the practitioner or such individual issued a prescription for the drug that was purchased;

''(D) the person knew, or had reason to know, that the practitioner or the individual referred to in subparagraph (C) did not, when issuing the prescription, have a qualifying medical relationship with the patient; and

''(E) the person received payment for the dispensing or sale of the drug.

For purposes of subparagraph (E), payment is received if money or other valuable consideration is received.

''(2) EXCEPTIONS.—Paragraph (1) does not apply to—

''(A) the dispensing or selling of a prescription drug pursuant to telemedicine practices sponsored by—

''(i) a hospital that has in effect a provider agreement under title XVIII of the Social Security Act (relating to the Medicare program); or

''(ii) a group practice that has not fewer than 100 physicians who have in effect provider agreements under such title; or

''(B) the dispensing or selling of a prescription drug pursuant to practices that promote the public health, as determined by the Secretary by regulation.

''(3) QUALIFYING MEDICAL RELATIONSHIP.—

''(A) IN GENERAL.—With respect to issuing a prescription for a drug for a patient, a practitioner has a qualifying medical relation-

ship with the patient for purposes of this section if—

"(i) at least one in-person medical evaluation of the patient has been conducted by the practitioner; or

"(ii) the practitioner conducts a medical evaluation of the patient as a covering practitioner.

"(B) IN-PERSON MEDICAL EVALUATION.—A medical evaluation by a practitioner is an in-person medical evaluation for purposes of this section if the practitioner is in the physical presence of the patient as part of conducting the evaluation, without regard to whether portions of the evaluation are conducted by other health professionals.

"(C) COVERING PRACTITIONER.—With respect to a patient, a practitioner is a covering practitioner for purposes of this section if the practitioner conducts a medical evaluation of the patient at the request of a practitioner who has conducted at least one in-person medical evaluation of the patient and is temporarily unavailable to conduct the evaluation of the patient. A practitioner is a covering practitioner

without regard to whether the practitioner has conducted any in-person medical evaluation of the patient involved.

''(4) RULES OF CONSTRUCTION.—

''(A) INDIVIDUALS REPRESENTED AS PRACTITIONERS.—A person who is not a practitioner (as defined in subsection (e)(1)) lacks legal capacity under this section to have a qualifying medical relationship with any patient.

''(B) STANDARD PRACTICE OF PHARMACY.—Paragraph (1) may not be construed as prohibiting any conduct that is a standard practice in the practice of pharmacy.

''(C) APPLICABILITY OF REQUIREMENTS.—Paragraph (3) may not be construed as having any applicability beyond this section, and does not affect any State law, or interpretation of State law, concerning the practice of medicine.

''(c) ACTIONS BY STATES.—

''(1) IN GENERAL.—Whenever an attorney general of any State has reason to believe that the interests of the residents of that State have been or are being threatened or adversely affected because any person has engaged or is engaging in a pattern

or practice that violates section 301(l), the State may bring a civil action on behalf of its residents in an appropriate district court of the United States to enjoin such practice, to enforce compliance with such section (including a nationwide injunction), to obtain damages, restitution, or other compensation on behalf of residents of such State, to obtain reasonable attorneys fees and costs if the State prevails in the civil action, or to obtain such further and other relief as the court may deem appropriate.

''(2) NOTICE.—The State shall serve prior written notice of any civil action under paragraph (1) or (5)(B) upon the Secretary and provide the Secretary with a copy of its complaint, except that if it is not feasible for the State to provide such prior notice, the State shall serve such notice immediately upon instituting such action. Upon receiving a notice respecting a civil action, the Secretary shall have the right—

''(A) to intervene in such action;

''(B) upon so intervening, to be heard on all matters arising therein; and

''(C) to file petitions for appeal.

''(3) CONSTRUCTION.—For purposes of bringing any civil action under paragraph (1), nothing in

this chapter shall prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of such State to conduct investigations or to administer oaths or affirmations or to compel the attendance of witnesses or the production of documentary and other evidence.

''(4) VENUE; SERVICE OF PROCESS.—Any civil action brought under paragraph (1) in a district court of the United States may be brought in the district in which the defendant is found, is an inhabitant, or transacts business or wherever venue is proper under section 1391 of title 28, United States Code. Process in such an action may be served in any district in which the defendant is an inhabitant or in which the defendant may be found.

''(5) ACTIONS BY OTHER STATE OFFICIALS.—

''(A) Nothing contained in this section shall prohibit an authorized State official from proceeding in State court on the basis of an alleged violation of any civil or criminal statute of such State.

