Calendar No. 270

110TH CONGRESS
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H. R. 2900

IN THE SENATE OF THE UNITED STATES

JULY 16, 2007
Received; read twice and placed on the calendar

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and for medical devices, to enhance the postmarket authorities of the Food and Drug Administration with respect to the safety of drugs, 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 Amendments Act of 2007''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

TITLE I—PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

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 ACT.—Except as otherwise specified, amendments made by this title to a section or other provision of law are amendments to such section or other

provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

SEC. 102. DEFINITIONS.

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

(1) in paragraph (1)—

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

(B) by striking subparagraph (B); and

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

(2) in paragraph (3)(C)—

(A) by striking ''505(j)(7)(A)'' and inserting ''505(j)(7)(A) (not including the discontinued section of such list),''; and

(B) by inserting before the period ''(not including the discontinued section of such list)'';

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

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

''(F) Postmarket safety activities with respect to drugs approved under human drug ap-

plications or supplements, including the following activities:

"(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.

"(iii) Developing and using improved analytical tools to assess potential safety problems, including access to external data bases.

"(iv) Implementing and enforcing section 505(o) (relating to postapproval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies).

"(v) Preparing and making publicly available (including on the website of the Food and Drug Administration) a summary analysis of the adverse drug reaction reports received for recently approved drugs, including identification of any new risks not previously identified, potential new risks, or known risks reported in un-

usual number not previously identified within 18 months of the drug's initial marketing or after exposure of 10,000 individuals to the drug, whichever is later.

''(vi) Conducting regular, bi-weekly screening of the Adverse Event Reporting System database and developing a report every 15 days on any new safety concerns.

''(vii) Ensuring that the reports available to the public under the Adverse Event Reporting System are updated at least every 6 months.

''(viii) Reporting to the Congress on—

''(I) the recommendations received in consultations with, and reports from, the Office of Surveillance and Epidemiology within the Food and Drug Administration on postmarket safety activities;

''(II) a description of the actions taken on those recommendations; and

''(III) if no action is taken, or a different action is taken relative to the action recommended by the Office of Surveillance and Epidemiology, an ex-

planation of why no action or a different action was taken.

''(ix) On an annual basis, reviewing the entire backlog of postmarket safety commitments to determine which commitments require revision or should be eliminated, reporting to the Congress on these determinations, and assigning start dates and estimated completion dates for such commitments.

''(x) Developing postmarket safety performance measures, including those listed in clauses (v) through (ix), that are as measurable and rigorous as the ones already developed for premarket review.'';

(5) in paragraph (8)—

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

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

(6) by redesignating paragraph (9) as paragraph (11); and

(7) by inserting after paragraph (8) the following paragraphs:

''(9) The term 'person' includes an affiliate thereof.

''(10) The term 'active', with respect to a commercial investigational new drug application, means such an application to which information was submitted during the relevant period.''.

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 ''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) FEES FOR APPLICATIONS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—A human drug application or supplement that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest, unless the fee is waived or reduced under subsection (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 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 positron emission tomography drug shall be subject under subparagraph (A) to one-sixth of an annual establishment fee with respect to each such establishment identified in the

application as producing 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 positron emission tomography drugs; and

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

''(iii) DEFINITION.—For purposes of this subparagraph, the term 'positron

emission tomography drug' has the meaning given to the term 'compounded positron emission tomography drug' in section 201(ii), except that subparagraph (1)(B) of such section shall not apply.''.

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

''(b) FEE REVENUE AMOUNTS.—

''(1) IN GENERAL.—For each of the fiscal years 2008 through 2012, fees under subsection (a) shall, except as provided in subsections (c), (d), (f), and (g), be established to generate a total revenue amount under such subsection that is equal to the sum of—

''(A) $392,783,000; and

''(B) an amount equal to the modified workload adjustment factor for fiscal year 2007 (as determined under paragraph (3)).

''(2) TYPES OF FEES.—Of the total revenue amount determined for a fiscal year under paragraph (1)—

''(A) one-third shall be derived from fees under subsection (a)(1) (relating to human drug applications and supplements);

''(B) one-third shall be derived from fees under subsection (a)(2) (relating to prescription drug establishments); and

''(C) one-third shall be derived from fees under subsection (a)(3) (relating to prescription drug products).

''(3) MODIFIED WORKLOAD ADJUSTMENT FACTOR FOR FISCAL YEAR 2007.—For purposes of paragraph (1)(B), the Secretary shall determine the modified workload adjustment factor by determining the dollar amount that results from applying the methodology that was in effect under subsection (c)(2) for fiscal year 2007 to the amount $354,893,000, except that, with respect to the portion of such determination that is based on the change in the total number of commercial investigational new drug applications, the Secretary shall count the number of such applications that were active during the most recent 12-month period for which data on such submissions is available.

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

''(A) IN GENERAL.—For each of the fiscal years 2008 through 2012, paragraph (1)(A) shall, subject to subparagraph (C), be applied

by substituting the amount determined under subparagraph (B) for '$392,783,000'.

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

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

''(ii) an 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 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 of fiscal years 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) 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 ''For fiscal year 2009 and subsequent fiscal years, 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 years of the preceding 6 fiscal years.''; and

(E) in the matter following subparagraph (C) (as added under 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 ''Beginning with fiscal year 2004,'' and inserting ''For fiscal year 2009 and subsequent fiscal years,'';

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

(i) by striking ''human drug applications,'' and inserting ''human drug applications (adjusted for changes in review activities, as described in the notice that the Secretary is required to publish in the Federal Register under this subparagraph),'';

(ii) by striking ''commercial investigational new drug applications,''; and

(iii) by inserting before the period the following: ‘‘, and the change in the total number of active commercial investigational new drug applications (adjusted for changes in review activities, as so described) during the most recent 12-month period for which data on such submissions is available’’;

(C) in subparagraph (B), by adding at the end the following: ‘‘Any adjustment for changes in review activities made in setting fees and revenue amounts for fiscal year 2009 may not result in the total workload adjustment being more than 2 percentage points higher than it would have been in the absence of 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 and revenue amounts for fiscal year 2009 and to make recommendations, if warranted, for future changes in the methodology for calculating the adjustment. After review of the recommendations, the Secretary

shall, if warranted, make appropriate changes to the methodology, and the changes shall be effective for each of the fiscal years 2010 through 2012. The Secretary shall not make any adjustment for changes in review activities for any fiscal year after 2009 unless such study has been completed.''.

(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.—For fiscal year 2010 and each subsequent fiscal year, the Secretary shall, before making adjustments under paragraphs (1) and (2), decrease the fee revenue amount established in subsection (b) if actual costs paid for rent and rent-related expenses for the preceding fiscal year are less than estimates made for such year in fiscal year 2006. Any reduction made under this paragraph shall not exceed the amount by which such costs fall below the

estimates made in fiscal year 2006 for such fiscal year, and shall not exceed $11,721,000 for 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 paragraph (3)(A))—

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

(ii) by striking ''paragraphs (1) and (2)'' and inserting ''paragraphs (1), (2), and (3)''; and

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

(B) in paragraph (5) (as so redesignated), 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)—

(A) by inserting after ''The Secretary shall grant'' the following: ''to a person who is named as the applicant in a human drug application''; and

(B) by inserting ''to that person'' after ''one or more fees assessed'';

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

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

''(2) CONSIDERATIONS.—In 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 involved and any affiliate of the applicant.''; and

(4) in paragraph (4) (as redesignated by paragraph (2)), in subparagraph (A), by inserting before the period the following: '', 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.—For each of the fiscal years 2008 through 2012, there is authorized to be appropriated for fees under this section an amount equal to the total revenue

amount determined under subsection (b) for the fiscal year, as adjusted or otherwise affected under subsection (c) and paragraph (4) of this subsection.''.

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

''(4) OFFSET.—If the sum of the cumulative amount of fees collected under this section for the fiscal years 2008 through 2010 and the amount of fees estimated to be collected under this section for fiscal year 2011 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2008 through 2011, the 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) EXEMPTION FOR ORPHAN DRUGS.—Section 736 (21 U.S.C. 379h) is further amended by adding at the end the following:

''(k) ORPHAN DRUGS.—A drug designated under section 526 for a rare disease or condition and approved under section 505 or under section 351 of the Public

Health Service Act shall be exempt from product and facility fees under this section, provided that the drug meets all of the following:

''(1) The drug had United States sales in the previous year of less than $25,000,000 for the active moiety, for all indications, dosage forms, and strengths for which the drug is approved and for any off-label uses.

''(2) The drug meets the public health requirements contained in this Act as such requirements are applied to requests for waivers for product and facility fees.

''(3) The drug is owned or licensed and marketed by a company that had less than $100,000,000 in gross worldwide revenue during the previous year.''.

(g) CONFORMING AMENDMENT.—Section 736(a) (21 U.S.C. 379h(a)) is amended in paragraphs (1)(A)(i), (1)(A)(ii), (2)(A), and (3)(A) by striking ''(c)(4)'' each place such term appears and inserting ''(c)(5)''.

SEC. 104. FEES RELATING TO ADVISORY REVIEW OF PRESCRIPTION-DRUG TELEVISION ADVERTISING.

Part 2 of subchapter C of chapter VII (21 U.S.C. 379g et seq.) is amended by adding after section 736 the following:

"SEC. 736A. FEES RELATING TO ADVISORY REVIEW OF PRESCRIPTION-DRUG TELEVISION ADVERTISING.

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

"(1) ADVISORY REVIEW FEE.—

"(A) IN GENERAL.—With respect to a proposed direct-to-consumer television advertisement (referred to in this section as a 'DTC advertisement'), each person that on or after October 1, 2007, submits such an advertisement for advisory review by the Secretary prior to its initial public broadcast (referred to in this section as 'prebroadcast advisory review') shall, except as provided in subparagraph (B), be subject to a fee established under subsection (c)(3).

"(B) EXCEPTION FOR REQUIRED SUBMISSIONS.—A DTC advertisement that is required under section 502(n) to be submitted to the Secretary prior to initial public broadcast is not subject to a fee under subparagraph (A) unless the sponsor designates the submission as a submission for prebroadcast advisory review.

"(C) NOTICE TO SECRETARY OF NUMBER OF ADVERTISEMENTS.—Not later than June 1

of each fiscal year, the Secretary shall publish a notice in the Federal Register requesting any person to notify the Secretary within 30 days of the number of DTC advertisements the person intends to submit for prebroadcast advisory review in the next fiscal year.

''(D) PAYMENT.—

''(i) IN GENERAL.—The fee required by subparagraph (A) (referred to in this section as 'an advisory review fee') shall be due not later than October 1 of the fiscal year in which the DTC advertisement involved is intended be submitted for prebroadcast advisory review, subject to subparagraph (F)(i).

''(ii) EFFECT OF SUBMISSION.—Notification of the Secretary under subparagraph (C) of the number of DTC advertisements a person intends to submit for prebroadcast advisory review is 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.

''(iii) NOTICE REGARDING CARRYOVER SUBMISSIONS.—In making a notification under subparagraph (C), the person involved shall in addition notify the Secretary if under subparagraph (F)(i) the person intends to submit a DTC advertisement for which the advisory review fee has already been paid. If the person does not so notify the Secretary, each DTC advertisement submitted by the person for prebroadcast advisory review in the fiscal year involved shall be subject to the advisory review fee.

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

''(i) LATE PAYMENT.—If a person has submitted a notification under subparagraph (C) with respect to a fiscal year and has not paid all advisory review fees due under subparagraph (D) on or before November 1 of such fiscal year, the fees are regarded as late and a revised due date and an increase in the amount of fees applies in accordance with this clause, notwithstanding any other provision of this

section. For such person, the advisory review fee for each DTC advertisement submitted in such fiscal year for prebroadcast advisory review shall be due and payable 20 days before the advertisement is submitted to the Secretary, and each such fee shall be revised to be equal to 150 percent of the fee that otherwise would have applied pursuant to subsection (c)(3).

''(ii) EXCEEDING IDENTIFIED NUMBER OF SUBMISSIONS.—If a person submits a number of DTC ads for prebroadcast advisory review in a fiscal year that exceeds the number identified by the person under subparagraph (C), a revised due date and an increase in the amount of fees applies under this clause for each submission in excess of such number, notwithstanding any other provision of this section. For each such DTC ad, the advisory review fee shall be due and payable 20 days before the advertisement is submitted to the Secretary, and the fee shall be revised to be equal to 150 percent

of the fee that otherwise would have applied pursuant to subsection (c)(3).

''(F) LIMITS.—

''(i) SUBMISSIONS.—For each advisory review fee paid by a person for a fiscal year, the person is entitled to acceptance for advisory review by the Secretary of one DTC advertisement and acceptance of one 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 not more than one 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 REFUNDS.—Except as provided by subsection (f), fees paid under subparagraph (A) shall not be refunded.

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

''(iv) RIGHT TO ADVISORY REVIEW NOT TRANSFERABLE.—The right to an advisory review under this paragraph 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 fee established under subsection (d)(2) referred to in this section as an 'operating reserve fee' for the first fiscal year in which an advisory review fee is assessed to such person. The person is not subject to an operating reserve fee for any other fiscal year.

''(B) PAYMENT.—Except as provided in subparagraph (C), the operating reserve fee shall be due no 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 under this section, that person submits any DTC advertisements for prebroadcast advisory review that are in excess

of the number identified by that person in response to the Federal Register notice described in subsection (a)(1)(C), that person shall 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 any fees required by subparagraph (A). Fees under this subparagraph shall be due 20 days before any DTC advertisement is submitted by such person to the Secretary for prebroadcast 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 subsections (c) and (g)(4).

''(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; U.S. 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, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia; 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 subsection will 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.—Beginning with fiscal year 2009, after the fee revenues established in subsection (b) 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 DTC advertisements for advisory review prior to initial broadcast. With respect to such adjustment:

"(A) The adjustment shall be determined by the Secretary based upon the number of DTC advertisements identified pursuant to subsection (a)(1)(C) for the upcoming fiscal year, excluding allowable previously paid carry over submissions. The adjustment shall be determined 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)). The Secretary shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

"(B) Under no circumstances shall the adjustment 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 FOR ADVISORY REVIEW.—

''(A) IN GENERAL.—Not later than August 1 of each fiscal year, the Secretary shall establish for the next fiscal year the DTC advertisement advisory review fee under subsection (a)(1), based on the revenue amounts established under subsection (b), the adjustments provided under paragraphs (1) and (2), and the number of DTC advertisements identified pursuant to subsection (a)(1)(C), 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 DTC advertisements so identified, excluding allowable previously-paid carry over submissions.

''(B) FISCAL YEAR 2008 FEE LIMIT.—Notwithstanding subsection (b) and the adjustments pursuant to this subsection, the fee established under subparagraph (A) for fiscal year 2008 may not be more than $83,000 per submission for advisory review.

''(C) ANNUAL FEE LIMIT.—Notwithstanding subsection (b) and the adjustments pursuant to this subsection, the fee established under subparagraph (A) 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.

''(D) 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 under this section in the event the fees collected in any subsequent fiscal year pursuant to subsection (a)(1) 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 DTC advertisements identified by that person pursuant to subsection (a)(1)(C) by the advisory review fee established pursuant to subsection (c)(3) for that fiscal year, except that 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 under this section in fiscal year 2008.

''(3) USE OF OPERATING RESERVE.—The Secretary may use funds from the reserves 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 subsections (b) and (c) and the amount of fees actually collected for that fiscal year pursuant to subsection (a)(1), or to pay costs of ending the program under this section if it is terminated pursuant to subsection (f) or not reauthorized beyond fiscal year 2012.

''(4) REFUND OF OPERATING RESERVES.—Within 120 days of the end of fiscal year 2012, or if the program under this section ends early pursuant to subsection (f), the Secretary, after setting aside sufficient operating reserve amounts to terminate the program under this section, 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 requirement, a submission for prebroadcast advisory review of a DTC 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) INITIAL FUNDING.—If on November 1, 2007, or 120 days after enactment of this provision, whichever is later, the Secretary has not received at least $11,250,000 in advisory review fees and operating reserve fees combined, the program under this section shall not commence and all collected fees shall be refunded.

''(2) LATER FISCAL YEARS.—Beginning in fiscal year 2009, if, on November 1 of the fiscal year, the combination of the operating reserves, annual fee

revenues from that fiscal year, and unobligated fee revenues from prior fiscal years falls below $9,000,000, adjusted for inflation (as described in subsection (c)(1)), the program under this section shall cease to exist, and the Secretary shall notify all participants, retain any money from the unused advisory review fees and the operating reserves needed to close down the program under this section, and refund the remainder of the unused fees and operating reserves. To the extent required to close down the program under this section, the Secretary shall first use unobligated advisory review fee revenues from prior fiscal years, then the operating reserves, and finally, unused advisory review fees from the relevant fiscal year.

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

''(1) IN GENERAL.—Fees authorized under subsection (a) of this section 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.—

''(A) IN GENERAL.—The fees authorized by this section—

''(i) 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

''(ii) shall be available for obligation only if the amounts appropriated as budget authority for such fiscal year are sufficient to support a number of full-time equivalent review employees that is not fewer than the number of such employees supported in fiscal year 2007.

''(B) REVIEW EMPLOYEES.—For purposes of subparagraph (A)(ii), the term 'full-time equivalent review employees' means the total combined number of full-time equivalent employees in—

''(i) the Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications, Food and Drug Administration; and

''(ii) the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Branch, Food and Drug Administration.

''(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2008 through 2012, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted pursuant to subsection (c) and paragraph (4) of this subsection, 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 subchapter:

''(1) The term 'advisory review' means reviewing and providing advisory comments on a proposed advertisement prior to its initial public broadcast.

''(2) The term 'advisory review fee' has the meaning indicated for such term in subsection (a)(1)(D).

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

''(4) The term 'direct-to-consumer television advertisement' means an advertisement for a prescription drug product as defined in section 735(3) intended to be displayed on any television channel for less than 3 minutes.

''(5) The term 'DTC advertisement' has the meaning indicated for such term in subsection (a)(1)(A).

''(6) The term 'operating reserve fee' has the meaning indicated for such term in subsection (a)(2)(A).

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

''(8) The term 'prebroadcast advisory review' has the meaning indicated for such term in subsection (a)(1)(A).

''(9) The term 'process for the advisory review of prescription drug advertising' means the activities necessary to review and provide advisory comments on DTC advertisements prior to public broadcast and, to the extent the Secretary has additional staff resources available under the program under this section that are not necessary for the advisory review of DTC advertisements, the activities necessary to review and provide advisory comments on other proposed advertisements and promotional material prior to public broadcast.

''(10) 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 com-

mittees, 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) closing down the program under this section pursuant to subsection (f)(2) if that becomes necessary.

"(11) The term 'resubmission' means a subsequent submission for advisory review of a direct-to-consumer television advertisement that has been revised 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.

''(12) 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. 105. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) PERFORMANCE REPORT.—Beginning with fiscal year 2008, not later than 120 days after the end of each fiscal year for which fees are collected under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 502(4) of the Prescription Drug User Fee Amendments of 2002 (Subtitle A of title V of Public Law 107–188) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(b) FISCAL REPORT.—Beginning with fiscal year 2008, not later than 120 days after the end of each fiscal year for which fees are collected under the part described

in subsection (a), the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

(c) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations to present to the 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 and representatives of patient and consumer advocacy groups, 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.

(4) PUBLIC AVAILABILITY OF MINUTES.—Before presenting the recommendations developed under paragraphs (1) and (2) to the Congress, the Secretary shall make publicly available, on the public website of the Food and Drug Administration, the minutes of all negotiations conducted under paragraph (1) or (2), as applicable, between the Food and Drug Administration and the regulated industry and representatives of patient and consumer advocacy groups.

SEC. 106. SUNSET DATES.

