112TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPORT
112–495

FOOD AND DRUG ADMINISTRATION REFORM ACT OF 2012

MAY 25, 2012.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. UPTON, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 5651]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 5651) 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 establish user-fee programs for generic drugs and biosimilars, and for other purposes, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

CONTENTS

PURPOSE AND SUMMARY

H.R. 5651, the "Food and Drug Administration Reform Act of 2012," was introduced on May 9, 2012, by Chairman Fred Upton (R–MI), Ranking Member Henry Waxman (D–CA), Subcommittee

on Health Chairman Joseph R. Pitts (R–PA), Subcommittee on Health Ranking Member Frank Pallone, Jr. (D–NJ), Chairman Emeritus Joe Barton (R–TX), and Chairman Emeritus John D. Dingell (D–MI) and referred to the Committee on Energy and Commerce.

The legislation would reauthorize the prescription drug user fee and medical device user fee, authorize a generic drug user fee and biosimilar user fee, reauthorize the Best Pharmaceuticals for Children Act and Pediatric Research Equity Act, institute reforms at the Food and Drug Administration (FDA) to improve the predictability, consistency, and transparency of its regulation of drugs and devices, and establish policies to address the drug shortage crisis.

BACKGROUND AND NEED FOR LEGISLATION

The United States (U.S.) has led the global medical device and biopharmaceutical industries for decades. This leadership has made the U.S. the medical innovation capital of the world, bringing hundreds of thousands of high-paying jobs to our country and life-saving devices and drugs to our nation's patients. The Prescription Drug User Fee Act and Medical Device User Fee and Modernization Act, enacted in 1992 and 2002, respectively, were essential in giving FDA the resources it needed to expedite device and drug reviews and thus help foster medical innovation.

Unfortunately, our nation's device and biopharmaceutical leadership is under threat. According to President Obama's Job Council, this threat comes, in part, from "the uncertain FDA regulatory environment."[1] The Jobs Council acknowledges, of course, that "[p]rotecting patients from harm is without question an essential element of what the public expects from the FDA" and notes that enabling the timely development of new therapies and technologies is another important such element, concluding that "[a]chieving both goals simultaneously is the critical challenge for the new drug and device approval process."

The Committee believes that the significant policy reforms contained in H.R. 5651, along with the additional resources and accountability measures in the user fee agreements, will address the regulatory uncertainty at FDA so the U.S. remains the world leader in medical innovation, device and drug jobs remain in the U.S., and U.S patients continue to benefit from new devices and drugs, without compromising FDA's appropriately stringent standards that protect patients from unsafe or ineffective devices and drugs.

H.R. 5651 also would authorize two new user fees. The new generic drug user fee would provide additional resources for the review and regulation of generic drugs. These resources would bring faster and more predictable review of generic drug applications and increased inspections of generic drug facilities, bringing parity to the frequency of inspections of foreign and domestic generic drug facilities. The new biosimilar user fee would provide additional resources to FDA for the review of biosimilar applications.

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[1] The Council commented as follows: "Today, however, our medical innovation ecosystem is in jeopardy. Investment in the life sciences area is declining at an alarming rate because of the escalating cost, time, and risk of developing new drugs and devices. While many factors have contributed to this decline . . . an important factor is the uncertain FDA regulatory environment." President's Council on Jobs and Competitiveness, Interim Report, *Building Confidence: Five Common-Sense Initiatives to Boost Jobs and Competitiveness* (29).

H.R. 5651 also would take important steps to address the current drug shortage crisis affecting the U.S. Although the root causes of drug shortages are complex and multi-faceted, the result is clear: patients, physicians, nurses, and pharmacists across the country face daily challenges in obtaining the drugs they need.

Finally, H.R. 5651 would modernize the Federal Food, Drug, and Cosmetic Act (FFDCA) to give FDA the tools necessary to deal with the increased globalization of the pharmaceutical supply chain.

HEARINGS

IMPACT OF MEDICAL DEVICE REGULATION ON JOBS AND PATIENTS

On February 17, 2011, the Subcommittee on Health held a hearing to examine the state of the medical device industry and the impact of regulations on job creation and patient access. The Subcommittee received testimony from Dr. Jeffrey E. Shuren, Director, Center for Devices and Radiological Health, FDA; ExploraMed Development, Limited Liability Company; the Foundry; Ralph Hall; Dr. Rita Redberg; and Dr. Steven E. Nissen.

IMPORT SAFETY: STATUS OF FDA'S SCREENING EFFORTS AT THE BORDER

On April 13, 2011, the Subcommittee on Oversight and Investigations held a hearing entitled "Import Safety: Status of FDA's Screening Efforts at the Border." The purpose of this hearing was to examine the current state of FDA's import screening processes and the pace of FDA's nationwide rollout of the automated entry review system, known as PREDICT. The witness for this hearing was the Honorable Margaret A. Hamburg, M.D., Commissioner of FDA.

PDUFA V: MEDICAL INNOVATION, JOBS, AND PATIENTS

On July 7, 2011, the Subcommittee on Health held a hearing entitled "PDUFA V: Medical Innovation, Jobs, and Patients." The purpose of the hearing was to examine issues expected to be discussed as part of the reauthorization of the Prescription Drug User Fee Act. The Subcommittee received testimony from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, FDA; OncoMed Pharmaceuticals Incorporation on behalf of the Biotechnology Industry Organization; Warburg Pincus Limited Liability Company; National Health Council; Friends of Cancer Research; and the Pew Charitable Trusts.

REGULATORY REFORM SERIES #5—FDA MEDICAL DEVICE REGULATION: IMPACT ON AMERICAN PATIENTS, INNOVATION AND JOBS

On July 20, 2011, the Subcommittee on Oversight and Investigations held a hearing entitled "Regulatory Reform Series #5—FDA Medical Device Regulation: Impact on American Patients, Innovation and Jobs." The purpose of the hearing was to examine the state of the medical device industry and the impact regulations and policies at the Center for Devices and Radiological Health have on patient access, innovation, and job creation. The Subcommittee received testimony from Dr. Jeffrey E. Shuren, Director, Center for Devices and Radiological Health, FDA; Fischell Biomedical; Tran-

scend Medical Inc.; Progressive Policy Institute; New England Journal of Medicine; Marti Conger; Carol Murphy; and Pam Sagan.

EXAMINING THE INCREASE IN DRUG SHORTAGES

On September 23, 2011, the Subcommittee on Health held a hearing entitled "Examining the Increase in Drug Shortages." The hearing examined the causes and effects of drug shortages in the U.S. health care system. The Subcommittee heard testimony from the Honorable Howard K. Koh, M.D., Assistant Secretary for Health, U.S. Department of Health and Human Services; Teva Health Systems; Healthcare Distribution Management Association; American Society of Health-System Pharmacists; Premier, Inc.; American Society of Clinical Oncology; Lancaster General Health; and the Cancer Institute of New Jersey.

IMPACT OF MEDICAL DEVICE AND DRUG REGULATION ON INNOVATION, JOBS AND PATIENTS: A LOCAL PERSPECTIVE

On September 26, 2011, the Subcommittee on Health held a field hearing entitled "Impact of Medical Device and Drug Regulation on Innovation, Jobs and Patients: A Local Perspective." The Subcommittee investigated how Federal regulations are impacting the medical device community. The Subcommittee received testimony from the California Healthcare Institute; Conatus Pharmaceuticals, Inc.; National Venture Capital Association; West Wireless Health Institute; BIOCOM, CONNECT; and TherOx, Inc.

REAUTHORIZATION OF PDUFA: WHAT IT MEANS FOR JOBS, INNOVATION AND PATIENTS

On February 1, 2012, the Subcommittee on Health held a hearing entitled "Reauthorization of PDUFA: What It Means for Jobs, Innovation, and Patients." The Subcommittee examined issues pertaining to the reauthorization of the Prescription Drug User Fee Act (PDUFA). This hearing also focused on the reauthorization of the Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act (PREA) and pharmaceutical supply chain issues. The Subcommittee received testimony from the Honorable Margaret A. Hamburg, M.D., Commissioner, FDA; Pfizer, Inc.; California Health Institute; Biotechnology Industry Organization; Pharmaceutical Research and Manufacturers of America; the Pew Charitable Trusts; National Organization for Rare Disorders; and American Academy of Pediatrics.

REVIEW OF THE PROPOSED GENERIC DRUG AND BIOSIMILARS, USER FEES AND FURTHER EXAMINATION OF DRUG SHORTAGES

On February 9, 2012, the Subcommittee on Health held a hearing entitled "The Review of the Proposed Generic Drug and Biosimilars User Fees and Further Examination of Drug Shortages." The Subcommittee examined issues pertaining to the proposed generic and biosimilars user fees and drug shortages. The Subcommittee received testimony from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, FDA; Mylan, Inc.; Generic Pharmaceutical Association; and St. Jude Children's Research Hospital.

REAUTHORIZATION OF MDUFA: WHAT IT MEANS FOR JOBS, INNOVATION AND PATIENTS

On February 15, 2012, the Subcommittee on Health held a hearing entitled "Reauthorization of MDUFA: What It Means for Jobs, Innovation, and Patients." The Subcommittee examined issues pertaining to the reauthorization of medical device user fees. The Subcommittee received testimony from Dr. Jeffrey E. Shuren, Director, Center for Devices and Radiological Health, FDA; Terumo BCT; Philips Healthcare; Versant Ventures; Consumers Union; Ralph Hall; Art Sedrakyan, M.D., Ph.D.; Aaron S. Kesselheim, M.D., J.D., M.P.H.; and Jim Shull.

FDA USER FEES 2012: HEARING ON ISSUES RELATED TO ACCELERATED APPROVAL, MEDICAL GAS, ANTIBIOTIC DEVELOPMENT AND DOWNSTREAM PHARMACEUTICAL SUPPLY CHAIN

On March 8, 2012, the Subcommittee on Health held a hearing entitled "FDA User Fees 2012: Hearing on Issues Related to Accelerated Approval, Medical Gas, Antibiotic Development and Downstream Pharmaceutical Supply Chain." The Subcommittee examined issues pertaining to the reauthorization of FDA user fees. The Subcommittee received testimony from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, FDA; Alnylam Pharmaceuticals; Friends of Cancer Research; Cubist Pharmaceuticals; John H. Powers, MD; Compressed Gas Association; Generic Pharmaceutical Association; Healthcare Distribution Management Association; National Community Pharmacists Association; and the Pew Charitable Trusts.

EXAMINING THE CURRENT STATE OF COSMETICS

On March 27, 2012, the Subcommittee on Health held a hearing entitled "Examining the Current State of Cosmetics." The Subcommittee evaluated the current state of the cosmetic industry. The Subcommittee received testimony from Michael M. Landa, J.D., Director, Center for Food Safety and Applied Nutrition, FDA; Personal Care Products Council; Jack Black Skincare; Peter Barton Hutt; Wholesale Supplies Plus; and California Department of Public Health.

FDA USER FEES 2012: HOW INNOVATION HELPS PATIENTS AND JOBS

On April 18, 2012, the Subcommittee on Health held a hearing entitled "FDA User Fees 2012: How Innovation Helps Patients and Jobs." The Subcommittee examined the impact of FDA user fees on patients and jobs. The Subcommittee received testimony from Dr. Janet Woodcock, Director, Center for Drug Evaluation and Research, FDA; Dr. Jeffrey E. Shuren, Director, Center for Devices and Radiological Health, FDA; Pharmaceutical Research and Manufacturers of America; Biotechnology Industry Organization; Generic Pharmaceutical Association; Advanced Medical Technology Association; and Pew Charitable Trusts.

COMMITTEE CONSIDERATION

The Subcommittee on Health held a legislative hearing on April 18, 2012, entitled, "FDA User Fees 2012: How Innovation Helps Patients and Jobs."

On May 8, 2012, the Subcommittee met in open markup session to consider a Committee Print to reauthorize various FDA user fee programs. The Subcommittee adopted an amendment, which included technical changes recommended by the FDA. Thereafter, the Subcommittee forwarded the Committee Print to the full Committee for consideration.

H.R. 5651, the "Food and Drug Administration Reform Act of 2012," was introduced on May 9, 2012, by Fred Upton (R–MI), Ranking Member Henry Waxman (D–CA), Subcommittee on Health Chairman Joseph R. Pitts (R–PA), Subcommittee on Health Ranking Member Frank Pallone, Jr. (D–NJ), Chairman Emeritus Joe Barton (R–TX), and Chairman Emeritus John D. Dingell (D–MI) and was referred to the Committee on Energy and Commerce.

On May 10, 2012, the Committee on Energy and Commerce met in open markup session to consider H.R. 5651, as introduced. The full Committee ordered H.R. 5651 to be reported to the House, without amendment, by a recorded vote of 46 yeas and 0 nays.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. A motion by Mr. Upton to order H.R. 5651 reported to the House, without amendment, was agreed to by a record vote of 46 yeas and 0 nays.

The following reflects the recorded votes taken during the Committee's consideration of the bill:

COMMITTEE ON ENERGY AND COMMERCE -- 112TH CONGRESS
ROLL CALL VOTE # 109

BILL: H.R. 5651, the "Food and Drug Administration Modernization Act of 2012"

AMENDMENT: A motion by Mr. Upton to order H.R. 5651 favorably reported to the House. (Final Passage)

DISPOSITION: AGREED TO, by a roll call vote of 46 Yeas to 0 Nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Upton	X			Mr. Waxman	X		
Mr. Barton	X			Mr. Dingell	X		
Mr. Stearns	X			Mr. Markey	X		
Mr. Whitfield	X			Mr. Towns	X		
Mr. Shimkus	X			Mr. Pallone	X		
Mr. Pitts	X			Mr. Rush	X		
Mrs. Bono Mack	X			Ms. Eshoo	X		
Mr. Walden	X			Mr. Engel	X		
Mr. Terry	X			Mr. Green	X		
Mr. Rogers				Ms. DeGette	X		
Mrs. Myrick	X			Mrs. Capps	X		
Mr. Sullivan				Mr. Doyle	X		
Mr. Murphy	X			Ms. Schakowsky	X		
Mr. Burgess				Mr. Gonzalez	X		
Mrs. Blackburn	X			Ms. Baldwin			
Mr. Bilbray	X			Mr. Ross			
Mr. Bass	X			Mr. Matheson	X		
Mr. Gingrey	X			Mr. Butterfield			
Mr. Scalise	X			Mr. Barrow	X		
Mr. Latta	X			Ms. Matsui	X		
Mrs. McMorris Rodgers	X			Mrs. Christensen			
Mr. Harper	X			Ms. Castor	X		
Mr. Lance	X			Mr. Sarbanes			
Mr. Cassidy	X						
Mr. Guthrie	X						
Mr. Olson	X						
Mr. McKinley	X						
Mr. Gardner	X						
Mr. Pompeo	X						
Mr. Kinzinger	X						
Mr. Griffith	X						

05/10/2012

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held legislative and oversight hearings and made findings that are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

In accordance with clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the performance goals and objectives of the Committee are reflected in the descriptive portions of this report.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 5651, the "Food and Drug Administration Reform Act of 2012," would result in no new or increased budget authority, entitlement authority, tax expenditures or revenues.

EARMARK

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI of the Rules of the House of Representatives, the Committee finds that H.R. 5651, the "Food and Drug Administration Reform Act of 2012," contains no earmarks, limited tax benefits, or limited tariff benefits.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, May 24, 2012.

Hon. FRED UPTON,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN:, The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 5651, the Food and Drug Administration Reform Act of 2012.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Julia Christensen.

Sincerely,

DOUGLAS W. ELMENDORF,
Director.

Enclosure.

H.R. 5651—Food and Drug Administration Reform Act of 2012

Summary: H.R. 5651 would authorize the collection and spending of fees by the Food and Drug Administration (FDA) for certain activities to expedite the marketing approval of prescription drugs and medical devices and to regulate drugs after they enter the market. The bill would provide the FDA with additional regulatory authority to improve the safety of the drug supply chain and establish an early warning notification system to mitigate or prevent critical drug shortages. It also would create a new approval procedure for breakthrough drug therapies and offer financial incentives to drug sponsors to produce certain antimicrobial drugs. The legislation would require FDA to publish the scientific or regulatory rationale for significant decisions issued by the agency regarding a device and establish an expedited process to appeal such decisions. In addition, the bill would permanently reauthorize FDA's programs that evaluate the use of drugs by children.

CBO expects that enacting the bill would affect the average price of prescription drugs available in the market. Some provisions in the bill would result in higher average prices for certain drugs; other provisions would accelerate the entry of generic versions of some drugs, which would lead to lower average prices. CBO estimates that the net effect of enacting H.R. 5651 would be to reduce the average price of prescription drugs slightly through 2017 and to increase prices in subsequent years.

CBO estimates that enacting H.R. 5651 would:

• Reduce direct spending, on net, by $72 million over the 2013–2017 period but increase direct spending by $244 million over the 2013–2022 period.

• Increase federal revenues by less than $500,000 over the 2013–2017 period but lower revenues, on net, by about $3 million over the 2013–2022 period.

Considering both the direct spending and revenue effects, we estimate that enacting H.R. 5651 would reduce budget deficits by approximately $72 million over the 2013–2017 period and increase them by $247 million over the 2013–2022 period. Pay-as-you-go procedures apply because enacting the legislation would affect direct spending and revenues.

Pursuant to section 504 of H. Con. Res. 112, the Concurrent Resolution on the Budget—Fiscal Year 2013, CBO estimates H.R. 5651 would increase direct spending by more than $5 billion in at least one of the four consecutive 10-year periods starting in 2023.

Implementing H.R. 5651 would also have several effects on spending subject to appropriation. The bill would authorize increased funding for a variety of FDA activities, but CBO estimates that the majority of the gross increase in FDA spending would be offset by increased collections of fees that would be credited against discretionary spending. On balance, CBO estimates that net discretionary spending (primarily by FDA) would rise by $337 million over the 2013–2017 period, assuming appropriation actions consistent with the bill.

H.R. 5651 contains both intergovernmental and private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). Extending the requirement to pay fees for medical devices and expanding the registration standards applied to drug manufacturers would be intergovernmental mandates as defined in UMRA

for state, local, or tribal governments that manufacture medical devices for commercial purposes. However, CBO estimates that the costs of complying with those mandates would be minimal and well below the threshold established in UMRA for intergovernmental mandates ($73 million in 2012, adjusted annually for inflation).

The legislation contains several mandates on the private sector as defined in UMRA. The most costly of those mandates would require that manufacturers of different types of drug and medical device products pay fees to the FDA. CBO estimates that the direct cost of all private-sector mandates in the bill would greatly exceed the annual threshold specified in UMRA ($146 million in 2012, adjusted annually for inflation) in each of the first five years that the mandates would be effective.

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 5651 is shown in the following table. The effects of this legislation fall primarily within budget functions 550 (health) and 570 (Medicare).

	By fiscal year, in millions of dollars—					
	2013	2014	2015	2016	2017	2013–2017
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Collections from Fees:						
Prescription Drugs	−720	−756	−800	−847	−945	−4,068
Medical Devices	−98	−115	−129	−133	−134	−609
Generic Drugs	−299	−306	−315	−323	−332	−1,575
Biosimilar Biological Products	−20	−21	−23	−28	−36	−128
Priority Review Vouchers	0	−6	−6	−6	−6	−23
Subtotal, Estimated Authorization Level	−1,137	−1,204	−1,273	−1,337	−1,453	−6,403
Subtotal, Estimated Outlays	−1,137	−1,204	−1,273	−1,337	−1,453	−6,403
Spending of Fees:						
Prescription Drugs	720	756	800	847	945	4,068
Medical Devices	98	115	129	133	134	609
Generic Drugs	299	306	315	323	332	1,575
Biosimilar Biological Products	20	21	23	28	36	128
Priority Review Vouchers	0	6	6	6	6	23
Subtotal, Estimated Authorization Level	1,137	1,204	1,273	1,337	1,453	6,403
Subtotal, Estimated Outlays	721	1,043	1,329	1,446	1,481	6,021
Net Changes from Fees:						
Estimated Authorization Level	0	0	0	0	0	0
Estimated Outlays	−416	−160	57	109	28	−383
Other Proposed Changes:						
Provisions Affecting Prescription Drugs (Titles VIII and IX):						
Estimated Authorization Level	59	68	77	77	77	359
Estimated Outlays	31	58	72	75	76	313
Provisions Affecting Pediatric Populations (Title V):						
Estimated Authorization Level	46	61	62	63	71	303
Estimated Outlays	24	52	59	62	69	266
Provisions Affecting Medical Devices (Title VII):						
Estimated Authorization Level	14	23	32	32	33	134
Estimated Outlays	10	18	27	31	33	118
Other Provisions and Effects:						
Estimated Authorization Level	3	5	5	6	6	25
Estimated Outlays	3	4	4	6	6	23
Total Changes in Discretionary Spending:						
Estimated Authorization Level	122	157	176	178	187	821
Estimated Outlays	−349	−28	219	283	212	337

	By fiscal year, in millions of dollars—					
	2013	2014	2015	2016	2017	2013–2017
CHANGES IN DIRECT SPENDING [a]						
Estimated Budget Authority	−14	−12	−15	−16	−14	−72
Estimated Outlays	−14	−12	−15	−16	−14	−72
CHANGE IN REVENUES [a]						
Estimated Revenues	0	*	*	*	*	*

[a] CBO estimates that enacting the bill would increase direct spending, on net, by $244 million over the 2013–2022 period and decrease revenues by about $3 million over that period. There would be a small effect on spending for health benefits by the United States Postal Service, which is classified as off budget. CBO estimates those amounts would be between −$500,000 and $500,000 annually over the 2013–2022 period.

Note: * = less than $500,000; components may not sum to totals because of rounding.

Basis of Estimate: For this estimate, CBO assumes that the legislation will be enacted by the end of fiscal year 2012 and that the Congress will take appropriation actions consistent with the bill for the funding of FDA activities and for triggering the collections of fees to offset the costs of some of those activities.

H.R. 5651 would reauthorize FDA's branded prescription drug and medical device fee programs through 2017 and would establish new fee programs covering generic drugs and biosimilar biological products. (Biological drugs are products derived from living organisms; biosimilars are those products that meet certain statutory requirements and are determined by FDA to be highly similar to drugs for which licenses were originally granted to innovator drug companies.) The bill also would establish a new fee program that provides vouchers for priority drug reviews to sponsors of marketing applications for drugs that treat rare pediatric diseases.

In addition, the legislation would authorize a number of other activities that are not supported by fees that would modify how the FDA regulates drugs and devices in a broad range of areas.

Spending Subject to Appropriation

Assuming appropriation action consistent with the bill, CBO estimates that implementing H.R. 5651 would reduce net discretionary outlays, primarily for FDA, by $349 million in 2013 and $28 million in 2014, mostly because the spending of fees lags somewhat behind their collection. CBO estimates that gross FDA spending in subsequent years would exceed the amounts collected from fees (because some of the spending under the bill would not be offset by fees) and that the net discretionary cost of implementing the bill would amount to $337 million over the 2013–2017 period.

Fee Programs Administered by FDA. H.R. 5651 would authorize five different fee programs within FDA to cover specific costs relating to the approval and marketing of prescription drugs (branded, generic, and biosimilar biological products) and medical devices, and to cover costs of conducting priority drug reviews through an incentive program that awards redeemable vouchers for such reviews to sponsors of certain applications for drugs that treat rare pediatric diseases. In fiscal year 2012, CBO estimates that FDA will collect $760 million in fees associated with the existing branded prescription drug and medical device fee programs that expire at the end of the year.

Under the bill, CBO estimates that FDA would assess about $6.4 billion in aggregate fees over the 2013–2017 period. Of that amount, $1.7 billion in collections would be generated by the new

fee programs for generic and biosimilar biological drugs and for priority review vouchers created under the legislation, and $4.7 billion in collections would be generated by the fee programs for branded prescription drugs and medical devices reauthorized by the bill. Except for the voucher program, the fee programs authorized under the bill would expire at the end of fiscal year 2017. The authority to award vouchers expires one year after the third voucher is awarded, but there is no limit on when the voucher can be redeemed.

H.R. 5651 specifies that drug and medical device fees would be collected and made available for obligation only to the extent, and in the amounts, provided in advance in appropriation acts, with one exception. The bill would allow certain new fees authorized for generic and biosimilar biological drugs to be collected and spent during the first program year (fiscal year 2013) until the date of enactment of a law providing appropriations through September 30, 2013. By allowing the assessment and spending of fee collections outside of an appropriation action, H.R. 5651 could generate increases in revenue or direct spending attributable to such fees. However, for this estimate, CBO assumes that both enactment of H.R. 5651 and the necessary appropriation action will occur before the end of fiscal year 2012. As a result, we expect that any fees assessed and spent in fiscal year 2013 would be classified as offsetting collections (that is, as an offset to discretionary spending).

CBO estimates that appropriation action consistent with the bill's authorizations for fee programs would reduce net discretionary outlays for FDA by $383 million over the 2013–2017 period. Because FDA would have the authority to spend the collections, the estimated budget authority for collections and spending would offset each other exactly for each fiscal year, while the spending of fee collections would initially lag behind the collections and thus generate net discretionary savings over the 2013–2017 period.

Costs for Activities Not Supported by Fees. H.R. 5651 would require that FDA modify certain agency procedures relating to the oversight of prescription drugs and devices; costs for many of the new activities would not be covered by fees. CBO estimates that activities not supported by fees under the bill would cost $720 million over the 2013–2017 period, assuming the appropriation of the necessary amounts.

Provisions Affecting Prescription Drugs (Titles VIII and IX). H.R. 5651 would enhance FDA's regulatory authorities relating to prescription drugs in several key areas. It would expand advance notification requirements for potential drug shortages and strengthen FDA's authority to expedite drug reviews and inspections of facilities that address critical drug shortages. The bill would increase FDA's oversight authority of the drug supply chain both in the United States and overseas through new registration and inspection requirements. The bill also would allow FDA to destroy certain counterfeit or adulterated imports valued at less than $2,000. To advance the development of breakthrough drug therapies, H.R. 5651 would create a new approval procedure for such products. CBO estimates that implementing such provisions and complying with other requirements contained in titles VIII and IX would increase FDA's costs by about $313 million over the 2013–2017 period.

Provisions Affecting Pediatric Populations (Title V). H.R. 5651 would permanently authorize FDA's pediatric drug programs. The bill would make permanent:

- An incentive program that grants market exclusivity to manufacturers that voluntarily conduct specified studies on the use of drugs in certain pediatric populations, the so-called pediatric exclusivity program;[1] and
- FDA's authority to require that drug manufacturers conduct tests on drugs for pediatric populations and make necessary labeling changes to reflect the appropriate information.

The legislation also would authorize the appropriation of $25 million per year to extend the research program at the National Institutes of Health for pediatric studies on drugs for each year from 2013 through 2017. The bill would also authorize the appropriation of $30 million annually over the 2013–2017 period to extend FDA's grant and contracts program for orphan products.

Assuming the appropriation of the necessary amounts, CBO estimates that implementing provisions that affect pediatric populations in title V of the bill would have a discretionary cost of $266 million the over 2013–2017 period.

Provisions Affecting Medical Devices (Title VII). Title VII would modify regulatory procedures under which FDA evaluates and approves medical device applications and tracks the safety of such devices. Among those changes the bill would:

- Include devices in FDA's system for identifying risks after a product is on the market;
- Require FDA to publish the scientific and regulatory rationale for any significant decision regarding a report or application;
- Establish a process for manufacturers that are seeking to submit or that have submitted a report or application to review with FDA the agency's documentation of significant decisions;
- Require FDA to regularly publish detailed decision summaries for each clearance of certain devices; and
- Extend and enhance the incentive program for device manufacturers to develop medical devices specifically designed for pediatric patients.

CBO estimates that the provisions affecting the regulation of medical devices under title VII would increase FDA's costs by about $118 million over the 2013–2017 period, assuming the appropriation of the necessary amounts.

Other Provisions and Effects. CBO estimates that implementing title VI and preparing certain regulatory science reports not covered by fees would cost $31 million over the 2013–2017 period, assuming the appropriation of the necessary amounts.

Several provisions in the bill would affect when lower-priced drugs enter the market. Changing the timing of availability of lower-priced drugs affects spending in federal health programs that pay for prescription drugs and biological products. We expect that enacting the bill would reduce the average price of drugs in the market slightly over the 2013–2017 period. CBO estimates that spending for federal health programs subject to appropriation—

[1] During such periods of pediatric exclusivity, FDA will not permit another manufacturer to market a version of the drug.

such as those operated by the Departments of Veterans Affairs and Defense—would fall by $8 million over that period, assuming that appropriation actions reflect the estimated reductions in costs.

Direct Spending

CBO estimates that enacting H.R. 5651 would reduce direct spending for federal health programs by $72 million over the 2013–2017 period but would increase direct spending by $244 million over the 2013–2022 period. That net impact reflects an increase in direct spending owing to provisions that would delay market entry of certain drugs (causing some federal health programs to have higher spending than under current law) and a decrease in direct spending owing to other provisions that would lower average prices paid for some drugs (allowing federal health programs to reduce their costs). CBO estimates that direct spending, on net, would begin to increase starting in 2018, when the effects of provisions that would delay the entry of lower-priced drugs exceeds the effects of provisions that would lead to earlier entry of lower-priced drugs.

Provisions that are expected to delay entry of lower-priced generic or biosimilar biological drugs are those that provide market exclusivity—periods during which FDA will not permit another manufacturer to market a version of the drug. Those provisions are aimed at encouraging the development of certain types of anti-microbial medications, innovative single enantiomer drugs, and pediatric indications and formulations for drugs.[2]

Section 862 would change the rules governing when a generic drug manufacturer forfeits its rights to market exclusivity because of failure to receive tentative approval from FDA. The legislation would increase the allowable time period to obtain such approval—now set at 30 months after filing an application—before forfeiture occurs. Thus, the bill would allow affected firms to retain sole marketing rights. In cases where fewer generic firms compete on products because a forfeiture is avoided, we anticipate that higher average prices would be charged in the market. Because CBO expects that the implementation of the fee program for the review of generic drugs will accelerate review times and lead to fewer forfeitures, holding all else equal, the estimated costs for section 862 reflect the incremental effect of this provision beyond the effect of the fee program.

Taken together, CBO estimates that provisions delaying the entry of generic or biosimilar biological drugs would increase the average prices of certain drugs and thereby increase direct spending for mandatory health programs such as Medicare, Medicaid, subsidies for enrollees in health insurance exchanges, and the Federal Employees Health Benefits and TRICARE-for-Life programs, by $412 million over the 2013–2022 period.

CBO expects that other provisions of H.R. 5651 would reduce the average price charged for drugs in the market. We estimate that the provision with the greatest effect on market entry by lower-priced generic drugs is section 863. It would reduce by 30 days the statutory timeframe for final agency action relating to certain citizen petitions that ask for a stay of FDA approval on a pending ge-

[2] Enantiomers are a class of molecules that are arranged as mirror images to one another. Such molecules can be found together in a mixture that forms the basis of many drugs.

neric drug application. (Under the bill, the limitation on the determination period would be 150 days.)

When both approval of the generic application and marketing of the drug hinge on the final determination date, earlier administrative action under the bill could lead to earlier generic entry. (Sometimes patents or market exclusivities delay entry of generics regardless of the date on which a citizen petition is resolved.) Thus, in certain cases, CBO expects that reducing the statutory timeframe by 30 days could lead to earlier marketing of lower-priced drugs.

CBO estimates that implementing section 863 and other provisions that shorten administrative timeframes for review of certain petitions would reduce direct spending for mandatory health programs by $168 million over the 2013–2022 period. CBO anticipates that the implementation of the fee program in title III would allow FDA to use its resources in such a manner that we can reasonably expect that the average review times for certain petitions would also fall over time because of that program. Thus, estimated savings generated by provisions that would shorten administrative timeframes in the bill reflect the incremental effect of such provisions beyond the effect of the fee program.