''(B) In addition to actions brought by an attorney general of a State under paragraph (1), such an action may be brought by officers of such State who are authorized by the State

to bring actions in such State on behalf of its residents.

''(d) EFFECT OF SECTION.—This section shall not apply to a person that is a registered exporter under section 804.

''(e) GENERAL DEFINITIONS.—For purposes of this section:

''(1) The term 'practitioner' means a practitioner referred to in section 503(b)(1) with respect to issuing a written or oral prescription.

''(2) The term 'prescription drug' means a drug that is described in section 503(b)(1).

''(3) The term 'qualifying medical relationship', with respect to a practitioner and a patient, has the meaning indicated for such term in subsection (b).

''(f) INTERNET-RELATED DEFINITIONS.—

''(1) IN GENERAL.—For purposes of this section:

''(A) The term 'Internet' means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected world-wide network of networks that employ the transmission control protocol/internet protocol, or any predecessor or successor protocols to

such protocol, to communicate information of all kinds by wire or radio.

''(B) The term 'link', with respect to the Internet, means one or more letters, words, numbers, symbols, or graphic items that appear on a page of an Internet site for the purpose of serving, when activated, as a method for executing an electronic command—

''(i) to move from viewing one portion of a page on such site to another portion of the page;

''(ii) to move from viewing one page on such site to another page on such site; or

''(iii) to move from viewing a page on one Internet site to a page on another Internet site.

''(C) The term 'page', with respect to the Internet, means a document or other file accessed at an Internet site.

''(D)(i) The terms 'site' and 'address', with respect to the Internet, mean a specific location on the Internet that is determined by Internet Protocol numbers. Such term includes the domain name, if any.

''(ii) The term 'domain name' means a method of representing an Internet address without direct reference to the Internet Protocol numbers for the address, including methods that use designations such as '.com', '.edu', '.gov', '.net', or '.org'.

''(iii) The term 'Internet Protocol numbers' includes any successor protocol for determining a specific location on the Internet.

''(2) AUTHORITY OF SECRETARY.—The Secretary may by regulation modify any definition under paragraph (1) to take into account changes in technology.

''(g) INTERACTIVE COMPUTER SERVICE; ADVERTISING.—No provider of an interactive computer service, as defined in section 230(f)(2) of the Communications Act of 1934 (47 U.S.C. 230(f)(2)), or of advertising services shall be liable under this section for dispensing or selling prescription drugs in violation of this section on account of another person's selling or dispensing such drugs, provided that the provider of the interactive computer service or of advertising services does not own or exercise corporate control over such person.''.

(b) INCLUSION AS PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

331) is amended by inserting after paragraph (k) the following:

''(l) The dispensing or selling of a prescription drug in violation of section 503B.''.

(c) INTERNET SALES OF PRESCRIPTION DRUGS; CONSIDERATION BY SECRETARY OF PRACTICES AND PROCEDURES FOR CERTIFICATION OF LEGITIMATE BUSINESSES.—In carrying out section 503B of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a) of this section), the Secretary of Health and Human Services shall take into consideration the practices and procedures of public or private entities that certify that businesses selling prescription drugs through Internet sites are legitimate businesses, including practices and procedures regarding disclosure formats and verification programs.

(d) REPORTS REGARDING INTERNET-RELATED VIOLATIONS OF FEDERAL AND STATE LAWS ON DISPENSING OF DRUGS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall, pursuant to the submission of an application meeting the criteria of the Secretary, make an award of a grant or contract to the National Clearinghouse on Internet Prescribing (op-

erated by the Federation of State Medical Boards) for the purpose of—

(A) identifying Internet sites that appear to be in violation of Federal or State laws concerning the dispensing of drugs;

(B) reporting such sites to State medical licensing boards and State pharmacy licensing boards, and to the Attorney General and the Secretary, for further investigation; and

(C) submitting, for each fiscal year for which the award under this subsection is made, a report to the Secretary describing investigations undertaken with respect to violations described in subparagraph (A).

(2) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out paragraph (1), there is authorized to be appropriated $100,000 for each of the first 3 fiscal years in which this section is in effect.

(e) EFFECTIVE DATE.—The amendments made by subsections (a) and (b) take effect 90 days after the date of enactment of this title, without regard to whether a final rule to implement such amendments has been promulgated by the Secretary of Health and Human Services under section 701(a) of the Federal Food, Drug, and Cos-

metic Act. The preceding sentence may not be construed as affecting the authority of such Secretary to promulgate such a final rule.