The amendments made by sections 102, 103, and 104 cease to be effective October 1, 2012.

TITLE II—MEDICAL DEVICE USER FEE AMENDMENTS OF 2007

SEC. 201. SHORT TITLE; REFERENCES IN TITLE.

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

(b) REFERENCES IN ACT.—Except as otherwise specified, amendments made by this title to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

Subtitle A—Fees Related to Medical Devices

SEC. 211. DEFINITIONS.

Section 737 (21 U.S.C. 379i) is amended—

(1) 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 after subparagraph (E) 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.'';

(2) by redesignating paragraphs (5), (6), (7), and (8) as paragraphs (7), (8), (9), and (11), respectively;

(3) by inserting after paragraph (4), as amended by paragraph (1) of this section, 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 de-

vice has been classified or the requirements applicable to a device.

''(6) The term 'annual fee', with respect to periodic reporting concerning a class III device, means the annual fee associated with periodic reports required by a PMA approval order (as described in section 814.82(a)(7) of title 21, Code of Federal Regulations (or any successor regulation)).'';

(4) in paragraph (9), as so redesignated—

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

(B) by striking ''April 2002'' and inserting ''October 2001'';

(5) by inserting after paragraph (9), as so amended, the following:

''(10) The term 'person' includes an affiliate thereof.''; and

(6) by inserting after paragraph (11), as redesignated by paragraph (2) of this section, the following:

''(12) The term 'establishment subject to registration' means an establishment that is required to register with the Secretary under section 510 and is one of the following types of establishments:

''(A) MANUFACTURER.—An establishment that makes by any means any article that is a device, as defined in section 201(h), 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.

''(C) SPECIFICATION DEVELOPER.—An establishment that develops specifications for a device that is distributed under the establishment's name but which performs no manufacturing, including an establishment that, in addition to developing specifications, also arranges for the manufacturing of devices labeled with another establishment's name by a contract manufacturer.''.

SEC. 212. AUTHORITY TO ASSESS AND USE DEVICE FEES.

(a) TYPES OF FEES.—

(1) IN GENERAL.—The designation and heading of paragraph (2) of section 738(a) (21 U.S.C. 379j(a)(2)) are amended to read as follows:

''(2) PREMARKET APPLICATION, PREMARKET REPORT, SUPPLEMENT, AND SUBMISSION FEE, AND

ANNUAL FEE FOR PERIODIC REPORTING CONCERNING A CLASS III DEVICE.—''.

(2) FEE AMOUNTS.—Section 738(a)(2)(A) (21 U.S.C. 379j(a)(2)(A)) is amended—

(A) in clause (iii), by striking ''a fee equal to the fee that applies'' and inserting ''a fee equal to 75 percent of the fee that applies'';

(B) in clause (iv), by striking ''21.5 percent'' and inserting ''15 percent'';

(C) in clause (v), by striking ''7.2 percent'' and inserting ''7 percent'';

(D) by redesignating clauses (vi) and (vii) as clauses (vii) and (viii), respectively;

(E) by inserting after clause (v), as amended by this paragraph, the following:

''(vi) For a 30-day notice, a fee equal to 1.6 percent of the fee that applies under clause (i).'';

(F) in clause (viii), as so redesignated, by striking ''1.42 percent'' and inserting ''1.84 percent''; and

(G) by inserting after such clause (viii) 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).".

(3) PAYMENT.—Section 738(a)(2)(C) (21 U.S.C. 379j(a)(2)(C)) is amended to read as follows:

"(C) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the premarket application, premarket report, supplement, premarket notification submission, 30-day notice, request for classification information, or periodic reporting concerning a class III device. Applicants submitting portions of applications pursuant to section 515(c)(3) shall pay such fees upon submission of the first portion of such applications.".

(4) REFUNDS.—Section 738(a)(2)(D) (21 U.S.C. 379j(a)(2)(D)) is amended by adding after clause (iii) the following:

"(iv) MODULAR APPLICATIONS WITHDRAWN BEFORE FIRST ACTION.—The Secretary shall refund 75 percent of the appli-

cation 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.''.

(5) ANNUAL ESTABLISHMENT REGISTRATION FEE.—Section 738(a) (21 U.S.C. 379j(a)) is amended by adding after paragraph (2) the following:

''(3) ANNUAL ESTABLISHMENT REGISTRATION FEE.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), each establishment subject to registration shall be subject to a fee for each initial or annual registration under section 510 beginning with its registration for fiscal year 2008.

''(B) EXCEPTION.—No fee shall be required under subparagraph (A) for an estab-

lishment operated by a State or Federal governmental entity or an Indian tribe (as defined in the Indian Self Determination and Educational Assistance Act), unless a device manufactured by the establishment is to be distributed commercially.

''(C) PAYMENT.—The fee required under subparagraph (A) shall be due once each fiscal year, upon the initial registration of the establishment or upon the annual registration under section 510.''.

(b) FEE AMOUNTS.—Section 738(b) (21 U.S.C. 379j(b)) is amended to read as follows:

''(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	$1,706	$1,851	$2,008	$2,179	$2,364.''.

(c) ANNUAL FEE SETTING.—

(1) IN GENERAL.—Section 738(c) (21 U.S.C. 379j(c)(1)) is amended—

(A) in the subsection heading, by striking ''Annual Fee Setting'' and inserting ''ANNUAL FEE SETTING''; and

(B) in paragraph (1), by striking the last sentence.

(2) ADJUSTMENT OF ANNUAL ESTABLISHMENT FEE.—Section 738(c) (21 U.S.C. 379j(c)), as amended by paragraph (1), is further amended—

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

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

''(2) ADJUSTMENT.—

''(A) IN GENERAL.—When setting fees for fiscal year 2010, the Secretary may increase the fee under subsection (a)(3)(A) (applicable to establishments subject to registration) only if the Secretary estimates that the number of establishments submitting fees for fiscal year 2009 is less than 12,250. The percentage increase shall be the percentage by which the estimate of establishments submitting fees in fiscal year 2009 is less than 12,750, but in no case may the per-

centage increase be more than 8.5 percent over that specified in subsection (b) for fiscal year 2010. If the Secretary makes any adjustment to the fee under subsection (a)(3)(A) for fiscal year 2010, then such fee for fiscal years 2011 and 2012 shall be adjusted so that such fee for fiscal year 2011 is equal to the adjusted fee for fiscal year 2010 increased by 8.5 percent, and such fee for fiscal year 2012 is equal to the adjusted fee for fiscal year 2011 increased by 8.5 percent.

''(B) PUBLICATION.—For any adjustment made under subparagraph (A), the Secretary shall publish in the Federal Register the Secretary's determination to make the adjustment and the rationale for the determination.''; and

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

(i) by striking ''For fiscal years 2006 and 2007, the Secretary'' and inserting ''The Secretary''; and

(ii) by striking ''for the first month of fiscal year 2008'' and inserting ''for the first month of the next fiscal year''.

(d) SMALL BUSINESSES; FEE WAIVER AND FEE REDUCTION REGARDING PREMARKET APPROVAL.—

(1) IN GENERAL.—Section 738(d)(1) (21 U.S.C. 379j(d)(1)) is amended—

(A) by striking ‘‘, partners, and parent firms’’; and

(B) by striking ‘‘clauses (i) through (vi) of subsection (a)(2)(A)’’ and inserting ‘‘clauses (i) through (v) and clauses (vii), (ix), and (x) of subsection (a)(2)(A)’’.

(2) RULES RELATING TO PREMARKET APPROVAL FEES.—

(A) DEFINITION.—Section 738(d)(2)(A) (21 U.S.C. 379j(d)(2)(A)) is amended by striking ‘‘, partners, and parent firms’’.

(B) EVIDENCE OF QUALIFICATION.—Section 738(d)(2)(B) (21 U.S.C. 379j(d)(2)(B)) is amended—

(i) by striking ‘‘(B) EVIDENCE OF QUALIFICATION.—An applicant’’ and inserting the following:

‘‘(B) EVIDENCE OF QUALIFICATION.—

‘‘(i) IN GENERAL.—An applicant’’;

(ii) by striking ''The applicant shall support its claim'' and inserting the following:

''(ii) FIRMS SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support its claim'';

(iii) by striking '', partners, and parent firms'' each place it appears;

(iv) by striking the last sentence and inserting ''If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates.''; and

(v) by adding at the end the following:

''(iii) FIRMS NOT SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—In the case of an applicant that has not previously submitted a Federal income tax return, the applicant and each of its affiliates shall demonstrate that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or

affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority of the country in which the applicant or, if applicable, affiliate is headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the applicant's or affiliate's gross receipts and sales for the most recent year in both the local currency of such country and in United States dollars, the exchange rate used in converting such local currency to dollars, and the dates during which these receipts and sales were collected. The applicant shall also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.''.

(3) REDUCED FEES.—Section 738(d)(2)(C) (21 U.S.C. 379j(d)(2)(C)) is amended to read as follows:

''(C) REDUCED FEES.—Where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fees

established under subsection (c)(1) may be paid at a reduced rate of—

"(i) 25 percent of the fee established under such subsection for a premarket application, a premarket report, a supplement (other than a 30-day notice), or periodic reporting 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.".

(e) SMALL BUSINESSES; FEE REDUCTION REGARDING PREMARKET NOTIFICATION SUBMISSIONS.—

(1) IN GENERAL.—Section 738(e)(1) (21 U.S.C. 379j(e)(1)) is amended—

(A) by striking "2004" and inserting "2008"; and

(B) by striking "(a)(2)(A)(vii)" and inserting "(a)(2)(A)(viii)".

(2) RULES RELATING TO PREMARKET NOTIFICATION SUBMISSIONS.—

(A) DEFINITION.—Section 738(e)(2)(A) (21 U.S.C. 379j(e)(2)(A)) is amended by striking ", partners, and parent firms".

(B) EVIDENCE OF QUALIFICATION.—Section 738(e)(2)(B) (21 U.S.C. 379j(e)(2)(A)) is amended—

(i) by striking ''(B) EVIDENCE OF QUALIFICATION.—An applicant'' and inserting the following:

''(B) EVIDENCE OF QUALIFICATION.—

''(i) IN GENERAL.—An applicant'';

(ii) by striking ''The applicant shall support its claim'' and inserting the following:

''(ii) FIRMS SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support its claim'';

(iii) by striking '', partners, and parent firms'' each place it appears;

(iv) by striking the last sentence and inserting ''If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates.''; and

(v) by adding at the end the following:

''(iii) FIRMS NOT SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—In the case of an

applicant that has not previously submitted a Federal income tax return, the applicant and each of its affiliates shall demonstrate that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority of the country in which the applicant or, if applicable, affiliate is headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the applicant's or affiliate's gross receipts and sales for the most recent year in both the local currency of such country and in United States dollars, the exchange rate used in converting such local currency to dollars, and the dates during which these receipts and sales were collected. The applicant shall also submit a statement signed by the head of the applicant's firm or by its chief financial officer

that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.''.

(3) REDUCED FEES.—Section 738(e)(2)(C) (21 U.S.C. 379j(e)(2)(C)) is amended to read as follows:

''(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).''.

(f) EFFECT OF FAILURE TO PAY FEES.—Section 738(f) (21 U.S.C. 379j(f)) is amended to read as follows:

''(f) EFFECT OF FAILURE TO PAY FEES.—

''(1) NO ACCEPTANCE OF SUBMISSIONS.—A premarket application, premarket report, supplement, premarket notification submission, 30-day notice, request for classification information, or periodic reporting concerning a class III device submitted by a person subject to fees under subsection (a)(2) and (a)(3) shall be considered incomplete and shall not be accepted by the Secretary until all fees owed by such person have been paid.

''(2) NO REGISTRATION.—Registration information submitted under section 510 by an establishment subject to registration shall be considered incomplete and shall not be accepted by the Secretary until the registration fee under subsection (a)(3) owed for the establishment has been paid. Until the fee is paid and the registration is complete, the establishment is deemed to have failed to register in accordance with section 510.''.

(g) CONDITIONS.—Section 738(g) (21 U.S.C. 379j(g)) is amended—

(1) in paragraph (1)(D)—

(A) in the matter preceding clause (i), by striking ''For fiscal year 2007'' and inserting ''For fiscal year 2007 and for each subsequent year'';

(B) in clause (i), by striking ''applicable to fiscal year 2007'' and inserting ''applicable to such fiscal year''; and

(C) in clause (ii)—

(i) by striking ''subparagraph (C)'' and inserting ''this subparagraph''; and

(ii) by striking ''for fiscal year 2006'' and inserting ''for the previous fiscal year''; and

(2) by amending paragraph (2) to read as follows:

''(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of subparagraph (C) or (D) of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate for premarket applications, supplements, premarket reports, premarket notification submissions, 30-day notices, requests for classification information, periodic reporting concerning a class III device, and establishment registrations at any time in such fiscal year, notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.''.

(h) CREDITING AND AVAILABILITY OF FEES.—

(1) AUTHORIZATION OF APPROPRIATIONS.—Section 738(h)(3) (21 U.S.C. 379j(h)(3)) is amended to read as follows:

''(3) AUTHORIZATIONS 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.".

(2) OFFSET.—Section 738(h)(4) (21 U.S.C. 379j(h)(3)) is amended to read as follows:

"(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 these four 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. 213. ANNUAL REPORTS.

Beginning with fiscal year 2008, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Com-

mittee on Health, Education, Labor, and Pensions of the Senate a report concerning—

(1) the progress of the Food and Drug Administration in achieving the goals identified in the letters from the Secretary of Health and Human Services to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, as set forth in the Congressional Record during such fiscal year, and the future plans of the Food and Drug Administration for meeting the goals, not later than 60 days after the end of each fiscal year during which fees are collected under part 3 of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.); and

(2) 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 (including a description of the use of such fees for postmarket safety activities), not later than 120 days after the end of each fiscal year during which fees are collected under the medical device user-fee program reauthorized by this title.

SEC. 214. CONSULTATION.

(a) IN GENERAL.—In developing recommendations to the Congress for the goals and plans for meeting the goals for the process for the review of medical device applications for fiscal years after fiscal year 2012, and for the reauthorization of sections 737 and 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i, 379j), the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall consult with the Committee on Energy and Commerce of the House of Representatives, the Committee on Health, Education, Labor, and Pensions of the Senate, appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry.

(b) RECOMMENDATIONS.—The Secretary shall publish in the Federal Register recommendations under subsection (a), after negotiations with the regulated industry and patient and consumer advocacy groups; shall present such recommendations to the congressional committees specified in such subsection; shall hold a meeting at which the public may present its views on such recommendations; and shall provide for a period of 30 days for the public to provide written comments on such recommendations.

SEC. 215. ADDITIONAL AUTHORIZATION OF APPROPRIATIONS FOR POSTMARKET SAFETY INFORMATION.

For the purpose of collecting, developing, reviewing, and evaluating postmarket safety information on medical devices, there are authorized to be appropriated to the Food and Drug Administration, in addition to the amounts authorized by other provisions of law for such purpose, $7,100,000 for fiscal year 2008, and for each of the fiscal years 2009 through 2012, $7,100,000 increased by the amount necessary to offset the effects of inflation occurring after October 1, 2007.

SEC. 216. EFFECTIVE DATE.

The amendments made by this title shall take effect on the date of the enactment of this title, except that fees shall be assessed for all premarket applications, premarket reports, supplements, and premarket notification submissions received on or after October 1, 2007, regardless of the date of enactment.

SEC. 217. SUNSET CLAUSE.

The amendments made by this title cease to be effective October 1, 2012, except that section 213 (regarding annual reports) ceases to be effective January 31, 2013.

Subtitle B—Amendments Regarding Regulation of Medical Devices

SEC. 221. 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. 222. REGISTRATION.

(a) ANNUAL REGISTRATION OF PRODUCERS OF DRUGS AND DEVICES.—Section 510(b) (21 U.S.C. 360(b)) is amended—

(1) by striking ''On or before'' and inserting ''(1) On or before'';

(2) by striking ''or a device or devices''; and

(3) by adding at the end the following:

''(2) During the period beginning on October 1 and ending on 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. 360(i)(1)) is amended by striking ''On or before December 31'' and all

that follows and inserting the following: ''Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States shall, through electronic means in accordance with the criteria of the Secretary—

''(A) upon first engaging in any such activity, immediately 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 drug or device in the United States that is known to the establishment, and the name of each person who imports or offers for import such drug or device to the United States for purposes of importation; and

''(B) each establishment subject to the requirements of subparagraph (A) shall thereafter—

''(i) with respect to drugs, register with the Secretary on or before December 31 of each year; and

''(ii) with respect to devices, register with the Secretary during the period beginning on October 1 and ending on December 31 of each year.''.

SEC. 223. 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), by striking ''Each person'' and all that follows through ''the following information:'' and inserting ''Each person who registers with the Secretary under this section shall report to the Secretary, with regard to drugs once during the month of June of each year and once during the month of December of each year, and with regard to devices once each year during the period beginning on October 1 and ending on December 31, the following information:''.

SEC. 224. ELECTRONIC REGISTRATION AND LISTING.

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

''(p)(1) Registrations and listings under this section (including the submission of updated information) shall be submitted to the Secretary by electronic means 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 infor-

mation 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.''.

SEC. 225. REPORT BY GOVERNMENT ACCOUNTABILITY OFFICE.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study on the appropriate use of the process under section 510(k) of the Federal Food, Drug, and Cosmetic Act as part of the device classification process to determine whether a new device is as safe and effective as a classified device.

(b) CONSIDERATION.—In determining the effectiveness of the premarket notification and classification authority under section 510(k) and subsections (f) and (i) of section 513, the study under subsection (a) shall consider the Secretary's evaluation of the respective intended uses and technologies of such devices, including the effectiveness of the Secretary's comparative assessment of technological characteristics such as device materials, principles of operations, and power sources.

(c) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall complete the study under subsection (a) and submit to the Congress a report on the results of such study.

SEC. 226. UNIQUE DEVICE IDENTIFICATION SYSTEM.

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

(1) by redesignating subsection (f) as subsection (g); and

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

''Unique Device Identification System

''(f) The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the labeling of devices to bear a unique identifier.''.

SEC. 227. FREQUENCY OF REPORTING FOR CERTAIN DEVICES.

Subparagraph (B) of section 519(a)(1) (21 U.S.C. 360i(a)(1)) is amended by striking ''were to recur;'' and inserting the following: ''were to recur, which report under this subparagraph—

''(i) shall be submitted in accordance with part 803 of title 21, Code of Federal Regulations (or successor regulations), if the device involved is—

''(I) a class III device;

''(II) a class II device that is permanently implantable, is life supporting, or is life sustaining; or

''(III) a type of device that the Secretary has by regulation determined should be subject to such part 803 in order to protect the public health; or

''(ii) shall, if the device is not subject to clause (i), be submitted in accordance with criteria established by the Secretary for reports made pursuant to this clause, which criteria shall require the reports to be in summary form and made on a quarterly basis;''.

SEC. 228. 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 the 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 Secretary'' 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 unless 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 de-

nies 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) in subparagraph (A), by striking ''(A) Persons'' and all that follows through the end and inserting the following: ''(A) Persons ac-

credited 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 paragraph (10)(C)(iii), by striking ''based'' and inserting ''base''.

SEC. 229. STUDY OF NOSOCOMIAL INFECTIONS RELATING TO MEDICAL DEVICES.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study on—

(1) the number of nosocomial infections attributable to new and reused medical devices; and

(2) the causes of such nosocomial infections, including the following:

(A) Reprocessed single use devices.

(B) Handling of sterilized medical devices.

(C) In-hospital sterilization of medical devices.

(D) Health care professionals' practices for patient examination and treatment.

(E) Hospital-based policies and procedures for infection control and prevention.

(F) Hospital-based practices for handling of medical waste.