Revenues

H.R. 5651 would affect revenues in two ways. First, CBO expects that enacting H.R. 5651 would result in slightly higher costs for private health insurance plans over the 2013–2022 period. In turn, raising the costs of health insurance plans would increase federal subsidies for health insurance purchased through an exchange. The portion of those tax credits that exceed taxpayers' liabilities are classified as outlays (and those effects are included in the direct spending estimate above), while the portions that reduce taxpayers' liabilities are recorded as changes in revenues. CBO estimates that H.R. 5651 would lower federal revenues by $3 million over the 2013–2022 period.

In addition, the bill would make certain violations of new requirements subject to criminal and civil money penalties. Collections of such penalties are classified as federal revenues. Criminal fines are deposited in the Crime Victims Fund, and later spent; however, CBO estimates that any net effects would not be significant in each year because of the small number of cases likely to be affected.

Pay-as-you-go considerations: The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting on-budget direct spending or revenues. The net changes in outlays and revenues that are subject to those pay-as-you-go procedures are shown in the following table.

CBO ESTIMATE OF PAY-AS-YOU-GO EFFECTS FOR H.R. 5651 AS ORDERED REPORTED BY THE HOUSE COMMITTEE ON ENERGY AND COMMERCE ON MAY 10, 2012

	By fiscal year, in millions of dollars—												
	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2012–2017	2012–2022
NET INCREASE OR DECREASE (−) IN THE ON-BUDGET DEFICIT													
Statutory Pay-As-You-Go Impact	0	−14	−12	−15	−16	−15	7	73	61	66	112	−73	247

Note: Components may not sum to totals because of rounding.

Estimated impact on state, local, and tribal governments: By continuing FDA's fee program, the bill would extend a requirement to pay fees on state, local, or tribal governments that manufacture medical devices for commercial purposes. That requirement would be an intergovernmental mandate as defined in UMRA, but CBO is unaware of any case in which a state, local, or tribal entity manufactures such devices for commercial purposes. CBO is aware of public institutions of higher education that manufacture drugs and are subject to FDA's registration and inspection standards. Thus, the provisions in the bill that increase the stringency of those standards would impose an intergovernmental mandate. Because few public institutions of higher education would be required to comply with the new standards, CBO estimates that the costs of complying with the mandates in H.R. 5651 would be minimal and well below the threshold established in UMRA ($73 million in 2012, adjusted annually for inflation).

Because the bill's requirements would result in lower costs for prescription drugs provided under the Medicaid program, CBO estimates that state spending for Medicaid would decrease by about $6 million over the 2013–2017 period.

Estimated impact on the private sector: The legislation contains several mandates on the private sector as defined in UMRA. The most costly of those mandates would require that manufacturers of branded prescription drugs, generic drugs, biosimilar biological products, and medical devices pay fees to FDA. CBO estimates that the direct cost of all private-sector mandates in the bill would greatly exceed the annual threshold specified in UMRA ($146 million in 2012, adjusted annually for inflation) in each of the first five years that the mandates would be effective.

In addition to imposing an increase in fees, H.R. 5651 also would impose a number of other mandates on the private sector. For example, several provisions in the bill would grant periods of market exclusivity for certain types of drugs. Those provisions impose a mandate by preventing manufacturers of generic or biosimilar versions of the drug from entering the market during that period. The bill also would expand requirements relating to the approval of pediatric drugs and would expand registration requirements on certain entities involved in the manufacture, preparation, propagation, compounding, or processing of drugs. Title VIII also would authorize the Secretary of Health and Human Services to destroy certain drugs intended for import that are refused admission to the United States. Title IX would require that manufacturers of certain drugs notify the FDA before discontinuing production of those drugs.

Previous CBO estimate: On May 11, 2012, CBO transmitted a cost estimate for S. 2516, the Food and Drug Administration Safety and Innovation Act, as reported by the Senate Committee on Health, Education, Labor, and Pensions on May 7, 2012. Both the House and Senate bills would make significant changes to the regulatory authority of the Food and Drug Administration relating to prescription drugs and devices. Although the bills contain many similar provisions, H.R. 5651 would address certain regulatory issues in different ways. CBO's cost estimates reflect those differences.

Estimate prepared by: Federal Costs: Julia Christensen, Lisa Ramirez-Branum, Daniel Hoople, Jamease Miles, Kalyani Parthasarathy, Ellen Werble, and Rebecca Yip; Impact on State, Local, and Tribal Governments: Lisa Ramirez-Branum; Impact on the Private Sector: Jimmy Jin.

Estimate approved by: Holly Harvey, Deputy Assistant Director for Budget Analysis.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

TITLE I—PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2012

The first title would authorize the Prescription Drug User Fee Amendments of 2012 (PDUFA).

Section 101—Short title; findings

In this section, Congress would find that the prescription drug user fee funds must go toward, as set forth in the goals identified in the letters from the Secretary of Health and Human Services to the Chairman of the House Committee on Energy and Commerce and Chairman of the Senate Committee on Health, Education, Labor, and Pensions, expediting the drug development process and review of human drug applications, including postmarket safety activities. These goals would include meeting time goals regarding the review of priority and standard drug applications, fostering greater interaction between drug sponsors and FDA, and increasing engagement with patients, including those with rare diseases.

Section 102—Definitions

This section would amend a statutory definition associated with the user fee.

Section 103—Authority to assess and use drug fees

This section would establish the user fee amounts for fiscal years 2013 through 2017 and adjustments to, and methodologies for calculating, those fees. FDA would collect these funds through application, establishment, and product fees. The section also would require FDA to contract with an independent firm to analyze the ade-

quacy of those adjustments and methodologies. Finally, based on such analysis, FDA could adopt changes to the methodologies.

Section 104—Reauthorization; reporting requirements

This section would require FDA to report, not later than 120 days after the end of each fiscal year, on its success in achieving the goals set forth in the letter from the Secretary of Health and Human Services to the Chairman of the House Committee on Energy and Commerce and Chairman of the Senate Committee on Health, Education, Labor, and Pensions. This report would include the status of the independent assessment of the Program for New Molecular Entities. This report also would include the progress of the review divisions of FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research on the following topics: (1) number of original standard new drug applications and biologics license applications filed per fiscal year; (2) number of original priority new drug applications and biologics license applications filed per fiscal year; (3) number of standard efficacy supplements filed per fiscal year; (4) number of priority efficacy supplements filed per fiscal year; (5) number of applications filed for review under accelerated approval per fiscal year; (6) number of applications filed for review as fast track products per fiscal year; and (7) number of applications filed for orphan-designated products per fiscal year. The section also would require FDA to submit a fiscal report on the use of the fees collected under the authority granted under Title I.

The section would authorize FDA to develop and present recommendations to Congress on the reauthorization of the user fee program by January 15, 2017.

Section 105—Sunset dates

The section would establish sunset dates for the user fee and related programs and provide technical clarifications for previous user fee legislation.

Section 106—Effective date

The title would take effect on October 1, 2012, or the date of enactment, whichever is later.

Section 107—Savings clause

This section would limit the effect of Title I on those applications and supplements filed before enactment of the title and clarify that the prescription drug user fee provisions in effect prior to October 1, 2012 would apply to such submissions.

TITLE II—MEDICAL DEVICE USER AMENDMENTS OF 2012

The second title would authorize the Medical Device User Fee Amendments of 2012.

Section 201—Short title; finding

In this section, Congress would find that the medical device user fee funds must go toward, as set forth in the goals identified in the letters from the Secretary of Health and Human Services to the Chairman of the House Committee on Energy and Commerce and Chairman of the Senate Committee on Health, Education, Labor,

and Pensions, expediting the process for the review of device applications and assuring the safety and effectiveness of devices.

Section 202—Definitions

This section would amend certain definitions in Section 737 of the FFDCA.

Section 203—Authority to assess and use device fees

This section would reauthorize the user fee program and set forth changes in the fees beginning in 2013. Under this section, FDA would collect the following amounts under the medical device user fee program: $97,722,301 for fiscal year 2013; $112,580,497 for fiscal year 2014; $125,767,107 for fiscal year 2015; $129,339,949 for fiscal year 2016; and $130,184,348 for fiscal year 2017. FDA would collect these funds through fees associated with submissions and establishment registration.

Section 204—Reauthorization; reporting requirements

This section would require FDA to report, not later than 120 days after the end of each fiscal year, on its success in achieving the goals set forth in the letter from the Secretary of Health and Human Services to the Chairman of the House Committee on Energy and Commerce and Chairman of the Senate Committee on Health, Education, Labor, and Pensions. The section also would require FDA to submit a fiscal report on the use of the fees collected under the authority granted under Title II.

The user fee agreement would include the following improvements: (1) FDA would have to report its total time for reviewing devices; (2) FDA's review process would include greater interaction between sponsors and the Agency; and (3) an independent entity would assess the device approval and clearance processes, and FDA would have to implement a corrective action plan to address deficiencies. In addition to the annual report referenced above, FDA would have to post certain information on its success in achieving the goals on a quarterly basis, including the status of the independent assessment.

Part of the user fee agreement includes the development of a transitional In Vitro Diagnostics (IVD) approach. The Committee applauds FDA for its commitment, as expressed in the MDUFA III Commitment Letter, to work with industry to develop a transitional IVD approach for the regulation of emerging diagnostic tests. The Committee is highly interested in developments with respect to the Agency's plans to develop a transitional IVD approach and looks forward to reviewing steps taken related to its implementation.

The section would authorize FDA to develop and present recommendations to Congress on the reauthorization of the user fee program by January 15, 2017.

Section 205—Savings Clause

This section would limit the effect of Title II on those applications and supplements filed before enactment of the Title, and clarify that the medical device user fee provisions in effect prior to October 1, 2012 would apply to such submissions.

Section 206—Effective date

Under this section, Title II would take effect on October 1, 2012, or the date of enactment, whichever is later.

Section 207—Sunset Clause

This section would set the expiration dates of the medical device user fee as October 1, 2017, and the expiration of the reporting requirement as January 31, 2018.

Section 208—Streamlined hiring authority to support activities related to the process for the review of device applications

This section would authorize FDA to streamline the hiring process to expedite the hiring of personnel necessary to achieve the performance goals.

TITLE III—FEES RELATING TO GENERIC DRUGS

This title would authorize the Generic Drug User Fee Amendments of 2012 (GDUFA).

Section 301—Short title; findings

In this section, Congress would find that the generic drug user fee funds must go toward, as set forth in the goals identified in the letters from the Secretary of Health and Human Services to the Chairman of the House Committee on Energy and Commerce and Chairman of the Senate Committee on Health, Education, Labor, and Pensions, human generic drug activities, which include the review of abbreviated new drug applications and facility inspections.

Section 302—Authority to assess and use human generic drug fees

This section would codify definitions key to implementing this new user fee, including the types of activities that FDA could fund with these fees. With respect to user fees, the section would authorize the following: one-time backlog fee; drug master file fee; abbreviated new drug application and prior approval supplement filing fee; and generic drug and active pharmaceutical facility fee. These fees would generate approximately $299,000,000 per year for fiscal years 2013 to 2017. For fiscal year 2013, $50,000,000 would come from the one-time backlog fee for applications pending with FDA on October 1, 2012, and the rest would come from the remaining user fees as follows: 6 percent from drug master file fees; 24 percent from abbreviated new drug and prior approval supplement filing fees; 56 percent from generic facility fees; and 14 percent from active pharmaceutical ingredient filing fees. In the fiscal years 2014 to 2017, there would be no backlog fee; the approximately $299,000,000 would come in each year from the remaining user fees in the percentages outlined in the previous sentence.

Section 303—Reauthorization; reporting requirements

This section would require FDA to report, not later than 120 days after the end of each fiscal year, on its success in achieving the goals set forth in the letter from the Secretary of Health and Human Services to the Chairman of the House Committee on Energy and Commerce and Chairman of the Senate Committee on Health, Education, Labor, and Pensions. The section also would re-

quire FDA to submit a fiscal report on the use of the fees collected under the authority granted under Title III. Finally, the section would authorize FDA to develop and present recommendations to Congress on the reauthorization of the user fee by January 15, 2017.

Section 304—Sunset dates

This section would set the expiration dates of the generic drug user fee program as October 1, 2017, and the expiration of the reporting requirement, described in section 303, as January 31, 2018.

Section 305—Effective date

Under this section, Title III would take effect on October 1, 2012, or the date of enactment, whichever is later.

Section 306—Amendment with respect to misbranding

This section would subject a manufacturer to a misbranding violation of the FFDCA for, if required, not paying a facility fee under section 744B(a)(4) or failing to provide a facility identification required under section 744B(f).

Section 307—Streamlined hiring authority to support activities related to the process for the review of generic drug applications

This section would authorize FDA to streamline its hiring process so it could hire the personnel necessary to achieve the performance goals.

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

Title IV contains language that would authorize the Biosimilars User Fee Amendments of 2012 (BSUFA).

Section 401—Short title; findings

In this section, Congress would find that the user fee funds must go toward, as set forth in the goals identified in the letters from the Secretary of Health and Human Services to the Chairman of the House Committee on Energy and Commerce and Chairman of the Senate Committee on Health, Education, Labor, and Pensions, expediting the process for the review of biosimilar biological product applications, including postmarket safety activities.

Section 402—Fees relating to biosimilar biological products

This section would codify definitions key to implementing these new user fees, including the types of activities that FDA could fund with these fees. This section also would authorize the following four types of user fees: application, product, establishment, and biosimilar product development. The first three would be set equal to the PDUFA rate for each type of fee. The product development fee would be set at 10 percent of the PDUFA application fee.

Section 403—Reauthorization; reporting requirements

This section would require FDA to report, not later than 120 days after the end of each fiscal year, on its success in achieving the goals set forth in the letter from the Secretary of Health and Human Services to the Chairman of the House Committee on En-

ergy and Commerce and Chairman of the Senate Committee on Health, Education, Labor, and Pensions. The section also would require FDA to submit a fiscal report on the use of the fees collected under the authority granted under Title IV. Under the section, a third party assessment will study the workload volume and full costs associated with biosimilar product applications. Finally, the section would authorize FDA to develop and present recommendations to Congress on the reauthorization of the user fee program by January 15, 2017.

Section 404—Sunset dates

This section would set the expiration date of the biosimilar user fee program as October 1, 2017, and the expiration of the reporting requirement, described in section 403, as January 31, 2018.

Section 405—Effective date

Under this section, Title IV would take effect on October 1, 2012, or the date of enactment, whichever is later.

Section 406—Savings clause

This section would limit the effect of Title IV on those applications and supplements filed before enactment of the title and clarify that the prescription drug user fee provisions in effect prior to October 1, 2012 would apply to such submissions.

Section 407—Conforming amendment

This section would conform section 735 of FFDCA to reflect the new biosimilars user fee.

TITLE V—BEST PHARMACEUTICALS FOR CHILDREN ACT (BPCA) AND PEDIATRIC RESEARCH EQUITY ACT (PREA)

The Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) foster the development of prescription drugs for children and safe use of drugs by children.

BPCA was established in 1997. It provides FDA with the authority to add six months to existing marketing exclusivity periods and listed patents for a drug or biologic in return for FDA-requested submission of pediatric studies.

PREA requires a manufacturer of a drug or biologic who submits an application to market a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration to also submit a pediatric assessment for that product.

BPCA has been very successful in spurring research in the pediatric population for rare conditions and encouraging companies to undertake research where there was no incentive to do so. The Committee commends the evaluation of promising pediatric cancer therapies for children with cancer through the pediatric preclinical testing program established in 2002 under BPCA. The Committee encourages the Department of Health and Human Services to continue to report to Congress on patient access to new therapeutic agents for pediatric cancer.

Section 501—Permanent extension of Best Pharmaceuticals for Children Act and Pediatric Research Equity Act

This section would reauthorize BPCA and PREA. It also would clarify that exclusivity under BPCA can only be granted based on a written request issued by FDA and that studies conducted under PREA could be included in a written request. It also would ensure safety-related labeling changes made for branded drugs as a result of BPCA are included on generic labels in all appropriate sections.

With respect to PREA, it would create a deferral extension pathway and require FDA to publicly report each deferral and deferral extension issued under PREA, including the name of the product sponsor and the date the drug was initially approved. The section also would remove a requirement that declined Written Requests be referred to the National Institutes of Health (NIH) Foundation, instead allowing these studies to be immediately referred to the National Institute for Child Health and Human Development. In addition, the section would allow FDA to issue a non-compliance letter to a product sponsor who fails to meet its post-marketing requirements under PREA and would require the product sponsor to respond to FDA's allegations in writing. These letters would be made public. Finally, regarding PREA, the section would require product sponsors to submit an "Initial Pediatric Plan" as part of the drug application process and outlines the process for submission. The plan would be submitted no later than 60 days after the end of phase 2 clinical trials or such other time negotiated between FDA and the sponsor and would include an outline of proposed pediatric studies and any request for a waiver or deferral of PREA requirements.

In addition to that described above, the section would require FDA to conduct a public meeting regarding the impact of BPCA and PREA on the development of new therapies for children with cancer.

Finally, this section would reauthorize the NIH fund, which is used to study "off-patent" drugs, at $25,000,000 for each fiscal year 2013 to 2017. This is the appropriated level in fiscal year 2012.

Section 502—Food and Drug Administration Report

The section would require FDA to submit a report to the Chairman of the House Committee on Energy and the Commerce and Chairman of the Senate Committee on Health, Education, Labor, and Pensions within 4 years of enactment and every 5 years thereafter. The report would have to include the following information: the number of waivers, deferrals, and non-compliance letters issued under PREA; an assessment of the effectiveness of pediatric study plans under PREA; the number of Written Requests issued, accepted, and declined under BPCA; an assessment of the effectiveness of studying drugs for rare diseases under BPCA; an assessment of the effectiveness of studying pediatric oncology drugs under BPCA and PREA; an assessment of the effectiveness of studying drugs in neonates under BPCA and PREA; an assessment of the effectiveness of studying biologics in pediatric populations under BPCA and PREA; and any suggestions for modification to BPCA and PREA that would improve pediatric drug research. Prior to submitting this report, FDA would have to consult with stakeholders.

Section 503—Internal Committee for Review of Pediatric Plans, Assessments, Deferrals, Deferral Extensions, and Waivers

The section would clarify the authority of FDA's Pediatric Review Committee (PeRC) to review deferral extensions under PREA. The section also would require the PeRC to include a neonatologist.

Section 504—Staff of Office of Pediatric Therapeutics

The section would require FDA's Office of Pediatric Therapeutics to have a neonatologist and pediatric epidemiologist on staff.

Section 505—Continuation of operation of Pediatric Advisory Committee

The section would reauthorize FDA's Pediatric Advisory Committee.

Section 506—Pediatric Subcommittee of the Oncologic Drugs Advisory Committee

The section would reauthorize the Pediatric Subcommittee of FDA's Oncologic Drugs Advisory Committee (ODAC).

TITLE VI—FDA ADMINISTRATIVE REFORMS

Title VI includes sections that would apply to the issuance of FDA guidance documents, conflicts of interest, electronic submission of applications, and regulation of laboratory developed tests.

Section 601—Public Participation in issuance of FDA guidance documents

The section would improve FDA's guidance document process by encouraging public participation in development of the draft guidance documents FDA utilizes to explain the agency's positions. The Committee believes that some draft guidance documents, in part due to lack of public participation in the development process, have created uncertainty and significant implementation issues. One example is the draft guidance entitled "Guidance for Industry and FDA Staff—510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device" issued on July 27, 2011.

The section would require that, for certain guidance documents, FDA would have to provide at least 30 days notice of its intent to issue the guidance document. During that 30-day period, FDA could meet with interested stakeholders. If FDA were to decide that such pre-issuance notice and involvement is impracticable, unnecessary, or contrary to the public interest, FDA would have to provide a reason why pre-issuance public notice and involvement is impracticable, unnecessary, or contrary to the public interest and publish the reason in the Federal Register.

Upon the issuance of a draft guidance document under the section, FDA would have to finalize the document within 18 months of the close of the comment period or the document would be null and void. Such time period could be extended by 180 days if FDA publishes a notification of such an extension in the Federal Register.

Every 5 years after the issuance of a final guidance under this section, the section would require FDA to analyze the guidance doc-

ument and if warranted by its analysis, modify, streamline, expand or repeal the document.

With respect to devices, the process set forth above would apply to notice to industry guidance letters and notice to industry advisory letters that meet the definition of a guidance document.

Section 602—Conflicts of interest

The Food and Drug Administration Amendments Act of 2007 (FDAAA, Public Law 110–85), included a provision designed to limit conflicts of interest and restrict those eligible to serve on FDA advisory committees. The Committee believes this provision has discouraged the use of the most qualified experts from serving on FDA advisory committees, thus preventing the advisory committees from providing the best guidance to FDA on important scientific issues. According to the testimony of Marc Boutin of the National Health Council before the Health Subcommittee in July, 2011, at the time of the testimony, FDA had a vacancy rate of 23 percent for its advisory committees, and this was attributable in part to the conflicts of interest policy.[2]

This section is intended to improve FDA's conflict of interest rules so the Agency's advisory committees have better access to the most knowledgeable experts. The section would strike the current statutory provisions governing recruitment and limits on waivers. In their place, the section would require FDA to actively recruit to fill the advisory committees so FDA has access to the most current expert advice. It also would require FDA to provide transparency regarding the type, nature, and magnitude of relevant financial interests of advisory committee members. Finally, the section would require FDA to provide an annual report on the implementation of the section and to update as necessary the guidance on disclosure of advisory committee conflicts of interest.

Section 603—Electronic submission of applications

This section would require electronic submission of drug, generic drug, biologic, and biosimilar applications following issuance of a final guidance by FDA. This section also would require an electronic copy for device pre-submissions and submissions following issuance of a final guidance by FDA

Section 604—Notification of FDA intent to regulate laboratory-developed tests

The section would prohibit FDA from issuing both draft and final guidance on the regulation of laboratory developed tests unless it notifies the House Energy and Commerce Committee and the Senate Committee on Health, Education, Labor, and Pensions of its intent to take such action at least 60 days prior to the issuance of such guidance.

TITLE VII—MEDICAL DEVICE REGULATORY REFORMS

Title VII includes significant reforms to premarket and postmarket device regulation.

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[2] Marc Boutin, Testimony before the Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, Hearing: "*Regulatory Reform Series #5—FDA Medical Device Regulation: Impact on American Patients, Innovation and Jobs*" (July 20, 2011), available at: *http://energycommerce.house.gov/hearings/hearingdetail.aspx?NewsID=8806*.

Subtitle A—Premarket Predictability

The Committee believes the sections in Subtitle A would add predictability, consistency, and transparency to the medical device premarket review process.

Sections 701—Investigational Device Exemption

The goal of section 701 is to address concerns that FDA may be disapproving pivotal investigations of new technologies solely because the output of the investigation will not yield a classification or approval status that could result in the marketing of a device. On the other hand, the Committee also heard reports from FDA that FDA had, in the past, permitted studies to go forward that FDA believed would not support approval, and when sponsors completed those trials, FDA was unable to approve the device. Nonetheless, as reflected in Section 701, the Committee believes manufacturers should be free to assume the risk that their studies may not support approval of a marketing application if the studies will provide useful information, so long as the study is conducted ethically and with reasonable risk to patients.

Because the investigation of a device may involve many steps to optimize its design, its intended use, and ultimately, its safety and effectiveness, the Committee sees little merit in limiting device investigations only to those that would likely support a marketing decision. A clinical investigation that would not demonstrate a reasonable assurance of safety and effectiveness to justify an approval, and yet provide valuable information to optimize the design and development of the device, should be approved and undertaken to develop that data and information. Under the section, FDA's approval of an IDE would signify that regulatory requirements have been met, and would not reflect FDA's judgment of the adequacy of the study design or the likelihood that the study will support a marketing application.

Accordingly, the sections would amend section 520(g) to prohibit FDA from disapproving an investigational device application because it may not support or meet the requirements of a substantial equivalence determination or a premarket approval if the investigational device application otherwise meets the requirements in section 520(g). Additionally, FDA would be barred from disapproving an investigational device application solely because additional or different investigations may be necessary to support a marketing application.

Section 702—Clarification of the Least Burdensome Standard

This section would reaffirm the least burdensome provisions added during the Food and Drug Administration Modernization Act of 1997 (FDAMA) and codify in statute the least burdensome concept as expressed in FDA's 2002 Guidance Document, "The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry." Specifically, section 702 would define the word "necessary" for purposes of ensuring that the information requested in the premarket notification and premarket approval contexts is only that information required to make a regulatory determination and does not include information that is merely of interest. This provision was

prompted by reports that despite FDA's own guidance stating that information requests should be limited to those relevant to making a regulatory decision, FDA's premarket notification and premarket approval reviews were becoming longer and more burdensome because some reviewers requested information that was unnecessary for regulatory decisions.

The section would define "necessary" in the premarket notification context to mean "the minimum required information that would support a determination of substantial equivalence between a new device and a predicate device." For example, in the premarket notification context, the Committee intends that FDA limit its requests for additional information to only that information that FDA needs to determine whether or not one device is substantially equivalent to a predicate device.

Section 703—Agency Documentation and Review of Significant Decisions

Section 703 would address concerns expressed by some in industry that significant premarket regulatory decisions are not adequately documented with a scientific or regulatory rationale. In some instances, FDA consideration of administrative appeals to supervisors sometimes takes longer than many original decisions. To address these concerns and problems, the section would require that the Agency completely document certain significant premarket decisions, including significant differences of opinion that occur during device reviews. Also, this section would clarify the process under 21 CFR 10.75 to persons who challenge significant premarket review decisions, that occur in the context of 510(k) submissions, and premarket approval and investigational device applications, and provide specific timelines for the reviews for those appeals.

Section 704—Transparency in the Clearance Process

Consistent with the direction in section 703 to require documentation of Agency decision-making, section 704 would require "detailed decision summaries" of certain 510(k) determinations. Only by creating transparency in decision-making can we ensure the review process functions as intended.

Section 705—Device Modifications Requiring Premarket Notification Prior to Marketing

Section 705 addresses when premarket notifications are required for legally marketed devices that have been modified. The Committee is very interested in this important determination. On July 27, 2011, FDA issued a draft guidance entitled "Guidance for Industry and FDA Staff–510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device," that, when finalized, would replace the 1997 guidance on 510(k) device modification entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device." The FDA issued the 2011 draft guidance because some stakeholders advocated the need to provide greater clarity and certainty to the 510(k) modification process. However, the Committee heard reports from stakeholders and some companies that the 1997 guidance document was satisfactory in addressing the many very difficult device assessment issues associated

with modifications, and the new draft guidance created too much uncertainty in the device industry.

Accordingly, the section would require that FDA submit a report to the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor, and Pension within 18 months. This report would include: (1) FDA's interpretation of key terms in FDA's regulations as specified in the section (see 21 CFR § 807.81(a)(3)); (2) analysis on how to leverage design controls that are a part of FDA's Quality System Regulation (see 21 CFR § 820.30), to reduce premarket submission burdens for changes that do not merit FDA's review resources; and (3) methods to ensure continued improvement of legally marketed devices. The section would require FDA to withdraw its July 27, 2011 draft device modification guidance and instead rely upon the January 10, 1997 guidance on device modification. Finally, this section would prohibit a draft version of such guidance until the report is submitted to the Committee, and further would prohibit a final version of such a guidance or regulation until one year after the Committee's receipt of the report.

Subtitle B—Patients Come First

This Subtitle would bring predictability, consistency, and transparency to device post-market activities of FDA.

Section 711—Establishment of Schedule and Promulgation of Regulation

The section would reaffirm the mandate of the Safe Medical Devices Act of 1990 (and recommendation of GAO) that FDA require premarket approval applications for pre-amendment Class III devices or reclassify them into Class I or Class II.[3]

Section 712—Program to Improve the Device Recall System

The Committee believes that FDA must learn from recall experience to minimize harms related to devices. Accordingly, the section would require FDA to establish a program to assess recalls and identify strategies to mitigate health risks. In support of this goal, the section would require: clarification of recall audit procedures to improve recall effectiveness checks; development of criteria to assess the effectiveness of corrections or action plans associated with recalls; and documentation of recall terminations. The program would identify, at a minimum, recall trends, the devices most subject to recalls, and the underlying causes of recalls.

Subtitle C—Novel Device Regulatory Relief

Section 721—Modification of de novo application process

This section would streamline the de novo classification process, which is used for novel, innovative devices of low to moderate risk. A device sponsor would no longer be required to submit a premarket notification and obtain a "not substantially equivalent" determination when it is clear that no predicate device exists for pur-

[3] Public Law 101–629; Government Accountability Office, MEDICAL DEVICES: FDA Should Take Steps to Ensure That High-Risk Device Types Are Approved through the Most Stringent Premarket Review Process (GAO–09–190) (January 2009), available at: *http://www.gao.gov/new.items/d09190.pdf*.

poses of a substantial equivalence determination. Under these circumstances, the first submission could be a de novo request for classification. If FDA believes a predicate device exists, or that the device is not of low to moderate risk, or that special controls to mitigate the risks cannot be developed for the device (i.e., that the device requires a PMA), the Agency could decline to review the submission under its de novo authority. Also, to facilitate the de novo process, submitters seeking a class II de novo classification would be required to provide a "special controls" proposal for FDA's consideration. By doing so, the Committee believes that the submitter could help identify the merits of a class II recommendation and assist prompt decisions by the FDA.

Subtitle D—Keeping American Competitive Through Harmonization

Section 731—Harmonization of device premarket review, inspection, and labeling symbols; report

The section clarifies that FDA could enter into agreements, when appropriate, with foreign countries on harmonizing regulatory requirements for activities, including inspections and common international labeling symbols of medical devices.

Section 732—Participation in International Fora

The section clarifies that FDA could, to the extent appropriate, provide transparency regarding FDA's involvement in international activities.

Subtitle E—FDA Renewing Efficiency From Outsider Reviewer Management

Section 741—Reauthorization of third party review

Consistent with ensuring timely and thorough reviews of certain premarket notification submissions, section 741 would reauthorize third party review of 510(k) submissions until October 1, 2017. Persons accredited by FDA could carry some of the review burden associated with determining whether a device is substantially equivalent to a predicate device.

Section 742—Reauthorization of third party inspection

This section would reauthorize the third inspection program until 2017.

Subtitle F—Humanitarian Device Reform

Section 751—Expanded access to humanitarian use devices

This section would extend the exemption from the prohibition against profit-making for pediatric devices that have been granted Humanitarian Device Exemptions to include certain devices intended for use in adults, and would establish that distribution of these devices under the profit exception is limited to the "annual distribution number." The Humanitarian Device Exemption would continue to be used to provide access to medical devices with conditions that affect 4,000 individuals or fewer. The "annual distribution number" in the section would mean the number of such devices needed to treat, diagnose, or cure a population of 4,000 indi-

viduals in the United States. Under this section, the Secretary would determine the number of such devices necessary to treat each such individual when the Secretary grants such exemption, or, for existing devices for which an exemption was already approved, at the time of the "determination."

Subtitle H—Records and Reports on Devices

Section 761—Unique Device identification system regulations

In 2007, under FDAAA, FDA was required to develop a regulation that would allow for a unique identifier on each medical device. FDA has not yet promulgated the regulation. The section would require FDA to issue the regulations not later than 120 days after enactment.

Section 762—Effective device sentinel system

This section would extend FDA's "Sentinel" postmarket risk identification and evaluation system to include medical devices and allow a broad use of data from a wide variety of sources in establishing the "Sentinel" system. The section would require FDA to engage stakeholders when developing the system for devices.