SEC. 808. PROHIBITING PAYMENTS TO UNREGISTERED FOREIGN PHARMACIES.

(a) IN GENERAL.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

''(g) RESTRICTED TRANSACTIONS.—

''(1) IN GENERAL.—The introduction of restricted transactions into a payment system or the completion of restricted transactions using a payment system is prohibited.

''(2) PAYMENT SYSTEM.—

''(A) IN GENERAL.—The term 'payment system' means a system used by a person described in subparagraph (B) to effect a credit transaction, electronic fund transfer, or money transmitting service that may be used in connection with, or to facilitate, a restricted transaction, and includes—

''(i) a credit card system;

''(ii) an international, national, regional, or local network used to effect a credit transaction, an electronic fund

transfer, or a money transmitting service; and

''(iii) any other system that is centrally managed and is primarily engaged in the transmission and settlement of credit transactions, electronic fund transfers, or money transmitting services.

''(B) PERSONS DESCRIBED.—A person referred to in subparagraph (A) is—

''(i) a creditor;

''(ii) a credit card issuer;

''(iii) a financial institution;

''(iv) an operator of a terminal at which an electronic fund transfer may be initiated;

''(v) a money transmitting business; or

''(vi) a participant in an international, national, regional, or local network used to effect a credit transaction, electronic fund transfer, or money transmitting service.

''(3) RESTRICTED TRANSACTION.—The term 'restricted transaction' means a transaction or transmittal, on behalf of an individual who places an unlawful drug importation request to any person en-

gaged in the operation of an unregistered foreign pharmacy, of—

''(A) credit, or the proceeds of credit, extended to or on behalf of the individual for the purpose of the unlawful drug importation request (including credit extended through the use of a credit card);

''(B) an electronic fund transfer or funds transmitted by or through a money transmitting business, or the proceeds of an electronic fund transfer or money transmitting service, from or on behalf of the individual for the purpose of the unlawful drug importation request;

''(C) a check, draft, or similar instrument which is drawn by or on behalf of the individual for the purpose of the unlawful drug importation request and is drawn on or payable at or through any financial institution; or

''(D) the proceeds of any other form of financial transaction (identified by the Board by regulation) that involves a financial institution as a payor or financial intermediary on behalf of or for the benefit of the individual for the purpose of the unlawful drug importation request.

''(4) UNLAWFUL DRUG IMPORTATION REQUEST.—The term 'unlawful drug importation request' means the request, or transmittal of a request, made to an unregistered foreign pharmacy for a prescription drug by mail (including a private carrier), facsimile, phone, or electronic mail, or by a means that involves the use, in whole or in part, of the Internet.

''(5) UNREGISTERED FOREIGN PHARMACY.—The term 'unregistered foreign pharmacy' means a person in a country other than the United States that is not a registered exporter under section 804.

''(6) OTHER DEFINITIONS.—

''(A) CREDIT; CREDITOR; CREDIT CARD.—The terms 'credit', 'creditor', and 'credit card' have the meanings given the terms in section 103 of the Truth in Lending Act (15 U.S.C. 1602).

''(B) ACCESS DEVICE; ELECTRONIC FUND TRANSFER.—The terms 'access device' and 'electronic fund transfer'—

''(i) have the meaning given the term in section 903 of the Electronic Fund Transfer Act (15 U.S.C. 1693a); and

''(ii) the term 'electronic fund transfer' also includes any fund transfer covered under Article 4A of the Uniform Commercial Code, as in effect in any State.

''(C) FINANCIAL INSTITUTION.—The term 'financial institution'—

''(i) has the meaning given the term in section 903 of the Electronic Transfer Fund Act (15 U.S.C. 1693a); and

''(ii) includes a financial institution (as defined in section 509 of the Gramm-Leach-Bliley Act (15 U.S.C. 6809)).

''(D) MONEY TRANSMITTING BUSINESS; MONEY TRANSMITTING SERVICE.—The terms 'money transmitting business' and 'money transmitting service' have the meaning given the terms in section 5330(d) of title 31, United States Code.

''(E) BOARD.—The term 'Board' means the Board of Governors of the Federal Reserve System.