(G) Other causes.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall complete the study under subsection (a) and submit to the Congress a report on the results of such study.

(c) DEFINITION.—In this section, the term ''nosocomial infection'' means an infection that is acquired while an individual is a patient at a hospital and was neither present nor incubating in the patient prior to receiving services in the hospital.

TITLE III—PEDIATRIC MEDICAL DEVICE SAFETY AND IMPROVEMENT ACT OF 2007

SEC. 301. SHORT TITLE.

This title may be cited as the ''Pediatric Medical Device Safety and Improvement Act of 2007''.

SEC. 302. 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 in-

clude, 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.—For purposes of this section, the term 'pediatric subpopulation' has the meaning given the term in section 520(m)(6)(E)(ii).".

SEC. 303. 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 paragraph (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.''; and

(3) by striking paragraph (6) and inserting after paragraph (5) the following new paragraphs:

''(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, 2013.

''(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.

''(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 Ad-

visory Committee, including obtaining any recommendations of such committee regarding whether the Secretary should take action under this Act in response to the report.

''(8) In consultation with the Office of Pediatric Therapeutics and the Center for Devices and Radiological Health, the Secretary shall provide for an annual review by the Pediatric Advisory Committee of all devices described in paragraph (6) to ensure that the exemption under paragraph (2) remains appropriate for the pediatric populations for which it is granted.''.

(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 condi-

tions 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 305.

(c) GUIDANCE.—Not later than 180 days after the date of enactment of this Act, 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. 304. ENCOURAGING PEDIATRIC MEDICAL DEVICE RESEARCH.

(a) ACCESS TO FUNDING.—The Director of the National Institutes of Health shall designate a contact point or office at the National Institutes of Health to help innovators and physicians access funding for pediatric medical device development.

(b) PLAN FOR PEDIATRIC MEDICAL DEVICE RESEARCH.—

(1) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Commissioner of Food and Drugs, 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.

(2) CONTENTS.—The plan under paragraph (1) shall include—

(A) the current status of federally funded pediatric medical device research;

(B) any gaps in such research, which may include a survey of pediatric medical providers regarding unmet pediatric medical device needs, as needed; and

(C) 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.

SEC. 305. 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 Act, 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—

(1) encourage innovation by connecting qualified individuals with pediatric device ideas with potential manufacturers;

(2) mentor and manage pediatric device projects through the development process, including product identification, prototype design, device development, and marketing;

(3) connect innovators and physicians to existing 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) assess the scientific and medical merit of proposed pediatric device projects;

(5) assess business feasibility and provide business advice;

(6) provide assistance with prototype development; and

(7) provide assistance with postmarket needs, including training, logistics, and reporting.

(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 304; 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.

(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. 306. AMENDMENTS TO OFFICE OF PEDIATRIC THERAPEUTICS AND PEDIATRIC ADVISORY COMMITTEE.

(a) 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".

(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

(iii) in subparagraph (C), by inserting ''(including drugs and biological products) and medical devices'' after ''therapeutics''.

SEC. 307. POSTMARKET STUDIES.

Section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l) is amended—

(1) in subsection (a)—

(A) by inserting '', or as a condition to approval of an application (or a supplement to an application) or a product development protocol under section 515 or as a condition to clearance of a premarket notification under section 510(k), for a pediatric population or pediatric subpopulation,'' after ''The Secretary may by order''; and

(B) by inserting '', or that is indicated for pediatric populations or subpopulations or is ex-

pected to have significant use in pediatric populations,'' after ''health consequences''; 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 STUDIES 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 or efficacy of the device.

''(c) DISPUTE RESOLUTION.—A manufacturer may request review under section 562 of any order or condition requiring postmarket surveillance under this section. During the pendency of such review, the device subject to such a postmarket surveillance order or condition shall not be deemed misbranded under section 502(t) or otherwise in violation of such order or condition or a related requirement of this Act unless deemed necessary to protect the public health.''.

TITLE IV—PEDIATRIC RESEARCH EQUITY ACT OF 2007

SEC. 401. SHORT TITLE.

This title may be cited as the ''Pediatric Research Equity Act of 2007''.

SEC. 402. REAUTHORIZATION OF PEDIATRIC RESEARCH EQUITY ACT.

(a) IN GENERAL.—Section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended to read as follows:

''SEC. 505B. RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.

''(a) NEW DRUGS AND BIOLOGICAL PRODUCTS.—

''(1) IN GENERAL.—A person that submits, on or after the date of enactment of the Pediatric Re-

search Equity Act of 2007, an application (or supplement to an application)—

"(A) under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration, or

"(B) under section 351 of the Public Health Service Act (42 U.S.C. 262) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration,

shall submit with the application the assessments described in paragraph (2).

"(2) ASSESSMENTS.—

"(A) IN GENERAL.—The assessments referred to in paragraph (1) shall contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate—

"(i) to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations; and

"(ii) to support dosing and administration for each pediatric subpopulation for

which the drug or the biological product is safe and effective.

"(B) SIMILAR COURSE OF DISEASE OR SIMILAR EFFECT OF DRUG OR BIOLOGICAL PRODUCT.—

"(i) IN GENERAL.—If the course of the disease and the effects of the drug are sufficiently similar in adults and pediatric patients, the Secretary may conclude that pediatric effectiveness can be extrapolated from adequate and well-controlled studies in adults, usually supplemented with other information obtained in pediatric patients, such as pharmacokinetic studies.

"(ii) EXTRAPOLATION BETWEEN AGE GROUPS.—A study may not be needed in each pediatric age group if data from one age group can be extrapolated to another age group.

"(iii) INFORMATION ON EXTRAPOLATION.—A brief documentation of the scientific data supporting the conclusion under clauses (i) and (ii) shall be included in the medical review that is collected as part of the application under section 505

of this Act or section 351 of the Public Health Service Act (42 U.S.C. 262).

''(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 effectiveness 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.

''(4) WAIVERS.—

''(A) FULL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection if the applicant certifies and the Secretary finds that—

''(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients is so small or the patients are geographically dispersed);

''(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups; or

''(iii) The drug or biological product—

''(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

''(II) is not likely to be used in a substantial number of pediatric patients.

''(B) PARTIAL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—

''(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);

''(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

''(iii) the drug or biological product—

''(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

"(II) is not likely to be used by a substantial number of pediatric patients in that age group; or

"(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

"(C) PEDIATRIC FORMULATION NOT POSSIBLE.—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation. An applicant seeking either a full or partial waiver 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.

"(D) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included

in the labeling for the drug or biological product.

''(b) MARKETED DRUGS AND BIOLOGICAL PRODUCTS.—

''(1) IN GENERAL.—Beginning on the date of enactment of the Pediatric Research Equity Act of 2007, after providing notice in the form of a letter 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 to submit by a specified date the assessments described in subsection (a)(2), 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) WAIVERS.—

''(A) FULL WAIVER.—At the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments under this subsection if the applicant certifies and the Secretary finds that—

''(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed); or

''(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups.

''(B) PARTIAL WAIVER.—At the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments under this subsection with respect to a specific pediatric age group if the

applicant certifies and the Secretary finds that—

"(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);

"(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

"(iii)(I) the drug or biological product—

"(aa) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

"(bb) is not likely to be used in a substantial number of pediatric patients in that age group; and

"(II) the absence of adequate labeling could not pose significant risks to pediatric patients; or

"(iv) the applicant can demonstrate that reasonable attempts to produce a pe-

diatric formulation necessary for that age group have failed.

"(C) PEDIATRIC FORMULATION NOT POSSIBLE.—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation. An applicant seeking either a full or partial waiver 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.

"(D) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

"(c) MEANINGFUL THERAPEUTIC BENEFIT.—For the purposes of paragraph (4)(A)(iii)(I) and (4)(B)(iii)(I) of subsection (a) and paragraphs (1)(B)(I) and

(2)(B)(iii)(I)(aa) of subsection (b), a drug or biological product shall be considered to represent a meaningful therapeutic benefit over existing therapies if the Secretary determines that—

''(1) if approved, the drug or biological product could represent an improvement in the treatment, diagnosis, or prevention of a disease, compared with marketed products adequately labeled for that use in the relevant pediatric population; or

''(2) the drug or biological product is in a class of products or for an indication for which there is a need for additional options.

''(d) SUBMISSION OF ASSESSMENTS.—If a person fails to submit an assessment described in subsection (a)(2), or a request for approval of a pediatric formulation described in subsection (a) or (b), in accordance with applicable provisions of subsections (a) and (b)—

''(1) the drug or biological product that is the subject of the assessment or request may be considered misbranded solely because of that failure and subject to relevant enforcement action (except that the drug or biological product shall not be subject to action under section 303); but

''(2) the failure to submit the assessment or request shall not be the basis for a proceeding—

''(A) to withdraw approval for a drug under section 505(e); or

''(B) to revoke the license for a biological product under section 351 of the Public Health Service Act.

''(e) MEETINGS.—Before and during the investigational process for a new drug or biological product, the Secretary shall meet at appropriate times with the sponsor of the new drug or biological product to discuss—

''(1) information that the sponsor submits on plans and timelines for pediatric studies; or

''(2) any planned request by the sponsor for waiver or deferral of pediatric studies.

''(f) REVIEW OF PEDIATRIC PLANS, DEFERRALS, AND WAIVERS.—

''(1) REVIEW.—Beginning not later than 30 days after the date of enactment of the Pediatric Research Equity Act of 2007, the Secretary shall utilize an internal committee to provide consultation to reviewing divisions on all pediatric plans and assessments prior to approval of an application or supplement for which a pediatric assessment is required under this section and all deferral and waiver requests granted pursuant to this section. Such internal committee shall include employees of the Food

and Drug Administration, with expertise in pediatrics (including representation from the Office of Pediatric Therapeutics), biopharmacology, statistics, chemistry, legal issues, pediatric ethics, and the appropriate expertise pertaining to the pediatric product under review, and other individuals designated by the Secretary.

''(2) ACTIVITY BY COMMITTEE.—The committee referred to in paragraph (1) may operate using appropriate members of such committee and need not convene all members of the committee.

''(3) DOCUMENTATION OF COMMITTEE ACTION.—For each drug or biological product, the committee referred to in paragraph (1) shall document, for each activity described in paragraph (4), which members of the committee participated in such activity.

''(4) REVIEW OF PEDIATRIC PLANS, DEFERRALS AND WAIVERS.—Consultation on pediatric plans and assessments by the internal committee pursuant to this section shall occur prior to approval of an application or supplement for which a pediatric assessment is required under this section. The internal committee shall review all requests for deferrals and waivers from the requirement to submit a pediatric

assessment granted under this section and shall provide recommendations as needed to reviewing divisions.

''(5) RETROSPECTIVE REVIEW OF PEDIATRIC PLANS, DEFERRALS AND WAIVERS.—Within one year after enactment of the Pediatric Research Equity Act of 2007, the committee shall conduct a retrospective review and analysis of a representative sample of assessments submitted and deferrals and waivers approved under this section since enactment of the Pediatric Research Equity Act of 2003. Such review shall include an analysis of the quality and consistency of pediatric information in pediatric assessments and the appropriateness of waivers and deferrals granted. Based on such review, the Secretary shall issue recommendations to the review divisions for improvements and initiate guidance to industry related to the scope of pediatric studies required under this section.

''(6) TRACKING OF ASSESSMENTS AND LABELING CHANGES.—Beginning on the date of enactment of the Pediatric Research Equity Act of 2007, the Secretary shall track and make 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 assessments conducted under this section;

"(B) the specific drugs and biological products and their 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 formulation was 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 (h)(2); and

''(I) an annual summary of information submitted pursuant to subsection (a)(3)(B).

''(7) COMMITTEE.—The committee utilized under paragraph (1) shall be the committee established under section 505A(f)(1).

''(g) LABELING CHANGES.—

''(1) PRIORITY STATUS FOR PEDIATRIC APPLICATIONS.—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 application or 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, on or after the date of enactment of the Pediatric Research

Equity Act of 2007, 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 of the application make any labeling change that the Commissioner determines to be appropriate; and

"(ii) if the sponsor does not agree within 30 days after the Commissioner's request 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 to make any labeling changes that the Commissioner determines to be appropriate.

"(D) MISBRANDING.—If the sponsor of the application, 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 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, on or after the date of enactment of the Pediatric Research Equity Act of 2007, 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 in pediatric populations or subpopulations, including whether such assessment results are inconclusive, the Secretary shall order the label 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.—Beginning on the date of enactment of the Pediatric Research Equity Act of 2007, 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)(6)(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 or section 1905 of title 18, United States Code.

''(i) ADVERSE EVENT REPORTING.—

''(1) REPORTING IN YEAR ONE.—Beginning on the date of enactment of the Pediatric Research Equity Act of 2007, during the one-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 the report, the Director of such Office shall provide for the review of the report by the Pediatric Advisory Committee, including ob-

taining 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 one-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 the report, the Director of such Office may provide for the review of the report 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.

''(j) SCOPE OF AUTHORITY.—Nothing in this section provides to the Secretary any authority to require a pediatric assessment of any drug or biological product, or any assessment regarding other populations or uses of a drug or biological product, other than the pediatric assessments described in this section.

''(k) ORPHAN DRUGS.—Unless the Secretary requires otherwise by regulation, this section does not apply

to any drug for an indication for which orphan designation has been granted under section 526.

''(l) INSTITUTE OF MEDICINE STUDY.—

''(1) IN GENERAL.—Not later than three years after the date of the enactment of the Pediatric Research Equity Act of 2007, the Secretary shall contract with the Institute of Medicine to conduct a study and report to Congress regarding the pediatric studies conducted pursuant to this section since 1997 and labeling changes made as a result of such studies.

''(2) CONTENT OF STUDY.—The study under paragraph (1) shall review and assess the use of extrapolation for pediatric subpopulations, the use of alternative endpoints for pediatric populations, neonatal assessment tools, the 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 this section from each review division within the Center for Drug Evaluation and Research in order to make the requested assessment.''.

(b) APPLICABILITY.—The amendment made in subsection (a) applies to assessments required under section 505B on or after the date of enactment of this Act.

SEC. 403. GOVERNMENT ACCOUNTABILITY OFFICE REPORT.

Not later than September 1, 2011, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, shall submit to the Congress a report that addresses the effectiveness of sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c) and section 409I of the Public Health Service Act (42 U.S.C. 284m) in ensuring that medicines used by children are tested and properly labeled. Such report shall include—

(1) the number and importance of drugs and biological products for children that are being tested as a result of the amendments made by this title and title V 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 and biological products for children that are not being tested for their use notwithstanding the provisions of this title and title V 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 title;

(3) the number of drugs and biological products 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 title, 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 sections 505A and 505B 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.

TITLE V—BEST PHARMACEUTICALS FOR CHILDREN ACT OF 2007

SEC. 501. SHORT TITLE.

This title may be cited as the ''Best Pharmaceuticals for Children Act of 2007''.

SEC. 502. REAUTHORIZATION OF BEST PHARMACEUTICALS FOR CHILDREN ACT.

(a) PEDIATRIC STUDIES OF DRUGS.—

(1) IN GENERAL.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended to read as follows:

''SEC. 505A. PEDIATRIC STUDIES OF DRUGS.

''(a) DEFINITIONS.—As used in this section, the term 'pediatric studies' or 'studies' means at least one clinical investigation (that, at the Secretary's discretion, may include pharmacokinetic studies) in pediatric age groups (including neonates in appropriate cases) in which a drug is anticipated to be used, and at the discretion of the Secretary, may include preclinical studies.

''(b) MARKET EXCLUSIVITY FOR NEW DRUGS.—

''(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 has determined that labeling changes are appropriate, such changes are approved within the timeframe requested by the Secretary—

''(A)(i)(I) the period referred to in subsection (c)(3)(E)(ii) of section 505, and in subsection (j)(5)(F)(ii) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section to four years, to forty-eight months, and to seven

and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

''(II) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(E) of such section, and in clauses (iii) and (iv) of subsection (j)(5)(F) of such section, is deemed to be three years and six months rather than three years; and

''(ii) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven years; and

''(B)(i) if the drug is the subject of—

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

''(II) a listed patent for which a certification has been submitted under sub-

sections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

''(ii) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).

''(2) EXCEPTION.—The Secretary shall not extend the period referred to in paragraph (1)(A) or (1)(B) if the determination is made later than one year prior to the expiration of such period.

''(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—

''(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 and such changes are approved within the timeframe requested by the Secretary—

''(A)(i)(I) the period referred to in subsection (c)(3)(E)(ii) of section 505, and in subsection (j)(5)(F)(ii) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and

one-half years, fifty-four months, and eight years, respectively; or

"(II) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(D) of such section, and in clauses (iii) and (iv) of subsection (j)(5)(F) of such section, is deemed to be three years and six months rather than three years; and

"(ii) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven years; and

"(B)(i) if the drug is the subject of—

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

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

the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B)(ii) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

''(ii) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions)

''(2) EXCEPTION.—The Secretary shall not extend the period referred to in paragraph (1)(A) or (1)(B) if the determination is made later than one year prior to the expiration of such period.

''(d) CONDUCT OF PEDIATRIC STUDIES.—

''(1) REQUEST FOR STUDIES.—

''(A) IN GENERAL.—The Secretary may, after consultation with the sponsor of an appli-

cation 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 one 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 stud-

ies (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 stating the reasons for declining the request.

"(ii) DISAGREE WITH REQUEST.—If, on or after the date of the enactment of the Best Pharmaceuticals for Children Act 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 the enactment of the Best Pharmaceuticals for Children Act of 2007, agrees to the request for such studies shall provide the Secretary, at the same time as the 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 accepting or rejecting the reports shall be to determine, within the 180-day period, 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.

''(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 the enactment of the Best Pharmaceuticals for Children Act 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 exclusivity 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 the enactment of the Best Pharmaceuticals for Children Act 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 one year after 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 one year period.

"(f) INTERNAL REVIEW OF WRITTEN REQUESTS AND PEDIATRIC STUDIES.—

"(1) INTERNAL REVIEW.—

"(A) IN GENERAL.—The Secretary shall establish an internal review committee to review all written requests issued on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, in accordance with paragraph (2).

"(B) MEMBERS.—The committee established under subparagraph (A) shall include individuals with expertise in pediatrics, biopharmacology, statistics, drugs and drug formulations, legal issues, pediatric ethics, the appropriate expertise, such as expertise in child and adolescent psychiatry, pertaining to the pediatric product under review, one or more experts from the Office of Pediatric Therapeutics, and other individuals designated by the Secretary.

"(2) REVIEW OF WRITTEN REQUESTS.—The committee established under paragraph (1) shall re-

view all written requests issued pursuant to this section prior to being issued.

''(3) TRACKING PEDIATRIC STUDIES AND LABELING CHANGES.—The Secretary shall track and make 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 and under section 409I of the Public Health Service Act;

''(B) the specific drugs and biological products and their uses, including labeled and off-labeled indications, studied under such sections;

''(C) the types of studies conducted under such sections, 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 such sections;

''(F) an annual summary of labeling changes made as a result of studies conducted

under such sections for distribution pursuant to subsection (k)(2); and

''(G) information regarding reports submitted on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007.

''(4) COMMITTEE.—The committee established under paragraph (1) shall be the committee utilized under section 505B(f)(1).

''(g) LIMITATIONS.—Notwithstanding subsection (c)(2), a drug to which the six-month period under subsection (b) or (c) has already been applied—

''(1) may receive an additional six-month period under subsection (c)(1)(A)(i)(II) for a supplemental application if all other requirements under this section are satisfied; and

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

''(h) RELATIONSHIP TO PEDIATRIC RESEARCH REQUIREMENTS.—Notwithstanding any other provision of law, if any pediatric study is required by a provision of law (including a regulation) other than this section and such study meets the completeness, timeliness, and other requirements of this section, such study shall be deemed

to satisfy the requirement for market exclusivity pursuant to this section.