Subtitle I—Miscellaneous

Section 771—Custom Devices

This section would clarify FDA's policy on custom devices for the unique needs of individuals and would require FDA to issue a final guidance on replication of custom devices within two years. As a condition of being exempt from sections 514 and 515 of the FFDCA, the manufacturer of a custom device must notify the Secretary of such device in a manner prescribed by the Secretary.

Section 772—Pediatric device reauthorization

This section would reauthorize, at the current authorization level, demonstration grants for non-profit consortia to promote pediatric device development.

Section 773—Report on regulation of health information technology

Under this section the Secretary of Health and Human Services, in consultation with the FDA Commissioner, the National Coordinator of Health Information Technology, and the Chairman of the Federal Communication Commission, would be charged with developing a report containing (1) recommendations on an appropriate regulatory framework for health information technology that is risk based and (2) a strategy to avoid regulatory duplication.

TITLE VIII—DRUG REGULATORY REFORMS

The bill includes numerous provisions to modernize FDA's drug authority to reflect the globalization of the pharmaceutical industry and to improve the drug review process.[4]

[4] Although not specifically part of this bill, over-the-counter (OTC) medicines play an increasingly vital role in America's health care system, and applications to switch drugs from prescription to OTC status are the primary source for expanding self-care into additional health categories. The Committee encourages FDA to improve the prescription-to-OTC switch process by, for example, addressing communication issues during sponsor preparation for advisory committee meetings, and by working with stakeholders to finalize draft guidance on self-selection

Subtitle A—Drug Supply Chain

Section 801—Registration of producers of drugs

This section would effectuate a change to the timing of drug establishment registration so that FDA has accurate and up-to-date information on domestic and foreign drug manufacturing facilities. Additionally, it would render misbranded drugs made in foreign facilities that are not duly registered, treating them the same as domestically made drugs.

Section 802—Inspection of Drugs

This section would authorize FDA to inspect domestic and foreign drug facilities on a risk-based schedule based on multiple risk factors, such as compliance history of the establishment; the inspection frequency and history of the establishment, including whether the facility has been inspected within the last four years; recalls associated with such facility; and the inherent risk of the drug associated with the establishment. FDA also could consider other factors deemed appropriate for establishing the risk-based schedule. The section also would require FDA to issue an annual report on inspections and make the report available to the public.

The Committee believes that this section would focus FDA resources on high-risk facilities that present the greatest risk to consumers and away from unnecessary or duplicative inspections of facilities with exceptional compliance histories. The Committee also believes a risk-based schedule would help to ensure inspection parity of domestic and foreign drug facilities.

Section 803—Drug supply quality and safety

This section would incorporate quality risk management oversight and controls into FDA's good manufacturing practices (GMP) authority.

Section 804—Prohibition against delaying, denying, limiting or refusing inspection

This section would render misbranded drugs from an establishment that is deemed to have delayed, limited, or denied an FDA inspection, thereby authorizing FDA to bar entry of such drugs. This would allow FDA to deny such products entry to domestic commerce. The section also would require FDA to issue guidance that defines the circumstances that would constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection.

Section 805—Destruction of adulterated, misbranded, or counterfeit drugs offered for import

This section would allow FDA to destroy counterfeit or adulterated imported drug products of minor monetary value or that have a reasonable probability of causing serious adverse health consequences or death. It is aimed at giving FDA a tool to address the large volume of small packages of misbranded, adulterated, or unapproved drugs coming through the country's international mail fa-

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studies for nonprescription drug products, since these studies are a critical part of prescription-to-nonprescription switch applications.

cilities. The section also would require FDA to issue regulations providing for notice and opportunity for a hearing on the destruction of such drugs either before or after destruction and establish an administrative process for restitution to ensure due process.

Section 806—Administrative detention

This section would allow FDA to detain, for a reasonable period, drugs found during inspection that the inspecting officer has reason to believe are adulterated or misbranded and require FDA to issue implementing regulations with respect to this authority.

Section 807—Enhanced criminal penalty for counterfeit drugs

This section would provide for up to 20 years of imprisonment for any person who knowingly holds, sells, or dispenses a counterfeit drug, and up to life imprisonment if the use of the counterfeit drug is the proximate cause of the consumer's death.

Section 808—Unique facility identification number

This section would require drug facilities and commercial importers of drugs to have a unique facility identification number that will be submitted to FDA at registration and at import. It requires FDA to issue guidance specifying the unique facility identifier system to be used and to take into account the utilization of existing unique identifiers and compatibility with customs automated systems to aid facilities in achieving compliance with this section. The provision also would authorize refusal of admission for imports if the appropriate UFIs are not provided.

Section 809—Documentation for admissibility of imports

This section would allow FDA to require certain documentation and information from importers so FDA can implement a risk-based approach to import screening. This section also would require FDA to issue regulations specifying the documentation or other information necessary to achieve compliance with this section, including the authority to exempt drugs such as those imported for research purposes only from the requirements on this section.

Section 810—Registration of commercial imports

This section would require commercial drug importers to register with FDA and mandate that FDA issue regulations clarifying the registration requirement included in this section and establishing good importer practices that specify measures importers shall take to ensure imported drugs are in compliance. Good importer practice regulations also could provide for expedited clearance for importers who volunteer to participate in partnership programs for highly compliant companies.

Section 811—Notification

This section would require a manufacturer, commercial importer, wholesale distributor, or other distributor (other than someone distributing drugs exclusively for retail sale) to notify the FDA if it knows the use of the drug could lead to serious injury or death, or if the drug is subject to significant loss or stolen, or if it is counter-

feited. Further, such notification would be made in such manner and by such means as FDA may specify by regulation or guidance.

Section 812—Exchange of information

This section would allow the FDA to ensure protection of information received under this authority. This section also would allow, upon satisfaction of several procedural protections, the FDA to share certain information that is otherwise exempt from disclosure with trusted foreign countries to better leverage resources. The section also would require FDA to ensure protection of information exchanged under this authority.

Section 813—Extraterritorial jurisdiction

This section would provide for explicit extraterritorial federal jurisdiction over a violation of the FFDCA to aid U.S. authorities in holding accountable those violating the Act, regardless of where the violative acts occur.

Section 814—Protection against international adulteration

This section would increase penalties for intentional adulteration of drugs that could cause serious adverse health consequences or death.

Section 815—Records for inspection

This section would allow the FDA to require documents in lieu of or in advance of a physical inspection.

Subtitle B—Medical Gas Safety

Medical gases are a class of drug products that have been used for over 100 years to treat medical conditions. Sections 821, 822, and 823 would streamline and modernize the regulation of medical gases.

Section 821—Regulation of medical gases

The section would define the current core medical gases and provide FDA the authority to add additional medical gases as it deems appropriate. The term "Designated Medical Gas" would include: Oxygen; Nitrogen; Nitrous Oxide; Carbon Dioxide; Helium; Carbon Monoxide; and Medical Air. The Committee intends the section to allow the Secretary to add new medical gases that have a history of safe and effective use, but prohibit FDA from adding a medical gas to the Designated Medical Gas list if that gas is subject to exclusivity under a New Drug Application. Prior to adding a new Designated Medical Gas, FDA would have to assess whether any investigational new drug applications for medical gases intended for humans or animals were pending.

The section would establish a process for the filing of a certification for a Designated Medical Gas. The FDA approval of a certification for a Designated Medical Gas would have the effect of deeming the Designated Medical Gas as approved under Section 505 or 512 of the FFDCA. The certification would provide approval for the certified Designated Medical Gas and any combination of certified Designated Medical Gases, as medically appropriate. The Committee intends the certification process to include common mixtures of the core gases. The Designated Medical Gas would be approved

for specific uses listed in the statute. The section further provides that FDA would have the authority to add additional uses to the list of approved uses so long as the uses are not subject to exclusivity under a New Drug Application.

The section also would do the following: (1) authorize FDA to promulgate warning statements for medical gases and set forth specific labeling requirements for medical gases because medical gas labels do not contain specific uses as is the case for other drug labels; (2) clarify the effect of certification on certain exclusivity rights traditionally granted for newly approved drugs; (3) guarantee FDA authority to withdraw or suspend a drug approval as provided under the FFDCA; (4) clarify the FFDCA prescription requirements as they are applied to Designated Medical Gases; and (5) ensure that Designated Medical Gases and combinations of Designated Medical Gases deemed to be approved under this Act would not be subject to FDA fees as the result of becoming approved through certification.

Section 822—Changes to regulations

This section would require FDA to, within 18 months, obtain input from medical gas manufacturers regarding the applicability of current federal drug regulations to medical gases, determine whether any changes are necessary to existing federal drug regulations, and submit a report to Congress regarding changes in the current federal drug regulations that the Secretary determines are necessary for medical gases.

FDA would be required to issue final regulations addressing those items identified in the report to Congress with 48 months. The Committee expects this process to address longstanding regulatory issues faced by the medical gas industry based on the unique characteristics of medical gases.

Section 823—Rules of construction

This section would preserve the NDA process for medical gases. The Committee believes this section would maintain the incentive to innovate and develop new uses for a new medical gas added to the list of Designated Medical Gases.

Subtitle C—Generating Antibiotic Incentives Now

The goal of this Subtitle is to foster the development of antibacterial and antifungal drugs that treat pathogens that cause serious and life-threatening infections. The Committee expects that antibacterial and antifungal drugs that are directed against the qualified pathogens listed generally would qualify for FDA's fast track and priority review process to speed drug approval because the Committee presumes that most of the new drugs generally would be intended to treat serious or life-threatening infections for which there is an unmet medical need. In five years, the Secretary would have to review the antibacterial and antifungal drugs that have been designated under this Subtitle to determine if the incentives listed are adequate to generate needed antibacterial and antifungal drugs. Additionally, at that time, the Secretary would review the list of qualifying pathogens to determine if changes are needed to address current unmet public health concerns.

Section 831—Extension of exclusivity period for drugs

This section would extend the exclusivity period for drugs that are determined to be a qualified infectious disease product for five additional years. Any extension would be in addition to pediatric exclusivity. Limitations to the exclusivity extension are outlined. The Secretary would designate a qualified infectious disease product based on it being an antibacterial or antifungal drug for humans to treat or prevent an infection caused by a qualifying pathogen—a resistant gram-positive pathogen, multidrug resistant gram-negative bacteria, multi-drug resistant tuberculosis, or any other infectious pathogen identified by the Secretary.

Section 832—Study on incentives for qualified infectious disease biological products

This section would direct the Government Accountability Office (GAO) to conduct a study to determine the need for incentives to encourage research, development, and marketing for qualified infectious disease biological products.

Section 833—Clinical trials

This section would require the Secretary to review the guidance for clinical trials with respect to antibacterial and antifungal drugs, revise the guidance to reflect scientific and medical advancements, and clarify the procedures and requirements for approval. This provision will address appropriate animal models of infection, in vitro techniques, and clinical study design for antimicrobial agents.

Section 834—Reassessment of qualified infectious disease product incentives in 5 years

This section would require the Secretary, in conjunction with the FDA and CDC, to provide a reassessment report on qualified infectious disease product incentives in five years. Based on the information presented, recommendations would be made regarding changes in the list of pathogens, additional program or incentive enhancements, and ways to encourage stewardship programs.

Section 835—Guidance on pathogen-focused antibacterial drug development

This section would instruct the Secretary to provide draft guidance on pathogen-focused antibacterial drug development by December 31, 2013, and final guidance by December 31, 2014.

Subtitle D—Accelerated Approval

Section 841—Expedited approval of drugs for serious or life-threatening diseases or conditions

The section would provide findings and a Sense of Congress that the accelerated approval and fast track provisions of Section 506 of the FFDCA should be enhanced and FDA should apply the provisions to help expedite the development and availability of treatments for serious or life-threatening diseases or conditions while maintaining existing safety and efficacy standards for such treatments.

The section also would require FDA to facilitate the development and expedite review of a drug intended to treat a serious or life-

threatening disease or condition and demonstrating potential to address unmet medical needs through, among other processes, conducting a rolling review of a submission for a fast track product. A sponsor of such a drug, known as a "fast track product" in the section, would have the ability to request a designation as a fast track product after the submission of an application for investigation, and FDA would have 60 days to review such request.

Under the section, FDA could approve an application for a product upon making a determination that, taking into account the severity or rarity of the disease or condition and the availability of alternative treatments, it has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality, or other clinical benefit. This provision is intended to clarify the existing standards for accelerated approval.

The section also would grant FDA the authority to use expedited procedures as prescribed by regulation to withdraw approval of a product approved under section 506 under certain conditions.

Finally, FDA would have to disseminate information to patients, doctors, and industry regarding the section and establish a program to foster the development of surrogate and clinical endpoints.

The Committee believes this section is especially important to those patients with rare diseases. Rare diseases affect more than 25 million Americans, yet only 5 percent of these diseases have FDA-approved treatments. The Committee recommends that FDA make use of the Agency's accelerated approval process across all applicable review divisions to the greatest extent possible without compromising existing standards to ensure products are safe and effective, so that safe and effective treatments designed to treat serious or life-threatening rare diseases can be brought to the marketplace in the most expeditious manner.

Section 842—Guidance; amended regulations

The section would require FDA to issue draft guidance to implement section 841 within one year of enactment. Within 1 year of issuance of the draft guidance, FDA must issue final guidance implementing section 841 and amend the accelerated approval regulations in parts 341 and 601 of title 21 of the Code of Federal Regulations as necessary to conform such regulations with the amendments made by section 841. In developing the guidance, FDA must consider "how to incorporate novel approaches to the review of surrogate endpoints based on physiologic and pharmacologic evidence in such guidance, especially in instances where the low prevalence of a disease renders the existence or collection of other types of data unlikely or impractical."

Section 843—Independent review

The section would allow FDA to authorize an independent assessment of the implementation of Section 841, including the impact on the development and timely availability of innovative treatments for patients suffering from serious or life-threatening conditions.

Subtitle E—Critical Path Reauthorization

Section 851—Reauthorization of the Critical Path Program

The section would reauthorize the Critical Path Public-Private Partnerships program at the current level of $6,000,000 per year.

The Committee acknowledges the work being done by the FDA in partnership with universities and non-profit organizations to create collaborations among health care practitioners, researchers, medical product manufacturers, and others to help accelerate development of new medical products that are essential for public health and to foster innovation in the manufacturing of medical products. The Committee encourages the Commissioner to continue to explore and fund these partnerships including those whose work includes modernizing and improving pharmaceutical manufacturing in the United States.

The Committee is aware of the important collaborative work that the FDA, Critical Path Institute (C-Path) and the Clinical Data Interchange Standards Consortium (CDISC) have done to establish the data standards for Alzheimer's disease clinical research and also to create a publicly available database of 22 industry trials containing data on 6,100 individual patients with Alzheimer's disease. In addition, 7 new testing methods have been designated by FDA as "qualified" for use in drug development and another 44 are in various stages of review by the FDA. We understand the FDA has asked CDISC and C-Path to work to develop data standards for additional, high priority, therapeutic areas. We encourage the FDA and its partners to continue this work on these important therapeutic areas because data standards and consensus on testing methods will speed the development and review of new medical products.

Subtitle F—Miscellaneous

Section 861—Reauthorization of provision relating to exclusivity of certain drugs containing single enantiomers

This section would reauthorize for an additional 5 years the enantiomer exclusivity authorized in 2007 that otherwise expires in 2012.

Section 862—Extension of period for first applicant to obtain tentative approval without forfeiting 180–day exclusivity period

Under current law, if a generic drug manufacturer challenges a brand manufacturer's patent as being either invalid or will not be infringed, and if it is the first generic drug manufacturer to make such challenge or makes it on the same day as the first challenger, it can be awarded 180 days of exclusivity from other generic competition. Except in certain circumstances, if FDA does not grant tentative approval within 30 months of the filing of the generic drug application, the generic company forfeits the 180–day exclusivity period. The provision would temporarily increase that tentative approval time period to 45 months. (The current average time for FDA to approve a generic drug application is 31 months.) This 45–month period would be gradually phased back down to 30 months as the FDA eliminates the backlog of pending generic applications pursuant to the generic drug user fee agreement.

Section 863—Final agency action relating to petitions and civil actions

Certain citizen petitions ask the Agency for a stay of action related to FDA approval of a pending application submitted under section 505(b)(2) or 505(j) of the Act due to scientific or medical questions about the application. The FDA is required to take final agency action on the petition within 180 days. This section would require the FDA to take final agency action on the petition within 150 days.

Section 864—Deadline for determination of certain petitions

Current law allows the FDA to deny a generic application if the drug that the generic application is referencing was withdrawn for safety or effectiveness reasons. Current FDA regulations allow a company to petition the FDA to determine if the reference drug was withdrawn for safety or effectiveness reasons. However, there is no timeframe under which the FDA must respond to the petition, and there have been instances of decision times lasting over 2 years. This section would require the FDA to respond to these petitions within 270 days, which should result in the quicker approval of generic drugs.

Section 865—Rare pediatric disease priority review voucher incentive program

This section would create a demonstration project that provides priority review vouchers to companies that develop a drug for a pediatric rare disease. The voucher would be redeemed by the company for a subsequent application or could be transferred to another company. The section would require the GAO to conduct a study for Congress on the effectiveness of the program. The study would have to be completed 1 year after the third priority review voucher is issued. The Secretary could no longer issue new priority review vouchers 1 year after the third voucher is issued so Congress may determine whether to continue the incentive.

Section 866—Combating prescription drug abuse

This section would task the Secretary of HHS with reviewing and reporting to Congress on current federal initiatives and identifying gaps and opportunities with respect to ensuring the safe use of prescription drugs with the potential for abuse.

Section 867—Assessment and modification of REMS

This section would make the Risk Evaluation and Mitigation Strategy (REMS) system more efficient by facilitating minor modifications of a drug's REMS with an adequate rationale to support such modification. Certain drugs are required to have REMS to ensure that the benefits of the drug outweigh the risks. Currently, the law is unclear as to whether sponsors can make minor modifications to the REMS without the need to have a full reassessment of the REMS. This provision would clarify the circumstances under which certain modifications could be initiated by sponsors and the FDA and made without a full assessment of the REMS.

Section 868—Consultation with external experts on rare diseases, targeted therapies, and genetic targeting of treatments

This section would provide for the creation of a list of external experts on products for rare diseases with whom FDA may consult.

Section 869—Breakthrough therapies

This section would expedite the development and review of a drug designated a "breakthrough therapy" through increased interaction with the Agency during the development process. To achieve this designation, a drug would have to be intended to treat a serious or life-threatening disease or condition, and have preliminary clinical evidence indicating that it may demonstrate substantial improvement over existing therapies.

Section 870—Grants and contracts for the development of orphan drugs

This section would reauthorize FDA's orphan drug grant program at the current level for five years. This grant program helps facilitate the development of orphan disease products.

TITLE IX—DRUG SHORTAGES

The frequency and impact of drug shortages have risen to critical levels, more than tripling since 2005. These shortages affect all segments of healthcare, including critically ill patients and patients undergoing surgery. There appear to be multiple causes of drug shortages, including issues involving manufacturing, raw materials, supply chain, consolidation, government regulations, and businesses decisions. Physicians, pharmacists, and patients are challenged daily to obtain the drugs they need. Title IX would aid in mitigating drug shortages and require a root cause analysis of the problem.

Section 901—Discontinuance and interruptions of manufacturing of certain drugs

This section would alter section 506C of the FFDCA to require manufacturers of certain drugs to notify FDA of a discontinuance of the manufacture of a drug, or an interruption of the manufacture of the drug that is likely to produce a meaningful disruption in market supply. The notification requirement would apply to drugs that are: (1) life-supporting, life-sustaining, intended for use in the prevention or treatment of a debilitating disease or condition; and (2) that are not radiopharmaceutical products or products derived from human plasma protein and their recombinant analogs. This section also would require the manufacturer to notify the Secretary at least six months prior to the date of the discontinuance or interruption, or if the discontinuance or interruption in manufacturing is impossible to predict 6 months in advance, as soon as practicable after the manufacturer learns of the discontinuance or interruption in manufacturing.

The section would require the Secretary to distribute information on the discontinuation or interruption of the manufacture of such drugs to appropriate physician, provider, and patient organizations. The bill would not authorize the Secretary to disclose trade secret or confidential commercial information subject to section 552(b)(4)

of title 5, United States Code, or section 1905 of title 18, United States Code.

Under the section, FDA would have to request that the Attorney General adjust the quotas of certain drugs and ingredients subject to the Controlled Substance Act if the Secretary receives a report under 506C and concludes that an adjustment is necessary to address shortages of these drugs.

Also, the section would establish a process relating to a manufacturer's failure to notify FDA under section 506C. If a manufacturer fails to submit information required, the Secretary would issue a letter, and a response would be required within 30 days. FDA would make the letter available to the public except for certain circumstances.

Finally, the section would require FDA to issue final regulations on key terms within 18 months.

As a whole, the Committee intends the terms "life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or medical condition" to mean any drug that is used to treat or prevent a serious disease or medical condition.

For example, the Committee considers any drug that is required during emergency or critical situations to stabilize organ systems or perform necessary procedures (such as resuscitation, surgery, ventilator support, etc.) to be a "life-supporting" drug for purposes of reporting to FDA a discontinuance or interruption in manufacturing of the product under this section. Examples include [5]:

Name of drug	Use	Type of drug
Norepinephrine	Treatment of shock	Autonomic neurotransmitter
Etomidate	General anesthesia	Anesthetic
Amiodarone	Anti-arrhythmic	Cardiovascular
Furosemide	Heart failure, hypertension	Cardiovascular
Heparin	Treatment of thrombosis	Hematology
Phenytoin	Epilepsy	Neurology
Sodium Chloride—IV	Fluid resuscitation	Electrolyte solution
Morphine	Pain control	Narcotic
Midazolam	Sedation	Anti-anxiety agent
Diazepam	Treatment of Status Epilepticus	Neurology

Additionally the Committee considers any drug that aims to treat serious illness or infection, is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life by restoring or taking over a vital bodily function to be a "life-sustaining" drug for the purposes of reporting to FDA a discontinuance or interruption in manufacturing of the product under this section. Examples include:

Name of drug	Use	Type of drug
Amikacin	Systemic infection	Antibiotic
Azithromycin	Infection	Antibiotic
Agalsidase beta	Fabry disease	Enzyme replacement
Cisplatin	Cancer	Oncology
Haloperidol	Schizophrenia	Psychiatry
Levothyroxine	Hypothyroidism	Endocrinology

[5] Drugs may fit into more than one of these definitions depending on the intended use. If a drug falls within any of the definitions listed, the drug must be reported if its manufacture is interrupted.

Name of drug	Use	Type of drug
Cyclosporine	Prevents rejection of transplants	Immunosuppressive agent
Components of parenteral nutrition	Provides nutrition	Parenteral nutrition

Finally, the Committee considers prevention measures, such as vaccines, drugs that stabilize a debilitating disease or serious condition, and drugs used to treat chronic medical conditions, such as diabetes, to be included within the phrase "intended for use in the prevention or treatment of a debilitating disease or serious condition" for the purposes of reporting to FDA a discontinuance or interruption in manufacturing of the product under this section. Examples include:

Name of drug	Use	Type of drug
MMR & V vaccine live	Measles, Mumps, etc. vaccine	Vaccine
Dextroamphetamine and Amphetamine salts.	ADHD	Amphetamine
Fluoxetine	Depression	Psychiatry
Albuterol	Asthma	Pulmonary

Section 902—Drug shortage list

The section would require FDA to maintain a drug shortage list and provide patients, providers, and the public with such information in order to prevent, mitigate, and manage drug shortages on the ground. The bill would include safeguards to prevent the release of trade secrets and confidential commercial information or information that could adversely affect public health, including if the release of the information would increase the possibility of hoarding.

Section 903—Quotas applicable to drugs in shortage

This section would amend section 306 of the Controlled Substances Act to require the Drug Enforcement Agency (DEA) to review requests to increase quotas of controlled substances and make a determination within 30 days if such a request pertains to a drug verified to be in shortage.

Section 904. Expedited review of major manufacturing changes for potential and verified shortages of drugs that are life-supporting, life-sustaining, or intended for use in the prevention of a debilitating disease or condition

This section would require FDA to expedite review of a supplemental application for a major manufacturing change if the manufacturer has submitted a notice to FDA under section 506C that a drug product is subject to a discontinuance or interruption in manufacturing and the manufacturer certifies that the major manufacturing change may prevent or alleviate the discontinuance or interruption in manufacturing of the drug. FDA would be required to complete the review within 60 days. The provision also would deny expedited review to manufacturers who make a certification in bad faith.

Section 905—Study on drug shortages

The section would authorize GAO to conduct a study to examine the causes of drug shortages and issue recommendations on how to

prevent or alleviate a drug shortage. This provision would provide needed data on how the regulatory framework, manufacturing challenges, drug pricing, or other factors contribute to drug shortages, as well as recommendations to address such issues.

The Committee has heard concerns that drug shortages are having a significant impact on important advancements in basic, clinical, and translational biomedical research, including clinical trials. The Committee also has been notified of studies and clinical trials which have been delayed, suspended, or halted due to shortages of drugs required for these studies. For example, there have been instances where oncology drugs on drug shortage lists are urgently needed for cancer clinical trials and other forms of cancer research.

Section 906—Annual report on drug shortages

This section would require FDA to issue an annual report on drug shortages that describes communication between FDA field inspectors and the drug shortage program, as well as coordination between FDA and DEA, and detail uses of authorities to address drug shortages.

Section 907—Attorney General report on drug shortages

This section would require DEA to issue an annual report on controlled substances that are in shortage, DEA actions when a shortage is identified, and a description of the coordination between DEA and FDA in mitigating shortages of these controlled substances.

Section 908—Hospital repackaging of drugs in shortage

This section would provide that a hospital within a health system (or a collection of hospitals that are owned and operated by the same entity and share access to databases with drug order information for their patients) would not need to register with FDA under section 510, on the basis that it engages in a type of repackaging in which the hospital divides the volume of a drug into smaller amounts to extend the supply of a drug in shortage and facilitate access to that drug to other hospitals within the same health system. This would apply only to hospitals within the same health system, and the repackaging would have to comply with State rules. This section would not apply after FDA issues final guidance on this issue.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * * * *

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

(a) * * *

* * * * * * *

(g)(1) * * *

(2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor. *The term "counterfeit drug" shall not include a drug or placebo intended for use in a clinical trial that is intentionally labeled or marked to maintain proper blinding of the study.*

* * * * * * *

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) * * *

* * * * * * *

(aaa) The failure to register in accordance with section 801(s).

(bbb) The failure to notify the Secretary in violation of section 568.

* * * * * * *

PENALTIES

SEC. 303. (a)(1) * * *

* * * * * * *

(3) Notwithstanding paragraph (2), any person who engages in any conduct described in section 301(i)(2) knowing or having reason to know that the conduct concerns the rendering of a drug as a counterfeit drug, or who engages in conduct described in section 301(i)(3) knowing or having reason to know that the conduct will cause a drug to be a counterfeit drug or knowing or having reason to know that a drug held, sold, or dispensed is a counterfeit drug, shall be fined in accordance with title 18, United States Code, or imprisoned not more than 20 years, or both, except that if the use of the counterfeit drug by a consumer is the proximate cause of the death of the consumer, the term of imprisonment shall be any term of years or for life.

(b)(1) * * *

* * * * * * *

(7) Notwithstanding subsection (a)(2), any person that knowingly and intentionally engages in an activity that results in a drug becoming adulterated under subsection (a)(1), (b), (c), or (d) of section 501 and having a reasonable probability of causing serious adverse health consequences or death shall be im-

prisoned for not more than 20 years or fined not more than $1,000,000, or both.

* * * * * * *

SEIZURE

SEC. 304. (a) * * *

* * * * * * *

(g)(1) If during an inspection conducted under section 704 of a facility or a vehicle, a device*, drug,* or tobacco product which the officer or employee making the inspection has reason to believe is adulterated or misbranded is found in such facility or vehicle, such officer or employee may order the device*, drug,* or tobacco product detained (in accordance with regulations prescribed by the Secretary) for a reasonable period which may not exceed twenty days unless the Secretary determines that a period of detention greater than twenty days is required to institute an action under subsection (a) or section 302, in which case he may authorize a detention period of not to exceed thirty days. Regulations of the Secretary prescribed under this paragraph shall require that before a device*, drug,* or tobacco product may be ordered detained under this paragraph the Secretary or an officer or employee designated by the Secretary approve such order. A detention order under this paragraph may require the labeling or marking of a device*, drug,* or tobacco product during the period of its detention for the purpose of identifying the device*, drug,* or tobacco product as detained. Any person who would be entitled to claim a device*, drug,* or tobacco product if it were seized under subsection (a) may appeal to the Secretary a detention of such device*, drug,* or tobacco product under this paragraph. Within five days of the date an appeal of a detention is filed with the Secretary, the Secretary shall after affording opportunity for an informal hearing by order confirm the detention or revoke it.

(2)(A) Except as authorized by subparagraph (B), a device*, drug,* or tobacco product subject to a detention order issued under paragraph (1) shall not be moved by any person from the place at which it is ordered detained until—

(i) * * *

* * * * * * *

whichever occurs first.

(B) A device *or drug* subject to a detention order under paragraph (1) may be moved—

(i) * * *

(ii) if not in final form for shipment, at the discretion of the manufacturer of the device *or drug* for the purpose of completing the work required to put it in such form.

* * * * * * *

SEC. 311. EXTRATERRITORIAL JURISDICTION.

There is extraterritorial jurisdiction over any violation of this Act relating to any article regulated under this Act if such article was intended for import into the United States or if any act in furtherance of the violation was committed in the United States.

* * * * * * *

CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

ADULTERATED DRUGS AND DEVICES

SEC. 501. A drug or device shall be deemed to be adulterated—
(a)(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopoeia to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess; or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 721(a), or (B) it is a color additive the intended use of which in or on drugs or devices is for purposes of coloring only and is unsafe within the meaning of section 721(a); or (5) if it is a new animal drug which is unsafe within the meaning of section 512; or (6) if it is an animal feed bearing or containing a new animal drug, and such animal feed is unsafe within the meaning of section 512. *For purposes of subparagraph (2)(B), the term "current good manufacturing practice" includes the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products.*

* * * * * * *

(j) If it is a drug and it has been manufactured, processed, packed, or held in any factory, warehouse, or establishment and the owner, operator, or agent of such factory, warehouse, or establishment delays, denies, or limits an inspection, or refuses to permit entry or inspection.

MISBRANDED DRUGS AND DEVICES

SEC. 502. A drug or device shall be deemed to be misbranded—
(a) * * *

* * * * * * *

(o) If it was manufactured, prepared, propagated, compounded, or processed in an establishment [in any State] not duly registered under section 510, *if it is a drug and was imported or offered for import by a commercial importer of drugs not duly registered under section 801(s),* if it was not included in a list required by section 510(j), if a notice or other information respecting it was not provided as required by such section or section 510(k), or if it does not bear such symbols from the uniform system for identification of devices prescribed under section 510(e) as the Secretary by regulation requires.

* * * * * * *

(aa) If it is a drug, or an active pharmaceutical ingredient, and it was manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid as required by section 744A(a)(4) or for which identifying information required by section 744B(f) has not been submitted, or it contains an active pharmaceutical ingredient that was manufactured, prepared, propagated, compounded, or processed in such a facility.

* * * * * * *

NEW DRUGS

SEC. 505. (a) * * *

* * * * * * *

(j)(1) * * *

* * * * * * *

(5)(A) * * *

* * * * * * *

(D) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—

(i) DEFINITION OF FORFEITURE EVENT.—In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) * * *

* * * * * * *

[(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.]

(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within 45 months after the date on which—

(aa) the application is filed and initially contains a certification described in paragraph (2)(A)(vii)(IV), or

(bb) the application is amended to first contain such a certification,

unless the failure is caused by a change in or a review of the requirements for approval of the appli-

cation imposed after the date on which the application is so filed or amended.