''(7) POLICIES AND PROCEDURES REQUIRED TO PREVENT RESTRICTED TRANSACTIONS.—

''(A) REGULATIONS.—The Board shall promulgate regulations requiring—

''(i) an operator of a credit card system;

''(ii) an operator of an international, national, regional, or local network used to effect a credit transaction, an electronic fund transfer, or a money transmitting service;

''(iii) an operator of any other payment system that is centrally managed and is primarily engaged in the transmission and settlement of credit transactions, electronic transfers or money transmitting services where at least one party to the transaction or transfer is an individual; and

''(iv) any other person described in paragraph (2)(B) and specified by the Board in such regulations,

to establish policies and procedures that are reasonably designed to prevent the introduction of a restricted transaction into a payment system or the completion of a restricted transaction using a payment system

''(B) REQUIREMENTS FOR POLICIES AND PROCEDURES.—In promulgating regulations under subparagraph (A), the Board shall—

''(i) identify types of policies and procedures, including nonexclusive examples, that shall be considered to be reasonably designed to prevent the introduction of restricted transactions into a payment system or the completion of restricted transactions using a payment system; and

''(ii) to the extent practicable, permit any payment system, or person described in paragraph (2)(B), as applicable, to choose among alternative means of preventing the introduction or completion of restricted transactions.

''(C) NO LIABILITY FOR BLOCKING OR REFUSING TO HONOR RESTRICTED TRANSACTION.—

''(i) IN GENERAL.—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, and any participant in such payment system that prevents or otherwise refuses to honor trans-

actions in an effort to implement the policies and procedures required under this subsection or to otherwise comply with this subsection shall not be liable to any party for such action.

''(ii) COMPLIANCE.—A person described in paragraph (2)(B) meets the requirements of this subsection if the person relies on and complies with the policies and procedures of a payment system of which the person is a member or in which the person is a participant, and such policies and procedures of the payment system comply with the requirements of the regulations promulgated under subparagraph (A).

''(D) ENFORCEMENT.—

''(i) IN GENERAL.—This section shall be enforced by the Federal functional regulators and the Federal Trade Commission under applicable law in the manner provided in section 505(a) of the Gramm-Leach-Bliley Act (15 U.S.C. 6805(a)).

''(ii) FACTORS TO BE CONSIDERED.—In considering any enforcement action

under this subsection against a payment system or person described in paragraph (2)(B), the Federal functional regulators and the Federal Trade Commission shall consider the following factors:

"(I) The extent to which the payment system or person knowingly permits restricted transactions.

"(II) The history of the payment system or person in connection with permitting restricted transactions.

"(III) The extent to which the payment system or person has established and is maintaining policies and procedures in compliance with regulations prescribed under this subsection.

"(8) TRANSACTIONS PERMITTED.—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, is authorized to engage in transactions with foreign pharmacies in connection with investigating violations or potential violations of any rule or requirement adopted by the payment system or person in connection with complying with paragraph (7). A payment system, or such a person, and its agents

and employees shall not be found to be in violation of, or liable under, any Federal, State or other law by virtue of engaging in any such transaction.

''(9) RELATION TO STATE LAWS.—No requirement, prohibition, or liability may be imposed on a payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, under the laws of any state with respect to any payment transaction by an individual because the payment transaction involves a payment to a foreign pharmacy.

''(10) TIMING OF REQUIREMENTS.—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, must adopt policies and procedures reasonably designed to comply with any regulations required under paragraph (7) within 60 days after such regulations are issued in final form.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall take effect on the day that is 90 days after the date of enactment of this Act.

(c) IMPLEMENTATION.—The Board of Governors of the Federal Reserve System shall promulgate regulations as required by subsection (g)(7) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), as

added by subsection (a), not later than 90 days after the date of enactment of this title.

SEC. 809. IMPORTATION EXEMPTION UNDER CONTROLLED SUBSTANCES IMPORT AND EXPORT ACT.

Section 1006(a)(2) of the Controlled Substances Import and Export Act (21 U.S.C. 956(a)(2)) is amended by striking ''not import the controlled substance into the United States in an amount that exceeds 50 dosage units of the controlled substance.'' and inserting ''import into the United States not more than 10 dosage units combined of all such controlled substances.''.

SEC. 810. SEVERABILITY.

If any provision of this title, an amendment by this title, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this title, the amendments made by this title, and the application of the provisions of such to any person or circumstance shall not affected thereby.

SEC. 811. PROTECTION OF HEALTH AND SAFETY.

This title, and the amendments made by this title, shall become effective only if the Secretary of Health and Human Services certifies to Congress that the implementation of this title (and amendments) will—

(1) pose no additional risk to the public's health and safety; and

(2) result in a significant reduction in the cost of covered products to the American consumer.

Passed the Senate May 9, 2007.

Attest:

Secretary.

110TH CONGRESS
1ST SESSION

S. 1082

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to reauthorize drug and device user fees and ensure the safety of medical products, and for other purposes.