''(i) LABELING CHANGES.—

''(1) PRIORITY STATUS FOR PEDIATRIC APPLICATIONS AND SUPPLEMENTS.—Any application or supplement to an application under section 505 proposing a labeling change as a result of any pediatric study conducted pursuant to this section—

''(A) shall be considered to be a priority application or 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, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Commissioner determines that the 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, not later than 180 days after the date of submission of the application—

"(i) the Commissioner shall request that the sponsor of the application make any labeling change that the Commissioner determines to be appropriate; and

"(ii) if the sponsor of the application does not agree within 30 days after the Commissioner's request 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 applica-

tion to make any labeling change that the Commissioner determines to be appropriate.

"(D) MISBRANDING.—If the sponsor of the application, 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 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.

"(j) OTHER LABELING CHANGES.—If, on or after the date of the enactment of the Best Pharmaceuticals for Children Act 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 in pediatric populations or subpopulations, including whether such study results are in-

conclusive, 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.

"(k) DISSEMINATION OF PEDIATRIC INFORMATION.—

"(1) IN GENERAL.—Not later than 180 days after the date of submission of a report on a pediatric study under this section, the Secretary shall make available to the public the medical, statistical, and clinical pharmacology reviews of pediatric studies conducted under subsection (b) or (c).

"(2) DISSEMINATION OF INFORMATION REGARDING LABELING CHANGES.—Beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary shall include as a requirement of a written request that the sponsors of the studies that result in labeling changes that are reflected in the annual summary developed pursuant to subsection (f)(3)(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.

"(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.

''(l) ADVERSE EVENT REPORTING.—

''(1) REPORTING IN YEAR ONE.—Beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, during the one-year period beginning on the date a labeling change is approved 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 the reports, the Director of such Office shall provide for the review of the reports 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 reports.

''(2) REPORTING IN SUBSEQUENT YEARS.—Following the one-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.

''(m) CLARIFICATION OF INTERACTION OF MARKET EXCLUSIVITY UNDER THIS SECTION AND MARKET EXCLUSIVITY AWARDED TO AN APPLICANT FOR APPROVAL OF A DRUG UNDER SECTION 505(j).—If a 180-day period under section 505(j)(5)(B)(iv) overlaps with a 6-month exclusivity period under this section, so that the applicant for approval of a drug under section 505(j) entitled to the 180-day period under that section loses a portion of the 180-day period to which the applicant is entitled for the drug, the 180-day period shall be extended from—

''(1) the date on which the 180-day period would have expired by the number of days of the overlap, if the 180-day period would, but for the application of this subsection, expire after the 6-month exclusivity period; or

''(2) the date on which the 6-month exclusivity period expires, by the number of days of the overlap if the 180-day period would, but for the application of this subsection, expire during the six-month exclusivity period.

''(n) REFERRAL IF PEDIATRIC STUDIES NOT COMPLETED.—

''(1) IN GENERAL.—Beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, if pediatric studies 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—

''(A) for a drug for which listed patents have not expired, make a determination regarding whether an assessment shall be required to be submitted under section 505B; or

''(B) for a drug that has no listed patents or has 1 or more listed patents that have expired, determine whether there are funds available under section 736 to award a grant to con-

duct the requested studies pursuant to paragraph (2).

''(2) FUNDING OF STUDIES.—If, pursuant to paragraph (1), the Secretary determines that there are funds available under section 736 to award a grant to conduct the requested pediatric studies, then the Secretary shall issue a proposal to award a grant to conduct the requested studies. If the Secretary determines that funds are not available under section 736, the Secretary shall refer the drug for inclusion on the list established under section 409I of the Public Health Service Act or the conduct of studies.

''(3) 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;

''(B) the name of any drug, its manufacturer, and the indications to be studied pursuant to a grant made under paragraph (2); and

''(C) any decision under paragraph (2) to include a drug on the list established under section 409I of the Public Health Service Act.

"(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.

"(o) PROMPT APPROVAL OF DRUGS UNDER SECTION 505(j) WHEN PEDIATRIC INFORMATION IS ADDED TO LABELING.—

"(1) GENERAL RULE.—A drug for which an application has been submitted or approved under section 505(j) shall not be considered ineligible for approval under that section or misbranded under section 502 on the basis that the labeling of the drug omits a pediatric indication or any other aspect of labeling pertaining to pediatric use when the omitted indication or other aspect is protected by patent or by exclusivity under clause (iii) or (iv) of section 505(j)(5)(F).

"(2) LABELING.—Notwithstanding clauses (iii) and (iv) of section 505(j)(5)(F), the Secretary may require that the labeling of a drug approved under section 505(j) that omits a pediatric indication or other aspect of labeling as described in paragraph (1) include—

"(A) a statement that, because of marketing exclusivity for a manufacturer—

''(i) the drug is not labeled for pediatric use; or

''(ii) in the case of a drug for which there is an additional pediatric use not referred to in paragraph (1), the drug is not labeled for the pediatric use under paragraph (1); and

''(B) a statement of any appropriate pediatric contraindications, warnings, or precautions that the Secretary considers necessary.

''(3) PRESERVATION OF PEDIATRIC EXCLUSIVITY AND OTHER PROVISIONS.—This subsection does not affect—

''(A) the availability or scope of exclusivity under this section;

''(B) the availability or scope of exclusivity under section 505 for pediatric formulations;

''(C) the question of the eligibility for approval of any application under section 505(j) that omits any other conditions of approval entitled to exclusivity under clause (iii) or (iv) of section 505(j)(5)(F); or

''(D) except as expressly provided in paragraphs (1) and (2), the operation of section 505.

''(p) INSTITUTE OF MEDICINE STUDY.—Not later than 3 years after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary 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 this section. The Institute of Medicine may devise an appropriate mechanism to review a representative sample of requests made and studies conducted pursuant to this 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);

''(2) review and assess such representative pediatric studies conducted under subsections (b) and (c) since 1997 and labeling changes made as a result of such studies;

''(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; and

''(4) make recommendations regarding appropriate incentives for encouraging pediatric studies of biologics.

''(q) SUNSET.—A drug may not receive any 6-month period under subsection (b) or (c) unless—

''(1) on or before October 1, 2012, the Secretary makes a written request for pediatric studies of the drug;

''(2) on or before October 1, 2012, an application for the drug is accepted for filing under section 505(b); and

''(3) all requirements of this section are met.''.

(2) EFFECTIVE DATE.—The amendment made by this subsection 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 the enactment of this Act.

(b) PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.—Section 409I of the Public Health Service Act (42 U.S.C. 284m) is amended to read as follows:

''SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.

''(a) LIST OF PRIORITY ISSUES IN PEDIATRIC THERAPEUTICS.—

''(1) IN GENERAL.—Not later than one year after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Com-

missioner 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 three 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 exper-

tise 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.

''(c) PROCESS FOR PROPOSED PEDIATRIC STUDY REQUESTS AND LABELING CHANGES.—

''(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 such section; and

"(B) there is no patent protection or market exclusivity protection for at least one 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.

"(2) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS LACKING EXCLUSIVITY.—The Commissioner of Food and Drugs, in consultation with the Director of the National Institutes of Health, may issue a written request based on the proposed pediatric study request for the indication or indications submitted pursuant to paragraph (1) (which shall include a timeframe for negotiations for an agreement) for pediatric studies concerning a drug identified under subsection (a) to all

holders of an approved application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act. Such a written request shall be made in a manner equivalent to the manner in which a written request is made under subsection (b) or (c) of section 505A of such Act, including with respect to information provided on the pediatric studies to be conducted pursuant to the request and using appropriate formulations for each age group for which the study is requested.

''(3) REQUESTS FOR PROPOSALS.—If the Commissioner of Food and Drugs does not receive a response to a written request issued under paragraph (2) not later than 30 days after the date on which a request was issued, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs, shall publish a request for proposals to conduct the pediatric studies described in the written request in accordance with subsection (b).

''(4) DISQUALIFICATION.—A holder that receives a first right of refusal shall not be entitled to respond to a request for proposals under paragraph (3).

''(5) CONTRACTS, GRANTS, OR OTHER FUNDING MECHANISMS.—A contract, grant, or other funding may be awarded under this section only if a proposal is submitted to the Secretary in such form and manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

''(6) REPORTING OF STUDIES.—

''(A) IN GENERAL.—On completion of a pediatric study in accordance with an award under this section, a report concerning the study shall be submitted to the Director of the National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data generated in connection with the study, including a written request if issued.

''(B) AVAILABILITY OF REPORTS.—Each report submitted under subparagraph (A) shall be considered to be in the public domain (subject to section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act) and shall be assigned a docket number by the Commissioner of Food and Drugs. An interested person may submit written comments concerning such pediatric studies to the Commissioner of Food and

Drugs, and the written comments shall become part of the docket file with respect to each of the drugs.

''(C) ACTION BY COMMISSIONER.—The Commissioner of Food and Drugs shall take appropriate action in response to the reports submitted under subparagraph (A) in accordance with paragraph (7).

''(7) REQUESTS FOR LABELING CHANGE.—During the 180-day period after the date on which a report is submitted under paragraph (6)(A), the Commissioner of Food and Drugs shall—

''(A) review the report and such other data as are available concerning the safe and effective use in the pediatric population of the drug studied;

''(B) negotiate with the holders of approved applications for the drug studied for any labeling changes that the Commissioner of Food and Drugs determines to be appropriate and requests the holders to make; and

''(C)(i) place in the public docket file a copy of the report and of any requested labeling changes; and

"(ii) publish in the Federal Register and through a posting on the website of the Food and Drug Administration a summary of the report and a copy of any requested labeling changes.

"(8) DISPUTE RESOLUTION.—

"(A) REFERRAL TO PEDIATRIC ADVISORY COMMITTEE.—If, not later than the end of the 180-day period specified in paragraph (7), the holder of an approved application for the drug involved does not agree to any labeling change requested by the Commissioner of Food and Drugs under that paragraph, the Commissioner of Food and Drugs shall refer the request to the Pediatric Advisory Committee.

"(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under subparagraph (A), the Pediatric Advisory Committee shall—

"(i) review the available information on the safe and effective use of the drug in the pediatric population, including study reports submitted under this section; and

"(ii) make a recommendation to the Commissioner of Food and Drugs as to appropriate labeling changes, if any.

"(9) FDA DETERMINATION.—Not later than 30 days after receiving a recommendation from the Pediatric Advisory Committee under paragraph (8)(B)(ii) with respect to a drug, the Commissioner of Food and Drugs shall consider the recommendation and, if appropriate, make a request to the holders of approved applications for the drug to make any labeling change that the Commissioner of Food and Drugs determines to be appropriate.

"(10) FAILURE TO AGREE.—If a holder of an approved application for a drug, within 30 days after receiving a request to make a labeling change under paragraph (9), does not agree to make a requested labeling change, the Commissioner of Food and Drugs may deem the drug to be misbranded under the Federal Food, Drug, and Cosmetic Act.

"(11) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under the Federal Food, Drug, and Cosmetic 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.

''(d) DISSEMINATION OF PEDIATRIC INFORMATION.—Not later than one year after the date of the enactment of the Best Pharmaceuticals for Children Act 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 four succeeding fiscal years.

''(2) AVAILABILITY.—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.''.

(c) FEES RELATING TO DRUGS.—Section 735(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379(6)) is amended by adding at the end the following new subparagraph:

''(G) Activities relating to the support of studies of drugs on pediatric populations under section 505A(n)(1).''.

(d) 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 this 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))''.

(e) 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 new subsection:

''(d) CONTINUATION OF OPERATION OF COMMITTEE.—Notwithstanding section 14 of the Federal Advisory Committee Act, the advisory committee shall continue to operate during the five-year period beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007.''.

(f) 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 new subparagraph:

''(D) provide recommendations to the internal review committee created under section 505A(f) of the Federal Food, Drug, and Cosmetic Act regarding the implementation of amendments to sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act with respect to the treatment of pediatric cancers.''; and

(B) by adding at the end the following new paragraph:

''(3) CONTINUATION OF OPERATION OF SUBCOMMITTEE.—Notwithstanding section 14 of the Federal Advisory Committee Act, the Subcommittee shall continue to operate during the five-year period beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007.''; and

(2) in subsection (d), by striking ''2003'' and inserting ''2009''.

(g) EFFECTIVE DATE AND LIMITATION FOR RULE RELATING TO TOLL-FREE NUMBER FOR ADVERSE EVENTS ON LABELING FOR HUMAN DRUG PRODUCTS.—

(1) 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.

(2) 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—

(A) for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355);

(B) that is not described under section 503(b)(1) of such Act (21 U.S.C. 353(b)(1)); and

(C) the packaging of which includes a toll-free number through which consumers can report complaints to the manufacturer or distributor of the drug.

TITLE VI—REAGAN-UDALL FOUNDATION

SEC. 601. 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, and including the incorporation of more sensitive and predictive tools and devices to measure safety;

''(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 para-

graph (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 appropriate 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 this Act, 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 disposition 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 Foun-

dation 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 expi-

ration 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 duration 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 Treasury 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 of the Federal Food, Drug, and Cosmetic Act (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 this subchapter.''.

(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. 602. 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.''.

SEC. 603. CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.

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. CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.

''(a) ESTABLISHMENT.—The Secretary, acting through the Commissioner of Food and Drugs, shall enter into collaborative agreements, to be known as Critical Path Public-Private Partnerships, with one or more eligible entities to implement the Critical Path Initiative of the Food and Drug Administration by developing innovative, collaborative projects in research, education, and outreach for the purpose of fostering medical product innovation, enabling the acceleration of medical product development, and enhancing medical product safety.

''(b) ELIGIBLE ENTITY.—In this section, the term 'eligible entity' means an entity that meets each of the following:

''(1) The entity is—

''(A) an institution of higher education (as such term is defined in section 101 of the Higher Education Act of 1965); or

''(B) an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of such Code.

''(2) The entity has experienced personnel and clinical and other technical expertise in the biomedical sciences.

''(3) The entity demonstrates to the Secretary's satisfaction that the entity is capable of—

''(A) developing and critically evaluating tools, methods, and processes—

''(i) to increase efficiency, predictability, and productivity of medical product development; and

''(ii) to more accurately identify the benefits and risks of new and existing medical products;

''(B) establishing partnerships, consortia, and collaborations with health care practitioners and other providers of health care goods or services; pharmacists; pharmacy benefit managers and purchasers; health maintenance orga-

nizations and other managed health care organizations; health care insurers; government agencies; patients and consumers; manufacturers of prescription drugs, biological products, diagnostic technologies, and devices; and academic scientists; and

''(C) securing funding for the projects of a Critical Path Public-Private Partnership from Federal and nonfederal governmental sources, foundations, and private individuals.

''(c) FUNDING.—The Secretary may not enter into a collaborative agreement under subsection (a) unless the eligible entity involved provides an assurance that the entity will not accept funding for a Critical Path Public-Private Partnership project from any organization that manufactures or distributes products regulated by the Food and Drug Administration unless—

''(1) the entity accepts such funding for such project from 2 or more such organizations; and

''(2) the entity provides assurances in its agreement with the Food and Drug Administration that the results of the Critical Path Public-Private Partnership project will not be influenced by any source of funding.

''(d) ANNUAL REPORT.—Not later than 18 months after the date of the enactment of this section, and annually thereafter, the Secretary, in collaboration with the parties to each Critical Path Public-Private Partnership, 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—

''(1) reviewing the operations and activities of the Partnerships in the previous year; and

''(2) addressing such other issues relating to this section as the Secretary determines to be appropriate.

''(e) DEFINITION.—In this section, the term 'medical product' includes a drug, a biological product, a device, and any combination of such products.

''(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $5,000,000 for fiscal year 2008 and such sums as may be necessary for each of fiscal years 2009 through 2012.''.

TITLE VII—CONFLICTS OF INTEREST

SEC. 701. 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, through the Office of Women's Health, the Office of Orphan Product Development, the Office of Pediatric Therapeutics, and other offices within the Food and Drug Administration

with relevant expertise, shall develop and implement strategies on effective outreach to potential members of advisory committees at universities, colleges, other academic research centers, professional and medical societies, and patient and consumer groups. 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 funding from the National Institutes of Health, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, or the Veterans Health Administration 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.

''(3) PARTICIPATION OF GUEST EXPERT WITH FINANCIAL INTEREST.—Notwithstanding any other provision of this section, an individual with a financial interest with respect to any matter considered by an advisory committee may be allowed to participate in a meeting of an advisory committee as a guest expert if the Secretary determines that the individual has particular expertise required for the meeting. An individual participating as a guest expert may provide information and expert opinion, but shall not participate in the discussion or voting by the members of the advisory 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) LIMITATIONS.—

''(A) ONE WAIVER PER COMMITTEE MEETING.—Notwithstanding any other provision of this section, with respect to each advisory committee, the Secretary shall not grant more than 1 waiver under paragraph (3) per committee meeting.

''(B) SCIENTIFIC WORK.—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 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—

(1) by striking paragraph (4); and

(2) by 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.

TITLE VIII—CLINICAL TRIAL DATABASES

SEC. 801. CLINICAL TRIAL REGISTRY DATABASE AND CLINICAL TRIAL RESULTS DATABASE.

(a) IN GENERAL.—Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended—

(1) in section 402, by striking subsection (i); and

(2) by inserting after section 492B the following new section:

"SEC. 492C. CLINICAL TRIAL REGISTRY DATABASE; CLINICAL TRIAL RESULTS DATABASE.

''(a) DEFINITIONS.—In this section:

''(1) APPLICABLE CLINICAL TRIAL.—The term 'applicable clinical trial'—

''(A) means a clinical trial that is conducted to test the safety or effectiveness (including comparative effectiveness) of a drug or device (irrespective of whether the clinical trial is federally or privately funded, and whether the clinical trial involves an approved or unapproved drug or device);

''(B) includes such a clinical trial that is conducted outside of the United States if—

"(i) there is an application or premarket notification pending before the Food and Drug Administration for approval or clearance of the drug or device involved under section 505, 510(k), or 515 of the Federal Food, Drug, and Cosmetic Act or section 351 of this Act; or

"(ii) the drug or device involved is so approved or cleared; and

"(C) notwithstanding subparagraphs (A) and (B), excludes—

"(i) a clinical trial to determine the safety of a use of a drug that is designed solely to detect major toxicities in the drug or to investigate pharmacokinetics, unless the clinical trial is designed to investigate pharmacokinetics in a special population or populations; and

"(ii) a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary focus is feasibility.

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

ical trial registry database under subsection (b) or the clinical trial results database under subsection (c), as applicable.

''(3) COMPLETION DATE.—The term 'completion date' means the date of the final collection of data from subjects in the clinical trial for the primary and secondary outcomes to be examined in the trial.

''(4) DEVICE.—The term 'device' has the meaning given to that term in section 201(h) of the Federal Food, Drug, and Cosmetic Act.

''(5) 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.

''(6) RESPONSIBLE PARTY.—The term 'responsible party', with respect to an applicable clinical trial, means—

''(A) the primary sponsor (as defined in the International Clinical Trials Registry Platform trial registration data set of the World Health Organization) of the clinical trial; or

''(B) the principal investigator of such clinical trial if so designated by such sponsor, so long as the principal investigator is responsible

for conducting the trial, has access to and control over the data, has the right to publish the results of the trial, and has the responsibility to meet all of the requirements under this section that are applicable to responsible parties.

''(b) CLINICAL TRIALS REGISTRY DATABASE.—

''(1) ESTABLISHMENT.—To enhance patient enrollment and provide a mechanism to track subsequent progress of clinical trials, the Secretary, acting through the Director of NIH, shall establish and administer a clinical trial registry database in accordance with this section (referred to in this section as the 'registry database'). The Director of NIH shall ensure that the registry database is made publicly available through the Internet.