[Effective on October 1, 2013, subclause (IV), (as amended by section 862(a)(1)), is further amended by subsection (b)(1)(A) of such section as follows:]

(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within ⟦45⟧ *42* months after the date on which—

(aa) the application is filed and initially contains a certification described in paragraph (2)(A)(vii)(IV), or

(bb) the application is amended to first contain such a certification,

unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is so filed or amended.

[Effective on October 1, 2014, subclause (IV), (as amended by section 862(a)(1) and (b)(1)(A)), is further amended by subsection (b)(1)(B) of such section as follows:]

(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within ⟦42⟧ *39* months after the date on which—

(aa) the application is filed and initially contains a certification described in paragraph (2)(A)(vii)(IV), or

(bb) the application is amended to first contain such a certification,

unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is so filed or amended.

[Effective on October 1, 2015, subclause (IV), (as amended by section 862(a)(1), (b)(1)(A), and (b)(1)(B)), is further amended by subsection (b)(1)(C) of such section as follows:]

(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within ⟦39⟧ *36* months after the date on which—

(aa) the application is filed and initially contains a certification described in paragraph (2)(A)(vii)(IV), or

(bb) the application is amended to first contain such a certification,

unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is so filed or amended.

[Effective on October 1, 2016, subclause (IV), (as amended by section 862(a)(1), (b)(1)(A), (b)(1)(B), and (b)(1)(C)), is further amended by subsection (b)(1)(D) of such section as follows:]

(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within [36] *33* months after the date on which—

(aa) the application is filed and initially contains a certification described in paragraph (2)(A)(vii)(IV), or

(bb) the application is amended to first contain such a certification,

unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is so filed or amended.

[Effective on October 1, 2017, subclause (IV), (as amended by section 862(a)(1), (b)(1)(A), (b)(1)(B), (b)(1)(C), and (b)(1)(D)), is further amended by subsection (b)(1)(E) of such section as follows:]

(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within [33] *30* months after the date on which—

(aa) the application is filed and initially contains a certification described in paragraph (2)(A)(vii)(IV), or

(bb) the application is amended to first contain such a certification,

unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is so filed or amended.

* * * * * * *

(k)(1) * * *

* * * * * * *

(3) ACTIVE POSTMARKET RISK IDENTIFICATION.—

(A) * * *

* * * * * * *

(C) ESTABLISHMENT OF THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—

(i) IN GENERAL.—The Secretary shall, not later than 1 year after the development of the risk identification and analysis methods under subparagraph (B), establish and maintain procedures—

(I) * * *

[(II) for the reporting (in a standardized form) of data on all serious adverse drug experiences (as defined in section 505–1(b)) submitted to the Secretary under paragraph (1), and those adverse events submitted by patients, providers, and drug sponsors, when appropriate;]

[(III)] *(II)* to provide for active adverse event surveillance using the following data sources, as available:

(aa) * * *

(bb) private sector health-related electronic data (such as [pharmaceutical purchase data and health insurance claims data] *medical device utilization data, health insurance claims data, and procedure and device registries*); and

* * * * * * *

[(IV)] *(III)* to identify certain trends and patterns with respect to data accessed by the system;

[(V)] *(IV)* to provide regular reports to the Secretary concerning adverse event trends, adverse event patterns, incidence and prevalence of adverse events, and other information the Secretary determines appropriate, which may include data on comparative national adverse event trends; and

[(VI)] *(V)* to enable the program to export data in a form appropriate for further aggregation, statistical analysis, and reporting.

* * * * * * *

(q) PETITIONS AND CIVIL ACTIONS REGARDING APPROVAL OF CERTAIN APPLICATIONS.—

(1) IN GENERAL.—

(A) * * *

* * * * * * *

(F) FINAL AGENCY ACTION.—The Secretary shall take final agency action on a petition not later than [180 days] *150 days* after the date on which the petition is submitted. The Secretary shall not extend such period for any reason, including—

(i) * * *

* * * * * * *

(G) EXTENSION OF [30-MONTH PERIOD] *PERIOD*.—If the filing of an application resulted in first-applicant status under subsection (j)(5)(D)(i)(IV) and approval of the application was delayed because of a petition, [the 30-month period] *the 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.

* * * * * * *

(2) EXHAUSTION OF ADMINISTRATIVE REMEDIES.—

(A) FINAL AGENCY ACTION WITHIN [180] *150* DAYS.—The Secretary shall be considered to have taken final agency action on a petition if—

(i) during the [180-day] *150-day* period referred to in paragraph (1)(F), 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

* * * * * * *

(u) CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.—
(1) * * *

* * * * * * *

(4) AVAILABILITY.—The election referred to in paragraph (1) may be made only in an application that is submitted to the Secretary after the date of the enactment of this subsection and before October 1, [2012] *2017*.

* * * * * * *

(w) DEADLINE FOR DETERMINATION ON CERTAIN PETITIONS.—The Secretary shall issue a final, substantive determination on a petition submitted pursuant to subsection (b) of section 314.161 of title 21, Code of Federal Regulations (or any successor regulations), no later than 270 days after the date the petition is submitted.

SEC. 505–1. RISK EVALUATION AND MITIGATION STRATEGIES.

(a) * * *

* * * * * * *

(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) * * *

* * * * * * *

(C) within a time period to be determined by the Secretary, if the Secretary, in consultation with the offices described in subsection (c)(2), 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] *an assessment is needed to evaluate whether the approved strategy should be modified to—*

(i) ensure the benefits of the drug outweigh the risks of the drug; or

(ii) minimize the burden on the health care delivery system of complying with the strategy.

[(D) within 15 days when ordered by the Secretary, in consultation with the offices described in subsection (c)(2),

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 elements to assure safe use are meeting the goal or whether the goal or such elements should be modified;

[(B) with respect to any postapproval study required under section 505(o) or otherwise undertaken by the responsible person to investigate a safety issue, the status of such study, including whether any difficulties completing the study have been encountered; and

[(C) with respect to any postapproval clinical trial required under section 505(o) or otherwise undertaken by the responsible party to investigate a safety issue, the status of such clinical trial, including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to requirements under subsections (i) and (j) of section 402 of the Public Health Service Act.] *for a drug shall include, with respect to each goal included in the strategy, an assessment of the extent to which the approved strategy, including each element of the strategy, is meeting the goal or whether 1 or more such goals or such elements should be modified.*

[(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 as provided in subsection (d)(3), including to eliminate assessments; or

[(B) adding, modifying, or removing an element to assure safe use under subsection (f).]

(4) MODIFICATION.—

(A) ON INITIATIVE OF RESPONSIBLE PERSON.—After the approval of a risk evaluation and mitigation strategy by the Secretary, the responsible person may, at any time, submit to the Secretary a proposal to modify the approved strategy. Such proposal may propose the addition, modification, or removal of any goal or element of the approved strategy and shall include an adequate rationale to support such proposed addition, modification, or removal of any goal or element of the strategy.

(B) ON INITIATIVE OF SECRETARY.—After the approval of a risk evaluation and mitigation strategy by the Secretary, the Secretary may, at any time, require a responsible person to submit a proposed modification to the strategy within 120 days or within such reasonable time as the Secretary specifies, if the Secretary, in consultation with the offices

described in subsection (c)(2), determines that 1 or more goals or elements should be added, modified, or removed from the approved strategy to—

(i) ensure the benefits of the drug outweigh the risks of the drug; or

(ii) minimize the burden on the health care delivery system of complying with the strategy.

(h) REVIEW OF PROPOSED STRATEGIES; REVIEW OF ASSESSMENTS *AND MODIFICATIONS* OF APPROVED STRATEGIES.—

(1) IN GENERAL.—The Secretary, in consultation with the offices described in subsection (c)(2), shall promptly review each proposed risk evaluation and mitigation strategy for a drug submitted under subsection (a) and each assessment of *and proposed modification to* an approved risk evaluation and mitigation strategy for a drug submitted under subsection (g)*, and, if necessary, promptly initiate discussions with the responsible person about such proposed strategy, assessment, or modification*.

[(2) DISCUSSION.—The Secretary, in consultation with the offices described in subsection (c)(2), shall initiate discussions with the responsible person for purposes of this subsection to determine a strategy not later than 60 days after any such assessment is submitted or, in the case of an assessment submitted under subsection (g)(2)(D), not later than 30 days after such assessment is submitted.**]**

[(3)**]** *(2)* ACTION.—

[(A) IN GENERAL.—Unless the dispute resolution process described under paragraph (4) or (5) applies, the Secretary, in consultation with the offices described in subsection (c)(2), shall describe any required risk evaluation and mitigation strategy for a drug, or any modification to any required strategy—

[(i) as part of the action letter on the application, when a proposed strategy is submitted under subsection (a) or a modification to the strategy is proposed as part of an assessment of the strategy submitted under subsection (g)(1); or

[(ii) in an order issued not later than 90 days after the date discussions of such modification begin under paragraph (2), when a modification to the strategy is proposed as part of an assessment of the strategy submitted under subsection (g)(1) or under any of subparagraphs (B) through (D) of subsection (g)(2).**]**

(A) IN GENERAL.—

(i) TIMEFRAME.—Unless the dispute resolution process described under paragraph (3) or (4) applies, and, except as provided in clause (ii) or clause (iii) below, the Secretary, in consultation with the offices described in subsection (c)(2), shall review and act on the proposed risk evaluation and mitigation strategy for a drug or any proposed modification to any required strategy within 180 days of receipt of the proposed strategy or modification.

(ii) MINOR MODIFICATIONS.—The Secretary shall review and act on a proposed minor modification, as de-

fined by the Secretary in guidance, within 60 days of receipt of such modification.

(iii) REMS MODIFICATION DUE TO SAFETY LABEL CHANGES.—Not later than 60 days after the Secretary receives a proposed modification to an approved risk evaluation and mitigation strategy to conform the strategy to approved safety label changes, including safety labeling changes initiated by the sponsor in accordance with FDA regulatory requirements, or to a safety label change that the Secretary has directed the holder of the application to make pursuant to section 505(o)(4), the Secretary shall review and act on such proposed modification to the approved strategy.

(iv) GUIDANCE.—The Secretary shall establish, through guidance, that responsible persons may implement certain modifications to an approved risk evaluation and mitigation strategy following notification to the Secretary.

* * * * * * *

[(C) PUBLIC AVAILABILITY.—Any action letter described in subparagraph (A)(i) or order described in subparagraph (A)(ii) shall be made publicly available.**]**

(C) PUBLIC AVAILABILITY.—Upon acting on a proposed risk evaluation and mitigation strategy or proposed modification to a risk evaluation and mitigation strategy under subparagraph (A), the Secretary shall make publicly available an action letter describing the actions taken by the Secretary under such subparagraph (A).

[(4)**]** *(3)* DISPUTE RESOLUTION AT INITIAL APPROVAL.—If a proposed risk evaluation and mitigation strategy is submitted under subsection (a)(1) in an application for initial approval of a drug and there is a dispute about the strategy, the responsible person shall use the major dispute resolution procedures as set forth in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007.

[(5)**]** *(4)* DISPUTE RESOLUTION IN ALL OTHER CASES.—

(A) REQUEST FOR REVIEW.—

(i) IN GENERAL.—**[**Not earlier than 15 days, and not later than 35 days, after discussions under paragraph (2) have begun, the**]** *The* responsible person may*, after the sponsor is required to make a submission under subsection (a)(2) or (g),* 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.

* * * * * * *

(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 for the action letter on the application if the responsible

person requests the dispute resolution process described in this paragraph and [if the Secretary—] *if the Secretary 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.*

[(i) has initiated the discussions described under paragraph (2) 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.]

* * * * * * *

[(6)] *(5)* 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);

* * * * * * *

(C) review a dispute under [paragraph (4) or (5)] *paragraph (3) or (4)*.

[(7)] *(6)* PROCESS FOR ADDRESSING DRUG CLASS EFFECTS.—

(A) * * *

* * * * * * *

[(8)] *(7)* INTERNATIONAL COORDINATION.—The Secretary, in consultation with the offices described in subsection (c)(2), 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 responsible person.

[(9)] *(8)* EFFECT.—Use of the processes described in [paragraphs (7) and (8)] *paragraphs (6) and (7).* shall not be the sole source of delay of action on an application or a supplement to an application for a drug.

* * * * * * *

SEC. 505A. PEDIATRIC STUDIES OF DRUGS.

(a) * * *

* * * * * * *

(d) CONDUCT OF PEDIATRIC STUDIES.—

(1) REQUEST FOR STUDIES.—

(A) IN GENERAL.—The Secretary may, after consultation with the sponsor of an application for an investigational

new drug under section 505(i), the sponsor of an application for a new drug under section 505(b)(1), or the holder of an approved application for a drug under section 505(b)(1), issue to the sponsor or holder a written request for the conduct of pediatric studies for such drug. In issuing such request, the Secretary shall take into account adequate representation of children of ethnic and racial minorities. Such request to conduct pediatric studies shall be in writing and shall include a timeframe for such studies and a request to the sponsor or holder to propose pediatric labeling resulting from such studies. *If a request under this subparagraph does not request studies in neonates, such request shall include a statement describing the rationale for not requesting studies in neonates.*

* * * * * * *

[(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.**]**

(h) Relationship to Pediatric Research Requirements.—Exclusivity under this section shall only be granted for the completion of a study or studies that are the subject of a written request and for which reports are submitted and accepted in accordance with subsection (d)(3). Written requests under this section may consist of a study or studies required under section 505B.

* * * * * * *

(k) DISSEMINATION OF PEDIATRIC INFORMATION.—

(1) * * *

(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)**]** *subsection (f)(6)(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.

* * * * * * *

(l) ADVERSE EVENT REPORTING.—

(1) REPORTING IN **[**YEAR ONE**]** *FIRST 18-MONTH PERIOD*.—Beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, during the **[**one-year**]** *18-month* 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] *PERIODS*.—Following the [one-year period] *18-month 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) PRESERVATION OF AUTHORITY.—Nothing in this subsection shall prohibit the Office of Pediatric Therapeutics from providing for the review of adverse event reports by the Pediatric Advisory Committee prior to the 18-month period referred to in paragraph (1), if such review is necessary to ensure safe use of a drug in a pediatric population.

[(3)] *(4)* EFFECT.—The requirements of this subsection shall supplement, not supplant, other review of such adverse event reports by the Secretary.

* * * * * * *

(n) REFERRAL IF PEDIATRIC STUDIES NOT [COMPLETED] *SUBMITTED*.—

(1) IN GENERAL.—Beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, if pediatric studies of a drug [have not been completed] *have not been submitted by the date specified in the written request issued and agreed upon* under subsection (d) and if the Secretary, through the committee established under section 505C, determines that there is a continuing need for information relating to the use of the drug in the pediatric population (including neonates, as appropriate), the Secretary shall carry out the following:

[(A) For a drug for which a listed patent has not expired, make a determination regarding whether an assessment shall be required to be submitted under section 505B(b). Prior to making such a determination, the Secretary may not take more than 30 days to certify whether the Foundation for the National Institutes of Health has sufficient funding at the time of such certification to initiate and fund all of the studies in the written request in their entirety within the timeframes specified within the written request. Only if the Secretary makes such certification in the affirmative, the Secretary shall refer all pediatric studies in the written request to the Foundation for the National Institutes of Health for the conduct of such studies, and such Foundation shall fund such studies. If no certification has been made at the end of the 30-day period, or if the Secretary certifies that funds are not sufficient to initiate and fund all the studies in their entirety, the Secretary shall consider whether assessments shall be required under section 505B(b) for such drug.

[(B) For a drug that has no listed patents or has 1 or more listed patents that have expired, the Secretary shall refer the drug for inclusion on the list established under section 409I of the Public Health Service Act for the conduct of studies.]

(A) For a drug for which there remains any listed patent or exclusivity protection eligible for extension under subsection (b)(1) or (c)(1) of this section, or any exclusivity protection eligible for extension under subsection (m)(2) or (m)(3) of section 351 of the Public Health Service Act, the Secretary shall make a determination regarding whether an assessment shall be required to be submitted under section 505B(b).

(B) For a drug that has no remaining listed patents or exclusivity protection eligible for extension under subsection (b)(1) or (c)(1) of this section, or any exclusivity protection eligible for extension under subsection (m)(2) or (m)(3) of section 351 of the Public Health Service Act, the Secretary shall refer the drug for inclusion on the list established under section 409I of the Public Health Service Act for the conduct of studies.

* * * * * * *

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

(1) * * *

(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) * * *

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

(B) a statement of any appropriate pediatric contraindications, warnings, precautions, or other information that the Secretary considers necessary to assure safe use.

* * * * * * *

[(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.]

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 the enactment of the Pediatric Research Equity Act of 2007, an application (or supplement to an application) *for a drug*—

(A) * * *

* * * * * * *

(3) DEFERRAL.—

(A) * * *

(B) DEFERRAL EXTENSION.—On the initiative of the Secretary or at the request of the applicant, the Secretary may grant an extension of a deferral under subparagraph (A) if—

(i) the Secretary finds that the criteria specified in subclause (II) or (III) of subparagraph (A)(i) continue to be met; and

(ii) the applicant submits the materials required under subparagraph (A)(ii).

(C) CONSIDERATION DURING DEFERRAL PERIOD.—If the Secretary has under this paragraph deferred the date by which an assessment must be submitted, then until the date specified in the deferral under subparagraph (A) (including any extension of such date under subparagraph (B))—

(i) the assessment shall not be considered late or delayed;

(ii) the Secretary shall not classify the assessment as late or delayed in any report, database, or public posting.

[(B)**]** *(D)* ANNUAL REVIEW.—

(i) * * *

[(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 Web site of the Food and Drug Administration.**]**

(ii) PUBLIC AVAILABILITY.—Not later than 60 days after the submission to the Secretary of the information submitted through the annual review under clause (i), the Secretary shall make available to the public in an easily accessible manner, including through the Web site of the Food and Drug Administration—

(I) such information;

(II) the name of the applicant for the product subject to the assessment;

(III) the date on which the product was approved; and

(IV) the date of each deferral or deferral extension under this paragraph for the product.

(4) WAIVERS.—

(A) * * *

* * * * * * *

(C) PEDIATRIC FORMULATION NOT POSSIBLE.—If a *partial* 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**]** *a 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 ac-

cessible manner, including through posting on the Web site of the Food and Drug Administration.

* * * * * * *

(b) MARKETED DRUGS AND BIOLOGICAL PRODUCTS.—

(1) IN GENERAL.—[After providing notice in the form of a letter (that, for a drug approved under section 505, references a declined written request under section 505A for a labeled indication which written request is not referred under section 505A(n)(1)(A) to the Foundation of the National Institutes of Health for the pediatric studies), the Secretary] *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) * * *

* * * * * * *

[(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.]

(d) FAILURE TO MEET REQUIREMENTS.—If a person fails to submit a required assessment described in subsection (a)(2), fails to meet the applicable requirements in subsection (a)(3), or fails to submit 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)(A) the Secretary shall issue a letter to such person informing such person of such failure;

(B) not later than 30 calendar days after the issuance of a letter under subparagraph (A), the person who receives such letter shall submit to the Secretary a written response to such letter; and

(C) not later than 45 calendar days after the issuance of a letter under subparagraph (A), the Secretary shall make such letter, and any response to such letter under subparagraph (B), available to the public on the Web site of the Food and Drug Administration, with appropriate redactions made to protect trade secrets and confidential commercial information, except that, if the Secretary determines that the letter under subparagraph (A) was issued in error, the requirements of this subparagraph shall not apply with respect to such letter; and

(2)(A) the drug or biological product that is the subject of the required assessment, applicable requirements in subsection (a)(3), or required request for approval of a pediatric formulation 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

(B) the failure to submit the required assessment, meet the applicable requirements in subsection (a)(3), or submit the required request for approval of a pediatric formulation shall not be the basis for a proceeding—

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

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

(e) INITIAL PEDIATRIC PLAN.—

(1) IN GENERAL.—

(A) SUBMISSION.—An applicant who is required to submit an assessment under subsection (a)(1) shall submit an initial pediatric plan.

(B) TIMING.—An applicant shall submit the initial pediatric plan under paragraph (1)—

(i) before the date on which the applicant submits the assessments under subsection (a)(2); and

(ii) not later than—

(I) 60 calendar days after the date of end-of-Phase 2 meeting (as such term is used in section 312.47 of title 21, Code of Federal Regulations, or successor regulations); or

(II) such other time as may be agreed upon between the Secretary and the applicant.

Nothing in this section shall preclude the Secretary from accepting the submission of an initial pediatric plan earlier than the date otherwise applicable under this subparagraph.

(C) CONTENTS.—The initial pediatric plan shall include—

(i) an outline of the pediatric studies that the applicant plans to conduct;

(ii) any request for a deferral, partial waiver, or waiver under this section, along with supporting information; and

(iii) other information the Secretary determines necessary, including any information specified in regulations under paragraph (5).

(2) MEETING.—

(A) IN GENERAL.—Subject to subparagraph (B), not later than 90 calendar days after receiving an initial pediatric plan under paragraph (1), the Secretary shall meet with the applicant to discuss the plan.

(B) WRITTEN RESPONSE.—If the Secretary determines that a written response to the initial pediatric plan is sufficient to communicate comments on the initial pediatric plan, and that no meeting is necessary the Secretary shall, not later than 90 days after receiving an initial pediatric plan under paragraph (1)—

(i) notify the applicant of such determination; and

(ii) provide to the applicant the Secretary's written comments on the plan.

(3) AGREED PEDIATRIC PLAN.—

(A) SUBMISSION.—The applicant shall submit to the Secretary a document reflecting the agreement between the Secretary and the applicant on the initial pediatric plan (referred to in this subsection as an "agreed pediatric plan").

(B) CONFIRMATION.—Not later than 30 days after receiving the agreed pediatric plan under subparagraph (A), the Secretary shall provide written confirmation to the applicant that such plan reflects the agreement of the Secretary.

(C) DEFERRAL AND WAIVER.—If the agreed pediatric plan contains a request from the applicant for a deferral, partial waiver, or waiver under this section, the written confirmation under subparagraph (B) shall include a recommendation from the Secretary as to whether such request meets the standards under paragraphs (3) or (4) of subsection (a).

(D) AMENDMENTS TO THE PLAN.—At the initiative of the Secretary or the applicant, the agreed pediatric plan may be amended at any time. The requirements of paragraph (2) shall apply to any such proposed amendment in the same manner and to the same extent as such requirements apply to an initial pediatric plan under paragraph (1). The requirements of subparagraphs (A) through (C) of this paragraph shall apply to any agreement resulting from such proposed amendment in the same manner and to the same extent as such requirements apply to an agreed pediatric plan.

(4) INTERNAL COMMITTEE.—The Secretary shall consult the internal committee under section 505C on the review of the initial pediatric plan, agreed pediatric plan, and any amendments to such plans.

(5) MANDATORY RULEMAKING.—Not later than one year after the date of enactment of the Food and Drug Administration Reform Act of 2012, the Secretary shall promulgate proposed regulations and guidance to implement the provisions of this subsection.

(6) EFFECTIVE DATE.—The provisions of this subsection shall take effect 180 calendar days after the date of enactment of the Food and Drug Administration Reform Act of 2012, irrespective of whether the Secretary has promulgated final regulations to carry out this subsection by such date.

(f) REVIEW OF PEDIATRIC PLANS, ASSESSMENTS, DEFERRALS, *DEFERRAL EXTENSIONS,* AND WAIVERS.—

(1) * * *

* * * * * * *

(4) REVIEW OF PEDIATRIC PLANS, ASSESSMENTS, DEFERRALS, *DEFERRAL EXTENSIONS,* AND WAIVERS.—Consultation on pediatric plans and assessments by the committee referred to in paragraph (1) 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 committee shall review all requests for deferrals*, deferral extensions,* and waivers from the requirement to submit a pediatric assessment granted under this section and shall provide recommendations as needed to reviewing divisions, including with respect to whether such a supplement, when submitted, shall be considered for priority review.

* * * * * * *

(6) TRACKING OF ASSESSMENTS AND LABELING CHANGES.—The Secretary, in consultation with the committee referred to in paragraph (1), shall track and make available to the public in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration—

(A) * * *

* * * * * * *

(D) the total number of deferrals *and deferral extensions* requested and granted under this section and, if granted, the reasons for such deferrals *and deferral extensions*, the timeline for completion, and the number completed and pending by the specified date, as outlined in subsection (a)(3);

* * * * * * *

(g) LABELING CHANGES.—

(1) DISPUTE RESOLUTION.—

(A) REQUEST FOR LABELING CHANGE AND FAILURE TO AGREE.—If, on or after the date of the 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] *after the date of the submission of an application or supplement that receives a priority review or 330 days after the date of the submission of an application or supplement that receives a standard review*—

(i) * * *

* * * * * * *

(2) OTHER LABELING CHANGES.—If, on or after the date of the 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 Sec-

retary shall order [the label of such product] *the labeling of such product* to include information about the results of the assessment and a statement of the Secretary's determination.

(h) DISSEMINATION OF PEDIATRIC INFORMATION.—

(1) IN GENERAL.—Not later than 210 days after the date of submission of *an application (or supplement to an application) that contains* a pediatric assessment under this section, *if the application (or supplement) receives a priority review, or not later than 330 days after the date of submission of an application (or supplement to an application) that contains a pediatric assessment under this section, if the application (or supplement) receives a standard review,* 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 Web site of the Food and Drug Administration.

* * * * * * *

(i) ADVERSE EVENT REPORTING.—

(1) REPORTING IN [YEAR ONE] *FIRST 18-MONTH PERIOD*.—Beginning on the date of the enactment of the Pediatric Research Equity Act of 2007, during the [one-year] *18-month* period beginning on the date a labeling change is made pursuant to subsection (g), the Secretary shall ensure that all adverse event reports that have been received for such drug (regardless of when such report was received) are referred to the Office of Pediatric Therapeutics. In considering such reports, the Director of such Office shall provide for the review of such 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] *PERIODS*.—Following the [one-year period] *18-month 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) PRESERVATION OF AUTHORITY.—Nothing in this subsection shall prohibit the Office of Pediatric Therapeutics from providing for the review of adverse event reports by the Pediatric Advisory Committee prior to the 18-month period referred to in paragraph (1), if such review is necessary to ensure safe use of a drug in a pediatric population.

[(3)] *(4)* EFFECT.—The requirements of this subsection shall supplement, not supplant, other review of such adverse event reports by the Secretary.

* * * * * * *

[(m) INTEGRATION WITH OTHER PEDIATRIC STUDIES.—The authority under this section shall remain in effect so long as an appli-

cation subject to this section may be accepted for filing by the Secretary on or before the date specified in section 505A(q).]

[(n)] *(m)* NEW ACTIVE INGREDIENT.—

(1) * * *

* * * * * * *

SEC. 505C. INTERNAL COMMITTEE FOR REVIEW OF PEDIATRIC PLANS, ASSESSMENTS, DEFERRALS, *DEFERRAL EXTENSIONS,* AND WAIVERS.

The Secretary shall establish an internal committee within the Food and Drug Administration to carry out the activities as described in sections 505A(f) and 505B(f). 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 *neonatology*, and the appropriate expertise pertaining to the pediatric product under review, such as expertise in child and adolescent psychiatry, and other individuals designated by the Secretary.

* * * * * * *

SEC. 505E. EXTENSION OF EXCLUSIVITY PERIOD FOR NEW QUALIFIED INFECTIOUS DISEASE PRODUCTS.

(a) EXTENSION.—If the Secretary approves an application pursuant to section 505 for a drug that has been determined to be a qualified infectious disease product under subsection (d), then the four- and five-year periods described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, the three-year periods described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection (j)(5)(F) of section 505, or the seven year period described in section 527, as applicable, shall be extended by five years.

(b) RELATION TO PEDIATRIC EXCLUSIVITY.—Any extension under subsection (a) of a period shall be in addition to any extension of the period under section 505A with respect to the drug.

(c) LIMITATIONS.—Subsection (a) does not apply to the approval of—

(1) a supplement to an application under section 505(b) for any qualified infectious disease product for which an extension described in subsection (a) is in effect or has expired;

(2) a subsequent application filed by the same sponsor or manufacturer of a qualified infectious disease product described in paragraph (1) (or a licensor, predecessor in interest, or other related entity) for—

(A) a change (not including a modification to the active moiety of the qualified infectious disease product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

(B) a modification to the active moiety of the qualified infectious disease product that does not result in a change in safety or effectiveness; or

(3) a product that does not meet the definition of a qualified infectious disease product under subsection (f) based upon its approved uses.

(d) DETERMINATION.—The manufacturer or sponsor of a drug may request that the Secretary designate a drug as a qualified in-

fectious disease product at any time in the drug development process prior to the submission of an application under section 505(b) for the drug, but not later than 45 days before the submission of such application. The Secretary shall, not later than 30 days after the submission of such request, determine whether the drug is a qualified infectious disease product.

(e) REGULATIONS.—The Secretary shall promulgate regulations for carrying out this section. The Secretary shall promulgate the initial regulations for carrying out this section not later than 12 months after the date of the enactment of this section.

(f) DEFINITIONS.—In this section:

(1) QUALIFIED INFECTIOUS DISEASE PRODUCT.—The term "qualified infectious disease product" means an antibacterial or antifungal drug for human use that treats or prevents an infection caused by a qualifying pathogen.

(2) QUALIFYING PATHOGEN.—The term "qualifying pathogen" means—

(A) resistant gram-positive pathogens, including methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant Staphylococcus aureus (VRSA), and vancomycin-resistant enterococcus (VRE);

(B) multidrug resistant gram-negative bacteria, including Acinetobacter, Klebsiella, Pseudomonas, and E. coli species;

(C) multi-drug resistant tuberculosis; or

(D) any other infectious pathogen identified for purposes of this section by the Secretary.

[SEC. 506. FAST TRACK PRODUCTS.

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

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

[(2) REQUEST FOR DESIGNATION.—The sponsor of a new drug may request the Secretary to designate the drug as a fast track product. A request for the designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

[(3) DESIGNATION.—Within 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track product and shall take such actions as are appropriate to expedite the development and review of the application for approval of such product.

[(b) APPROVAL OF APPLICATION FOR A FAST TRACK PRODUCT.—

[(1) IN GENERAL.—The Secretary may approve an application for approval of a fast track product under section 505(c) or section 351 of the Public Health Service Act upon a determination that the product has an effect on a clinical endpoint or on a

surrogate endpoint that is reasonably likely to predict clinical benefit.

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

[(A) that the sponsor conduct appropriate post-approval studies to validate the surrogate endpoint or otherwise confirm the effect on the clinical endpoint; and

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

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

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

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

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

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

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

[(1) IN GENERAL.—If the Secretary determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective, the Secretary shall evaluate for filing, and may commence review of portions of, an application for the approval of the product before the sponsor submits a complete application. The Secretary shall commence such review only if the applicant—

[(A) provides a schedule for submission of information necessary to make the application complete; and

[(B) pays any fee that may be required under section 736.

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

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

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

[(2) establish a program to encourage the development of surrogate endpoints that are reasonably likely to predict clin-

ical benefit for serious or life-threatening conditions for which there exist significant unmet medical needs.]

SEC. 506. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS.

(a) DESIGNATION OF A DRUG AS A BREAKTHROUGH THERAPY.—

(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a drug, expedite the development and review of such drug if the drug is intended, alone or in combination with 1 or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on 1 or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. (In this section, such a drug is referred to as a "breakthrough therapy".)

(2) REQUEST FOR DESIGNATION.—The sponsor of a drug may request the Secretary to designate the drug as a breakthrough therapy. A request for the designation may be made concurrently with, or at any time after, the submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

(3) DESIGNATION.—

(A) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a breakthrough therapy and shall take such actions as are appropriate to expedite the development and review of the application for approval of such drug.

(B) ACTIONS.—The actions to expedite the development and review of an application under subparagraph (A) may include, as appropriate—

(i) holding meetings with the sponsor and the review team throughout the development of the drug;

(ii) providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the non-clinical and clinical data necessary for approval is as efficient as practicable;

(iii) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review;

(iv) assigning a cross-disciplinary project lead for the Food and Drug Administration review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and

(v) taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment.

(b) DESIGNATION OF DRUG AS A FAST TRACK PRODUCT.—

(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a new drug, facilitate the development and expedite the review of such drug if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. (In this section, such a drug is referred to as a "fast track product".)

(2) REQUEST FOR DESIGNATION.—The sponsor of a new drug may request the Secretary to designate the drug as a fast track product. A request for the designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act.

(3) DESIGNATION.—Within 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track product and shall take such actions as are appropriate to expedite the development and review of the application for approval of such product.

(c) ACCELERATED APPROVAL OF A DRUG FOR A SERIOUS OR LIFE-THREATENING DISEASE OR CONDITION, INCLUDING A FAST TRACK PRODUCT.—

(1) IN GENERAL.—The Secretary may approve an application for approval of a product for a serious or life-threatening disease or condition, including a fast track product, under section 505(c) of this Act or section 351(a) of the Public Health Service Act upon making a determination that the product has an effect on—

(A) a surrogate endpoint that is reasonably likely to predict clinical benefit; or

(B) a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit,

taking into account the severity or rarity of the disease or condition and the availability of alternative treatments. The evidence to support that an endpoint is reasonably likely to predict clinical benefit may include epidemiological, pathophysiologic, pharmacologic, therapeutic or other evidence developed using, for example, biomarkers, or other scientific methods or tools.

(2) LIMITATION.—Approval of a product under this subsection may, as determined by the Secretary, be subject to the following requirements—

(A) that the sponsor conduct appropriate post-approval studies to verify and describe the predicted effect of the product on irreversible morbidity or mortality or other clinical benefit; and

(B) that the sponsor submit copies of all promotional materials related to the product, at least 30 days prior to dissemination of the materials—

(i) during the preapproval review period; and

(ii) following approval, for a period that the Secretary determines to be appropriate.

(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a product approved pursuant to this subsection using expedited procedures (as prescribed by the Secretary in regulations, which shall include an opportunity for an informal hearing) if—

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

(B) a study required to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the product fails to verify and describe such effect or benefit;

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

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

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

(1) IN GENERAL.—If the Secretary determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective, the Secretary shall evaluate for filing, and may commence review of portions of, an application for the approval of the product before the sponsor submits a complete application. The Secretary shall commence such review only if the applicant—

(A) provides a schedule for submission of information necessary to make the application complete; and

(B) pays any fee that may be required under section 736.

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

(f) AWARENESS EFFORTS.—The Secretary shall—

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

(2) establish a program to encourage the development of surrogate and clinical endpoints, including biomarkers, and other scientific methods and tools that can assist the Secretary in determining whether the evidence submitted in an application is reasonably likely to predict clinical benefit for serious or life-threatening conditions for which there exist significant unmet medical needs.

(g) REPORT.—Beginning in fiscal year 2013, the Secretary shall annually prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and make

publicly available, with respect to this section for the previous fiscal year—

(1) the number of drugs for which a sponsor requested designation as a breakthrough therapy;

(2) the number of products designated as a breakthrough therapy; and

(3) for each product designated as a breakthrough therapy, a summary of the actions taken under subsection (a)(3).

* * * * * * *

SEC. 506A. MANUFACTURING CHANGES.

(a) * * *

* * * * * * *

(c) MAJOR MANUFACTURING CHANGES.—

(1) * * *

* * * * * * *

(3) CHANGES ADDRESSING A DRUG SHORTAGE.—

(A) CERTIFICATION.—

(i) DESCRIPTION.—A certification is described in this subparagraph if the manufacturer, having notified the Secretary of an interruption or discontinuance of a drug in accordance with Section 506C, certifies (in such certification) that the major manufacturing change for which approval is being sought may prevent or alleviate a discontinuance or interruption of such drug.

(ii) BAD FAITH EXCEPTION.—Subparagraphs (B) and (C) do not apply in the case of a certification which the Secretary determines to be made in bad faith.

(B) EXPEDITED REVIEW.—If a certification described in subparagraph (A) is submitted in connection with a supplemental application for a major manufacturing change, the Secretary shall—

(i) expedite any technical review or inspection necessary for consideration of the supplemental application;

(ii) provide any technical assistance necessary to facilitate approval of the supplemental application; and

(iii) not later than 60 days after receipt of the certification, complete review of the supplemental application.

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SEC. 506B. REPORTS OF POSTMARKETING STUDIES.

(a) * * *

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(e) NOTIFICATION.—With respect to studies of the type required under ⟦section 506(b)(2)(A)⟧ *section 506(c)(2)(A)* or under section 314.510 or 601.41 of title 21, Code of Federal Regulations, as each of such sections was in effect on the day before the effective date of this subsection, the Secretary may require that a sponsor who, for reasons not satisfactory to the Secretary, fails to complete by its deadline a study under any of such sections of such type for a drug or biological product (including such a study conducted after

such effective date) notify practitioners who prescribe such drug or biological product of the failure to complete such study and the questions of clinical benefit, and, where appropriate, questions of safety, that remain unanswered as a result of the failure to complete such study. Nothing in this subsection shall be construed as altering the requirements of the types of studies required under [section 506(b)(2)(A)] *section 506(c)(2)(A)* or under section 314.510 or 601.41 of title 21, Code of Federal Regulations, as so in effect, or as prohibiting the Secretary from modifying such sections of title 21 of such Code to provide for studies in addition to those of such type.

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

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

[(1) that is—

[(A) life-supporting;

[(B) life-sustaining; or

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

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

[(3) that is not a product that was originally derived from human tissue and was replaced by a recombinant product,

shall notify the Secretary of a discontinuance of the manufacture of the drug at least 6 months prior to the date of the discontinuance.

[(b) REDUCTION IN NOTIFICATION PERIOD.—The notification period required under subsection (a) for a manufacturer may be reduced if the manufacturer certifies to the Secretary that good cause exists for the reduction, such as a situation in which—

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

[(2) a biomaterials shortage prevents the continuation of the manufacturing for the 6-month period;

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

[(4) continuation of the manufacturing for the 6-month period may cause substantial economic hardship for the manufacturer;

[(5) the manufacturer has filed for bankruptcy under chapter 7 or 11 of title 11, United States Code; or

[(6) the manufacturer can continue the distribution of the drug involved for 6 months.

[(c) DISTRIBUTION.—To the maximum extent practicable, the Secretary shall distribute information on the discontinuation of the drugs described in subsection (a) to appropriate physician and patient organizations.]

SEC. 506C. DISCONTINUANCE AND INTERRUPTIONS OF MANUFACTURING OF CERTAIN DRUGS.

(a) IN GENERAL.—A manufacturer of a drug subject to section 503(b)(1)—

(1) that is—

(A) life-supporting;

(B) life-sustaining; or

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

(2) that is not a radio pharmaceutical drug product, a product derived from human plasma protein and their recombinant analogs, or any other product as designated by the Secretary,

shall notify the Secretary of a discontinuance of the manufacture of the drug, or an interruption of the manufacture of the drug that is likely to lead to a meaningful disruption in the manufacturer's supply of the drug, and the reason for such discontinuance or interruption, in accordance with subsection (b).

(b) TIMING.—A notice required by subsection (a) shall be submitted to the Secretary—

(1) at least 6 months prior to the date of the discontinuance or interruption; or

(2) if compliance with paragraph (1) is not possible, as soon as practicable.

(c) DISTRIBUTION.—To the maximum extent practicable, the Secretary shall distribute information on the discontinuation or interruption of the manufacture of the drugs described in subsection (a) to appropriate organizations, including physician, health provider, and patient organizations, as described in section 506D.

(d) CONFIDENTIALITY.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

(e) COORDINATION WITH ATTORNEY GENERAL.—Not later than 30 days after the receipt of a notification described in subsection (a), the Secretary shall—

(1) determine whether the notification pertains to a controlled substance subject to a production quota under section 306 of the Controlled Substances Act; and

(2) if necessary, as determined by the Secretary—

(A) notify the Attorney General that the Secretary has received such a notification;

(B) request that the Attorney General increase the aggregate and individual production quotas under section 306 of the Controlled Substances Act applicable to such controlled substance and any ingredient therein to a level the Secretary deems necessary to address a shortage of a controlled substance based on the best available market data; and

(C) if the Attorney General determines that the level requested is not necessary to address a shortage of a controlled substance, the Attorney General shall provide to the Secretary a written response detailing the basis for the Attorney General's determination.

The Secretary shall make the written response provided under subparagraph (C) available to the public on the Web site of the Food and Drug Administration.

(f) FAILURE TO MEET REQUIREMENTS.—If a person fails to submit information required under subsection (a) in accordance with subsection (b)—

(1) the Secretary shall issue a letter to such person informing such person of such failure;

(2) not later than 30 calendar days after the issuance of a letter under paragraph (1), the person who receives such letter shall submit to the Secretary a written response to such letter setting forth the basis for noncompliance and providing information required under subsection (a); and

(3) not later than 45 calendar days after the issuance of a letter under paragraph (1), the Secretary shall make such letter and any response to such letter under paragraph (2) available to the public on the Web site of the Food and Drug Administration, with appropriate redactions made to protect information described in subsection (d), except that, if the Secretary determines that the letter under paragraph (1) was issued in error or, after review of such response, the person had a reasonable basis for not notifying as required under subsection (a), the requirements of this paragraph shall not apply.

SEC. 506D. DRUG SHORTAGE LIST.

(a) ESTABLISHMENT.—The Secretary shall maintain an up-to-date list of drugs that are determined by the Secretary to be in shortage in the United States.

(b) CONTENTS.—For each drug on such list, the Secretary shall include the following information:

(1) The name of the drug in shortage.

(2) The name of each manufacturer of such drug.

(3) The reason for the shortage, as determined by the Secretary, selecting from the following categories:

(A) Requirements related to complying with good manufacturing practices.

(B) Regulatory delay.

(C) Shortage of an active ingredient.

(D) Shortage of an inactive ingredient component.

(E) Discontinuation of the manufacture of the drug.

(F) Delay in shipping of the drug.

(G) Demand increase for the drug.

(4) The estimated duration of the shortage as determined by the Secretary.

(c) PUBLIC AVAILABILITY.—

(1) IN GENERAL.—Subject to paragraphs (2) and (3), the Secretary shall make the information in such list publicly available.

(2) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—Nothing in this section alters or amends section 1905 of title 18, United States Code, or section 552(b)(4) of title 5 of such Code.

(3) PUBLIC HEALTH EXCEPTION.—The Secretary may choose not to make information collected under this section publicly available under paragraph (1) if the Secretary determines that disclosure of such information would adversely affect the public health (such as by increasing the possibility of hoarding or other disruption of the availability of drug products to patients).

SEC. 506E. HOSPITAL REPACKAGING OF DRUGS IN SHORTAGE.

(a) DEFINITIONS.—In this section:

(1) DRUG.—The term "drug" excludes any controlled substance (as such term is defined in section 102 of the Controlled Substances Act).

(2) HEALTH SYSTEM.—The term "health system" means a collection of hospitals that are owned and operated by the same entity and that share access to databases with drug order information for their patients.

(3) REPACKAGE.—For the purposes of this section only, the term "repackage", with respect to a drug, means to divide the volume of a drug into smaller amounts in order to—

(A) extend the supply of a drug in response to the placement of the drug on a drug shortage list described in subsection (b); and

(B) facilitate access to the drug by hospitals within the same health system.

(b) EXCLUSION FROM REGISTRATION.—Notwithstanding any other provision of this Act, a hospital shall not be considered an establishment for which registration is required under section 510 solely because it repackages a drug and transfers it to another hospital within the same health system in accordance with the conditions in subsection (c)—

(1) during any period in which the drug is listed on the Drug Shortage List of the Food and Drug Administration; or

(2) during the 60-day period following any period described in paragraph (1).

(c) CONDITIONS.—Subsection (b) shall only apply to a hospital, with respect to the repackaging of a drug for transfers to another hospital within the same health system, if the following conditions are met:

(1) DRUG FOR INTRASYSTEM USE ONLY.—In no case may a drug that has been repackaged in accordance with this section be sold or otherwise distributed by the health system or a hospital within the system to an entity or individual that is not a hospital within such health system.

(2) COMPLIANCE WITH STATE RULES.—Repackaging of a drug under this section shall be done in compliance with applicable State requirements in which the health system is located.

(d) TERMINATION.—This section shall not apply on or after the date on which the Secretary issues final guidance that clarifies the policy of the Food and Drug Administration regarding hospital pharmacies repackaging and safely transferring repackaged drugs to other hospitals within the same health system during a drug shortage.

* * * * * * *

SEC. 510. (a) * * *

(b)(1) [On or before] *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 drug or drugs shall register with the Secretary his name, places of business, [and all such establishments] *all such establishments, and the unique facility identifier of each such establishment*.

* * * * * * *

(c) Every person upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices in any establishment which he owns or operates in any State shall immediately register with the Secretary his

name, place of business, [and such establishment] *such establishment, and the unique facility identifier of such establishment*.

* * * * * * *

(h)*(1)* Every establishment in any State registered with the Secretary pursuant to this section *with respect to the manufacture, preparation, propagation, compounding, or processing of a device* shall be subject to inspection pursuant to section 704 and every such establishment engaged in the manufacture, propagation, compounding, or processing [of a drug or drugs or] of a device or devices classified in class II or III shall be so inspected by one or more officers or employees duly designated by the Secretary, or by persons accredited to conduct inspections under section 704(g), at least once in the 2-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive 2-year period thereafter.

(2) INSPECTIONS WITH RESPECT TO DRUG ESTABLISHMENTS.—With respect to the manufacture, preparation, propagation, compounding, or processing of a drug:

(A) IN GENERAL.—Every establishment that is required to be registered with the Secretary under this section shall be subject to inspection pursuant to section 704.

(B) RISK-BASED SCHEDULE.—In the case of an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs (referred to in this subsection as a "drug establishment"), the inspections required under subparagraph (A) shall be conducted by officers or employees duly designated by the Secretary, on a risk-based schedule established by the Secretary.

(C) RISK FACTORS.—In establishing the risk-based schedule under subparagraph (B), the Secretary shall allocate resources to inspect establishments according to the known safety risks of such establishments, based on the following factors:

(i) The compliance history of the establishment.

(ii) The inspection frequency and history of the establishment, including whether it has been inspected pursuant to section 704 within the last four years.

(iii) The record, history, and nature of recalls linked to the establishment.

(iv) The inherent risk of the drug manufactured, prepared, propagated, compounded, or processed at the establishment.

(v) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

(D) EFFECT OF STATUS.—In determining the risk associated with an establishment for purposes of establishing a risk-based schedule under subparagraph (B), the Secretary shall not consider whether the drugs manufactured, prepared, propagated, compounded, or processed by such establishment are drugs described in section 503(b)(1).

(E) ANNUAL REPORT ON INSPECTIONS OF ESTABLISHMENTS.—Not later than February 1 of each year, the Secretary shall submit to Congress a report that contains the following:

(i) The number of domestic and foreign establishments registered pursuant to this section in the previous calendar year.

(ii) The number of such registered domestic and foreign establishments that the Secretary inspected in the previous calendar year.

(iii) The number of such registered establishments that list one or more drugs approved pursuant to an application filed under section 505(j).

(iv) The number of such registered establishments that list one or more drugs approved pursuant to an application filed under section 505(b).

(v) The number of registered establishments that list both drug products approved pursuant to an application filed under section 505(j) and drug products approved pursuant to an application filed under section 505(b).

(vi) A description of how the Secretary implemented the risk-based schedule under subparagraph (B) utilizing the factors under subparagraph (C).

(F) PUBLIC AVAILABILITY OF ANNUAL REPORTS.—The Secretary shall make the report required under subparagraph (E) available to the public on the Internet Web site of the Food and Drug Administration.

(i)(1) 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 unique facility identifier 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⟧ *during the period beginning on October 1 and ending on* December 31 of each year; and

* * * * * * *

⟦(n)⟧ *(n)(1)* The Secretary shall review the report required in subsection (k) and make a determination under section 513(f)(1) not later than 90 days after receiving the report.

(2)(A) Not later than 18 months after the enactment of this paragraph, the Secretary shall 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 regarding when a premarket notification under subsection (k) should be submitted for a modification or change to a legally marketed device. The report shall include the Secretary's interpretation of the following terms: "could significantly affect the safety or effectiveness of the device", "a signifi-

cant change or modification in design, material, chemical composition, energy source, or manufacturing process,", and "major change or modification in the intended use of the device". The report also shall discuss possible processes for industry to use to determine whether a new submission under subsection (k) is required and shall analyze how to leverage existing quality system requirements to reduce premarket burden, facilitate continual device improvement. and provide reasonable assurance of safety and effectiveness of modified devices. In developing such report, the Secretary shall consider the input of interested stakeholders.

(B) The Secretary shall withdraw the Food and Drug Administration draft guidance entitled "Guidance for Industry and FDA Staff—510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device", dated July 27, 2011, and shall not use this draft guidance as part of, or for the basis of, any premarket review or any compliance or enforcement decisions or actions. The Secretary shall not issue—

(i) any draft guidance or proposed regulation that addresses when to submit a premarket notification submission for changes and modifications made to a manufacturer's previously cleared device before the receipt by the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate of the report required in subparagraph (A); and

(ii) any final guidance or regulation on that topic for one year after date of receipt of such report by the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

(C) The Food and Drug Administration guidance entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device", dated January 10, 1997, shall be in effect until the subsequent issuance of guidance or promulgation, if appropriate, of a regulation described in subparagraph (B), and the Secretary shall interpret such guidance in a manner that is consistent with the manner in which the Secretary has interpreted such guidance since 1997.

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(q) GUIDANCE ON SUBMISSION OF UNIQUE FACILITY IDENTIFIERS.—

(1) IN GENERAL.—Not later than 2 years after the date of the enactment of this subsection, the Secretary shall, by guidance, specify—

(A) the unique facility identifier system to be used to meet the requirements of—

(i) subsections (b)(1), (c), and (i)(1)(A) of this section; and

(ii) section 801(s) (relating to registration of commercial importers); and

(B) the form, manner, and timing of submissions of unique facility identifiers under the provisions specified in subparagraph (A).

(2) CONSIDERATION.—In developing the guidance under paragraph (1), the Secretary shall take into account the utilization of existing unique identification schemes and compatibility with customs automated systems.

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CLASSIFICATION OF DEVICES INTENDED FOR HUMAN USE

Device Classes

SEC. 513. (a)(1) * * *

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(3)(A) * * *

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(D)(i) * * *

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(iii) For purposes of clause (ii), the term "necessary" means the minimum required information that would support a determination by the Secretary that an application provides reasonable assurance of the effectiveness of the device.

(iv) Nothing in this subparagraph shall alter the criteria for evaluating an application for premarket approval of a device.

[(iii)**]** *(v)* The determination of the Secretary with respect to the specification of valid scientific evidence under clauses (i) and (ii) shall be binding upon the Secretary, unless such determination by the Secretary could be contrary to the public health.

* * * * * * *

Initial Classification and Reclassification of Certain Devices

(f)(1) Any device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before the date of the enactment of this section is classified in class III unless—

(A) the device—

(i) * * *

(ii) is substantially equivalent to another device within such type**[**, or**]***;*

(B) the Secretary in response to a petition submitted under paragraph (3) has classified such device in class I or II**[**.**]***; or*

(C) the device is classified pursuant to a request submitted under paragraph (2).

* * * * * * *

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

device and provide detailed information and reasons for the recommended classification.**]**.

(ii) In lieu of submitting a report under section 510(k) and submitting a request for classification under clause (i) for a device, if a person determines there is no legally marketed device upon which to base a determination of substantial equivalence (as defined in subsection (i)), a person may submit a request under this clause for the Secretary to classify the device.

(iii) Upon receipt of a request under clause (i) or (ii), the Secretary shall classify the device subject to the request under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1) within 120 days.

(iv) Notwithstanding clause (iii), the Secretary may decline to undertake a classification of a device pursuant to a request under clause (ii) if the Secretary—

(I) identifies a legally marketed device that would permit a substantial equivalence determination under paragraph (1) for the device; or

(II) determines that the device submitted is not of low-moderate risk or special controls to mitigate the risks cannot be developed for the device.

(v) The person submitting the request for classification under this subparagraph may recommend to the Secretary a classification for the device and shall, if recommending classification in class II, include in the request an initial draft proposal for applicable special controls, as described in subsection (a)(1)(B), that are necessary, in conjunction with general controls, to provide reasonable assurance of safety and effectiveness and a description of how the special controls provide such assurance. Any such request shall describe the device and provide detailed information and reasons for the recommended classification.

(B)(i) **[**Not later than 60 days after the date of the submission of the request under subparagraph (A), the Secretary**]** *The Secretary* shall by written order classify the device involved. Such classification shall be the initial classification of the device for purposes of paragraph (1) and any device classified under this paragraph shall be a predicate device for determining substantial equivalence under paragraph (1).

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Substantial Equivalence

(i)(1)(A) * * *

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

(ii) For purposes of clause (i), the term "necessary" means the minimum required information that would support a determination of substantial equivalence between a new device and a predicate device.

(iii) Nothing in this subparagraph shall alter the standard for determining substantial equivalence between a new device and a predicate device.

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PREMARKET APPROVAL

SEC. 515. (a) * * *

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Application for Premarket Approval

(c)(1) * * *

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(4)(A) Prior to the submission of an application under this subsection, the Secretary shall accept and review any portion of the application that the applicant and the Secretary agree is complete, ready, and appropriate for review, except that such requirement does not apply, and the Secretary has discretion whether to accept and review such portion, during any period in which, under section **[**738(g)**]** *738(h)*, the Secretary does not have the authority to collect fees under section 738(a).

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SEC. 517A. AGENCY DOCUMENTATION AND REVIEW OF SIGNIFICANT DECISIONS REGARDING DEVICES.

(a) DOCUMENTATION OF RATIONALE FOR SIGNIFICANT DECISIONS.—

(1) IN GENERAL.—The Secretary shall completely document the scientific and regulatory rationale for any significant decision of the Center for Devices and Radiological Health regarding submission or review of a report under section 510(k), an application under section 515, or an application for an exemption under section 520(g), including documentation of significant controversies or differences of opinion and the resolution of such controversies or differences of opinion.

(2) PROVISION OF DOCUMENTATION.—Upon request, the Secretary shall furnish such complete documentation to the person who is seeking to submit, or who has submitted, such report or application.

(b) REVIEW OF SIGNIFICANT DECISIONS.—

(1) REQUEST FOR SUPERVISORY REVIEW OF SIGNIFICANT DECISION.—Any person may request a supervisory review of the significant decision described in subsection (a)(1). Such review may be conducted at the next supervisory level or higher above the individual who made the significant decision.

(2) SUBMISSION OF REQUEST.—A person requesting a supervisory review under paragraph (1) shall submit such request to the Secretary not later than 30 days after such decision and shall indicate in the request whether such person seeks an in-person meeting or a teleconference review.

(3) TIMEFRAME.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary shall schedule an in-person or teleconference review, if so requested, not later than 30 days after

such request is made. The Secretary shall issue a decision to the person requesting a review under this subsection not later than 45 days after the request is made under paragraph (1), or, in the case of a person who requests an in-person meeting or teleconference, 30 days after such meeting or teleconference.

(B) EXCEPTION.—Subparagraph (A) shall not apply in cases that are referred to experts outside of the Food and Drug Administration.

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SEC. 518A. PROGRAM TO IMPROVE THE DEVICE RECALL SYSTEM.

(a) IN GENERAL.—The Secretary shall—

(1) establish a program to routinely and systematically assess information relating to device recalls and use such information to proactively identify strategies for mitigating health risks presented by defective or unsafe devices;

(2) clarify procedures for conducting device recall audit checks to improve the ability of investigators to perform those checks in a consistent manner;

(3) develop detailed criteria for assessing whether a person performing a device recall has performed an effective correction or action plan for the recall; and

(4) document the basis for each termination by the Food and Drug Administration of a device recall.

(b) ASSESSMENT CONTENT.—The program established under subsection (a)(1) shall, at a minimum, identify—

(1) trends in the number and types of device recalls;

(2) devices that are most frequently the subject of a recall; and

(3) underlying causes of device recalls.

(c) DEFINITION.—In this section, the term "recall" means—

(1) the removal from the market of a device pursuant to an order of the Secretary under subsection (b) or (e) of section 518; or

(2) the correction or removal from the market of a device at the initiative of the manufacturer or importer of the device that is required to be reported to the Secretary under section 519(g).

RECORDS AND REPORTS ON DEVICES

SEC. 519. (a) * * *

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(h) INCLUSION OF DEVICES IN POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—

(1) IN GENERAL.—The Secretary shall amend the procedures established and maintained under clauses (i), (ii), (iii), and (v) of section 505(k)(3)(C) in order to expand the postmarket risk identification and analysis system established under such section to include and apply to devices.

(2) DATA.—In expanding the system as described in paragraph (1), the Secretary shall use relevant data with respect to devices cleared under section 510(k) or approved under section 515, which may include claims data, patient survey data, and

standardized analytic files that allow for the pooling and analysis of data from disparate data environments.

(3) STAKEHOLDER INPUT.—To help ensure effective implementation of the system as described in paragraph (1) with respect to devices, the Secretary shall engage outside stakeholders in development of the system, and gather information from outside stakeholders regarding the content of an effective sentinel program, through a public hearing, advisory committee meeting, maintenance of a public docket, or other similar public measures.

(4) VOLUNTARY SURVEYS.—Chapter 35 of title 44, United States Code, shall not apply to the collection of voluntary information from health care providers, such as voluntary surveys or questionnaires, initiated by the Secretary for purposes of postmarket risk identification, mitigation, and analysis for devices.

GENERAL PROVISIONS RESPECTING CONTROL OF DEVICES INTENDED FOR HUMAN USE

SEC. 520. (a) * * *

[Custom Devices

[(b) Sections 514 and 515 do not apply to any device which, in order to comply with the order of an individual physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing) necessarily deviates from an otherwise applicable performance standard or requirement prescribed by or under section 515 if (1) the device is not generally available in finished form for purchase or for dispensing upon prescription and is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution, and (2) such device—

[(A)(i) is intended for use by an individual patient named in such order of such physician or dentist (or other specially qualified person so designated) and is to be made in a specific form for such patient, or

[(ii) is intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of such physician or dentist (or other specially qualified person so designated), and

[(B) is not generally available to or generally used by other physicians or dentists (or other specially qualified persons so designated).]

(b) CUSTOM DEVICES.—

(1) IN GENERAL.—The requirements of sections 514 and 515 shall not apply to a device that—

(A) is created or modified in order to comply with the order of an individual physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing);

(B) in order to comply with an order described in subparagraph (A), necessarily deviates from an otherwise ap-

plicable performance standard under section 514 or requirement under section 515;

(C) is not generally available in the United States in finished form through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution;

(D) is designed to treat a unique pathology or physiological condition that no other device is domestically available to treat;

(E)(i) is intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of such physician or dentist (or other specially qualified person so designated); or

(ii) is intended for use by an individual patient named in such order of such physician or dentist (or other specially qualified person so designated);

(F) is assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of individuals described in clause (i) or (ii) of subparagraph (E); and

(G) may have common, standardized design characteristics, chemical and material compositions, and manufacturing processes as commercially distributed devices.

(2) LIMITATIONS.—Paragraph (1) shall apply to a device only if—

(A) such device is for the purpose of treating a sufficiently rare condition, such that conducting clinical investigations on such device would be impractical; and

(B) production of such device under paragraph (1) is limited to no more than 5 units per year of a particular device type, provided that such replication otherwise complies with this section.

(3) GUIDANCE.—Not later than 2 years after the date of enactment of this section, the Secretary shall issue final guidance on replication of multiple devices described in paragraph (2)(B).

(4) NOTIFICATION TO THE SECRETARY.—The manufacturer of such device created or modified as described in paragraph (1) shall notify the Secretary on an annual basis, in a manner prescribed by the Secretary, of the manufacture of such device.

* * * * * * *

Exemption for Devices for Investigational Use

(g)(1) * * *

(2)(A) * * *

(B) The conditions prescribed pursuant to subparagraph (A) shall include the following:

(i) * * *

(ii) A requirement that the person applying for an exemption for a device assure the establishment and maintenance of such records, and the making of such reports to the Secretary of *safety or effectiveness* data obtained as a result of the investigational use of the device during the exemption, as the Secretary determines will enable him to assure compliance with such

conditions, review the progress of the investigation, and evaluate the safety and effectiveness of the device.

* * * * * * *

(4)(A) * * *

* * * * * * *

(C) Consistent with paragraph (1), the Secretary shall not disapprove an application under this subsection because the Secretary determines that—

(i) the investigation may not support a substantial equivalence or de novo classification determination or approval of the device;

(ii) the investigation may not meet a requirement, including a data requirement, relating to the approval or clearance of a device; or

(iii) an additional or different investigation may be necessary to support clearance or approval of the device.

Release of Safety and Effectiveness Information

(h)(1) * * *

* * * * * * *

(5) Subject to subsection (c) and section 301(j), the Secretary shall regularly publish detailed decision summaries for each clearance of a device under section 510(k) requiring clinical data.

* * * * * * *

Humanitarian Device Exemption

(m)(1) * * *

* * * * * * *

(6)(A) Except as provided in ⟦subparagraph (D)⟧ *subparagraph (C)*, 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 the 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).**]**

(i) The device with respect to which the exemption is granted—

(I) 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; or

(II) is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe.

(ii) During any calendar year, the number of such devices distributed during that year under each exemption granted under this subsection does not exceed the number of such devices needed to treat, diagnose, or cure a population of 4,000 individuals in the United States (referred to in this paragraph as the "annual distribution number").

* * * * * * *

(iv) The request for such exemption is submitted on or before October 1, **[**2012**]** *2017*.

* * * * * * *

[(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)**]** *(C)* 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)**]** *(D)*(i) * * *

* * * * * * *

(7) The Secretary shall refer any report of an adverse event **[**regarding a device**]** *regarding a device described in paragraph (6)(A)(i)(I)* for which the prohibition under paragraph (3) does not apply pursuant to paragraph (6)(A) that the Secretary receives to the Office of Pediatric Therapeutics, established under section 6 of the Best Pharmaceuticals for Children Act (Public Law 107–109). In considering the report, the Director of the Office of Pediatric Therapeutics, in consultation with experts in the Center for Devices and Radiological Health, shall provide for periodic review of the report by the Pediatric Advisory Committee, including obtaining any recommendations of such committee regarding whether the

Secretary should take action under this Act in response to the report.

(8) The Secretary, acting through the Office of Pediatric Therapeutics and the Center for Devices and Radiological Health, shall provide for an annual review by the Pediatric Advisory Committee [of all devices described in paragraph (6)] *of all devices described in paragraph (6)(A)(i)(I)* to ensure that the exemption under paragraph (2) remains appropriate for the pediatric populations for which it is granted.

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SEC. 523. ACCREDITED PERSONS.

(a) * * *

(b) ACCREDITATION.—

(1) * * *

(2) ACCREDITATION.—

(A) * * *

* * * * * * *

(E) PERIODIC REACCREDITATION.—

(i) PERIOD.—Subject to suspension or withdrawal under subparagraph (B), any accreditation under this section shall be valid for a period of 3 years after its issuance.

(ii) RESPONSE TO REACCREDITATION REQUEST.—Upon the submission of a request by an accredited person for reaccreditation under this section, the Secretary shall approve or deny such request not later than 60 days after receipt of the request.