''(2) CONTENT.—The Secretary shall promulgate regulations for the submission to the registry database of clinical trial information that—

''(A) conforms to the International Clinical Trials Registry Platform trial registration data set of the World Health Organization;

''(B) 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;

"(C) includes a statement of the estimated completion date for the clinical trial;

"(D) includes the identity and contact information of the responsible party;

"(E) 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, or the device is not cleared under section 510(k) or approved under section 515 of the Federal Food, Drug, and Cosmetic Act, specifies whether or not there is expanded access to the drug or device 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;

"(F) includes, with respect to any individual who is not an employee of the responsible party for the clinical trial or of the manufacturer of the drug or device involved, information on whether the responsible party or manufacturer has entered into any agreement with such individual that restricts in any manner the ability of the individual—

''(i) to discuss the results of the trial at a scientific meeting or any other public or private forum; or

''(ii) to publish the results of the trial, or a description or discussion of the results of the trial, in a scientific or academic journal; and

''(G) requires the inclusion of such other data elements to the registry database as appropriate.

''(3) FORMAT AND STRUCTURE.—

''(A) SEARCHABLE CATEGORIES.—The Director of NIH shall ensure that the public may search the entries in the registry database by 1 or more of the following criteria:

''(i) The indication being studied in the clinical trial, using Medical Subject Headers (MeSH) descriptors.

''(ii) The safety issue being studied in the clinical trial.

''(iii) The enrollment status of the clinical trial.

''(iv) The sponsor of the clinical trial.

''(B) FORMAT.—The Director of the NIH shall ensure that the registry database is easily

used by patients, and that entries are easily compared.

''(4) DATA SUBMISSION.—The responsible party for an applicable clinical trial shall submit to the Director of NIH for inclusion in the registry database the clinical trial information described in paragraph (2).

''(5) TRUTHFUL CLINICAL TRIAL INFORMATION.—

''(A) IN GENERAL.—The clinical trial information submitted by a responsible party under this subsection shall not be false or misleading.

''(B) EFFECT.—Subparagraph (A) shall not have the effect of requiring clinical trial information to include information from any source other than the clinical trial involved.

''(6) TIMING OF SUBMISSION.—Except as provided in paragraph (7), the clinical trial information for a clinical trial required to be submitted under this subsection shall be submitted not later than 14 days after the first patient is enrolled in such clinical trial.

''(7) UPDATES.—The responsible party for an applicable clinical trial shall submit to the Director

of NIH for inclusion in the registry database periodic updates to reflect changes to the clinical trial information submitted under this subsection. Such updates—

"(A) shall be provided not less than once every 6 months until information on the results of the trial is submitted under subsection (c);

"(B) shall include identification of the dates of any such changes;

"(C) not later than 30 days after the enrollment status of such clinical trial changes, shall include an update of the enrollment status; and

"(D) not later than 30 days after the completion date of the clinical trial, shall include a report to the Director that such clinical trial is complete.

"(8) APPLICABILITY OF DEVICE TRIALS.—In the case of an applicable clinical trial regarding a device, the responsible person for the trial shall submit to the Director of NIH the clinical trial information as required in paragraph (4), but the Director may not make the information publicly available through the registry database until the device is approved or cleared (as the case may be).

''(c) CLINICAL TRIALS RESULTS DATABASE.—

''(1) ESTABLISHMENT.—To ensure that results of clinical trials are made public and that patients and providers have current information regarding the results of clinical trials, the Secretary, acting through the Director of NIH, shall establish and administer a clinical trial results database in accordance with this section (referred to in this section as the 'results database'). The Director of NIH shall ensure that the results database is made publicly available through the Internet.

''(2) SEARCHABLE CATEGORIES.—The Director of NIH shall ensure that the public may search the entries in the results database by 1 or more of the following:

''(A) The indication studied in the clinical trial, using Medical Subject Headers (MeSH) descriptors.

''(B) The safety issue studied in the clinical trial.

''(C) Whether an application for the tested indication is approved, pending approval, withdrawn, or not submitted.

''(D) The phase of the clinical trial.

"(E) The name of the drug or device that is the subject of the clinical trial.

"(F) Within the documents described in clauses (i) and (ii) of paragraph (3)(B), the following information, as applicable:

"(i) The sponsor of the clinical trial.

"(ii) Each financial sponsor of the clinical trial.

"(3) CONTENTS.—

"(A) IN GENERAL.—The responsible party for an applicable clinical trial shall submit to the Director of NIH for inclusion in the results database the clinical trial information described in subparagraph (B).

"(B) REQUIRED ELEMENTS.—In submitting clinical trial information for a clinical trial to the Director of NIH for inclusion in the results database, the responsible party shall include, with respect to such clinical trial, the following information:

"(i) The information described in subparagraphs (A) through (E) of subsection (b)(2).

"(ii) A summary that is written in non-technical, understandable language for patients that includes the following:

"(I) The purpose of the clinical trial.

"(II) The sponsor of the clinical trial.

"(III) A point of contact for information about the clinical trial.

"(IV) A description of the patient population tested in the clinical trial.

"(V) A general description of the clinical trial and results, including a description of and the reasons for any changes in the clinical trial design that occurred since the date of submission of clinical trial information for inclusion in the registry database established under subsection (b) and a description of any significant safety information.

"(iii) A summary that is technical in nature that includes the following:

"(I) The purpose of the clinical trial.

''(II) The sponsor of the clinical trial.

''(III) Each financial sponsor of the clinical trial.

''(IV) A point of contact for scientific information about the clinical trial.

''(V) A description of the patient population tested in the clinical trial.

''(VI) A general description of the clinical trial and results, including a description of and the reasons for any changes in the clinical trial design that occurred since the date of submission of clinical trial information for the clinical trial in the registry database established under subsection (b).

''(VII) Summary data describing the results, including—

''(aa) whether the primary endpoint was achieved, including relevant statistics;

''(bb) an assessment of any secondary endpoints, if applica-

ble, including relevant statistics; and

"(cc) any significant safety information, including a summary of the incidence of serious adverse events observed in the clinical trial and a summary of the most common adverse events observed in the clinical trial and the frequencies of such events.

"(iv) With respect to the group of subjects receiving the drug or device involved, and each comparison group of subjects, the percentage of individuals who ceased participation as subjects and the reasons for ceasing participation.

"(v) With respect to an individual who is not an employee of the responsible party for the clinical trial or of the manufacturer of the drug or device involved, information (to the extent not submitted under subsection (b)(2)(F)) on any agreement that the responsible party or manufacturer has entered into with such individual that re-

stricts in any manner the ability of the individual—

"(I) to discuss the results of the trial at a scientific meeting or any other public or private forum; or

"(II) to publish the results of the trial, or a description or discussion of the results of the trial, in a scientific or academic journal.

"(vi) The completion date of the clinical trial.

"(vii) A link to the Internet web posting of any adverse regulatory actions taken by the Food and Drug Administration, such as a warning letter, that was substantively based on the clinical trial design, outcome, or representation made by the applicant about the design or outcome of the clinical trial.

"(C) LINKS IN DATABASE.—The Director of NIH shall ensure that the results database includes the following:

"(i) Links to Medline citations to publications reporting results from each appli-

cable drug clinical trial and applicable device clinical trial.

''(ii) Links to the entry for the product that is the subject of an applicable drug clinical trial in the National Library of Medicine database of structured product labels, if available.

''(iii) Links described in clauses (i) and (ii) for data bank entries for clinical trials submitted to the data bank prior to enactment of this section, as available.

''(4) TIMING.—

''(A) IN GENERAL.—Except as provided in subparagraphs (B) and (C), a responsible party shall submit to the Director of NIH for inclusion in the results database clinical trial information for an applicable clinical trial not later than 1 year after the earlier of—

''(i) the estimated completion date of the trial, as submitted under subsection (b)(2); or

''(ii) the actual date of the completion, or termination before completion, of the trial, as applicable.

"(B) EXTENSIONS.—The Director of NIH may provide an extension of the deadline for submission of clinical trial information under subparagraph (A) if the responsible party for the trial submits to the Director a written request that demonstrates good cause for the extension and provides an estimate of the date on which the information will be submitted. The Director of NIH may grant more than one such extension for the clinical trial involved.

"(C) UPDATES.—The responsible party for an applicable clinical trial shall submit to the Director of NIH for inclusion in the results database periodic updates to reflect changes in the clinical trial information submitted under this subsection. Such updates—

"(i) shall be provided not less frequently than once every 6 months during the 10-year period beginning on the date on which information is due under subparagraph (A);

"(ii) shall identify the dates on which the changes were made; and

"(iii) shall include, not later than 30 days after any change in the regulatory

status of the drug or device involved, an update informing the Director of NIH of such change.

''(5) TRUTHFUL CLINICAL TRIAL INFORMATION.—

''(A) IN GENERAL.—The clinical trial information submitted by a responsible party under this subsection shall not be false or misleading in any particular.

''(B) EFFECT.—Subparagraph (A) shall not have the effect of requiring clinical trial information with respect to a clinical trial to include information from any source other than such clinical trial.

''(6) PUBLIC AVAILABILITY OF RESULTS.—

''(A) PRE-APPROVAL STUDIES.—Except as provided in subparagraph (E), with respect to an applicable clinical trial that is completed before the drug is initially approved under section 505 of the Federal Food, Drug, and Cosmetic Act or initially licensed under section 351 of this Act, or the device is initially cleared under section 510(k) or approved under section 515 of the Federal Food, Drug, and Cosmetic Act, the Director of NIH shall make publicly available

on the results database the clinical trial information submitted for such clinical trial not later than 30 days after—

"(i) the drug or device is approved under such section 505, licensed under such section 351, cleared under such section 510(k), or approved under such section 515, as applicable; or

"(ii) the Secretary issues a not approvable letter or a not substantially equivalent letter for the drug or device under such section 505, 351, 510(k), or 515, as applicable.

"(B) MEDICAL AND CLINICAL PHARMACOLOGY REVIEWS OF PRE-APPROVAL STUDIES.—Not later than 90 days after the date applicable under clause (i) or (ii) of subparagraph (A) with respect to an applicable clinical trial, the Director of NIH shall make publicly available on the results database a summary of the available medical and clinical pharmacology reviews conducted by the Food and Drug Administration for such trial.

"(C) POST-APPROVAL STUDIES.—Except as provided in subparagraphs (D) and (E), with

respect to an applicable clinical trial that is completed after the drug is initially approved under such section 505 or licensed under such section 351, or the device is initially cleared under such section 510(k) or approved under such section 515, the Director of NIH shall make publicly available on the results database the clinical trial information submitted for such clinical trial not later than 30 days after the date of such submission.

''(D) SEEKING APPROVAL OF A NEW USE FOR THE DRUG OR DEVICE.—

''(i) IN GENERAL.—If the manufacturer of the drug or device is the sponsor or a financial sponsor of an applicable clinical trial, and such manufacturer certifies to the Director of NIH that such manufacturer has filed, or will file within 1 year, an application seeking approval under such section 505, licensing under such section 351, clearance under such section 510(k), or approval under such section 515 for the use studied in such clinical trial (which use is not included in the labeling of the approved drug or device), then the Director

of NIH shall make publicly available on the results database the clinical trial information submitted for such clinical trial on the earlier of the date that is 30 days after the date—

"(I) the new use of the drug or device is approved under such section 505, licensed under such section 351, cleared under such section 510(k), or approved under such section 515;

"(II) the Secretary issues a not approvable letter or a not substantially equivalent letter for the new use of the drug or device under such section 505, 351, 510(k), or 515; or

"(III) the application or premarket notification under such section 505, 351, 510(k), or 515 is withdrawn.

"(ii) LIMITATION ON CERTIFICATION.—If a manufacturer makes a certification under clause (i) with respect to a clinical trial, the manufacturer shall make such a certification with respect to each applicable clinical trial that is required to

be submitted in an application for approval of the use studied in the clinical trial.

''(iii) 2-YEAR LIMITATION.—The clinical trial information subject to clause (i) shall be made publicly available on the results database on the date that is 2 years after the date the certification referred to in clause (i) was made to the Director of NIH, if a regulatory action referred to in subclause (I), (II), or (III) of clause (i) has not occurred by such date.

''(iv) MEDICAL AND CLINICAL PHARMACOLOGY REVIEWS.—Not later than 90 days after the date applicable under subclause (I), (II), or (III) of clause (i) or clause (iii) with respect to an applicable clinical trial, the Director of NIH shall make publicly available on the results database a summary of the available medical and clinical pharmacology reviews conducted by the Food and Drug Administration for such trial.

''(E) SEEKING PUBLICATION.—

''(i) IN GENERAL.—If the principal investigator of an applicable clinical trial is

seeking publication in a peer-reviewed biomedical journal of a manuscript based on the results of the clinical trial and the responsible party so certifies to the Director of NIH—

"(I) the responsible party shall notify the Director of NIH of the publication date of such manuscript not later than 15 days after such date; and

"(II) the Director of NIH shall make publicly available on the results database the clinical trial information submitted for such clinical trial on the date that is 30 days after the publication date of such manuscript.

"(ii) LIMITATIONS.—The clinical trial information subject to clause (i)—

"(I) shall be made publicly available on the results database on the date that is 2 years after the date that the clinical trial information was required to be submitted to the Director of NIH if the manuscript referred

to in such clause has not been published by such date; and

"(II) shall not be required to be made publicly available under section 552 of title 5, United States Code (commonly known as the 'Freedom of Information Act'), prior to the date applicable to such clinical trial information under this subparagraph.

"(7) VERIFICATION OF SUBMISSION PRIOR TO PUBLIC AVAILABILITY.—In the case of clinical trial information that is submitted under this subsection, but is not made publicly available pending either regulatory action or publication under subparagraph (D) or (E) of paragraph (6), as applicable, the Director of NIH shall respond to inquiries from other Federal agencies and peer-reviewed journals to confirm that such clinical trial information has been submitted but has not yet been made publicly available on the results database.

"(d) UPDATES; TRACKING OF CHANGES IN SUBMITTED INFORMATION.—The Director of NIH shall ensure that updates submitted to the Director under subsections (b)(7) and (c)(4) do not result in the removal from the registry database or the results database of the

original submissions or of any preceding updates, and that information in such databases is presented in a manner that enables users to readily access each original submission and to track the changes made by the updates.

"(e) COORDINATION AND COMPLIANCE.—

"(1) CONSULTATION WITH OTHER FEDERAL AGENCIES.—The Secretary shall—

"(A) consult with other agencies that conduct human studies in accordance with part 46 of title 45, Code of Federal Regulations (or any successor regulations), to determine if any such studies are applicable clinical trials; and

"(B) develop with such agencies appropriate procedures to ensure that clinical trial information for such applicable clinical trials is submitted under subsection (b) and (c).

"(2) COORDINATION OF REGISTRY DATABASE AND RESULTS DATABASE.—

"(A) IN GENERAL.—Each entry in the registry database under subsection (b) or the results database under subsection (c) shall include a link to the corresponding entry in the results database or the registry database, respectively.

"(B) MISSING ENTRIES.—

"(i) IN GENERAL.—If, based on a review of the entries in the registry database under subsection (b), the Director of NIH determines that a responsible party has failed to submit required clinical trial information to the results database under subsection (c), the Director of NIH shall inform the responsible party involved of such failure and permit the responsible party to correct the failure within 30 days.

"(ii) FAILURE TO CORRECT.—If the responsible party does not correct a failure to submit required clinical trial information within the 30-day period described under clause (i), the Director of NIH shall report such noncompliance to the scientific peer review committees of the Federal research agencies and to the Office of Human Research Protections.

"(iii) PUBLIC NOTICE OF FAILURE TO CORRECT.—The Director of NIH shall include in the clinical trial registry database entry and the clinical trial results database entry for each applicable clinical trial a notice of any uncorrected failure to submit

required clinical trial information and shall provide that the public may easily search for such entries.

''(3) ACTION ON APPLICATIONS.—

''(A) VERIFICATION PRIOR TO FILING.—The Secretary, acting through the Commissioner of Food and Drugs, shall verify that the clinical trial information required under subsections (b) and (c) for an applicable clinical trial is submitted pursuant to such subsections, as applicable—

''(i) when considering a drug or device for an exemption under section 505(i) or section 520(g) of the Federal Food, Drug, and Cosmetic Act; and

''(ii) prior to filing an application or premarket notification under section 505, 510(k), or 515 of the Federal Food, Drug, and Cosmetic Act or section 351 of this Act, that includes information from such clinical trial.

''(B) NOTIFICATION.—If the Secretary determines under subparagraph (A) that clinical trial information has not been submitted as required by subsection (b) or (c), the Secretary

shall notify the applicant and the responsible party of such noncompliance and require submission of such information within 30 days.

"(C) REFUSAL TO FILE.—If the responsible party does not remedy such noncompliance within 30 days of receipt of notification under subparagraph (B), the Secretary shall refuse to file, approve, or clear such application or premarket notification.

"(4) CONTENT REVIEW.—

"(A) IN GENERAL.—To ensure that the summary documents described in subsection (c)(3) are non-promotional, and are not false or misleading in any particular under subsection (c)(5), the Secretary shall compare such documents to the results data of the clinical trial for a representative sample of applicable clinical trials by—

"(i) acting through the Commissioner of Food and Drugs to examine the results data for such clinical trials submitted to Secretary when such data are submitted—

"(I) for review as part of an application under section 505 or 515 of the Federal Food, Drug, and Cos-

metic Act or under section 351 of this Act or a premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act; or

''(II) in an annual status report on the drug or device under such application;

''(ii) acting with the Federal agency that funds such clinical trial in whole or in part by a grant to examine the results data for such clinical trials; and

''(iii) acting through inspections under section 704 of the Federal Food, Drug, and Cosmetic Act to examine results data for such clinical trials not described in clause (i) or (ii).

''(B) NOTICE OF NONCOMPLIANCE.—If the Secretary determines that the clinical trial information submitted in such a summary document is false or misleading in any particular, the Secretary shall notify the responsible party and give such party an opportunity to remedy such noncompliance by submitting the required revised clinical trial information within 30 days of such notification.

''(f) PENALTIES FOR NONCOMPLIANCE.—

''(1) IN GENERAL.—The following acts and the causing thereof are unlawful:

''(A) The failure to submit clinical trial information as required by this section.

''(B) The submission of clinical trial information under this section that is false or misleading in any particular in violation of subsection (b)(5) or (c)(5).

''(2) CERTAIN PENALTIES.—Section 303(a) of the Federal Food, Drug, and Cosmetic Act applies with respect to a violation of paragraph (1) to the same extent and in the same manner as such section 303(a) applies with respect to a violation of section 301 of such Act.

''(3) CONSIDERATIONS.—In determining whether to apply a penalty under paragraph (2) or under paragraph (4) for a violation described in paragraph (1), the Secretary, acting through the Commissioner of Food and Drugs, shall consider—

''(A) whether the responsible party promptly corrects the noncompliance when provided notice;

"(B) whether the responsible party has engaged in a pattern or practice of noncompliance; and

"(C) the extent to which the noncompliance involved may have significantly misled health care providers or patients concerning the safety or effectiveness of the drug involved.

"(4) CIVIL PENALTIES.—

"(A) IN GENERAL.—A person is subject to a civil penalty in accordance with this paragraph if the person commits a violation described in paragraph (1) and fails to correct the violation by the end of the 30-day period described in subparagraph (B).

"(B) NOTIFICATION.—If a person is in violation of paragraph (1), the Secretary shall notify the person of such noncompliance and give the person a 30-day period to correct such violation before imposing a civil penalty under this paragraph.

"(C) AMOUNT OF PENALTY.—The amount of a civil penalty under this subsection shall be not more than a total of $15,000 for all violations adjudicated in a single proceeding in the case of an individual, and not more than

$10,000 per day until the violation is corrected in the case of any other person, except that if the person is a nonprofit entity the penalty may not exceed a total of $15,000 for all violations adjudicated in a single proceeding.

''(D) PROCEDURES.—The provisions of paragraphs (4) through (6) of section 303(f) of the Federal Food, Drug, and Cosmetic Act apply to the imposition of a penalty under this subsection to the same extent and in the same manner as such provisions apply to a penalty imposed under such section 303(f).

''(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $10,000,000 for each fiscal year.''.

(b) CONFORMING AMENDMENTS.—

(1) INVESTIGATIONAL NEW DRUGS.—Section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) is amended—

(A) in paragraph (1)—

(i) in subparagraph (C), by striking ''and'' after the semicolon;

(ii) in subparagraph (D)—

(I) by aligning the indentation of such subparagraph with the indenta-

tion of subparagraphs (A), (B), and (C); and

(II) by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end the following:

''(E) the submission to the Director of NIH of clinical trial information for the clinical investigation at issue required under section 492C of the Public Health Service Act for inclusion in the registry database and the results database described in such section.'';

(B) in paragraph (3)(B)—

(i) in clause (i), by striking ''or'' after the semicolon;

(ii) in clause (ii), by striking the period at the end and inserting ''; or''; and

(iii) by adding at the end the following:

''(iii) clinical trial information for the clinical investigation at issue was not submitted in compliance with section 492C of the Public Health Service Act.''; and

(C) 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 will be submitted for inclusion in the registry database and results database, as applicable, described in section 492C of the Public Health Service Act.''.

(2) REFUSAL TO APPROVE NEW DRUG APPLICATION.—Section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)) is amended—

(A) in the first sentence, by inserting after ''in any particular;'' the following: ''or (8) the applicant failed to submit the clinical trial information for any applicable clinical trial as required by section 492C of the Public Health Service Act;''; and

(B) in the second sentence, by striking ''clauses (1) through (6)'' and inserting ''paragraphs (1) through (8)''.

(3) INVESTIGATIONAL NEW DEVICES.—Subparagraph (B) of section 520(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)(2)) is amended—

(A) by redesignating clause (iii) as clause (iv); and

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

''(iii) A requirement that the person applying for an exemption for a device assure that such person is in compliance with the requirements of section 492C of the Public Health Service Act for the submission of clinical trial information for inclusion in the registry database and the results database described in such section.''.

(4) REFUSAL TO CLEAR NEW DEVICE PREMARKET NOTIFICATION REPORT.—Subsection (k) of section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended—

(A) in paragraph (1), by striking ''and'' at the end; and

(B) in paragraph (2), by striking the period at the end and inserting '', and''; and

(C) by adding at the end the following:

''(3) action taken by such person to comply with requirements under section 492C of the Public Health Service Act for the submission of clinical trial information for inclusion in the registry database and the results database described in such section.''.

(5) REFUSAL TO APPROVE NEW DEVICE APPLICATION.—Paragraph (2) of section 515(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)) is amended—

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

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

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

''(F) the applicant is in violation of the requirements under section 492C of the Public Health Service Act for the submission of clinical trial information for inclusion in the registry database or the results database described in such section.''.

(c) GUIDANCE.—Not later than 180 days after the date of the enactment of this Act, the Commissioner of Food and Drugs, in consultation with the Director of the National Institutes of Health, shall issue guidance to clarify which clinical trials are applicable clinical trials (as defined in section 492C of the Public Health Service Act, as amended by this section) and required to be submitted for inclusion in the clinical trial registry database described in such section.

(d) 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 any requirement 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 section 492C 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 databases under subsections (b) and (c) of such section 492C, if submitted in compliance with such section 492C, 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.).

(e) EFFECTIVE DATES.—

(1) ESTABLISHMENT OF REGISTRY DATABASE AND RESULTS DATABASE.—Not later than 1 year after the date of the enactment of this Act, the Director of NIH shall establish the registry database and the results database of clinical trials of drugs and devices in accordance with section 492C of the Public Health Service Act (as amended by subsection (a)).

(2) CLINICAL TRIALS INITIATED PRIOR TO OPERATION OF REGISTRY DATABASE.—The responsible party (as defined in such section 492C) for an applicable clinical trial (as defined in such section 492C) that is initiated after the date of the enactment of this Act and before the date such registry database is established under paragraph (1) of this subsection, shall submit required clinical trial information not later than 120 days after the date such registry database is established.

(3) CLINICAL TRIALS INITIATED AFTER OPERATION OF REGISTRY DATABASE.—The responsible party (as defined in such section 492C) for an applicable clinical trial (as defined in such section 492C) that is initiated after the date such registry database is established under paragraph (1) of this subsection

shall submit required clinical trial information in accordance with subsection (b) of such section 492C.

(4) TRIALS COMPLETED BEFORE OPERATION OF RESULTS DATABASE.—

(A) IN GENERAL.—Subsection (c) of such section 492C shall take effect 90 days after the date the results database is established under paragraph (1) of this subsection with respect to any applicable clinical trial (as defined in such section 492C) that—

(i) involves a drug to treat a serious or life-threatening condition; and

(ii) is completed between the date of the enactment of this Act and such date of establishment under paragraph (1) of this subsection.

(B) OTHER TRIALS.—Except as provided in subparagraph (A), subsection (c) of such section 492C shall take effect 180 days after the date that the results database is established under paragraph (1) of this subsection with respect to any applicable clinical trial that is completed between the date of the enactment of this Act and such date of establishment under paragraph (1).

(5) TRIALS COMPLETED AFTER ESTABLISHMENT OF RESULTS DATABASE.—Subsection (c) of such section 492C shall apply to any clinical trial that is completed after the date that the results database is established under paragraph (1) of this subsection.

(6) RETROACTIVITY OF DATABASE.—

(A) VOLUNTARY SUBMISSIONS.—The Secretary of Health and Human Services (referred to in this paragraph as the ''Secretary'') shall establish procedures and mechanisms to allow for the voluntary submission to the Secretary—

(i) of clinical trial information for inclusion in the registry database (as defined in such section 492C) on applicable clinical trials (as defined in such section 492C) initiated before the date of the enactment of this Act; and

(ii) of clinical trial information for inclusion in the results database (as defined in such section 492C) on applicable clinical trials (as defined in such section 492C) completed before the date of the enactment of this Act.

(B) REQUIRED SUBMISSIONS.—Notwithstanding the preceding paragraphs of this subsection, in any case in which the Secretary determines that submission of clinical trial information for an applicable clinical trial (as defined in such section 492C) described in clause (i) or (ii) of subparagraph (A) is in the interest of the public health—

(i) the Secretary may require that such information be submitted to the Secretary in accordance with such section 492C; and

(ii) failure to comply with such a requirement shall be treated as a violation of the corresponding requirement of such section 492C.

(7) STATUS OF CLINICALTRIALS.GOV WEBSITE.—

(A) IN GENERAL.—After receiving public comment and not later than 90 days after the date of the enactment of this Act, the Secretary shall publish in the Federal Register a notice determining the more efficient approach to establishing the registry database described in

subsection (b) of such section 492C and whether such approach is—

(i) that such registry database should expand and build upon the data bank described in section 402(i) of the Public Health Service Act (as in effect on the day before the date of the enactment of this Act); or

(ii) that such registry database should supplant the data bank described in such section 402(i) (as in effect on the day before the date of the enactment of this Act).

(B) CLINICALTRIALS.GOV SUPPLANTED.—If the Secretary determines to apply the approach described under subparagraph (A)(ii), the Secretary shall maintain an archive of the data bank described in such section 402(i) (as in effect on the day before the date of the enactment of this Act) on the Internet website of the National Library of Medicine.

SEC. 802. STUDY BY GOVERNMENT ACCOUNTABILITY OFFICE.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study to determine whether information on the trials registry and database is consid-

ered promotional and to evaluate the implementation of this database.

(b) REPORT.—Not later than one year after the date of the enactment of this Act, the Comptroller General shall complete the study under subsection (a) and submit to the Congress a report on the results of such study.

TITLE IX—ENHANCED AUTHORITIES REGARDING POSTMARKET SAFETY OF DRUGS

SEC. 901. POSTMARKET STUDIES AND CLINICAL TRIALS REGARDING HUMAN DRUGS; RISK EVALUATION AND MITIGATION STRATEGIES.

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

''(o) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING.—

''(1) IN GENERAL.—A responsible person may not introduce or deliver for introduction into interstate commerce the new drug involved if the person is in violation of a requirement established under paragraph (3) or (4) with respect to the drug.

''(2) DEFINITIONS.—For purposes of this subsection:

''(A) RESPONSIBLE PERSON.—The term 'responsible person' means a person who—

''(i) has submitted to the Secretary a covered application that is pending; or

''(ii) is the holder of an approved covered application.

''(B) COVERED APPLICATION.—The term 'covered application' means—

''(i) an application under subsection (b) for a drug that is subject to section 503(b); and

''(ii) an application under section 351 of the Public Health Service Act.

''(C) NEW SAFETY INFORMATION; SERIOUS RISK.—The terms 'new safety information', 'serious risk', and 'signal of a serious risk' have the meanings given such terms in section 505–1(b).

''(3) STUDIES AND CLINICAL TRIALS.—

''(A) IN GENERAL.—For any or all of the purposes specified in subparagraph (B), the Secretary may, subject to subparagraph (C), require a responsible person for a drug to conduct a postapproval study or studies of the drug, or a postapproval clinical trial or trials of the

drug, on the basis of scientific information, including information regarding chemically-related or pharmacologically-related drugs.

"(B) PURPOSES OF STUDY OR TRIAL.—The purposes referred to in this subparagraph with respect to a postapproval study or postapproval clinical trial are the following:

"(i) To assess a known serious risk related to the use of the drug involved.

"(ii) To assess signals of serious risk related to the use of the drug.

"(iii) To identify a serious risk.

"(C) ESTABLISHMENT OF REQUIREMENT AFTER APPROVAL OF COVERED APPLICATION.—The Secretary may require a postapproval study or studies or postapproval trial or trials for a drug for which an approved covered application is in effect as of the date on which the Secretary seeks to establish such requirement only if the Secretary becomes aware of new safety information. For each study required to be conducted under this subparagraph, the Secretary shall require that the applicant submit a timetable for completion of the study and shall require the applicant to periodically report to the

Secretary on the status of the study. Unless the applicant demonstrates good cause for failure to comply with such timeline, the applicant shall be in violation of this subsection. The Secretary shall determine what constitutes good cause under the preceding sentence.

''(4) SAFETY LABELING CHANGES REQUESTED BY SECRETARY.—

''(A) NEW SAFETY INFORMATION.—The Secretary shall promptly notify the responsible person if the Secretary becomes aware of new safety information that the Secretary believes should be included in the labeling of the drug.

''(B) RESPONSE TO NOTIFICATION.—Following notification pursuant to subparagraph (A), the responsible person shall within 30 days—

''(i) submit 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; or

''(ii) notify the Secretary that the responsible person does not believe a labeling

change is warranted and submit a statement detailing the reasons why such a change is not warranted.

''(C) REVIEW.—Upon receipt of such supplement, the Secretary shall promptly review and act upon such supplement. If the Secretary disagrees with the proposed changes in the supplement or with the statement setting forth the responsible person's reasons why no labeling change is necessary, the Secretary shall initiate discussions with the responsible person to reach agreement on whether the labeling for the drug should be modified to reflect the new safety information, and if so, the contents of such labeling changes.

''(D) DISCUSSIONS.—Such discussions shall not extend for more than 30 days after the response to the notification under subparagraph (B), unless the Secretary determines an extension of such discussion period is warranted.

''(E) ORDER.—Within 15 days of the conclusion of the discussions under subparagraph (D), the Secretary may issue an order directing the responsible person to make such a labeling

change as the Secretary deems appropriate to address the new safety information. Within 15 days of such an order, the responsible person shall submit a supplement containing the labeling change.

"(F) DISPUTE RESOLUTION.—Within 5 days of receiving an order under subparagraph (E), the responsible person may appeal using the Food and Drug Administration's normal dispute resolution procedures established by the Secretary in regulation and guidance.

"(G) VIOLATION.—If the change required by an order under subparagraph (E) is not made by the date so specified, the responsible person shall be considered to be in violation of this section.

"(H) SERIOUS PUBLIC HEALTH THREAT.—Notwithstanding subparagraphs (A) through (F), if the Secretary concludes that failure to make such a labeling change is necessary to protect against a serious public health threat, the Secretary may accelerate the timelines in such subparagraphs.

"(I) RULE OF CONSTRUCTION.—This paragraph shall not be construed to affect the re-

sponsibility of the responsible person to maintain its label in accordance with existing requirements, including subpart B and section 314.70 of title 21, Code of Federal Regulations (or any successor regulations).

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

''(1) IN GENERAL.—A person may not introduce or deliver for introduction into interstate commerce a new drug if—

''(A)(i) the application for such drug is approved under subsection (b) or (j) and is subject to section 503(b); or

''(ii) the application for such drug is approved under section 351 of the Public Health Service Act; and

''(B) a risk evaluation and mitigation strategy is required under section 505–1 with respect to the drug and—

''(i) the person fails to maintain compliance with the requirements of the approved strategy or with other requirements under section 505–1, including requirements regarding assessments of approved strategies; or

''(ii) in the case of a requirement for such a strategy that is first established after the applicable application referred to in subparagraph (A) was approved with respect to the drug, the Secretary, after notice and opportunity for a hearing, publishes in the Federal Register a statement that the person is not cooperating with the Secretary in developing such a strategy for the drug.

''(2) REQUIRED STATEMENT DURING APPROVAL PROCESS.—In the case of an application approved under subsection (b) or (j) for a new drug that is subject to section 503(b), or an application approved under section 351 of the Public Health Service Act, or a supplement to such an application that requires substantive data, the Secretary may not approve the application or supplement unless the person involved has complied with the following:

''(A) The person has submitted to the Secretary a statement that provides the following information:

''(i) Whether the person believes that a risk evaluation and mitigation strategy should be required under section 505–1.

''(ii) Whether a postmarket study or clinical trial should be required under subsection (o)(3).

''(B) In making the statement under subparagraph (A), the person took into account each of the following factors:

''(i) The estimated size of the population likely to use the drug involved.

''(ii) The seriousness of the disease or condition that is to be treated with the drug.

''(iii) The expected benefit of the drug with respect to such disease or condition.

''(iv) The expected or actual duration of treatment with the drug.

''(v) The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug.

''(3) CERTAIN POSTMARKET STUDIES.—The failure to conduct a postmarket study under subpart H of part 314 of title 21, Code of Federal Regulations (or any successor regulation), is deemed to be a violation of paragraph (1).''.

(b) REQUIREMENTS REGARDING STRATEGIES.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505 the following section:

"SEC. 505–1. RISK EVALUATION AND MITIGATION STRATEGIES.

"(a) SUBMISSION OF PROPOSED STRATEGY.—

"(1) INITIAL APPROVAL.—A person who submits an application referred to in section 505(p)(1)(A) (referred to in this section as a 'covered application') shall submit to the Secretary as part of the application a proposed risk evaluation and mitigation strategy if the Secretary determines such a strategy is necessary to ensure that the benefits of the drug involved outweigh the risks of the drug. In making such a determination, the Secretary shall consider the statement submitted by the person under section 505(p)(2) with respect to the drug and shall consider the following factors:

"(A) The estimated size of the population likely to use the drug involved.

"(B) The seriousness of the disease or condition that is to be treated with the drug.

"(C) The expected benefit of the drug with respect to such disease or condition.

"(D) The expected or actual duration of treatment with the drug.

"(E) The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug.

"(F) The availability and safety of a drug or other treatment, if any, for such disease or condition to which the safety of the drug may be compared.

"(G) Whether the drug is a new molecular entity.

"(2) POSTAPPROVAL REQUIREMENT.—

"(A) IN GENERAL.—If the Secretary approves a covered application and does not when approving the application require a risk evaluation and mitigation strategy under paragraph (1), the Secretary may subsequently require such a strategy for the drug involved if the Secretary becomes aware of new safety information and makes a determination that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks of the drug.

"(B) SUBMISSION OF PROPOSED STRATEGY.—Not later than 120 days after the Sec-

retary notifies the holder of an approved covered application that the Secretary has made a determination under subparagraph (A) with respect to the drug involved, or within such other time as the Secretary requires to protect the public health, the holder shall submit to the Secretary a proposed risk evaluation and mitigation strategy.

''(3) APPROVAL OF NEW INDICATION FOR USE.—The applicability of paragraph (2) includes applicability to a drug for which an approved covered application was in effect on the day before the effective date of this section and for which, on or after such effective date, the holder of the approved application submits to the Secretary a supplemental application seeking approval of a new indication for use of the drug.

''(4) ABBREVIATED NEW DRUG APPLICATIONS.—The applicability of this section to an application under section 505(j) is subject to subsection (i).

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

''(1) 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—

"(A) an adverse event occurring in the course of the use of the drug in professional practice;

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

"(C) an adverse event occurring from abuse of the drug;

"(D) an adverse event occurring from withdrawal of the drug; and

"(E) any failure of expected pharmacological action of the drug.

"(2) COVERED APPLICATION.—The term 'covered application' has the meaning indicated for such term in subsection (a)(1).

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

"(A) a serious risk or an unexpected serious risk associated with use of the drug that the Secretary has become aware of since the drug was approved, since the risk evaluation and mitigation strategy was required, or since

the last assessment of the approved risk evaluation and mitigation strategy for the drug; or

''(B) the effectiveness of the approved risk evaluation and mitigation strategy for the drug obtained since the last assessment of such strategy.

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

''(A) results in—

''(i) death;

''(ii) an adverse drug experience that places 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

"(B) based on appropriate medical judgment, may jeopardize the patient and may require a medical or surgical intervention to prevent an outcome described under subparagraph (A).

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

"(6) SIGNAL OF A SERIOUS RISK.—The term 'signal of a serious risk' means information related to a serious adverse drug experience associated with use of a drug and derived from—

"(A) a clinical trial;

"(B) adverse event reports;

"(C) a postapproval study, including a study under section 505(o)(3);

"(D) peer-reviewed biomedical literature; or

"(E) data derived from a postmarket risk identification and analysis system under section 505(k)(3).

"(7) RESPONSIBLE PERSON.—The term 'responsible person' has the meaning indicated for such term in subsection (e)(2).

"(8) UNEXPECTED SERIOUS RISK.—The term 'unexpected serious risk' means a serious adverse

drug experience that is not listed in the labeling of a drug, or that may be symptomatically and pathophysiologically related to an adverse drug experience identified in the labeling, but differs from such adverse drug experience because of greater severity, specificity, or prevalence.

''(c) CONTENTS.—A proposed risk evaluation and mitigation strategy under subsection (a) shall—

''(1) include the timetable required under subsection (d); and

''(2) to the extent required by the Secretary, include additional elements described in subsections (e) and (f).

''(d) MINIMAL STRATEGY.—For purposes of subsection (c)(1), the risk evaluation and mitigation strategy for a drug shall require a timetable for submission of assessments of the strategy that—

''(1) is not less frequent than once annually for the first 3 years after the strategy is initially approved;

''(2) includes an assessment in the seventh year after the strategy is so approved; and

''(3) subject to paragraph (2), for subsequent years—

''(A) is at a frequency specified in the strategy;

''(B) is increased or reduced in frequency as necessary as provided for in subsection (g)(4)(A); and

''(C) is eliminated after the 3-year period described in paragraph (1) if the Secretary determines that serious risks of the drug have been adequately identified and assessed and are being adequately managed.