(iii) CRITERIA.—Not later than 120 days after the date of the enactment of this subparagraph, the Secretary shall establish and publish in the Federal Register criteria to reaccredit or deny reaccreditation to persons under this section. The reaccreditation of persons under this section shall specify the particular activities under subsection (a), and the devices, for which such persons are reaccredited.

* * * * * * *

(c) DURATION.—The authority provided by this section terminates [October 1, 2012] *October 1, 2017*.

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SUBCHAPTER B—DRUGS FOR RARE DISEASES OR CONDITIONS

* * * * * * *

SEC. 529. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR RARE PEDIATRIC DISEASES.

(a) DEFINITIONS.—In this section:

(1) PRIORITY REVIEW.—The term "priority review", with respect to a human drug application as defined in section 735(1), means review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures of the Food and Drug Administration and goals identi-

fied in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012.

(2) PRIORITY REVIEW VOUCHER.—The term "priority review voucher" means a voucher issued by the Secretary to the sponsor of a rare pediatric disease product application that entitles the holder of such voucher to priority review of a single human drug application submitted under section 505(b)(1) or section 351(a) of the Public Health Service Act after the date of approval of the rare pediatric disease product application.

(3) RARE PEDIATRIC DISEASE.—The term "rare pediatric disease" means a disease that meets each of the following criteria:

(A) The disease primarily affects individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents.

(B) The disease is a rare disease or condition, within the meaning of section 526.

(4) RARE PEDIATRIC DISEASE PRODUCT APPLICATION.—The term "rare pediatric disease product application" means a human drug application, as defined in section 735(1), that—

(A) is for a drug or biological product—

(i) that is for the prevention or treatment of a rare pediatric disease;

(ii) that contains no active ingredient (including any ester or salt of the active ingredient) that has been previously approved in any other application under section 505(b)(1), 505(b)(2), or 505(j) of this Act or section 351(a) or 351(k) of the Public Health Service Act;

(B) is submitted under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act;

(C) the Secretary deems eligible for priority review;

(D) that relies on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population;

(E) that does not seek approval for an adult indication in the original rare pediatric disease product application; and

(F) is approved after the date of the enactment of the Prescription Drug User Fee Amendments of 2012.

(b) PRIORITY REVIEW VOUCHER.—

(1) IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of a rare pediatric disease product application upon approval by the Secretary of such rare pediatric disease product application.

(2) TRANSFERABILITY.—

(A) IN GENERAL.—The sponsor of a rare pediatric disease product application that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher. There is no limit on the number of times a priority review voucher may be transferred before such voucher is used.

(B) NOTIFICATION OF TRANSFER.—Each person to whom a voucher is transferred shall notify the Secretary of such change in ownership of the voucher not later than 30 days after such transfer.

(3) LIMITATION.—A sponsor of a rare pediatric disease product application may not receive a priority review voucher under this section if the rare pediatric disease product application was submitted to the Secretary prior to the date that is 90 days after the date of enactment of the Prescription Drug User Fee Amendments of 2012.

(4) NOTIFICATION.—

(A) IN GENERAL.—The sponsor of a human drug application shall notify the Secretary not later than 90 days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a legally binding commitment to pay for the user fee to be assessed in accordance with this section.

(B) TRANSFER AFTER NOTICE.—The sponsor of a human drug application that provides notification of the intent of such sponsor to use the voucher for the human drug application under subparagraph (A) may transfer the voucher after such notification is provided, if such sponsor has not yet submitted the human drug application described in the notification.

(5) TERMINATION OF AUTHORITY.—The Secretary may not award any priority review vouchers under paragraph (1) after the last day of the 1-year period that begins on the date that the Secretary awards the third rare pediatric disease priority voucher under this section.

(c) PRIORITY REVIEW USER FEE.—

(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary, based on the difference between—

(A) the average cost incurred by the Food and Drug Administration in the review of a human drug application subject to priority review in the previous fiscal year; and

(B) the average cost incurred by the Food and Drug Administration in the review of a human drug application that is not subject to priority review in the previous fiscal year.

(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2012, the amount of the priority review user fee for that fiscal year.

(4) PAYMENT.—

(A) IN GENERAL.—The priority review user fee required by this subsection shall be due upon the notification by a sponsor of the intent of such sponsor to use the voucher, as specified in subsection (b)(4)(A). All other user fees associated with the human drug application shall be due as required by the Secretary or under applicable law.

(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary's procedures for paying such fees.

(C) NO WAIVERS, EXEMPTIONS, REDUCTIONS, OR REFUNDS.—The Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

(5) OFFSETTING COLLECTIONS.—Fees collected pursuant to this subsection for any fiscal year—

(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

(B) shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.

(d) DESIGNATION PROCESS.—

(1) IN GENERAL.—Upon the request of the manufacturer or the sponsor of a new drug, the Secretary may designate—

(A) the new drug as a drug for a rare pediatric disease; and

(B) the application for the new drug as a rare pediatric disease product application.

(2) REQUEST FOR DESIGNATION.—The request for a designation under paragraph (1), shall be made at the same time a request for designation of orphan disease status under section 526 or fast-track designation under section 506 is made. Requesting designation under this subsection is not a prerequisite to receiving a priority review voucher under this section.

(3) DETERMINATION BY SECRETARY.—Not later than 60 days after a request is submitted under paragraph (1), the Secretary shall determine whether—

(A) the disease or condition that is the subject of such request is a rare pediatric disease; and

(B) the application for the new drug is a rare pediatric disease product application.

(e) MARKETING OF RARE PEDIATRIC DISEASE PRODUCTS.—

(1) IN GENERAL.—The Secretary shall deem a rare pediatric disease product application incomplete if such application does not contain a description of the plan of the sponsor of such application to market the product in the United States.

(2) REVOCATION.—The Secretary may revoke any priority review voucher awarded under subsection (b) if the rare pediatric disease product for which such voucher was awarded is not marketed in the United States within the 365 day period beginning on the date of the approval of such drug under section 505 of this Act or section 351 of the Public Health Service Act.

(3) POSTAPPROVAL PRODUCTION REPORT.—The sponsor of an approved rare pediatric disease product shall submit a report to the Secretary not later than 5 years after the approval of the applicable rare pediatric disease product application. Such report shall provide the following information, with respect to each of the first 4 years after approval of such product:

(A) The estimated population in the United States suffering from the rare pediatric disease.

(B) The estimated demand in the United States for such rare pediatric disease product.

(C) The actual amount of such rare pediatric disease product distributed in the United States.

(f) NOTICE AND REPORT.—

(1) NOTICE OF ISSUANCE OF VOUCHER AND APPROVAL OF PRODUCTS UNDER VOUCHER.—The Secretary shall publish a notice in the Federal Register and on the Web site of the Food and Drug Administration not later than 30 days after the occurrence of each of the following:

(A) The Secretary issues a priority review voucher under this section.

(B) The Secretary approves a drug pursuant to an application submitted under section 505(b) of this Act or section 351(a) of the Public Health Service Act for which the sponsor of the application used a priority review voucher under this section.

(2) REPORT.—If, after the last day of the 1-year period that begins on the date that the Secretary awards the third rare pediatric disease priority voucher under this section, a sponsor of an application submitted under section 505(b) of this Act or section 351(a) of the Public Health Service Act for a drug uses a priority review voucher under this section for such application, the Secretary shall 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 document—

(A) notifying such Committees of the use of such voucher; and

(B) identifying the drug for which such priority review voucher is used.

(g) ELIGIBILITY FOR OTHER PROGRAMS.—Nothing in this section precludes a sponsor who seeks a priority review voucher under this section from participating in any other incentive program, including under this Act.

(h) RELATION TO OTHER PROVISIONS.—The provisions of this section shall supplement, not supplant, any other provisions of this Act or the Public Health Service Act that encourage the development of drugs for tropical diseases and rare pediatric diseases.

(i) GAO STUDY AND REPORT.—

(1) STUDY.—

(A) IN GENERAL.—Beginning on the date that the Secretary awards the third rare pediatric disease priority voucher under this section, the Comptroller General of the United States shall conduct a study of the effectiveness of awarding rare pediatric disease priority vouchers under this section in the development of on human drug products that treat or prevent such diseases.

(B) CONTENTS OF STUDY.—In conducting the study under subparagraph (A), the Comptroller General shall examine the following:

(i) The indications for which each rare disease product for which a priority review voucher was awarded

was approved under section 505 or section 351 of the Public Health Service Act.

(ii) Whether, and to what extent, an unmet need related to the treatment or prevention of a rare pediatric disease was met through the approval of such a rare disease product.

(iii) The value of the priority review voucher if transferred.

(iv) Identification of each drug for which a priority review voucher was used.

(v) The length of the period of time between the date on which a priority review voucher was awarded and the date on which it was used.

(2) REPORT.—Not later than 1 year after the date under paragraph (1)(A), the Comptroller General shall 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 containing the results of the study under paragraph (1).

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SUBCHAPTER E—GENERAL PROVISIONS RELATING TO DRUGS AND DEVICES

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SEC. 566. CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.

(a) * * *

* * * * * * *

[(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.**]**

(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $6,000,000 for each of fiscal years 2013 through 2017.

* * * * * * *

SEC. 568 NOTIFICATION.

(a) NOTIFICATION TO SECRETARY.—With respect to a drug, the Secretary may require notification to the Secretary by a regulated person if the regulated person knows—

(1) that the use of such drug in the United States may result in serious injury or death;

(2) of a significant loss or known theft of such drug intended for use in the United States; or

(3) that—

(A) such drug has been or is being counterfeited; and

(B)(i) the counterfeit product is in commerce in the United States or could be reasonably expected to be introduced into commerce; or

(ii) such drug has been or is being imported into the United States or may reasonably be expected to be offered for import into the United States.

(b) MANNER OF NOTIFICATION.—Notification under this section shall be made in such manner and by such means as the Secretary may specify by regulation or guidance.

(c) SAVINGS CLAUSE.—Nothing in this section shall be construed as limiting any other authority of the Secretary to require notifications related to a drug under any other provision of this Act or the Public Health Service Act.

(d) DEFINITION.—In this section, the term "regulated person" means—

(1) a person who is required to register under section 510 or 801(s);

(2) a wholesale distributor of a drug product; or

(3) any other person that distributes drugs except a person that distributes drugs exclusively for retail sale.

SEC. 568. CONSULTATION WITH EXTERNAL EXPERTS ON RARE DISEASES, TARGETED THERAPIES, AND GENETIC TARGETING OF TREATMENTS.

(a) IN GENERAL.—For the purpose of promoting the efficiency of and informing the review by the Food and Drug Administration of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted, the following shall apply:

(1) CONSULTATION WITH STAKEHOLDERS.—Consistent with sections X.C and IX.E.4 of the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017, as referenced in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012, the Secretary shall ensure that opportunities exist, at a time the Secretary determines appropriate, for consultations with stakeholders on the topics described in subsection (b).

(2) CONSULTATION WITH EXTERNAL EXPERTS.—

(A) IN GENERAL.—The Secretary shall develop and maintain a list of external experts who, because of their special expertise, are qualified to provide advice on rare disease issues, including topics described in subsection (c). The Secretary may, when appropriate to address a specific regulatory question, consult such external experts on issues related to the review of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted, including the topics described in subsection (b), when such consultation is necessary because the Secretary lacks the specific scientific, medical, or technical expertise necessary for the performance of the Secretary's regulatory responsibilities and the necessary expertise can be provided by the external experts.

(B) EXTERNAL EXPERTS.—For purposes of subparagraph (A), external experts are individuals who possess scientific or medical training that the Secretary lacks with respect to one or more rare diseases.

(b) TOPICS FOR CONSULTATION.—Topics for consultation pursuant to this section may include—

(1) rare diseases;

(2) the severity of rare diseases;

(3) the unmet medical need associated with rare diseases;

(4) the willingness and ability of individuals with a rare disease to participate in clinical trials;

(5) an assessment of the benefits and risks of therapies to treat rare diseases;

(6) the general design of clinical trials for rare disease populations and subpopulations; and

(7) the demographics and the clinical description of patient populations.

(c) CLASSIFICATION AS SPECIAL GOVERNMENT EMPLOYEES.—The external experts who are consulted under this section may be considered special government employees, as defined under section 202 of title 18, United States Code.

(d) PROTECTION OF CONFIDENTIAL INFORMATION AND TRADE SECRETS.—

(1) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to alter the protections offered by laws, regulations, and policies governing disclosure of confidential commercial or trade secret information, and any other information exempt from disclosure pursuant to section 552(b) of title 5, United States Code, as such provisions would be applied to consultation with individuals and organizations prior to the date of enactment of this section.

(2) CONSENT REQUIRED FOR DISCLOSURE.—The Secretary shall not disclose confidential commercial or trade secret information to an expert consulted under this section without the written consent of the sponsor unless the expert is a special government employee (as defined under section 202 of title 18, United States Code) or the disclosure is otherwise authorized by law.

(e) OTHER CONSULTATION.—Nothing in this section shall be construed to limit the ability of the Secretary to consult with individuals and organizations as authorized prior to the date of enactment of this section.

(f) NO RIGHT OR OBLIGATION.—

(1) NO RIGHT TO CONSULTATION.—Nothing in this section shall be construed to create a legal right for a consultation on any matter or require the Secretary to meet with any particular expert or stakeholder.

(2) NO ALTERING OF GOALS.—Nothing in this section shall be construed to alter agreed upon goals and procedures identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012.

(3) NO CHANGE TO NUMBER OF REVIEW CYCLES.—Nothing in this section is intended to increase the number of review cycles as in effect before the date of enactment of this section.

(g) NO DELAY IN PRODUCT REVIEW.—Prior to a consultation with an external expert, as described in this section, relating to an investigational new drug application under section 505(i), a new drug application under section 505(b), or a biologics license application under section 351 of the Public Health Service Act, the Director of the Center for Drug Evaluation and Research or the Director of the Center for Biologics Evaluation and Research (or appropriate Division Director), as appropriate, shall determine that—

(1) such consultation will—

(A) facilitate the Secretary's ability to complete the Secretary's review;

(B) address outstanding deficiencies in the application; and

(C) increase the likelihood of an approval decision in the current review cycle; or

(2) the sponsor authorized such consultation.

* * * * * * *

Subchapter G—Medical Gases

SEC. 575. DEFINITIONS.

In this subchapter:

(1) The term "designated medical gas" means any of the following:

(A) Oxygen that meets the standards set forth in an official compendium.

(B) Nitrogen that meets the standards set forth in an official compendium.

(C) Nitrous oxide that meets the standards set forth in an official compendium.

(D) Carbon dioxide that meets the standards set forth in an official compendium.

(E) Helium that meets the standards set forth in an official compendium.

(F) Carbon monoxide that meets the standards set forth in an official compendium.

(G) Medical air that meets the standards set forth in an official compendium.

(H) Any other medical gas deemed appropriate by the Secretary, after taking into account any investigational new drug application or investigational new animal drug application for the same medical gas submitted in accordance with regulations applicable to such applications in title 21 of the Code of Federal Regulations, unless any period of exclusivity under section 505(c)(3)(E)(ii) or section 505(j)(5)(F)(ii), or the extension of any such period under section 505A, applicable to such medical gas has not expired.

(2) The term "medical gas" means a drug that—

(A) is manufactured or stored in a liquefied, nonliquefied, or cryogenic state; and

(B) is administered as a gas.

SEC. 576. REGULATION OF MEDICAL GASES.

(a) CERTIFICATION OF DESIGNATED MEDICAL GASES.—

(1) SUBMISSION.—Beginning 180 days after the date of enactment of this section, any person may file with the Secretary a request for certification of a medical gas as a designated medical gas. Any such request shall contain the following information:

(A) A description of the medical gas.

(B) The name and address of the sponsor.

(C) The name and address of the facility or facilities where the medical gas is or will be manufactured.

(D) Any other information deemed appropriate by the Secretary to determine whether the medical gas is a designated medical gas.

(2) GRANT OF CERTIFICATION.—The certification requested under paragraph (1) is deemed to be granted unless, within 60 days of the filing of such request, the Secretary finds that—

(A) the medical gas subject to the certification is not a designated medical gas;

(B) the request does not contain the information required under paragraph (1) or otherwise lacks sufficient information to permit the Secretary to determine that the medical gas is a designated medical gas; or

(C) denying the request is necessary to protect the public health.

(3) EFFECT OF CERTIFICATION.—

(A) IN GENERAL.—

(i) APPROVED USES.—A designated medical gas for which a certification is granted under paragraph (2) is deemed, alone or in combination, as medically appropriate, with another designated medical gas or gases for which a certification or certifications have been granted, to have in effect an approved application under section 505 or 512, subject to all applicable post-approval requirements, for the following indications for use:

(I) In the case of oxygen, the treatment or prevention of hypoxemia or hypoxia.

(II) In the case of nitrogen, use in hypoxic challenge testing.

(III) In the case of nitrous oxide, analgesia.

(IV) In the case of carbon dioxide, use in extracorporeal membrane oxygenation therapy or respiratory stimulation.

(V) In the case of helium, the treatment of upper airway obstruction or increased airway resistance.

(VI) In the case of medical air, to reduce the risk of hyperoxia.

(VII) In the case of carbon monoxide, use in lung diffusion testing.

(VIII) Any other indication for use for a designated medical gas or combination of designated medical gases deemed appropriate by the Secretary, unless any period of exclusivity under clause (iii) or (iv) of section 505(c)(3)(E), clause (iii) or (iv) of section 505(j)(5)(F), or section 527, or the extension of any such period under section 505A, applicable to such indication for use for such gas or combination of gases has not expired.

(ii) LABELING.—The requirements of sections 503(b)(4) and 502(f) are deemed to have been met for a designated medical gas if the labeling on final use container for such medical gas bears—

(I) the information required by section 503(b)(4);

(II) a warning statement concerning the use of the medical gas as determined by the Secretary by regulation; and

(III) appropriate directions and warnings concerning storage and handling.

(B) INAPPLICABILITY OF EXCLUSIVITY PROVISIONS.—

(i) NO EXCLUSIVITY FOR A CERTIFIED MEDICAL GAS.—No designated medical gas deemed under subparagraph (A)(i) to have in effect an approved application is eligible for any period of exclusivity under section 505(c), 505(j), or 527, or the extension of any such period under section 505A, on the basis of such deemed approval.

(ii) EFFECT ON CERTIFICATION.—No period of exclusivity under section 505(c), 505(j), or section 527, or the extension of any such period under section 505A, with respect to an application for a drug product shall prohibit, limit, or otherwise affect the submission, grant, or effect of a certification under this section, except as provided in subsection (a)(3)(A)(i)(VIII) and section 575(1)(H).

(4) WITHDRAWAL, SUSPENSION, OR REVOCATION OF APPROVAL.—

(A) WITHDRAWAL, SUSPENSION OF APPROVAL.—Nothing in this subchapter limits the Secretary's authority to withdraw or suspend approval of a drug product, including a designated medical gas deemed under this section to have in effect an approved application under section 505 or section 512 of this Act.

(B) REVOCATION OF CERTIFICATION.—The Secretary may revoke the grant of a certification under paragraph (2) if the Secretary determines that the request for certification contains any material omission or falsification.

(b) PRESCRIPTION REQUIREMENT.—

(1) IN GENERAL.—A designated medical gas shall be subject to the requirements of section 503(b)(1) unless the Secretary exercises the authority provided in section 503(b)(3) to remove such medical gas from the requirements of section 503(b)(1), the gas is approved for use without a prescription pursuant to an application under section 505 or 512, or the use in question is authorized pursuant to another provision of this Act relating to use of medical products in emergencies.

(2) OXYGEN.—

(A) NO PRESCRIPTION REQUIRED FOR CERTAIN USES.—Notwithstanding paragraph (1), oxygen may be provided without a prescription for the following uses:

(i) For use in the event of depressurization or other environmental oxygen deficiency.

(ii) For oxygen deficiency or for use in emergency resuscitation, when administered by properly trained personnel.

(B) LABELING.—For oxygen provided pursuant to subparagraph (A), the requirements of section 503(b)(4) shall be deemed to have been met if its labeling bears a warning

that the oxygen can be used for emergency use only and for all other medical applications a prescription is required.

SEC. 577. INAPPLICABILITY OF DRUG FEES TO DESIGNATED MEDICAL GASES.

A designated medical gas, alone or in combination with another designated gas or gases (as medically appropriate) deemed under section 576 to have in effect an approved application shall not be assessed fees under section 736(a) on the basis of such deemed approval.

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CHAPTER VII—GENERAL AUTHORITY

SUBCHAPTER A—GENERAL ADMINISTRATIVE PROVISIONS

REGULATIONS AND HEARINGS

SEC. 701. (a) * * *

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(h)(1)(A) * * *

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[(C) For guidance documents that set forth initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues, the Secretary shall ensure public participation prior to implementation of guidance documents, unless the Secretary determines that such prior public participation is not feasible or appropriate. In such cases, the Secretary shall provide for public comment upon implementation and take such comment into account.**]**

(C) For any guidance document that sets forth initial interpretations of a statute or regulation, sets forth changes in interpretation or policy that are of more than a minor nature, includes complex scientific issues, or covers highly controversial issues—

(i) the Secretary—

(I) at least 30 days before issuance of a draft of such guidance document, shall publish notice in the Federal Register of the Secretary's intent to prepare such guidance document; and

(II) during preparation and before issuance of such guidance document, may meet with interested stakeholders, including industry, medical, and scientific experts and others, and solicit public comment;

(ii) if the Secretary for good cause finds that, with respect to such guidance document, compliance with clause (i) is impracticable, unnecessary, or contrary to the public interest—

(I) the Secretary shall publish such finding and a brief statement of the reasons for such finding in the Federal Register;

(II) clause (i) shall not apply with respect to such guidance document; and

(III) during a 90-day period beginning not later than the date of issuance of the draft of such guidance document, the Secretary may meet with interested stakeholders, including industry, medical, and scientific experts and others, and shall solicit public comment;

(iii) beginning on the date of enactment of the Food and Drug Administration Reform Act of 2012, upon issuance of a draft guidance document under clause (i) or (ii), the Secretary shall—

(I) designate the document as draft or final; and

(II) not later than 18 months after the close of the comment period for such guidance, issue a final version of such guidance document in accordance with clauses (i) and (ii);

(iv) the Secretary may extend the deadline for issuing final guidance under clause (iii)(II) by not more than 180 days upon submission by the Secretary of a notification of such extension in the Federal Register;

(v) if the Secretary issues a draft guidance document and fails to finalize the draft by the deadline determined under clause (iii)(II), as extended under clause (iv), the Secretary shall, beginning on the date of such deadline, treat the draft as null and void; and

(vi) not less than every 5 years after the issuance of a final guidance document in accordance with clause (iii), the Secretary shall—

(I) conduct a retrospective analysis of such guidance document to ensure it is not outmoded, ineffective, insufficient, or excessively burdensome; and

(II) based on such analysis, modify, streamline, expand, or repeal the guidance document in accordance with what has been learned.

(D) With respect to devices, a notice to industry guidance letter, a notice to industry advisory letter, and any similar notice that sets forth initial interpretations of a statute or regulation or sets forth changes in interpretation or policy shall be treated as a guidance document for purposes of subparagraph (C).

(E) The following shall not be treated as a guidance document for purposes of subparagraph (C):

(i) Any document that does not set forth an initial interpretation or a reinterpretation of a statute or regulation.

(ii) Any document that sets forth or changes a policy relating to internal procedures of the Food and Drug Administration.

(iii) Agency reports, general information documents provided to consumers or health professionals, speeches, journal articles and editorials, media interviews, press materials, warning letters, memoranda of understanding, or communications directed to individual persons or firms.

* * * * * * *

FACTORY INSPECTION

SEC. 704. (a)(1) * * *

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(4)(A) Any records or other information that the Secretary may inspect under this section from a person that owns or operates an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug shall, upon the request of the Secretary, be provided to the Secretary by such person, in advance of or in lieu of an inspection, within a reasonable timeframe, within reasonable limits, and in a reasonable manner, and in either electronic or physical form, at the expense of such person. The Secretary's request shall include a sufficient description of the records requested.

(B) Upon receipt of the records requested under subparagraph (A), the Secretary shall provide to the person confirmation of receipt.

(C) Nothing in this paragraph supplants the authority of the Secretary to conduct inspections otherwise permitted under this Act in order to ensure compliance with this Act.

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(g)(1) * * *

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(11) The authority provided by this subsection terminates on [October 1, 2012] *October 1, 2017*.

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CONFIDENTIAL INFORMATION

SEC. 708. [The Secretary may provide] *(a) CONTRACTORS.—The Secretary may provide* any information which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section to a person other than an officer or employee of the Department if the Secretary determines such other person requires the information in connection with an activity which is undertaken under contract with the Secretary, which relates to the administration of this Act, and with respect to which the Secretary (or an officer or employee of the Department) is not prohibited from using such information. The Secretary shall require as a condition to the provision of information under this section that the person receiving it take such security precautions respecting the information as the Secretary may by regulation prescribe.

(b) ABILITY TO RECEIVE AND PROTECT CONFIDENTIAL INFORMATION.—Except pursuant to an order of a court of the United States, the Secretary shall not be required to disclose under section 552 of title 5, United States Code, or any other provision of law, any information relating to drugs obtained from a Federal, State, or local government agency, or from a foreign government agency, if the agency has requested that the information be kept confidential. For purposes of section 552 of title 5, United States Code, this subsection shall be considered a statute described in section 552(b)(3)(B).

(c) AUTHORITY TO ENTER INTO MEMORANDA OF UNDERSTANDING FOR PURPOSES OF INFORMATION EXCHANGE.—The Secretary may

enter into written agreements regarding the exchange of information referenced in section 301(j) subject to the following criteria:

(1) CERTIFICATION.—The Secretary may only enter into written agreements under this subsection with foreign governments that the Secretary has certified as having the authority and demonstrated ability to protect trade secret information from disclosure. Responsibility for this certification shall not be delegated to any officer or employee other than the Commissioner of Food and Drugs.

(2) WRITTEN AGREEMENT.—The written agreement under this subsection shall include a commitment by the foreign government to protect information exchanged under this subsection from disclosure unless and until the sponsor gives written permission for disclosure or the Secretary makes a declaration of a public health emergency pursuant to section 319 of the Public Health Service Act that is relevant to the information.

(3) INFORMATION EXCHANGE.—The Secretary may provide to a foreign government that has been certified under paragraph (1), and that has executed a written agreement under paragraph (2), information referenced in section 301(j) in the following circumstances:

(A) Information concerning the inspection of a facility may be provided if—

(i) the Secretary reasonably believes, or the written agreement described in paragraph (2) establishes, that the government has authority to otherwise obtain such information; and

(ii) the written agreement executed under paragraph (2) limits the recipient's use of the information to the recipient's civil regulatory purposes.

(B) Information not described in subparagraph (A) may be provided as part of an investigation, or to alert the foreign government to the potential need for an investigation, if the Secretary has reasonable grounds to believe that a drug has a reasonable probability of causing serious adverse health consequences or death.

(d) NO LIMITATION ON AUTHORITY.—This section shall not affect the authority of the Secretary to provide or disclose information under any other provision of law.

* * * * * * *

SEC. 712. CONFLICTS OF INTEREST.

(a) * * *

[(b) APPOINTMENTS TO ADVISORY COMMITTEES.—

[(1) RECRUITMENT.—

[(A) IN GENERAL.—The Secretary shall—

[(i) 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;

[(ii) seek input from professional medical and scientific societies to determine the most effective informational and recruitment activities; and

[(iii) 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)(2) of this section for service on the committee at a meeting of the committee.

[(c) DISCLOSURES; PROHIBITIONS ON PARTICIPATION; WAIVERS.—

[(1) DISCLOSURE OF FINANCIAL INTEREST.—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) PROHIBITIONS AND WAIVERS ON PARTICIPATION.—

[(A) IN GENERAL.—Except as provided under subparagraph (B), a member of an advisory committee may not participate with respect to a particular matter considered in an advisory committee meeting 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.

[(B) WAIVER.—If the Secretary determines it necessary to afford the advisory committee essential expertise, the Secretary may grant a waiver of the prohibition in sub-

paragraph (A) to permit a member described in such subparagraph to—

[(i) participate as a non-voting member with respect to a particular matter considered in a committee meeting; or

[(ii) participate as a voting member with respect to a particular matter considered in a committee meeting.

[(C) LIMITATION ON WAIVERS AND OTHER EXCEPTIONS.—

[(i) DEFINITION.—For purposes of this subparagraph, the term "exception" means each of the following with respect to members of advisory committees:

[(I) A waiver under section 505(n)(4) (as in effect on the day before the date of the enactment of the Food and Drug Administration Amendments Act of 2007).

[(II) A written determination under section 208(b) of title 18, United States Code.

[(III) A written certification under section 208(b)(3) of such title.

[(ii) DETERMINATION OF TOTAL NUMBER OF MEMBERS SLOTS AND MEMBER EXCEPTIONS DURING FISCAL YEAR 2007.—The Secretary shall determine—

[(I)(aa) for each meeting held by any advisory committee during fiscal year 2007, the number of members who participated in the meeting; and

[(bb) the sum of the respective numbers determined under item (aa) (referred to in this subparagraph as the "total number of 2007 meeting slots"); and

[(II)(aa) for each meeting held by any advisory committee during fiscal year 2007, the number of members who received an exception for the meeting; and

[(bb) the sum of the respective numbers determined under item (aa) (referred to in this subparagraph as the "total number of 2007 meeting exceptions").

[(iii) DETERMINATION OF PERCENTAGE REGARDING EXCEPTIONS DURING FISCAL YEAR 2007.—The Secretary shall determine the percentage constituted by—

[(I) the total number of 2007 meeting exceptions; divided by

[(II) the total number of 2007 meeting slots.

[(iv) LIMITATION FOR FISCAL YEARS 2008 THROUGH 2012.—The number of exceptions at the Food and Drug Administration for members of advisory committees for a fiscal year may not exceed the following:

[(I) For fiscal year 2008, 95 percent of the percentage determined under clause (iii) (referred to in this clause as the "base percentage").

[(II) For fiscal year 2009, 90 percent of the base percentage.

[(III) For fiscal year 2010, 85 percent of the base percentage.

[(IV) For fiscal year 2011, 80 percent of the base percentage.

[(V) For fiscal year 2012, 75 percent of the base percentage.

[(v) ALLOCATION OF EXCEPTIONS.—The exceptions authorized under clause (iv) for a fiscal year may be allocated within the centers or other organizational units of the Food and Drug Administration as determined appropriate by the Secretary.

[(3) 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 (except as provided in subparagraph (B)) not 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 (2)(B) 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 Web site 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 (2)(B) 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 Web site 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.]

(b) RECRUITMENT FOR ADVISORY COMMITTEES.—

(1) IN GENERAL.—The Secretary shall—

(A) develop and implement strategies on effective outreach to potential members of advisory committees at universities, colleges, other academic research centers, profes-

sional and medical societies, and patient and consumer groups;

(B) seek input from professional medical and scientific societies to determine the most effective informational and recruitment activities;

(C) at least every 180 days, request referrals for potential members of advisory committees from a variety of stakeholders, including—

(i) product developers, patient groups, and disease advocacy organizations; and

(ii) relevant—

(I) professional societies;

(II) medical societies;

(III) academic organizations; and

(IV) governmental organizations; and

(D) in carrying out subparagraphs (A) and (B), take into account the levels of activity (including the numbers of annual meetings) and the numbers of vacancies of the advisory committees.

(2) RECRUITMENT ACTIVITIES.—The recruitment activities under paragraph (1) may include—

(A) advertising the process for becoming an advisory committee member at medical and scientific society conferences;

(B) 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

(C) 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 whom the Food and Drug Administration can contact regarding the nomination of individuals to serve on advisory committees.