''(e) ADDITIONAL POTENTIAL ELEMENTS OF STRATEGY.—

''(1) IN GENERAL.—The Secretary may under subsection (c)(2) require that the risk evaluation and mitigation strategy for a drug include 1 or more of the additional elements described in this subsection if the Secretary makes the determination required with respect to the element involved.

''(2) MEDGUIDE; PATIENT PACKAGE INSERT.—The risk evaluation and mitigation strategy for a drug may require that, as applicable, the person submitting the covered application or the holder of the approved such application (referred to in this section as the 'responsible person') develop for distribution to each patient when the drug is dispensed—

"(A) a Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations); and

"(B) a patient package insert, if the Secretary determines that such insert may help mitigate a serious risk of the drug.

"(3) COMMUNICATION PLAN.—The risk evaluation and mitigation strategy for a drug may require that the responsible person conduct a communication plan to health care providers, if, with respect to such drug, the Secretary determines that such plan may support implementation of an element of the strategy. Such plan may include—

"(A) sending letters to health care providers;

"(B) disseminating information about the elements of the risk evaluation and mitigation 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

"(C) disseminating information to health care providers through professional societies

about any serious risks of the drug and any protocol to assure safe use.

''(f) RESTRICTIONS ON DISTRIBUTION OR USE.—

''(1) IN GENERAL.—If the Secretary determines that a drug shown to be effective can be safely used only if distribution or use of such drug is restricted, the Secretary may under subsection (c)(2) require as elements of the risk evaluation and mitigation strategy such restrictions on distribution or use as are needed to ensure safe use of the drug.

''(2) ASSURING ACCESS AND MINIMIZING BURDEN.—Elements of a risk evaluation and mitigation strategy included under paragraph (1) shall—

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

''(B) be posted publicly by the Secretary with an explanation of how such elements will mitigate the observed safety risk, which posting shall be made within 30 days after the date on which the Secretary requires the element involved;

''(C) considering the risk referred to in subparagraph (A), 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

''(D) 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.

''(3) ELEMENTS.—The restrictions on distribution or use described in paragraph (1) shall include 1 or more goals to evaluate or mitigate a serious risk listed in the labeling of the drug, and may require that—

''(A) health care providers that prescribe the drug have special training or experience, or are specially certified, which training or certification with respect to the drug is available to any willing provider from a frontier area;

''(B) pharmacies, practitioners, or health care settings that dispense the drug are specially certified, which training or certification with respect to the drug is available to any willing provider from a frontier area;

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

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

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

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

''(4) IMPLEMENTATION SYSTEM.—The restrictions on distribution or use described in paragraph (1) may require a system through which the responsible person is able to—

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

''(B) work to improve implementation of the restrictions by health care providers, pharmacists, patients, and other parties in the health care system who are responsible for implementing the restrictions; and

''(C) notify wholesalers of the drug of those health care providers—

''(i) who are responsible for implementing the restrictions; and

''(ii) whom the responsible person knows have failed to meet their responsibilities for implementing the restrictions, after the responsible person has informed such party of such failure and such party has not remedied such failure.

''(5) LIMITATION.—No holder of an approved application shall use any restriction on distribution required by the Secretary as necessary to assure safe use of the drug to block or delay approval of an application under section 505(b)(2) or (j) or to prevent application of such restriction under subsection (i)(1)(B) to a drug that is the subject of an abbreviated new drug application.

''(6) BIOEQUIVALENCE TESTING.—Notwithstanding any other provisions in this subsection, the

holder of an approved application that is subject to distribution restrictions required under this subsection that limit the ability of a sponsor seeking approval of an application under subsection 505(b)(2) or (j) to purchase on the open market a sufficient quantity of drug to conduct bioequivalence testing shall provide to such a sponsor a sufficient amount of drug to conduct bioequivalence testing if the sponsor seeking approval under section 505(b)(2) or (j)—

''(A) agrees to such restrictions on distribution as the Secretary finds necessary to assure safe use of the drug during bioequivalence testing; and

''(B) pays the holder of the approved application the fair market value of the drug purchased for bioequivalence testing.

''(7) LETTER BY SECRETARY.—Upon a showing by the sponsor seeking approval under section 505(b)(2) or (j) that the sponsor has agreed to such restrictions necessary to assure safe use of the drug during bioequivalence testing, the Secretary shall issue to the sponsor seeking to conduct bioequivalence testing a letter that describes the Secretary's finding which shall serve as proof that the sponsor

has satisfied the requirements of subparagraph (6)(A).

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

''(A) seek input from patients, physicians, pharmacists, and other health care providers about how elements to assure safe use under this subsection 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;

''(B) 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

"(C) considering such input and evaluations—

"(i) issue or modify agency guidance about how to implement the requirements of this subsection; and

"(ii) modify elements under this subsection for 1 or more drugs as appropriate.

"(9) WAIVER IN PUBLIC HEALTH EMERGENCIES.—The Secretary may waive any restriction on distribution or use under this subsection 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 restriction or use under this subsection has been applied, if the Secretary has—

"(A) declared a public health emergency under such section 319; and

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

"(g) ASSESSMENT AND MODIFICATION OF APPROVED STRATEGY.—

''(1) VOLUNTARY ASSESSMENTS.—After the approval of a risk evaluation and mitigation strategy under subsection (a), the responsible person involved may, subject to paragraph (2), submit to the Secretary an assessment of, and propose a modification to, the approved strategy for the drug involved at any time.

''(2) REQUIRED ASSESSMENTS.—A responsible person shall, subject to paragraph (5), submit an assessment of, and may propose a modification to, the approved risk evaluation and mitigation strategy for a drug—

''(A) when submitting a supplemental application for a new indication for use under section 505(b) or under section 351 of the Public Health Service Act, unless the drug is not subject to section 503(b) and the risk evaluation and mitigation strategy for the drug includes only the timetable under subsection (d);

''(B) when required by the strategy, as provided for in such timetable under subsection (d);

''(C) within a time period to be determined by the Secretary, if the Secretary determines

that new safety or effectiveness information indicates that—

''(i) an element under subsection (d) or (e) should be modified or included in the strategy; or

''(ii) an element under subsection (f) should be modified or included in the strategy; or

''(D) within 15 days when ordered by the Secretary, if the Secretary determines that there may be a cause for action by the Secretary under section 505(e).

''(3) REQUIREMENTS FOR ASSESSMENTS.—An assessment under paragraph (1) or (2) of an approved risk evaluation and mitigation strategy for a drug shall include—

''(A) with respect to any goal under subsection (f), an assessment of the extent to which the restrictions on distribution or use are meeting the goal or whether the goal or such restrictions should be modified;

''(B) with respect to any postapproval study required under section 505(o)(3), the status of such study, including whether any dif-

ficulties completing the study have been encountered; and

''(C) with respect to any postapproval clinical trial required under section 505(o), 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 section 492C of the Public Health Service Act.

''(4) 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 subsection (d) or the addition, modification, or removal of any element under subsection (e) or (f), such as—

''(A) modifying the timetable for assessments of the strategy under subsection (d), including to eliminate assessments; or

''(B) adding, modifying, or removing a restriction on distribution or use under subsection (f).

''(5) 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 paragraph (2) is not required.

''(h) REVIEW OF PROPOSED STRATEGIES; REVIEW OF ASSESSMENTS OF APPROVED STRATEGIES.—

''(1) IN GENERAL.—The Secretary shall promptly review each proposed risk evaluation and mitigation strategy for a drug submitted under subsection (a) and each assessment of an approved risk evaluation and mitigation strategy for a drug submitted under subsection (g).

''(2) MARKETING PLAN.—

''(A) IN GENERAL.—As part of a review conducted under this subsection, the Secretary may require the applicant to submit information regarding its marketing plan and practices

for the drug, so as to allow the Secretary to determine whether any of the proposed or ongoing marketing activities undermine any of the requirements of the risk evaluation and mitigation strategy.

''(B) RULE OF CONSTRUCTION.—Subparagraph (A) may not be construed as authorizing the Secretary to make or direct any change in the marketing plan or practices involved. The preceding sentence does not affect any authority of the Secretary under this Act, other than the authority of the Secretary under subparagraph (A).

''(3) DISCUSSION.—The Secretary shall initiate discussions with a responsible person for purposes of this subsection to determine a strategy—

''(A) if the proposed strategy is submitted as part of an application or supplemental application under subsection (a) or subsection (g)(2)(A), not less than 60 days before the action deadline for the application that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug develop-

ment process and the process for the review of human drug applications);

"(B) if the assessment is submitted under subparagraph (B) or (C) or subsection (g)(2), not later than 20 days after such submission;

"(C) if the assessment is submitted under subsection (g)(1) or subsection (g)(2)(D) , not later than 30 days after such submission; or

"(D) if the assessment is submitted under subsection (g)(2)(D), not later than 10 days after such submission.

"(4) ACTION.—

"(A) IN GENERAL.—Unless the responsible person requests the dispute resolution process described under paragraph (5), the Secretary shall approve and describe the risk evaluation and mitigation strategy for a drug, or any modification to the strategy—

"(i) as part of the action letter on the application, when a proposed strategy is submitted under subsection (a) or an assessment of the strategy is submitted under subsection (g)(1); or

"(ii) in an order issued not later than 50 days after the date discussions of such

modification begin under paragraph (3), when an assessment of the strategy is submitted under subsection (g)(1) or under any of subparagraphs (B) through (D) of subsection (g)(2).

''(B) 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 subparagraph (A).

''(C) PUBLIC AVAILABILITY.—Any action letter described in subparagraph (A)(i) or order described in subparagraph (A)(ii) shall be made publicly available.

''(5) DISPUTE RESOLUTION.—

''(A) REQUEST FOR REVIEW.—

''(i) IN GENERAL.—Not earlier than 15 days, and not later than 35 days, after discussions under paragraph (3) have begun, the responsible person may request in writing that a dispute about the strategy be reviewed by the Drug Safety Oversight Board under subsection (j), except that the determination of the Secretary to require a risk evaluation and mitigation

strategy is not subject to review under this paragraph. The preceding sentence does not prohibit review under this paragraph of the particular elements of such a strategy.

''(ii) SCHEDULING.—Upon receipt of a request under clause (i), the Secretary shall schedule the dispute involved for review under subparagraph (B) and, not later than 5 business days of scheduling the dispute for review, shall publish by posting on the Internet or otherwise a notice that the dispute will be reviewed by the Drug Safety Oversight Board.

''(B) SCHEDULING REVIEW.—If a responsible person requests review under subparagraph (A), the Secretary—

''(i) 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

''(ii) 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).

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

"(i) FURTHER DISCUSSION OR ADMINISTRATIVE APPEALS.—A request for review under subparagraph (A) shall not preclude further discussions to reach agreement on the risk evaluation and mitigation strategy, and such a request shall not preclude the use of administrative appeals within the Food and Drug Administration to reach agreement on the strategy, including appeals as described in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the process for the review of human drug applications) for procedural or scientific matters involving the review of human drug applications and supplemental applications that cannot be resolved at the divisional level.

"(ii) AGREEMENT TERMINATES DISPUTE RESOLUTION.—At any time before a decision and order is issued under subparagraph (G) , the Secretary and the responsible person 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.

''(D) MEETING OF THE BOARD.—At a meeting of the Drug Safety Oversight Board described in subparagraph (B), the Board shall—

''(i) hear from both parties; and

''(ii) review the dispute.

''(E) RECORD OF PROCEEDINGS.—The Secretary shall ensure that the proceedings of any such meeting are recorded, transcribed, and made public within 30 days of the meeting. The Secretary shall redact the transcript to protect any trade secrets or other confidential information described in section 552(b)(4) of title 5, United States Code.

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

days after the Board provides such written recommendation to the Secretary, the Secretary shall make the recommendation available to the public.

''(G) ACTION BY THE SECRETARY.—

''(i) ACTION LETTER.—With respect to a proposal or assessment referred to in paragraph (1), the Secretary shall issue an action letter that resolves the dispute not later than the later of—

''(I) the action deadline referred to in paragraph (3)(A); or

''(II) 7 days after receiving the recommendation of the Drug Safety Oversight Board.

''(ii) ORDER.—With respect to an assessment of an approved risk evaluation and mitigation strategy under subsection (g)(1) or under any of subparagraphs (B) through (D) of subsection (g)(2), the Secretary shall issue an order, which shall be made public, that resolves the dispute not later than 7 days after receiving the recommendation of the Drug Safety Oversight Board.

"(H) 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 subparagraph (G).

"(I) EFFECT ON ACTION DEADLINE.—With respect to a proposal or assessment referred to in paragraph (1), the Secretary shall be considered to have met the action deadline referred to in paragraph (3)(A) with respect to the application involved if the responsible person requests the dispute resolution process described in this paragraph and if the Secretary—

"(i) has initiated the discussions described under paragraph (3) not less than 60 days before such action deadline; 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 subparagraphs (B), (F), and (G), respectively.

"(J) 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 subparagraph (C)(i) with respect to such drug may serve on the Drug Safety Oversight Board at a meeting under subparagraph (D) to review a dispute about the risk evaluation and mitigation strategy for such drug.

''(K) 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 subparagraph (D) of the Drug Safety Oversight Board.

''(6) USE OF ADVISORY COMMITTEES.—The Secretary may convene a meeting of 1 or more advisory committees of the Food and Drug Administration to—

''(A) review a concern about the safety of a drug or class of drugs, including before an assessment of the risk evaluation and mitigation strategy or strategies of such drug or drugs is required to be submitted under any of subparagraphs (B) through (D) of subsection (g)(2);

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

"(C) review a dispute under paragraph (5).

"(7) PROCESS FOR ADDRESSING DRUG CLASS EFFECTS.—

"(A) IN GENERAL.—When a concern about a serious risk of a drug may be related to the pharmacological class of the drug, the Secretary may defer assessments of the approved risk evaluation and mitigation strategies for such drugs until the Secretary has convened 1 or more public meetings to consider possible responses to such concern. If the Secretary defers an assessment under this subparagraph, the Secretary shall give notice to the public of the deferral not later than 5 days of the deferral.

"(B) PUBLIC MEETINGS.—Such public meetings may include—

"(i) 1 or more meetings of the reviewed entities for such drugs;

"(ii) 1 or more meetings of 1 or more advisory committees of the Food and Drug Administration, as provided for under paragraph (6); or

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

''(C) ACTION.—After considering the discussions from any meetings under subparagraph (B), 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.

''(8) INTERNATIONAL COORDINATION.—The Secretary may coordinate the timetable for submission of assessments under subsection (d), or a study or clinical trial under section 505(o)(3), 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. If the Secretary takes action to coordinate

such timetable, the Secretary shall give notice to the public of the action not later than 5 days after the action.

''(9) EFFECT.—Use of the processes described in paragraphs (7) and (8) shall not delay action on an application or a supplement to an application for a drug.

''(i) ABBREVIATED NEW DRUG APPLICATIONS.—

''(1) IN GENERAL.—A drug that is the subject of an abbreviated new drug application under section 505(j) is subject to only the following elements of the risk evaluation and mitigation strategy required under subsection (a) for the applicable listed drug:

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

''(B) Restrictions on distribution or use, if required under subsection (f) for the listed drug. A drug that is the subject of an abbreviated new drug application and the listed drug shall use a single, shared system under subsection (f)(4). The Secretary may waive the requirement under the preceding sentence for a drug that is the subject of an abbreviated new

drug application if the Secretary determines that—

''(i) it is not practical for the drug to use such single, shared system; or

''(ii) the burden of using the single, shared system outweighs the benefit of using the single system.

''(2) ACTION BY SECRETARY.—For an applicable listed drug for which a drug is approved under section 505(j), the Secretary—

''(A) shall undertake any communication plan to health care providers required under subsection (e)(3) for the applicable listed drug; and

''(B) shall inform the responsible person for the drug that is so approved if the risk evaluation and mitigation strategy for the applicable listed drug is modified.

''(j) DRUG SAFETY OVERSIGHT BOARD.—

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

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

''(A) be composed of scientists and health care practitioners appointed by the Secretary,

each of whom is an employee of the Federal Government;

''(B) include representatives from offices throughout the Food and Drug Administration;

''(C) include at least 1 representative from each of the National Institutes of Health and the Department of Health and Human Services (other than the Food and Drug Administration);

''(D) include such representatives as the Secretary shall designate from other appropriate agencies that wish to provide representatives; and

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

(c) REGULATION OF 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 under this paragraph is subject to section 505(p) of the Federal Food, Drug, and Cosmetic Act.''; and

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

(d) PREREVIEW OF ADVERTISEMENTS.—

(1) SENSE OF CONGRESS.—It is the sense of the Congress that—

(A) "Guidance for Industry Consumer-Directed Broadcast Advertisements" issued by the Food and Drug Administration in August, 1999, represents generally good guidance for direct-to-consumer (DTC) advertising of prescription medicines and other treatments;

(B) direct-to-consumer advertising as an accurate source of health information for all populations, specifically including the elderly populations, children, chronically ill and racial and ethnic minority populations, should be made more reliable by ensuring the truth and credibility of information provided through such advertising; and

(C) the Congress will work with the Food and Drug Administration to ensure that information provided through direct-to-consumer advertising of prescription medicines and other treatments is not false or misleading and com-

municates clearly and sensitively to all communities.

(2) PREREVIEW.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(A) in section 301 (21 U.S.C. 331), by adding at the end the following:

''(jj) The dissemination of a television advertisement without complying with section 503B.''; and

(B) by inserting after section 503A the following:

''SEC. 503B. PREREVIEW OF TELEVISION ADVERTISEMENTS.

''(a) IN GENERAL.—The Secretary may require the submission of any television advertisement for a drug (including any script, story board, rough, or a completed video production of the television advertisement) to the Secretary for review under this section not later than 45 days before dissemination of the television advertisement.

''(b) REVIEW.—In conducting a review of a television advertisement under this section, the Secretary may make recommendations—

''(1) on changes that are—

''(A) necessary to protect the consumer good and well-being; or

''(B) consistent with prescribing information for the product under review; and

''(2) if appropriate and if information exists, on statements for inclusion in the advertisement to address the specific efficacy of the drug as it relates to a specific population group, including elderly populations, children, and racially and ethnically diverse populations.

''(c) NO AUTHORITY TO REQUIRE CHANGES.—This section does not authorize the Secretary to make or direct changes in any material submitted pursuant to subsection (a).

''(d) ELDERLY POPULATIONS, CHILDREN, RACIALLY AND ETHNICALLY DIVERSE COMMUNITIES.—In formulating recommendations under subsection (b), the Secretary shall take into consideration the impact of the advertised drug on elderly populations, children, and racially and ethnically diverse communities.

''(e) SPECIFIC DISCLOSURES.—

''(1) SERIOUS RISK; SAFETY PROTOCOL.—In conducting a review of a television advertisement under this section, if the Secretary determines that the advertisement would be false or misleading without a specific disclosure about a serious risk listed in the labeling of the drug involved, the Secretary

may require inclusion of such disclosure in the advertisement.

''(2) DATE OF APPROVAL.—In conducting a review of a television advertisement under this section, the Secretary may require the advertisement to include, for a period not to exceed 2 years from the date of the approval of the drug under section 505, a specific disclosure of such date of approval if the Secretary determines that the advertisement would otherwise be false or misleading.

''(f) RULE OF CONSTRUCTION.—Nothing in this section may be construed as having any effect on the authority of the Secretary under section 314.550, 314.640, 601.45, or 601.94 of title 21, Code of Federal Regulations (or successor regulations).''.

(3) DIRECT-TO-CONSUMER ADVERTISEMENTS.—

(A) IN GENERAL.—Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) is amended by adding at the end the following: ''In the case of an advertisement for a drug subject to section 503(b)(1) presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications

shall be presented in a clear and conspicuous manner.''.

(B) REGULATIONS TO DETERMINE CLEAR AND CONSPICUOUS MANNER.—The Secretary of Health and Human Services shall by regulation establish standards for determining whether a major statement relating to side effects and contraindications 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 subparagraph (A)) is presented in the manner required under such section.

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

(A) by redesignating subsection (g) (relating to civil penalties) as subsection (f); and

(B) by adding at the end the following:

''(g)(1) With respect to a person who is a holder of an approved application under section 505 for a drug subject to section 503(b) or under section 351 of the Public Health Service Act, any such person who disseminates a direct-to-consumer advertisement that is false or misleading shall be liable to the United States for a civil penalty in an amount not to exceed $250,000 for the first

such violation in any 3-year period, and not to exceed $500,000 for each subsequent violation in any 3-year period. No other civil monetary penalties in this Act (including the civil penalty in section 303(f)(3)) shall apply to a violation regarding direct-to-consumer advertising. For purposes of this paragraph: (A) 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 one violation. (B) On and after the date of the receipt of such a notice, all violations under this paragraph occurring in a single day shall be considered one 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 person to be assessed 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 person 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 person to be assessed a civil penalty under paragraph (1), the Secretary, in determining the amount of the civil penalty, shall take into account the nature, circumstances, extent, and gravity of the violation or violations, including the following factors:

''(A) Whether the person submitted the advertisement or a similar advertisement for review under section 736A.

''(B) Whether the person submitted the advertisement for review if required under section 503B.

''(C) Whether, after submission of the advertisement as described in subparagraph (A) or (B), the person disseminated the advertisement before the end of the 45-day comment period.

''(D) Whether the person incorporated any comments made by the Secretary with regard to the advertisement into the advertisement prior to its dissemination.

''(E) Whether the person ceased distribution of the advertisement upon receipt of the written notice referred to in paragraph (2) for such advertisement.

''(F) Whether the person had the advertisement reviewed by qualified medical, regulatory, and legal reviewers prior to its dissemination.

''(G) Whether the violations were material.

''(H) Whether the person who created the advertisement acted in good faith.

''(I) Whether the person 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 person.

''(K) Such other matters, as justice may require.

''(4)(A) Subject to subparagraph (B), no person shall be required to pay a civil penalty under paragraph (1) if the person submitted the advertisement to the Secretary and disseminated such advertisement after incorporating any comment received from the Secretary other than a recommendation subject to subsection 503B(c).

''(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 person 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, or 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 owed by the United States to the person charged.

''(6) Any person 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 person 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) On an annual basis, the Secretary shall report to the Congress on direct-to-consumer advertising and its ability to communicate to subsets of the general population, including elderly populations, children, and racial and ethnic minority communities. The Secretary shall establish a permanent advisory committee to advise the Secretary with respect to such report. The membership of the advisory committee shall consist of nationally recognized medical, advertising, and communications experts, including experts representing subsets of the general population. The members of the advisory committee shall serve with-

out pay, but may receive travel expenses, including per diem in lieu of subsistence in accordance with applicable provisions under subchapter I of chapter 57 of title 5, United States Code. The advisory committee shall study direct-to-consumer advertising as it relates to increased access to health information and decreased health disparities for these populations. The annual report required by this paragraph shall recommend effective ways to present and disseminate information to these populations. Such report shall also make recommendations regarding impediments to the participation of elderly populations, children, racially and ethnically diverse communities, and medically underserved populations in clinical drug trials and shall recommend best practice approaches for increasing the inclusion of such subsets of the general population. The Secretary shall submit the first annual report under this paragraph to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives not later than 18 months after the advisory committee has been convened by the Secretary.

''(8) If any person fails to pay an assessment of a civil penalty under paragraph (1)—

''(A) after the order making the assessment becomes final, and if such person does not file a peti-

tion 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 of the United States 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 the 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.''.

(e) RULE OF CONSTRUCTION REGARDING PEDIATRIC STUDIES.—This title and the amendments made by this title may not be construed as affecting the authority of the Secretary of Health and Human Services to request pediatric studies under section 505A of the Federal Food, Drug, and Cosmetic Act or to require such studies under section 505B of such Act.

SEC. 902. 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:

''(y) If it is a drug subject to an approved risk evaluation and mitigation strategy pursuant to section 505(p) and the person responsible for complying with the strategy fails to comply with a requirement of such strategy provided for under subsection (d), (e), or (f) of section 505–1.

''(z) If it is a drug, and the responsible person (as such term is used in section 505(o)) is in violation of a requirement established under paragraph (3) (relating to postmarket studies and clinical trials) or paragraph (4) (relating to labeling) of section 505(o) with respect to such drug.''.

(b) CIVIL PENALTIES.—Section 303(f) of the Federal Food, Drug, and Cosmetic Act, as redesignated by section 901(d)(4), 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) Any applicant (as such term is used in section 505–1) who violates a requirement of section 505(o), section 505(p), or section 505–1 shall be subject to a civil monetary penalty of—

''(A) not more than $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding; or

''(B) in the case of a violation that continues after the Secretary provides notice of such violation to the applicant, not more than $10,000,000 per violation, and not to exceed $50,000,000 for all such violations adjudicated in a single proceeding.

If a violation referred to in subparagraph (A) or (B) is continuing in nature and poses a substantial threat to the public health, the Secretary may impose a civil penalty not to exceed $1,000,000 per day during such time period such person is in violation.'';

(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. 903. 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 section 505–1(g)(2)(D).''.

SEC. 904. BENEFIT-RISK ASSESSMENTS.

Not later than 1 year after the date of the enactment of this Act, the Commissioner of Food and Drugs shall submit to the Congress a report on how best to communicate to the public the risks and benefits of new drugs and the role of the risk evaluation and mitigation strategy in assessing such risks and benefits. As part of such study, the Commissioner shall consider the possibility of including in the labeling and any direct-to-consumer advertisements of a newly approved drug or indication a unique symbol indicating the newly approved status of the drug or indication for a period after approval.

SEC. 905. POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM FOR ACTIVE SURVEILLANCE AND ASSESSMENT.

(a) FINDINGS.—Congress finds the following:

(1) It is in the best interests of healthcare providers and patients that a postmarketing surveillance system be developed that will enable active surveillance of disparate sources of data to identify signals of unexpected adverse events and trends in the frequency of known adverse events, to provide data on the outcomes of off label uses, and to enable identification of safety issues earlier than can be done today.

(2) Such a system can best be developed through public private partnerships to develop methods and tools for conducting surveillance using electronic databases that currently contain data on millions of patient encounters and are expected to grow significantly in the next decade, as well as electronic databases that contain millions of medical product purchases, health care claims, and similar information relevant to product use, efficacy, and safety.

(3) Therefore, this section directs the Secretary of Health and Human Services to enter into such public private partnerships as are necessary to develop such a surveillance system and the tools and

methods necessary to conduct active surveillance using the system.

(b) DEVELOPMENT OF THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—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) The Secretary shall establish public private partnerships to develop tools and methods to enable the Secretary and others to use available electronic databases to create a robust surveillance system that will support active surveillance on important drug safety questions including detecting and assessing drug safety signals; monitoring the frequency of known adverse events; and evaluating the outcomes of off label uses. Such surveillance shall provide for adverse event surveillance using the following data sources:

''(A) Federal health-related electronic data (such as data from the Medicare program and the health systems of the Department of Veterans Affairs).

''(B) Private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data).

''(C) Other information as the Secretary deems useful to create a robust system to identify and assess adverse events and potential drug safety signals and to evaluate the extent and outcomes of off label uses of drugs.

''(4) Not later than 1 year after the date of the enactment of this paragraph, the Secretary, in consultation with experts including individuals who are recognized in the field of data privacy and security, shall develop methods for integrating and analyzing safety data from multiple sources and mechanisms for obtaining access to such data. Such methods and mechanisms shall not compromise the protection of individually identifiable health information.

''(5) Not later than 2 years after the date of the enactment of this paragraph, the Secretary shall have entered into partnerships that will allow the analysis of available data from the various data sources using the standards and methods to identify drug safety signals and trends. Such analysis shall not disclose individually identifiable health information when presenting such drug safety signals and trends or when responding to inquiries regarding such drug safety signals and trends.

''(6) Not later than 4 years after the date of the enactment of this paragraph, the Secretary shall report to

the Congress on the ways in which the Secretary has used the surveillance system described in this subsection to identify specific drug safety signals and to better understand the outcomes associated with drugs marketed in the United States.

''(7) Disclosure of individually identifiable information is prohibited in the surveillance system described in this subsection. Nothing in this subsection prohibits lawful disclosure of such information for other purposes.

''(8) Nothing in this subsection shall be construed as limiting public health activities authorized under law.''.

(c) AUTHORIZATION OF APPROPRIATIONS.—To carry out activities under the amendment made by subsection (b) 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, in addition to such funds, $25,000,000 for each of fiscal years 2008 through 2012.

(d) GAO REPORT.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General of the United States shall evaluate data confidentiality and security issues relating to collection, transmission, and maintenance of data for the surveillance system developed pursuant to this section, and make recommendations to the Committee on Energy and Com-

merce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate, and any other congressional committees of relevant jurisdiction, regarding the need for any additional legislative or regulatory actions to ensure confidentiality and security of this data or otherwise address confidentiality and security issues to ensure the effective operation of the surveillance system.

SEC. 907. STATEMENT FOR INCLUSION IN DIRECT-TO-CONSUMER ADVERTISEMENTS OF DRUGS.

Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352), as amended by section 901(d)(3), is further amended by striking ''of this Act, except that'' and inserting ''of this Act, and in the case of any direct-to-consumer advertisement the following statement: 'You are encouraged to report adverse effects of prescription drug medication to the FDA. Log onto www.fda.gov/medwatch or call 1–800-FDA-1088.', except that''.

SEC. 908. CLINICAL TRIAL GUIDANCE FOR ANTIBIOTIC DRUGS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 510 the following:

"SEC. 511. CLINICAL TRIAL GUIDANCE FOR ANTIBIOTIC DRUGS.

''(a) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary, acting through the Commissioner of Food and Drugs, shall issue guidance for the conduct of clinical trials with respect to antibiotic drugs, including antimicrobials to treat acute bacterial sinusitis, acute bacterial otitis media, and acute bacterial exacerbation of chronic bronchitis. Such guidelines shall indicate the appropriate animal models of infection, in vitro techniques, and valid microbiologic surrogate markers.

''(b) REVIEW.—Not later than 5 years after the date of enactment of this section, the Secretary, acting through the Commissioner of Food and Drugs, shall review and update the guidance described under subsection (a) to reflect developments in scientific and medical information and technology.''.

SEC. 909. PROHIBITION AGAINST FOOD TO WHICH DRUGS OR BIOLOGICAL PRODUCTS HAVE BEEN ADDED.

Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by section 901(d)(2)(A), is amended by adding at the end the following:

''(kk) The introduction or delivery for introduction into interstate commerce of any food to which has been added—

''(1) a drug approved under section 505,

''(2) a biological product licensed under section 351 of the Public Health Service Act, or

''(3) a drug or biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,

unless such drug or biological product was marketed in food before any approval of the drug under section 505 of this Act, before licensure of the biological product under section 351 of the Public Health Service Act, and before any substantial clinical investigations involving the drug or biological product have been instituted, or unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, approving the addition of such drug or biological product to the food.''.

SEC. 910. ASSURING PHARMACEUTICAL SAFETY.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505B the following:

"SEC. 505C. PHARMACEUTICAL SECURITY.

"(a) IN GENERAL.—The Secretary shall develop standards and identify and validate effective technologies for the purpose of securing the prescription drug distribution system against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs.

"(b) STANDARDS DEVELOPMENT.—

"(1) IN GENERAL.—The Secretary shall, in consultation with the agencies specified in paragraph (3), prioritize and develop standards for the identification, validation, authentication, and tracking of prescription drugs.

"(2) PROMISING TECHNOLOGIES.—The standards developed under this subsection shall address promising technologies, including—

"(A) radio frequency identification technology;

"(B) nanotechnology;

"(C) encryption technologies; and

"(D) other track-and-trace technologies.

"(3) INTERAGENCY COLLABORATION.—In carrying out this subsection, the Secretary shall consult with Federal health and security agencies, including—

"(A) the Administrator of the Drug Enforcement Administration;

''(B) the Secretary of the Department of Homeland Security;

''(C) the Secretary of Commerce; and

''(D) other appropriate Federal and State agencies.

''(c) INSPECTION AND ENFORCEMENT.—

''(1) IN GENERAL.—The Secretary shall expand and enhance the resources and facilities of the Office of Regulatory Affairs of the Food and Drug Administration to protect the prescription drug distribution system against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs.

''(2) ACTIVITIES.—The Secretary shall undertake enhanced and joint enforcement activities with other Federal agencies and State officials, and establish regional capacities for the validation of prescription drugs and the inspection of the prescription drug distribution system.

''(d) DEFINITION.—In this section, the term 'prescription drug' means a drug subject to section 503(b)(1).''.

SEC. 911. ORPHAN ANTIBIOTIC DRUGS.

(a) PUBLIC MEETING.—The Commissioner of Food and Drugs shall convene a public meeting 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 section 5(a) 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.—Section 5(c) 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 is authorized to be appropriated $30,000,000 for each of fiscal years 2008 through 2012.''.

SEC. 912. CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.

(a) IN GENERAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by section 901(a), is amended by adding at the end the following:

''(q) PETITIONS AND CIVIL ACTIONS REGARDING APPROVAL OF CERTAIN APPLICATIONS.—

''(1) IN GENERAL.—With respect to a pending application under subsection (b)(2) or (j), if a petition is submitted 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, the following applies, subject to paragraph (5):

"(A) The Secretary may not, on the basis of the petition, delay approval of the application unless the Secretary determines that a delay is necessary to protect the public health and provides the applicant with a written explanation of the reasons for the delay. Consideration of a petition shall be separate and apart from the review and approval of the application.

"(B) The Secretary shall take final agency action on the petition not later than 180 days after the date on which the petition is submitted. The Secretary shall not extend such period, even with the consent of the petitioner, for any reason, including based upon the submission of comments relating to the petition or supplemental information supplied by the petitioner.

"(C) If the Secretary determines that the petition was submitted with the primary purpose of delaying approval of a drug under subsection (b)(2) or (j), the Secretary may deny the petition at any point.

"(D) If the filing of the application resulted in first-applicant status under subsection (j)(5)(D)(i)(IV), the 30-month period under such subsection is deemed to be extended by a period of time equal to the period beginning on the date on which the Secretary received the petition and ending on the date of final agency action on the petition (inclusive of such beginning and ending dates), without regard to whether the Secretary grants, in whole or in part, or denies, in whole or in part, the petition.

"(E) The Secretary may not consider the petition for review unless it is signed and contains the following certification: 'I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known

to the party on whose behalf this petition is submitted on or about the following date: _____. 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.'.

''(2) EXHAUSTION OF ADMINISTRATIVE REMEDIES.—

''(A) FINAL AGENCY ACTION WITHIN 180 DAYS.—The Secretary shall be considered to have taken final agency action on a petition referred to in paragraph (1) if—

''(i) during the 180-day period referred to in subparagraph (B) of such paragraph, the Secretary makes a final decision within the meaning of section 10.45(d) of title 21, Code of Federal Regulations (or any successor regulation); or

''(ii) such period expires without the Secretary having made such a final decision.

''(B) DISMISSAL OF CERTAIN CIVIL ACTIONS.—If a civil action is filed with respect to any issue raised in a petition under paragraph (1) before the Secretary has taken final agency action on the petition within the meaning of subparagraph (A), the court shall dismiss the action for failure to exhaust administrative remedies.

''(3) APPLICABILITY OF CERTAIN REGULATIONS.—The provisions of this section are in addition to the requirements for the submission of a petition to the Secretary that apply under section 10.30 or 10.35 of title 21, Code of Federal Regulations (or any successor regulations).

''(4) ANNUAL REPORT ON DELAYS IN APPROVALS PER PETITIONS.—The Secretary shall annually submit to the Congress a report that specifies—

''(A) the number of applications under subsections (b)(2) and (j) that were approved during the preceding 12-month period;

''(B) the number of such applications whose effective dates were delayed by petitions referred to in paragraph (1) during such period; and

''(C) the number of days by which the applications were so delayed.

''(5) EXCEPTIONS.—This subsection does not apply to—

''(A) a petition that relates solely to the timing of the approval of an application pursuant to subsection (j)(5)(B)(iv); or

''(B) a petition that is made by the sponsor of an 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) DEFINITION.—For purposes of this subsection, the term 'petition' includes any request to the Secretary for an action described in paragraph (1), without regard to whether the request is characterized as a petition.''.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit a report to the Congress on ways to encourage the early submission of petitions under section 505(q), as added by subsection (a).

SEC. 913. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—For carrying out this title and the amendments made by this title, there is authorized to be

appropriated $25,000,000 for each of fiscal years 2008 through 2012.

(b) RELATION TO OTHER FUNDING.—The authorization of appropriations under subsection (a) is in addition to any other funds available for carrying out this title and the amendments made by this title.

SEC. 914. EFFECTIVE DATE AND APPLICABILITY.

(a) EFFECTIVE DATE.—This title takes effect 180 days after the date of the enactment of this Act.

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

(1) IN GENERAL.—A drug that was approved before the effective date of this Act is, in accordance with paragraph (2), deemed to have in effect an approved risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act (as added by section 901 of this title) (referred to in this section as the ''Act'') if there are in effect on the effective date of this Act 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) ELEMENTS OF STRATEGY; ENFORCEMENT.—The approved risk evaluation and mitigation strategy in effect for a drug under paragraph (1)—

(A) is deemed to consist of the elements described in paragraphs (1) and (2) of section 505–1(d) of the Act and any additional elements under subsections (d) and (e) of such section in effect for such drug on the effective date of this Act; and

(B) is subject to enforcement by the Secretary to the same extent as any other risk evaluation and mitigation strategy under section 505–1 of the Act.

(3) SUBMISSION.—Not later than 180 days after the effective date of this Act, the holder of an approved application for which a risk evaluation and mitigation strategy is deemed to be in effect under paragraph (1) shall submit to the Secretary a proposed risk evaluation and mitigation strategy. Such proposed strategy is subject to section 505–1 of the Act as if included in such application at the time of submission of the application to the Secretary.

(c) OTHER DRUGS APPROVED BEFORE THE EFFECTIVE DATE.—The Secretary, on a case-by-case basis, may require the holder of an application approved before the

effective date of this Act to which subsection (b) does not apply to submit a proposed risk evaluation and mitigation strategy in accordance with the timeframes provided for in subparagraphs (C) through (D) of section 505–1(g)(2) of the Act if the Secretary determines (with respect to such drug or with respect to the group of drugs to which such drug belongs) that—

(1) an element described under section 505–1(d)(1) of the Act may require modification; or

(2) a standard for adding an element described in subsection (e) or (d) of section 505–1 of the Act that is not in effect with respect to such drug or class of drugs may apply.

(d) USE OF ADVISORY COMMITTEES; PROCESS FOR ADDRESSING DRUG CLASS EFFECTS.—In imposing a requirement under subsection (c), the Secretary—

(1) may convene a meeting of 1 or more advisory committees of the Food and Drug Administration in accordance with paragraph (6) of section 505–1(h) of the Act; and

(2) may use the process described in paragraph (7) of such section 505–1(h) (relating to addressing drug class effects).

Passed the House of Representatives July 11, 2007.

Attest: LORRAINE C. MILLER,

Clerk.

Calendar No. 270

110TH CONGRESS
1ST SESSION

H. R. 2900

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and for medical devices, to enhance the postmarket authorities of the Food and Drug Administration with respect to the safety of drugs, and for other purposes.

JULY 16, 2007

Received; read twice and placed on the calendar