(3) EXPERTISE.—In carrying out this subsection, the Secretary shall seek to ensure that the Secretary has access to the most current expert advice.

(c) DISCLOSURE OF DETERMINATIONS AND CERTIFICATIONS.—Notwithstanding section 107(a)(2) of the Ethics in Government Act of 1978, the following shall apply:

(1) 15 OR MORE DAYS IN ADVANCE.—As soon as practicable, but (except as provided in paragraph (2)) not 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, or a written certification as referred to in section 208(b)(3) of such title, applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 or 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—

(A) the type, nature, and magnitude of the financial interests of the advisory committee member to which such determination or certification applies; and

(B) the reasons of the Secretary for such determination or certification, including, as appropriate, the public health interest in having the expertise of the member with respect to the particular matter before the advisory committee.

(2) 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, or a written certification as referred to in section 208(b)(3) of such title applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 or 552a of title 5, United States Code) on the Internet Website of the Food and Drug Administration, the information described in subparagraphs (A), (B), and (C) of paragraph (1) as soon as practicable after the Secretary makes such determination or certification, 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)(3)⟧ *subsection (c)* (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)(3) 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)(3) 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.⟧

(e) ANNUAL REPORT.—

(1) IN GENERAL.—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—

(A) with respect to the fiscal year that ended on September 30 of the previous year, the number of persons nominated for participation at meetings for each advisory committee, the number of persons so nominated, and willing to serve, the number of vacancies on each advisory committee, and the number of persons contacted for service as members on each advisory committee meeting for each advisory committee who did not participate because of the potential for such participation to constitute a disqualifying financial interest under section 208 of title 18, United States Code;

(B) with respect to such year, the number of persons contacted for services as members for each advisory committee meeting for each advisory committee who did not participate because of reasons other than the potential for such participation to constitute a disqualifying financial interest under section 208 of title 18, United States Code;

(C) with respect to such year, the number of members attending meetings for each advisory committee; and

(D) with respect to such year, the aggregate number of disclosures required under subsection (d) and the percentage of individuals to whom such disclosures did not apply who served on such committee.

(2) PUBLIC AVAILABILITY.—Not later than 30 days after submitting any report under paragraph (1) to the committees specified in such paragraph, the Secretary shall make each such report available to the public.

(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.⟧ *shall—*

(1) review guidance of the Food and Drug Administration with respect to advisory committees regarding disclosure of conflicts of interest and the application of section 208 of title 18, United States Code; and

(2) update such guidance as necessary to ensure that the Food and Drug Administration receives appropriate access to needed scientific expertise, with due consideration of the requirements of such section 208.

* * * * * * *

SEC. 714. STREAMLINED HIRING AUTHORITY.

(a) IN GENERAL.—In addition to any other personnel authorities under other provisions of law, the Secretary may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, appoint employees to positions in the Food and Drug Administration to perform, administer, or support activities described in subsection (b), if the Secretary determines that such appointments are needed to achieve the objectives specified in subsection (c).

(b) ACTIVITIES DESCRIBED.—The activities described in this subsection are—

(1) activities under this Act related to the process for the review of device applications (as defined in section 737(8)); and

(2) activities under this Act related to human generic drug activities (as defined in section 744A).

(c) OBJECTIVES SPECIFIED.—The objectives specified in this subsection are—

(1) with respect to the activities under subsection (b)(1), the goals referred to in section 738A(a)(1); and

(2) with respect to the activities under subsection (b)(2), the goals referred to in section 744C(a).

(d) INTERNAL CONTROLS.—The Secretary shall institute appropriate internal controls for appointments under this section.

(e) SUNSET.—The authority to appoint employees under this section shall terminate on the date that is three years after the date of enactment of this section.

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SUBCHAPTER C—FEES

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PART 2—FEES RELATING TO DRUGS

SEC. 735. DEFINITIONS.

For purposes of this part:

(1) The term "human drug application" means an application for—

(A) * * *

(B) licensure of a biological product under subsection (a) [or (k)] of section 351 of the Public Health Service Act.

* * * * * * *

(7) The term "costs of resources allocated for the process for the review of human drug applications" means the [expenses incurred in connection with] *expenses in connection with* the process for the review of human drug applications for—

(A) * * *

* * * * * * *

SEC. 736. AUTHORITY TO ASSESS AND USE DRUG FEES.

(a) TYPES OF FEES.—Beginning in [fiscal year 2008] *fiscal year 2013*, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) HUMAN DRUG APPLICATION AND SUPPLEMENT FEE.—

(A) IN GENERAL.—Each person that submits, on or after September 1, 1992, a human drug application or a supplement shall be subject to a fee as follows:

(i) A fee established under subsection [(c)(5)] *(c)(4)* for a human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required for approval.

(ii) A fee established under subsection [(c)(5)] *(c)(4)* for a human drug application for which clinical data with respect to safety or effectiveness are not required or a supplement for which clinical data (other than bioavailability or bioequivalence studies) with respect

to safety or effectiveness are required. Such fee shall be half of the amount of the fee established under clause (i).

* * * * * * *

(2) PRESCRIPTION DRUG ESTABLISHMENT FEE.—

(A) IN GENERAL.—Except as provided in subparagraphs (B) and (C), each person that—

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

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

shall be assessed an annual fee established under subsection [(c)(5)] *(c)(4)* for each prescription drug establishment listed in its approved human drug application as an establishment that manufactures the prescription drug product named in the application. The annual establishment fee shall be assessed in each fiscal year in which the prescription drug product named in the application is assessed a fee under paragraph (3) unless the prescription drug establishment listed in the application does not engage in the manufacture of the prescription drug product during the fiscal year. The establishment fee shall be [payable on or before October 1 of each year] *due on the later of the first business day on or after October 1 of such fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section*. Each such establishment shall be assessed only one fee per establishment, notwithstanding the number of prescription drug products manufactured at the establishment. In the event an establishment is listed in a human drug application by more than one applicant, the establishment fee for the fiscal year shall be divided equally and assessed among the applicants whose prescription drug products are manufactured by the establishment during the fiscal year and assessed product fees under paragraph (3).

* * * * * * *

(3) PRESCRIPTION DRUG PRODUCT FEE.—

(A) IN GENERAL.—Except as provided in subparagraph (B), each person who is named as the applicant in a human drug application, and who, after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall pay for each such prescription drug product the annual fee established under [subsection (c)(5)] *subsection (c)(4)*. Such fee shall be [payable on or before October 1 of each year.] *due on the later of the first business day on or after October 1 of each such fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for each such fiscal year under this section.* Such fee shall be paid only once for each product for a fiscal year in which the fee is payable.

[(B) EXCEPTION.—A prescription drug product shall not be assessed a fee under subparagraph (A) if such product

is identified on the list compiled under section 505(j)(7)(A) with a potency described in terms of per 100 mL, or if such product is the same product as another product approved under an application filed under section 505(b) or 505(j), under an abbreviated application filed under section 507 (as in effect on the day before the date of enactment of the Food and Drug Administration Modernization Act of 1997), or under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984.]

(B) EXCEPTION.—A prescription drug product shall not be assessed a fee under subparagraph (A) if such product is—

(i) identified on the list compiled under section 505(j)(7)(A) with a potency described in terms of per 100 mL;

(ii) the same product as another product that—

(I) was approved under an application filed under section 505(b) or 505(j); and

(II) is not in the list of discontinued products compiled under section 505(j)(7)(A);

(iii) the same product as another product that was approved under an abbreviated application filed under section 507 (as in effect on the day before the date of enactment of the Food and Drug Administration Modernization Act of 1997); or

(iv) the same product as another product that was approved under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984.

(b) FEE REVENUE AMOUNTS.—

(1) IN GENERAL.—For each of the [fiscal years 2008 through 2012] *fiscal years 2013 through 2017*, 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] *$693,099,000;*

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

(B) the dollar amount equal to the inflation adjustment for fiscal year 2013 (as determined under paragraph (3)(A)); and

(C) the dollar amount equal to the workload adjustment for fiscal year 2013 (as determined under paragraph (3)(B)).

* * * * * * *

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

[(II) for fiscal year 2009, $35,000,000;

[(III) for fiscal year 2010, $45,000,000;

[(IV) for fiscal year 2011, $55,000,000; and

[(V) for fiscal year 2012, $65,000,000.

[(c) ADJUSTMENTS.—

[(1) INFLATION ADJUSTMENT.—For fiscal year 2009 and subsequent fiscal years, 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 years of the preceding 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.—For fiscal year 2009 and subsequent fiscal years, 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 for the process for the review of human drug applications. With respect to such adjustment:

[(A) The adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of human drug applications (adjusted for changes in review activities, as described in the notice that the Secretary is required to publish in the Federal Reg-

ister under this subparagraph), efficacy supplements, and manufacturing supplements submitted to the Secretary, 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. 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 for the fiscal year established in subsection (b), as adjusted for inflation under paragraph (1). 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.

[(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.—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.—

[(A) INCREASE IN FEES.—For fiscal year 2012, the Secretary may, in addition to adjustments under this paragraph and paragraphs (1), (2), and (3), further increase the fee revenues and fees established in subsection (b) if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for the process for the review of human drug applications for the first 3 months of fiscal year 2013. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2012. If the Secretary has carryover balances for such process in excess of 3 months of such operating reserves, the adjustment under this subparagraph shall not be made.

[(B) DECREASE IN FEES.—

[(i) IN GENERAL.—For fiscal year 2012, the Secretary may, in addition to adjustments under this paragraph and paragraphs (1), (2), and (3), decrease the fee revenues and fees established in subsection (b) by the amount determined in clause (ii), if, for fiscal year 2009 or 2010—

[(I) the amount of the total appropriations 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 appropriations for the Food and Drug Administration for fiscal year 2008 (excluding the amount of fees appropriated for such fiscal year), adjusted as provided under paragraph (1); and

[(II) the amount of the total appropriations expended for the process for the review of human drug applications 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 expended for the process for the review of human drug applications at the Food and Drug Administration for fiscal year 2008 (excluding the amount of fees appropriated for such fiscal year), adjusted as provided under paragraph (1).

[(ii) AMOUNT OF DECREASE.—The amount determined in this clause is the lesser of—

[(I) the amount equal to the sum of the amounts that, for each of fiscal years 2009 and 2010, is the lesser of—

[(aa) the excess amount described in clause (i)(II) for such fiscal year; or

[(bb) the amount specified in subsection (b)(4)(B)(ii) for such fiscal year; or

[(II) $65,000,000.

[(iii) LIMITATIONS.—

[(I) FISCAL YEAR CONDITION.—In making the determination under clause (ii), an amount described in subclause (I) of such clause for fiscal year 2009 or 2010 shall be taken into account only if subclauses (I) and (II) of clause (i) apply to such fiscal year.

[(II) RELATION TO SUBPARAGRAPH (A).—The Secretary shall limit any decrease under this paragraph if such a limitation is necessary to provide for the 3 months of operating reserves described in subparagraph (A).

[(5) ANNUAL FEE SETTING.—The Secretary shall, 60 days before the start of each fiscal year that begins after September 30, 2007, establish, for the next fiscal year, application, product, and establishment fees under subsection (a), based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection.

[(6) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of human drug applications.]

(3) FISCAL YEAR 2013 INFLATION AND WORKLOAD ADJUSTMENTS.—For purposes of paragraph (1), the dollar amount of the inflation and workload adjustments for fiscal year 2013 shall be determined as follows:

(A) INFLATION ADJUSTMENT.—The inflation adjustment for fiscal year 2013 shall be the sum of—

(i) $652,709,000 multiplied by the result of an inflation adjustment calculation determined using the methodology described in subsection (c)(1)(B); and

(ii) $652,709,000 multiplied by the result of an inflation adjustment calculation determined using the methodology described in subsection (c)(1)(C).

(B) WORKLOAD ADJUSTMENT.—Subject to subparagraph (C), the workload adjustment for fiscal 2013 shall be—

(i) $652,709,000 plus the amount of the inflation adjustment calculated under subparagraph (A); multiplied by

(ii) the amount (if any) by which a percentage workload adjustment for fiscal year 2013, as determined using the methodology described in subsection (c)(2)(A), would exceed the percentage workload adjustment (as so determined) for fiscal year 2012, if both such adjustment percentages were calculated using the 5-year base period consisting of fiscal years 2003 through 2007.

(C) LIMITATION.—Under no circumstances shall the adjustment under subparagraph (B) result in fee revenues for fiscal year 2013 that are less than the sum of the amount under paragraph (1)(A) and the amount under paragraph (1)(B).

(c) ADJUSTMENTS.—

(1) INFLATION ADJUSTMENT.—For fiscal year 2014 and subsequent fiscal years, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year by the amount equal to the sum of—

(A) one;

(B) the average annual percent 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 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 735(6)) for the first 3 years of the preceding 4 fiscal years, and

(C) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and

benefits costs to total costs of the process for the review of human drug applications (as defined in section 735(6)) for the first 3 years of the preceding 4 fiscal years.

The adjustment made each fiscal year under this paragraph shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2013 under this paragraph.

(2) WORKLOAD ADJUSTMENT.—For fiscal year 2014 and subsequent fiscal years, 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 for the process for the review of human drug applications. With respect to such adjustment:

(A) The adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of 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), efficacy supplements, and manufacturing supplements submitted to the Secretary, 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. 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 sum of the amount under subsection (b)(1)(A) and the amount under subsection (b)(1)(B), as adjusted for inflation under paragraph (1).

(C) The Secretary shall contract with an independent accounting or consulting firm to periodically review the adequacy of the adjustment and publish the results of those reviews. The first review shall be conducted and published by the end of fiscal year 2013 (to examine the performance of the adjustment since fiscal year 2009), and the second review shall be conducted and published by the end of fiscal year 2015 (to examine the continued performance of the adjustment). The reports shall evaluate whether the adjustment reasonably represents actual changes in workload volume and complexity and present options to discontinue, retain, or modify any elements of the adjustment. The reports shall be published for public comment. After review of the reports and receipt of public comments, the Secretary shall, if warranted, adopt appropriate changes to the methodology. If the Secretary adopts changes to the methodology based on the first report, the changes shall be effective for the first fiscal year for which fees are set after the Secretary adopts such changes and each subsequent fiscal year.

(3) FINAL YEAR ADJUSTMENT.—For fiscal year 2017, the Secretary may, in addition to adjustments under this paragraph and paragraphs (1) and (2), further increase the fee revenues

and fees established in subsection (b) if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for the process for the review of human drug applications for the first 3 months of fiscal year 2018. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2017. If the Secretary has carryover balances for such process in excess of 3 months of such operating reserves, the adjustment under this subparagraph shall not be made.

(4) ANNUAL FEE SETTING.—The Secretary shall, not later than 60 days before the start of each fiscal year that begins after September 30, 2012, establish, for the next fiscal year, application, product, and establishment fees under subsection (a), based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection.

(5) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of human drug applications.

* * * * * * *

(g) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—[Fees authorized] *Subject to paragraph (2)(C), fees authorized* under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of human drug applications.

(2) COLLECTIONS AND APPROPRIATION ACTS.—

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

(i) [shall be retained] *shall be collected and available* 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 only be collected and available] *shall be available* to defray increases in the costs of the resources allocated for the process for the review of human drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997 multiplied by the adjustment factor.

* * * * * * *

(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in

accordance with authority provided in advance in a prior year appropriations Act.

(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the [fiscal years 2008 through 2012] *fiscal years 2013 through 2017*, 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.

(4) OFFSET.—If the sum of the cumulative amount of fees collected under this section for the [fiscal years 2008 through 2010] *fiscal years 2013 through 2015* and the amount of fees estimated to be collected under this section for [fiscal year 2011] *fiscal year 2016* 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] *fiscal year 2017*.

* * * * * * *

[Effective October 1, 2017, section 105(a) of H.R. 5651 provides for a repeal of sections 735 and 736 (as amended by the bill).]

[SEC. 735. DEFINITIONS.

[For purposes of this part:

[(1) The term "human drug application" means an application for—

[(A) approval of a new drug submitted under section 505(b), or

[(B) licensure of a biological product under subsection (a) of section 351 of the Public Health Service Act.

Such term does not include a supplement to such an application, does not include an application with respect to whole blood or a blood component for transfusion, does not include an application with respect to a bovine blood product for topical application licensed before September 1, 1992, an allergenic extract product, or an in vitro diagnostic biologic product licensed under section 351 of the Public Health Service Act, does not include an application with respect to a large volume parenteral drug product approved before September 1, 1992, does not include an application for a licensure of a biological product for further manufacturing use only, and does not include an application or supplement submitted by a State or Federal Government entity for a drug that is not distributed commercially. Such term does include an application for licensure, as described in subparagraph (B), of a large volume biological product intended for single dose injection for intravenous use or infusion.

[(2) The term "supplement" means a request to the Secretary to approve a change in a human drug application which has been approved.

[(3) The term "prescription drug product" means a specific strength or potency of a drug in final dosage form—

[(A) for which a human drug application has been approved,

[(B) which may be dispensed only under prescription pursuant to section 503(b), and

[(C) which is on the list of products described in section 505(j)(7)(A) (not including the discontinued section of such list) or is on a list created and maintained by the Secretary of products approved under human drug applications under section 351 of the Public Health Service Act (not including the discontinued section of such list).

Such term does not include whole blood or a blood component for transfusion, does not include a bovine blood product for topical application licensed before September 1, 1992, an allergenic extract product, or an in vitro diagnostic biologic product licensed under section 351 of the Public Health Service Act. Such term does not include a biological product that is licensed for further manufacturing use only, and does not include a drug that is not distributed commercially and is the subject of an application or supplement submitted by a State or Federal Government entity. Such term does include a large volume biological product intended for single dose injection for intravenous use or infusion.

[(4) The term "final dosage form" means, with respect to a prescription drug product, a finished dosage form which is approved for administration to a patient without substantial further manufacturing (such as capsules, tablets, or lyophilized products before reconstitution).

[(5) The term "prescription drug establishment" means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within five miles of each other and at which one or more prescription drug products are manufactured in final dosage form. For purposes of this paragraph, the term "manufactured" does not include packaging.

[(6) The term "process for the review of human drug applications" means the following activities of the Secretary with respect to the review of human drug applications and supplements:

[(A) The activities necessary for the review of human drug applications and supplements.

[(B) The issuance of action letters which approve human drug applications or which set forth in detail the specific deficiencies in such applications and, where appropriate, the actions necessary to place such applications in condition for approval.

[(C) The inspection of prescription drug establishments and other facilities undertaken as part of the Secretary's review of pending human drug applications and supplements.

[(D) Activities necessary for the review of applications for licensure of establishments subject to section 351 of the Public Health Service Act and for the release of lots of biologics under such section.

[(E) Monitoring of research conducted in connection with the review of human drug applications.

[(F) Postmarket safety activities with respect to drugs approved under human drug applications 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) Carrying out section 505(k)(5) (relating to adverse event reports and postmarket safety activities).

[(7) The term "costs of resources allocated for the process for the review of human drug applications" means the expenses in connection with the process for the review of human drug applications for—

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

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

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

[(D) collecting fees under section 736 and accounting for resources allocated for the review of human drug applications and supplements.

[(8) The term "adjustment factor" applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 1996.

[(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.

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

[(A) one business entity controls, or has the power to control, the other business entity; or

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

[SEC. 736. AUTHORITY TO ASSESS AND USE DRUG FEES.

[(a) TYPES OF FEES.—Beginning infiscal year 2013, the Secretary shall assess and collect fees in accordance with this section as follows:

[(1) HUMAN DRUG APPLICATION AND SUPPLEMENT FEE.—

[(A) IN GENERAL.—Each person that submits, on or after September 1, 1992, a human drug application or a supplement shall be subject to a fee as follows:

[(i) A fee established under subsection for a human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required for approval.

[(ii) A fee established under subsection for a human drug application for which clinical data with respect to safety or effectiveness are not required or a supplement for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required. Such fee shall be half of the amount of the fee established under clause (i).

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

[(C) EXCEPTION FOR PREVIOUSLY FILED APPLICATION OR SUPPLEMENT.—If a human drug application or supplement was submitted by a person that paid the fee for such application or supplement, was accepted for filing, and was not approved or was withdrawn (without a waiver), the submission of a human drug application or a supplement for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

[(D) REFUND OF FEE IF APPLICATION REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any application or supplement which is refused for filing or withdrawn without a waiver before filing.

[(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).

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

[(G) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an application or supplement is withdrawn after the application or supplement was filed, the Secretary may refund the

fee or a portion of the fee if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

[(2) PRESCRIPTION DRUG ESTABLISHMENT FEE.—

[(A) IN GENERAL.—Except as provided in subparagraphs (B) and (C), each person that—

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

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

shall be assessed an annual fee established under subsection (c)(4) for each prescription drug establishment listed in its approved human drug application as an establishment that manufactures the prescription drug product named in the application. The annual establishment fee shall be assessed in each fiscal year in which the prescription drug product named in the application is assessed a fee under paragraph (3) unless the prescription drug establishment listed in the application does not engage in the manufacture of the prescription drug product during the fiscal year. The establishment fee shall be due on the later of the first business day on or after October 1 of such fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section. Each such establishment shall be assessed only one fee per establishment, notwithstanding the number of prescription drug products manufactured at the establishment. In the event an establishment is listed in a human drug application by more than one applicant, the establishment fee for the fiscal year shall be divided equally and assessed among the applicants whose prescription drug products are manufactured by the establishment during the fiscal year and assessed product fees under paragraph (3).

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

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

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

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

[(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 ap-

proved 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 paragraph (1)(B) of such section shall not apply.

[(3) PRESCRIPTION DRUG PRODUCT FEE.—

[(A) IN GENERAL.—Except as provided in subparagraph (B), each person who is named as the applicant in a human drug application, and who, after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall pay for each such prescription drug product the annual fee established under subsection (c)(4). Such fee shall be due on the later of the first business day on or after October 1 of each such fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for each such fiscal year under this section. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable.

[(B) EXCEPTION.—A prescription drug product shall not be assessed a fee under subparagraph (A) if such product is—

[(i) identified on the list compiled under section 505(j)(7)(A) with a potency described in terms of per 100 mL;

[(ii) the same product as another product that—

[(I) was approved under an application filed under section 505(b) or 505(j); and

[(II) is not in the list of discontinued products compiled under section 505(j)(7)(A);

[(iii) the same product as another product that was approved under an abbreviated application filed under section 507 (as in effect on the day before the date of

enactment of the Food and Drug Administration Modernization Act of 1997); or

[(iv) the same product as another product that was approved under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984.

[(b) FEE REVENUE AMOUNTS.—

[(1) IN GENERAL.—For each of the fiscal years 2013 through 2017, 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) $693,099,000;

[(B) the dollar amount equal to the inflation adjustment for fiscal year 2013 (as determined under paragraph (3)(A)); and

[(C) the dollar amount equal to the workload adjustment for fiscal year 2013 (as determined under paragraph (3)(B)).

[(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) FISCAL YEAR 2013 INFLATION AND WORKLOAD ADJUSTMENTS.—For purposes of paragraph (1), the dollar amount of the inflation and workload adjustments for fiscal year 2013 shall be determined as follows:

[(A) INFLATION ADJUSTMENT.—The inflation adjustment for fiscal year 2013 shall be the sum of—

[(i) $652,709,000 multiplied by the result of an inflation adjustment calculation determined using the methodology described in subsection (c)(1)(B); and

[(ii) $652,709,000 multiplied by the result of an inflation adjustment calculation determined using the methodology described in subsection (c)(1)(C).

[(B) WORKLOAD ADJUSTMENT.—Subject to subparagraph (C), the workload adjustment for fiscal 2013 shall be—

[(i) $652,709,000 plus the amount of the inflation adjustment calculated under subparagraph (A); multiplied by

[(ii) the amount (if any) by which a percentage workload adjustment for fiscal year 2013, as determined using the methodology described in subsection (c)(2)(A), would exceed the percentage workload adjustment (as so determined) for fiscal year 2012, if both such adjustment percentages were calculated using the 5-year base period consisting of fiscal years 2003 through 2007.

[(C) LIMITATION.—Under no circumstances shall the adjustment under subparagraph (B) result in fee revenues for fiscal year 2013 that are less than the sum of the amount under paragraph (1)(A) and the amount under paragraph (1)(B).

[(c) ADJUSTMENTS.—

[(1) INFLATION ADJUSTMENT.—For fiscal year 2014 and subsequent fiscal years, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year by the amount equal to the sum of—

[(A) one;

[(B) the average annual percent 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 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 735(6)) for the first 3 years of the preceding 4 fiscal years, and

[(C) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 735(6)) for the first 3 years of the preceding 4 fiscal years.

The adjustment made each fiscal year under this paragraph shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2013 under this paragraph.

[(2) WORKLOAD ADJUSTMENT.—For fiscal year 2014 and subsequent fiscal years, 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 for the process for the review of human drug applications. With respect to such adjustment:

[(A) The adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of 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), efficacy supplements, and manufacturing supplements submitted to the Secretary, 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. 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 sum of the amount under subsection (b)(1)(A) and the amount under subsection (b)(1)(B), as adjusted for inflation under paragraph (1).

[(C) The Secretary shall contract with an independent accounting or consulting firm to periodically review the adequacy of the adjustment and publish the results of those reviews. The first review shall be conducted and published by the end of fiscal year 2013 (to examine the performance of the adjustment since fiscal year 2009), and the second review shall be conducted and published by the end of fiscal year 2015 (to examine the continued performance of the adjustment). The reports shall evaluate whether the adjustment reasonably represents actual changes in workload volume and complexity and present options to discontinue, retain, or modify any elements of the adjustment. The reports shall be published for public comment. After review of the reports and receipt of public comments, the Secretary shall, if warranted, adopt appropriate changes to the methodology. If the Secretary adopts changes to the methodology based on the first report, the changes shall be effective for the first fiscal year for which fees are set after the Secretary adopts such changes and each subsequent fiscal year.

[(3) FINAL YEAR ADJUSTMENT.—For fiscal year 2017, the Secretary may, in addition to adjustments under this paragraph and paragraphs (1) and (2), further increase the fee revenues and fees established in subsection (b) if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for the process for the review of human drug applications for the first 3 months of fiscal year 2018. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2017. If the Secretary has carryover balances for such process in excess of 3 months of such operating reserves, the adjustment under this subparagraph shall not be made.

[(4) ANNUAL FEE SETTING.—The Secretary shall, not later than 60 days before the start of each fiscal year that begins after September 30, 2012, establish, for the next fiscal year, application, product, and establishment fees under subsection (a), based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection.

[(5) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of human drug applications.

[(d) FEE WAIVER OR REDUCTION.—

[(1) IN GENERAL.—The Secretary shall grant to a person who is named as the applicant in a human drug application a waiver from or a reduction of one or more fees assessed to that person under subsection (a) where the Secretary finds that—

[(A) such waiver or reduction is necessary to protect the public health,

[(B) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances,

[(C) the fees to be paid by such person will exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of human drug applications for such person, or

[(D) the applicant involved is a small business submitting its first human drug application to the Secretary for review.

[(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.

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

[(4) RULES RELATING TO SMALL BUSINESSES.—

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

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

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

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

[(e) EFFECT OF FAILURE TO PAY FEES.—A human drug application or supplement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid.

[(f) LIMITATIONS.—

[(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 1997 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 1997 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

[(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because 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 human drug applications and supplements, prescription drug establishments, and prescription drug products at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

[(g) CREDITING AND AVAILABILITY OF FEES.—

[(1) IN GENERAL.—Subject to paragraph (2)(C), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of human drug applications.

[(2) COLLECTIONS AND APPROPRIATION ACTS.—

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

[(i) shall be collected and available 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 to defray increases in the costs of the resources allocated for the process for the review of human drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997 multiplied by the adjustment factor.

[(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of human drug applications—

[(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

[(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in such subparagraph; and

[(II) such costs are not more than 5 percent below the level specified in such subparagraph.

[(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

[(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2013 through 2017, 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.

[(4) OFFSET.—If the sum of the cumulative amount of fees collected under this section for the fiscal years 2013 through 2015 and the amount of fees estimated to be collected under this section for fiscal year 2016 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 2017.

[(h) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

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

[(j) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in the process of the review of human drug applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

[(k) ORPHAN DRUGS.—

[(1) EXEMPTION.—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 establishment fees under this section, if the drug meets all of the following conditions:

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

[(B) The drug is owned or licensed and is marketed by a company that had less than $50,000,000 in gross worldwide revenue during the previous year.

[(2) EVIDENCE OF QUALIFICATION.—An exemption under paragraph (1) applies with respect to a drug only if the applicant involved submits a certification that its gross annual revenues did not exceed $50,000,000 for the preceding 12 months before the exemption was requested.]

* * * * * * *

SEC. 736B. 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 this part, 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 101(c) of the Food and Drug Administration Amendments Act of 2007 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all human drug applications and supplements in the cohort.]

(a) PERFORMANCE REPORT.—

(1) IN GENERAL.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this part, 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—

(A) the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals, including the status of the independent assessment described in such letters; and

(B) the progress of the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research in achieving the goals, and future plans for meeting the goals, including, for each review division—

(i) the number of original standard new drug applications and biologics license applications filed per fiscal year for each review division;

(ii) the number of original priority new drug applications and biologics license applications filed per fiscal year for each review division;

(iii) the number of standard efficacy supplements filed per fiscal year for each review division;

(iv) the number of priority efficacy supplements filed per fiscal year for each review division;

(v) the number of applications filed for review under accelerated approval per fiscal year for each review division;

(vi) the number of applications filed for review as fast track products per fiscal year for each review division; and

(vii) the number of applications filed for orphan-designated products per fiscal year for each review division.

(2) INCLUSION.—The report under this subsection for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all human drug applications and supplements in the cohort.

(b) FISCAL REPORT.—Beginning with fiscal year [2008] *2013*, not later than 120 days after the end of each fiscal year for which fees

are collected under this part, 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.

* * * * * * *

(d) 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] *2017*, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

(A) * * *

* * * * * * *

(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, [2012] *2017*, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), 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.

* * * * * * *

[Effective January 31, 2018, section 105(b) of H.R. 5651 provides for a repeal of section 736B (as amended by the bill).]

[SEC. 736B. REAUTHORIZATION; REPORTING REQUIREMENTS.

[(a) PERFORMANCE REPORT.—

[(1) IN GENERAL.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this part, 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—

[(A) the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals, including the status of the independent assessment described in such letters; and

[(B) the progress of the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research in achieving the goals, and future plans for meeting the goals, including, for each review division—

[(i) the number of original standard new drug applications and biologics license applications filed per fiscal year for each review division;

[(ii) the number of original priority new drug applications and biologics license applications filed per fiscal year for each review division;

[(iii) the number of standard efficacy supplements filed per fiscal year for each review division;

[(iv) the number of priority efficacy supplements filed per fiscal year for each review division;

[(v) the number of applications filed for review under accelerated approval per fiscal year for each review division;

[(vi) the number of applications filed for review as fast track products per fiscal year for each review division; and

[(vii) the number of applications filed for orphan-designated products per fiscal year for each review division.

[(2) INCLUSION.—The report under this subsection for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all human drug applications and supplements in the cohort.

[(b) FISCAL REPORT.—Beginning with fiscal year, not later than 120 days after the end of each fiscal year for which fees are collected under this part, 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) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

[(d) 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, 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) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—

[(A) publish a notice in the Federal Register requesting public input on the reauthorization;

[(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

[(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

[(D) publish the comments on the Food and Drug Administration's Internet Web site.

[(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

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

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

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

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

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

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

[(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2017, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), 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.

[(6) MINUTES OF NEGOTIATION MEETINGS.—

[(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the public Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

[(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.]

* * * * * * *

PART 3—FEES RELATING TO DEVICES

* * * * * * *

SEC. 737. DEFINITIONS.

For purposes of this part:

(1) * * *

* * * * * * *

(9) The term "costs of resources allocated for the process for the review of device applications" means the expenses [incurred] in connection with the process for the review of device applications for—

(A) * * *

* * * * * * *

(10) The term "adjustment factor" applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for [October 2001] *October 2011*.

* * * * * * *

(13) The term "establishment subject to a registration fee" 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, 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, within the meaning of section 201(ll)(2)(A), performs additional processing and manufacturing operations on a single-use device that has previously been used on a patient.

[(C) SPECIFICATION DEVELOPER.—An establishment that develops specifications for a device that is distributed under the establishment's name but 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.] *is registered (or is required to register) with the Secretary under section 510 because such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of a device.*

SEC. 738. AUTHORITY TO ASSESS AND USE DEVICE FEES.

(a) TYPES OF FEES.—

(1) IN GENERAL.—Beginning in [fiscal year 2008] *fiscal year 2013*, the Secretary shall assess and collect fees in accordance with this section.

(2) PREMARKET APPLICATION, PREMARKET REPORT, SUPPLEMENT, AND SUBMISSION FEE, AND ANNUAL FEE FOR PERIODIC REPORTING CONCERNING A CLASS III DEVICE.—

(A) IN GENERAL.—Except as provided in subparagraph (B) and [subsections (d) and (e)] *subsections (d), (e), and (f)*, each person who submits any of the following, on or after [October 1, 2002] *October 1, 2012*, shall be subject to a fee established under [subsection (c)(1)] *subsection (c)* for the fiscal year involved in accordance with the following:

(i) * * *

* * * * * * *

(viii) For a premarket notification submission, a fee equal to [1.84] *2* percent of the fee that applies under clause (i).

* * * * * * *

(3) ANNUAL ESTABLISHMENT REGISTRATION FEE.—

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

* * * * * * *

(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.] *later of—*

(i) the initial or annual registration (as applicable) of the establishment under section 510; or

(ii) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

[(b) FEE AMOUNTS.—Except as provided in subsections (c), (d), (e), and (h) 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.]

(b) FEE AMOUNTS.—

(1) IN GENERAL.—Subject to subsections (c), (d), (e), (f), and (i), for each of fiscal years 2013 through 2017, fees under subsection (a) shall be derived from the base fee amounts specified in paragraph (2), to generate the total revenue amounts specified in paragraph (3).

(2) BASE FEE AMOUNTS SPECIFIED.—For purposes of paragraph (1), the base fee amounts specified in this paragraph are as follows:

Fee Type	*Fiscal Year 2013*	*Fiscal Year 2014*	*Fiscal Year 2015*	*Fiscal Year 2016*	*Fiscal Year 2017*
Premarket Application	*$248,000*	*$252,960*	*$258,019*	*$263,180*	*$268,443*
Establishment Registration	*$2,575*	*$3,200*	*$3,750*	*$3,872*	*$3,872*

(3) TOTAL REVENUE AMOUNTS.—For purposes of paragraph (1), the total revenue amounts specified in this paragraph are as follows:

(A) $97,722,301 for fiscal year 2013.

(B) $112,580,497 for fiscal year 2014.

(C) $125,767,107 for fiscal year 2015.

(D) $129,339,949 for fiscal year 2016.

(E) $130,184,348 for fiscal year 2017.

(c) ANNUAL FEE SETTING*; ADJUSTMENTS*.—

[(1) IN GENERAL.—The Secretary shall, 60 days before the start of each fiscal year after September 30, 2002, publish in the Federal Register fees under subsection (a).

[(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 fewer than 12,250. The percentage increase shall be the percentage by which the estimate of establishments submitting fees in fiscal year 2009 is fewer than 12,750, but in no case may the percentage 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.]

(1) IN GENERAL.—The Secretary shall, 60 days before the start of each fiscal year after September 30, 2012, establish fees under subsection (a), based on amounts specified under subsection (b) and the adjustments provided under this subsection, and publish such fees, and the rationale for any adjustments to such fees, in the Federal Register.

(2) INFLATION ADJUSTMENTS.—

(A) ADJUSTMENT TO TOTAL REVENUE AMOUNTS.—For fiscal year 2014 and each subsequent fiscal year, the Secretary shall adjust the total revenue amount specified in subsection (b)(3) for such fiscal year by multiplying such amount by the applicable inflation adjustment under subparagraph (B) for such year.

(B) APPLICABLE INFLATION ADJUSTMENT TO TOTAL REVENUE AMOUNTS.—The applicable inflation adjustment for a fiscal year is—

(i) for fiscal year 2014, the base inflation adjustment under subparagraph (C) for such fiscal year; and

(ii) for fiscal year 2015 and each subsequent fiscal year, the product of—

(I) the base inflation adjustment under subparagraph (C) for such fiscal year; and

(II) the product of the base inflation adjustment under subparagraph (C) for each of the fiscal years preceding such fiscal year, beginning with fiscal year 2014.

(C) BASE INFLATION ADJUSTMENT TO TOTAL REVENUE AMOUNTS.—

(i) IN GENERAL.—Subject to further adjustment under clause (ii), the base inflation adjustment for a fiscal year is the sum of one plus—

(I) the average annual percent 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 3 years of the preceding 4 fiscal years, multiplied by 0.60; and

(II) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by 0.40.

(ii) LIMITATIONS.—For purposes of subparagraph (B), if the base inflation adjustment for a fiscal year under clause (i)—

(I) is less than 1, such adjustment shall be considered to be equal to 1; or

(II) is greater than 1.04, such adjustment shall be considered to be equal to 1.04.

(D) ADJUSTMENT TO BASE FEE AMOUNTS.—For each of fiscal years 2014 through 2017, the base fee amounts specified in subsection (b)(2) shall be adjusted as needed, on a uniform proportionate basis, to generate the total revenue amounts under subsection (b)(3), as adjusted for inflation under subparagraph (A).

(3) VOLUME-BASED ADJUSTMENTS TO ESTABLISHMENT REGISTRATION BASE FEES.—For each of fiscal years 2014 through 2017, after the base fee amounts specified in subsection (b)(2) are adjusted under paragraph (2)(D), the base establishment registration fee amounts specified in such subsection shall be further adjusted, as the Secretary estimates is necessary in order for total fee collections for such fiscal year to generate the total revenue amounts, as adjusted under paragraph (2).

[(3)**]** *(4)* LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of device applications.

[(4)**]** *(5)* SUPPLEMENT.—

(A) * * *

* * * * * * *

(f) FEE WAIVER OR REDUCTION.—

(1) IN GENERAL.—The Secretary may, at the Secretary's sole discretion, grant a waiver or reduction of fees under subsection

(a)(2) or (a)(3) if the Secretary finds that such waiver or reduction is in the interest of public health.

(2) LIMITATION.—The sum of all fee waivers or reductions granted by the Secretary in any fiscal year under paragraph (1) shall not exceed 2 percent of the total fee revenue amounts established for such year under subsection (c).

(3) DURATION.—The authority provided by this subsection terminates October 1, 2017.

[(f)**]** *(g)* EFFECT OF FAILURE TO PAY FEES.—

(1) * * *

* * * * * * *

[(g)**]** *(h)* CONDITIONS.—

(1) PERFORMANCE GOALS; TERMINATION OF PROGRAM.—With respect to the amount that, under the salaries and expenses account of the Food and Drug Administration, is appropriated for a fiscal year for devices and radiological products, fees may not be assessed under subsection (a) for the fiscal year, and the Secretary is not expected to meet any performance goals identified for the fiscal year, if—

(A) the amount so appropriated for the fiscal year, excluding the amount of fees appropriated for the fiscal year, is more than 1 percent less than **[**$205,720,000**]** *$280,587,000* multiplied by the adjustment factor applicable to such fiscal year; or

* * * * * * *

[(h)**]** *(i)* CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—**[**Fees authorized**]** *Subject to paragraph (2)(C), fees authorized* under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriation Acts. Such fees are authorized to be appropriated 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 review of device applications.

(2) COLLECTIONS AND APPROPRIATION ACTS.—

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

(i) **[**shall be retained**]** *subject to subparagraph (C), shall be collected and available* 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 only be **[**collected and**]** available to defray increases in the costs of the resources allocated for the process for the review of device applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees

collected under this section, for [fiscal year 2002] *fiscal year 2009* multiplied by the adjustment factor.

* * * * * * *

(C) PROVISION FOR EARLY YEAR PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

[(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.]

(3) AUTHORIZATIONS OF APPROPRIATIONS.—For each of the fiscal years 2013 through 2017, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount specified under subsection (b)(3) for the fiscal year, as adjusted under subsection (c) and, for fiscal year 2017 only, as further adjusted under paragraph (4).

(4) OFFSET.—If the cumulative amount of fees collected during [fiscal years 2008, 2009, and 2010] *fiscal years 2013, 2014, and 2015*, added to the amount estimated to be collected for [fiscal year 2011] *fiscal year 2016*, which estimate shall be based upon the amount of fees received by the Secretary through [June 30, 2011] *June 30, 2016*, exceeds [the amount of fees specified in aggregate in] *the cumulative amount appropriated pursuant to* 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] *fiscal year 2017*.

[(i)] *(j)* COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

[(j)] *(k)* WRITTEN REQUESTS FOR REFUNDS.—To qualify for consideration for a refund under subsection (a)(2)(D), a person shall submit to the Secretary a written request for such refund not later than 180 days after such fee is due.

[(k)] *(l)* CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in the process of the review of device applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

SEC. 738A. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) REPORTS.—

[(1) PERFORMANCE REPORT.—For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year

during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(c) of the Food and Drug Administration Amendments Act of 2007 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all device premarket applications and reports, supplements, and premarket notifications in the cohort.]

(1) PERFORMANCE REPORT.—

(A) IN GENERAL.—Beginning with fiscal year 2013, for each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives annual reports concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(B) PUBLICATION.—With regard to information to be reported by the Food and Drug Administration to industry on a quarterly and annual basis pursuant to the letters described in section 201(b) of the Medical Device User Fee Amendments Act of 2012, the Secretary shall make such information publicly available on the Internet Website of the Food and Drug Administration not later than 60 days after the end of each quarter or 120 days after the end of each fiscal year, respectively, to which such information applies. This information shall include the status of the independent assessment identified in the letters described in such section 201(b).

(C) UPDATES.—The Secretary shall include in each report under subparagraph (A) information on all previous cohorts for which the Secretary has not given a complete response on all device premarket applications and reports, supplements, and premarket notifications in the cohort.

(2) FISCAL REPORT.—For fiscal years [2008 through 2012] *2013 through 2017*, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

* * * * * * *

(b) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of device applications for the first 5 fiscal years after fiscal year [2012] *2017*, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

(A) * * *

* * * * * * *

(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, [2012] *2017*, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), 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.

* * * * * * *

[Effective January 31, 2018, section 207(a) of H.R. 5651 provides for a repeal of section 738A (as amended by the bill).]

[SEC. 738A. REAUTHORIZATION; REPORTING REQUIREMENTS.

[(a) REPORTS.—

[(1) PERFORMANCE REPORT.—

[(A) IN GENERAL.—Beginning with fiscal year 2013, for each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives annual reports concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

[(B) PUBLICATION.—With regard to information to be reported by the Food and Drug Administration to industry on a quarterly and annual basis pursuant to the letters described in section 201(b) of the Medical Device User Fee Amendments Act of 2012, the Secretary shall make such information publicly available on the Internet Website of the Food and Drug Administration not later than 60 days after the end of each quarter or 120 days after the end of each fiscal year, respectively, to which such information applies. This information shall include the status of the independent assessment identified in the letters described in such section 201(b).

[(C) UPDATES.—The Secretary shall include in each report under subparagraph (A) information on all previous cohorts for which the Secretary has not given a complete response on all device premarket applications and reports, supplements, and premarket notifications in the cohort.

[(2) FISCAL REPORT.—For fiscal years 2013 through 2017, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education,

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

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

[(b) REAUTHORIZATION.—

[(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of device applications for the first 5 fiscal years after fiscal year 2017, 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) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—

[(A) publish a notice in the Federal Register requesting public input on the reauthorization;

[(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a)(1);

[(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

[(D) publish the comments on the Food and Drug Administration's Internet Web site.

[(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

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

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

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

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

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

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

[(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2017, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), 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.

[(6) MINUTES OF NEGOTIATION MEETINGS.—

[(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the public Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

[(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.]

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PART 7—FEES RELATING TO GENERIC DRUGS

SEC. 744A. DEFINITIONS.

For purposes of this part:

(1) The term "abbreviated new drug application"—

(A) means an application submitted under section 505(j), an abbreviated application submitted under section 507 (as in effect on the day before the date of enactment of the Food and Drug Administration Modernization Act of 1997), or an abbreviated new drug application submitted pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984; and

(B) does not include an application for a positron emission tomography drug.

(2) The term "active pharmaceutical ingredient" means—

(A) a substance, or a mixture when the substance is unstable or cannot be transported on its own, intended—

(i) to be used as a component of a drug; and

(ii) to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the human body; or

(B) a substance intended for final crystallization, purification, or salt formation, or any combination of those activities, to become a substance or mixture described in subparagraph (A).

(3) The term "adjustment factor" means a factor applicable to a fiscal year that is the Consumer Price Index for all urban con-

sumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 2011.

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

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

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

(5)(A) The term "facility"—

(i) means a business or other entity—

(I) under one management, either direct or indirect; and

(II) at one geographic location or address engaged in manufacturing or processing an active pharmaceutical ingredient or a finished dosage form; and

(ii) does not include a business or other entity whose only manufacturing or processing activities are one or more of the following: repackaging, relabeling, or testing.

(B) For purposes of subparagraph (A), separate buildings within close proximity are considered to be at one geographic location or address if the activities in them are—

(i) closely related to the same business enterprise;

(ii) under the supervision of the same local management; and

(iii) capable of being inspected by the Food and Drug Administration during a single inspection.

(C) If a business or other entity would meet the definition of a facility under this paragraph but for being under multiple management, the business or other entity is deemed to constitute multiple facilities, one per management entity, for purposes of this paragraph.

(6) The term "finished dosage form" means—

(A) a drug product in the form in which it will be administered to a patient, such as a tablet, capsule, solution, or topical application;

(B) a drug product in a form in which reconstitution is necessary prior to administration to a patient, such as oral suspensions or lyophilized powders; or

(C) any combination of an active pharmaceutical ingredient with another component of a drug product for purposes of production of a drug product described in subparagraph (A) or (B).

(7) The term "generic drug submission" means an abbreviated new drug application, an amendment to an abbreviated new drug application, or a prior approval supplement to an abbreviated new drug application.

(8) The term "human generic drug activities" means the following activities of the Secretary associated with generic drugs and inspection of facilities associated with generic drugs:

(A) The activities necessary for the review of generic drug submissions, including review of drug master files referenced in such submissions.

(B) The issuance of—

(i) approval letters which approve abbreviated new drug applications or supplements to such applications; or

(ii) complete response letters which set forth in detail the specific deficiencies in such applications and, where appropriate, the actions necessary to place such applications in condition for approval.

(C) The issuance of letters related to Type II active pharmaceutical drug master files which—

(i) set forth in detail the specific deficiencies in such submissions, and where appropriate, the actions necessary to resolve those deficiencies; or

(ii) document that no deficiencies need to be addressed.

(D) Inspections related to generic drugs.

(E) Monitoring of research conducted in connection with the review of generic drug submissions and drug master files.

(F) Postmarket safety activities with respect to drugs approved under abbreviated new drug applications 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) insofar as those activities relate to abbreviated new drug applications.

(v) Carrying out section 505(k)(5) (relating to adverse-event reports and postmarket safety activities).

(G) Regulatory science activities related to generic drugs.

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

(10) The term "prior approval supplement" means a request to the Secretary to approve a change in the drug substance, drug product, production process, quality controls, equipment, or facilities covered by an approved abbreviated new drug application when that change has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.

(11) The term "resources allocated for human generic drug activities" means the expenses for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration,

advisory committees, and costs related to such officers and employees 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; and

(D) collecting fees under subsection (a) and accounting for resources allocated for the review of abbreviated new drug applications and supplements and inspection related to generic drugs.

(12) The term "Type II active pharmaceutical ingredient drug master file" means a submission of information to the Secretary by a person that intends to authorize the Food and Drug Administration to reference the information to support approval of a generic drug submission without the submitter having to disclose the information to the generic drug submission applicant.

SEC. 744B. AUTHORITY TO ASSESS AND USE HUMAN GENERIC DRUG FEES.

(a) TYPES OF FEES.—Beginning in fiscal year 2013, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) ONE-TIME BACKLOG FEE FOR ABBREVIATED NEW DRUG APPLICATIONS PENDING ON OCTOBER 1, 2012.—

(A) IN GENERAL.—Each person that owns an abbreviated new drug application that is pending on October 1, 2012, and that has not received a tentative approval prior to that date, shall be subject to a fee for each such application, as calculated under subparagraph (B).

(B) METHOD OF FEE AMOUNT CALCULATION.—The amount of each one-time backlog fee shall be calculated by dividing $50,000,000 by the total number of abbreviated new drug applications pending on October 1, 2012, that have not received a tentative approval as of that date.

(C) NOTICE.—Not later than October 31, 2012, the Secretary shall cause to be published in the Federal Register a notice announcing the amount of the fee required by subparagraph (A).

(D) FEE DUE DATE.—The fee required by subparagraph (A) shall be due no later than 30 calendar days after the date of the publication of the notice specified in subparagraph (C).

(2) DRUG MASTER FILE FEE.—

(A) IN GENERAL.—Each person that owns a Type II active pharmaceutical ingredient drug master file that is referenced on or after October 1, 2012, in a generic drug submission by any initial letter of authorization shall be subject to a drug master file fee.

(B) ONE-TIME PAYMENT.—If a person has paid a drug master file fee for a Type II active pharmaceutical ingredient drug master file, the person shall not be required to pay a subsequent drug master file fee when that Type II active pharmaceutical ingredient drug master file is subsequently referenced in generic drug submissions.

(C) NOTICE.—

(i) FISCAL YEAR 2013.—Not later than October 31, 2012, the Secretary shall cause to be published in the Federal Register a notice announcing the amount of the drug master file fee for fiscal year 2013.

(ii) FISCAL YEAR 2014 THROUGH 2017.—Not later than 60 days before the start of each of fiscal years 2014 through 2017, the Secretary shall cause to be published in the Federal Register the amount of the drug master file fee established by this paragraph for such fiscal year.

(D) AVAILABILITY FOR REFERENCE.—

(i) IN GENERAL.—Subject to subsection (g)(2)(C), for a generic drug submission to reference a Type II active pharmaceutical ingredient drug master file, the drug master file must be deemed available for reference by the Secretary.

(ii) CONDITIONS.—A drug master file shall be deemed available for reference by the Secretary if—

(I) the person that owns a Type II active pharmaceutical ingredient drug master file has paid the fee required under subparagraph (A) within 20 calendar days after the applicable due date under subparagraph (E); and

(II) the drug master file has not failed an initial completeness assessment by the Secretary, in accordance with criteria to be published by the Secretary.

(iii) LIST.—The Secretary shall make publicly available on the Internet Web site of the Food and Drug Administration a list of the drug master file numbers that correspond to drug master files that have successfully undergone an initial completeness assessment, in accordance with criteria to be published by the Secretary, and are available for reference.

(E) FEE DUE DATE.—

(i) IN GENERAL.—Subject to clause (ii), a drug master file fee shall be due no later than the date on which the first generic drug submission is submitted that references the associated Type II active pharmaceutical ingredient drug master file.

(ii) LIMITATION.—No fee shall be due under subparagraph (A) for a fiscal year until the later of—

(I) 30 calendar days after publication of the notice provided for in clause (i) or (ii) of subparagraph (C), as applicable; or

(II) 30 calendar days after the date of enactment of an appropriations Act providing for the collection and obligation of fees under this section.

(3) ABBREVIATED NEW DRUG APPLICATION AND PRIOR APPROVAL SUPPLEMENT FILING FEE.—

(A) IN GENERAL.—Each applicant that submits, on or after October 1, 2012, an abbreviated new drug application or a prior approval supplement to an abbreviated new drug

application shall be subject to a fee for each such submission in the amount established under subsection (d).

(B) NOTICE.—

(i) FISCAL YEAR 2013.—Not later than October 31, 2012, the Secretary shall cause to be published in the Federal Register a notice announcing the amount of the fees under subparagraph (A) for fiscal year 2013.

(ii) FISCAL YEARS 2014 THROUGH 2017.—Not later than 60 days before the start of each of fiscal years 2014 through 2017, the Secretary shall cause to be published in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

(C) FEE DUE DATE.—

(i) IN GENERAL.—Except as provided in clause (ii), the fees required by subparagraphs (A) and (F) shall be due no later than the date of submission of the abbreviated new drug application or prior approval supplement for which such fee applies.

(ii) SPECIAL RULE FOR 2013.—For fiscal year 2013, such fees shall be due on the later of—

(I) the date on which the fee is due under clause (i);

(II) 30 calendar days after publication of the notice referred to in subparagraph (B)(i); or

(III) if an appropriations Act is not enacted providing for the collection and obligation of fees under this section by the date of submission of the application or prior approval supplement for which the fees under subparagraphs (A) and (F) apply, 30 calendar days after the date that such an appropriations Act is enacted.

(D) REFUND OF FEE IF ABBREVIATED NEW DRUG APPLICATION IS NOT CONSIDERED TO HAVE BEEN RECEIVED.—The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any abbreviated new drug application or prior approval supplement to an abbreviated new drug application that the Secretary considers not to have been received within the meaning of section 505(j)(5)(A) for a cause other than failure to pay fees.

(E) FEE FOR AN APPLICATION THE SECRETARY CONSIDERS NOT TO HAVE BEEN RECEIVED, OR THAT HAS BEEN WITHDRAWN.—An abbreviated new drug application or prior approval supplement that was submitted on or after October 1, 2012, and that the Secretary considers not to have been received, or that has been withdrawn, shall, upon resubmission of the application or a subsequent new submission following the applicant's withdrawal of the application, be subject to a full fee under subparagraph (A).

(F) ADDITIONAL FEE FOR ACTIVE PHARMACEUTICAL INGREDIENT INFORMATION NOT INCLUDED BY REFERENCE TO TYPE II ACTIVE PHARMACEUTICAL INGREDIENT DRUG MASTER FILE.—An applicant that submits a generic drug submission on or after October 1, 2012, shall pay a fee, in the amount determined under subsection (d)(3), in addition to the fee required under subparagraph (A), if—

(i) such submission contains information concerning the manufacture of an active pharmaceutical ingredient at a facility by means other than reference by a letter of authorization to a Type II active pharmaceutical drug master file; and

(ii) a fee in the amount equal to the drug master file fee established in paragraph (2) has not been previously paid with respect to such information.

(4) GENERIC DRUG FACILITY FEE AND ACTIVE PHARMACEUTICAL INGREDIENT FACILITY FEE.—

(A) IN GENERAL.—Facilities identified, or intended to be identified, in at least one generic drug submission that is pending or approved to produce a finished dosage form of a human generic drug or an active pharmaceutical ingredient contained in a human generic drug shall be subject to fees as follows:

(i) GENERIC DRUG FACILITY.—Each person that owns a facility which is identified or intended to be identified in at least one generic drug submission that is pending or approved to produce one or more finished dosage forms of a human generic drug shall be assessed an annual fee for each such facility.

(ii) ACTIVE PHARMACEUTICAL INGREDIENT FACILITY.—Each person that owns a facility which produces, or which is pending review to produce, one or more active pharmaceutical ingredients identified, or intended to be identified, in at least one generic drug submission that is pending or approved or in a Type II active pharmaceutical ingredient drug master file referenced in such a generic drug submission, shall be assessed an annual fee for each such facility.

(iii) FACILITIES PRODUCING BOTH ACTIVE PHARMACEUTICAL INGREDIENTS AND FINISHED DOSAGE FORMS.—Each person that owns a facility identified, or intended to be identified, in at least one generic drug submission that is pending or approved to produce both one or more finished dosage forms subject to clause (i) and one or more active pharmaceutical ingredients subject to clause (ii) shall be subject to fees under both such clauses for that facility.

(B) AMOUNT.—The amount of fees established under subparagraph (A) shall be established under subsection (d).

(C) NOTICE.—

(i) FISCAL YEAR 2013.—For fiscal year 2013, the Secretary shall cause to be published in the Federal Register a notice announcing the amount of the fees provided for in subparagraph (A) within the timeframe specified in subsection (d)(1)(B).

(ii) FISCAL YEARS 2014 THROUGH 2017.—Within the timeframe specified in subsection (d)(2), the Secretary shall cause to be published in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

(D) FEE DUE DATE.—

(i) FISCAL YEAR 2013.—For fiscal year 2013, the fees under subparagraph (A) shall be due on the later of—

(I) not later than 45 days after the publication of the notice under subparagraph (B); or

(II) if an appropriations Act is not enacted providing for the collection and obligation of fees under this section by the date of the publication of such notice, 30 days after the date that such an appropriations Act is enacted.

(ii) FISCAL YEARS 2014 THROUGH 2017.—For each of fiscal years 2014 through 2017, the fees under subparagraph (A) for such fiscal year shall be due on the later of—

(I) the first business day on or after October 1 of each such year; or

(II) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees under this section for such year.

(5) DATE OF SUBMISSION.—For purposes of this part, a generic drug submission or Type II pharmaceutical master file is deemed to be "submitted" to the Food and Drug Administration—

(A) if it is submitted via a Food and Drug Administration electronic gateway, on the day when transmission to that electronic gateway is completed, except that a submission or master file that arrives on a weekend, Federal holiday, or day when the Food and Drug Administration office that will review that submission is not otherwise open for business shall be deemed to be submitted on the next day when that office is open for business; and

(B) if it is submitted in physical media form, on the day it arrives at the appropriate designated document room of the Food and Drug Administration.

(b) FEE REVENUE AMOUNTS.—

(1) IN GENERAL.—

(A) FISCAL YEAR 2013.—For fiscal year 2013, fees under subsection (a) shall be established to generate a total estimated revenue amount under such subsection of $299,000,000. Of that amount—

(i) $50,000,000 shall be generated by the one-time backlog fee for generic drug applications pending on October 1, 2012, established in subsection (a)(1); and

(ii) $249,000,000 shall be generated by the fees under paragraphs (2) through (4) of subsection (a).

(B) FISCAL YEARS 2014 THROUGH 2017.—For each of the fiscal years 2014 through 2017, fees under paragraphs (2) through (4) of subsection (a) shall be established to generate a total estimated revenue amount under such subsection that is equal to $299,000,000, as adjusted pursuant to subsection (c).

(2) TYPES OF FEES.—In establishing fees under paragraph (1) to generate the revenue amounts specified in paragraph (1)(A)(ii) for fiscal year 2013 and paragraph (1)(B) for each of fiscal years 2014 through 2017, such fees shall be derived from

the fees under paragraphs (2) through (4) of subsection (a) as follows:

(A) 6 percent shall be derived from fees under subsection (a)(2) (relating to drug master files).

(B) 24 percent shall be derived from fees under subsection (a)(3) (relating to abbreviated new drug applications and supplements). The amount of a fee for a prior approval supplement shall be half the amount of the fee for an abbreviated new drug application.

(C) 56 percent shall be derived from fees under subsection (a)(4)(A)(i) (relating to generic drug facilities). The amount of the fee for a facility located outside the United States and its territories and possessions shall be not less than $15,000 and not more than $30,000 higher than the amount of the fee for a facility located in the United States and its territories and possessions, as determined by the Secretary on the basis of data concerning the difference in cost between inspections of facilities located in the United States, including its territories and possessions, and those located outside of the United States and its territories and possessions.

(D) 14 percent shall be derived from fees under subsection (a)(4)(A)(ii) (relating to active pharmaceutical ingredient facilities). The amount of the fee for a facility located outside the United States and its territories and possessions shall be not less than $15,000 and not more than $30,000 higher than the amount of the fee for a facility located in the United States, including its territories and possessions, as determined by the Secretary on the basis of data concerning the difference in cost between inspections of facilities located in the United States and its territories and possessions and those located outside of the United States and its territories and possessions.

(c) ADJUSTMENTS.—

(1) INFLATION ADJUSTMENT.— For fiscal year 2014 and subsequent fiscal years, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year, by an amount equal to the sum of—

(A) one;

(B) the average annual percent 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 3 years of the preceding 4 fiscal years multiplied by the proportion of personnel compensation and benefits costs to total costs of human generic drug activities for the first 3 years of the preceding 4 fiscal years; and

(C) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and

benefits costs to total costs of human generic drug activities for the first 3 years of the preceding 4 fiscal years.

The adjustment made each fiscal year under this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2013 under this subsection.

(2) FINAL YEAR ADJUSTMENT.—For fiscal year 2017, the Secretary may, in addition to adjustments under paragraph (1), further increase the fee revenues and fees established in subsection (b) if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for human generic drug activities for the first 3 months of fiscal year 2018. Such fees may only be used in fiscal year 2018. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2017. If the Secretary has carryover balances for such activities in excess of 3 months of such operating reserves, the adjustment under this subparagraph shall not be made.

(d) ANNUAL FEE SETTING.—

(1) FISCAL YEAR 2013.—For fiscal year 2013—

(A) the Secretary shall establish, by October 31, 2012, the one-time generic drug backlog fee for generic drug applications pending on October 1, 2012, the drug master file fee, the abbreviated new drug application fee, and the prior approval supplement fee under subsection (a), based on the revenue amounts established under subsection (b); and

(B) the Secretary shall establish, not later than 45 days after the date to comply with the requirement for identification of facilities in subsection (f)(2), the generic drug facility fee and active pharmaceutical ingredient facility fee under subsection (a) based on the revenue amounts established under subsection (b).

(2) FISCAL YEARS 2014 THROUGH 2017.—Not more than 60 days before the first day of each of fiscal years 2014 through 2017, the Secretary shall establish the drug master file fee, the abbreviated new drug application fee, the prior approval supplement fee, the generic drug facility fee, and the active pharmaceutical ingredient facility fee under subsection (a) for such fiscal year, based on the revenue amounts established under subsection (b) and the adjustments provided under subsection (c).

(3) FEE FOR ACTIVE PHARMACEUTICAL INGREDIENT INFORMATION NOT INCLUDED BY REFERENCE TO TYPE II ACTIVE PHARMACEUTICAL INGREDIENT DRUG MASTER FILE.—In establishing the fees under paragraphs (1) and (2), the amount of the fee under subsection (a)(3)(F) shall be determined by multiplying—

(A) the sum of—

(i) the total number of such active pharmaceutical ingredients in such submission; and

(ii) for each such ingredient that is manufactured at more than one such facility, the total number of such additional facilities; and

(B) the amount equal to the drug master file fee established in subsection (a)(2) for such submission.

(e) LIMIT.—The total amount of fees charged, as adjusted under subsection (c), for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for human generic drug activities.

(f) IDENTIFICATION OF FACILITIES.—

(1) PUBLICATION OF NOTICE; DEADLINE FOR COMPLIANCE.—Not later than October 1, 2012, the Secretary shall cause to be published in the Federal Register a notice requiring each person that owns a facility described in subsection (a)(4)(A), or a site or organization required to be identified by paragraph (4), to submit to the Secretary information on the identity of each such facility, site, or organization. The notice required by this paragraph shall specify the type of information to be submitted and the means and format for submission of such information.

(2) REQUIRED SUBMISSION OF FACILITY IDENTIFICATION.—Each person that owns a facility described in subsection (a)(4)(A) or a site or organization required to be identified by paragraph (4) shall submit to the Secretary the information required under this subsection each year. Such information shall—

(A) for fiscal year 2013, be submitted not later than 60 days after the publication of the notice under paragraph (1); and

(B) for each subsequent fiscal year, be submitted, updated, or reconfirmed on or before June 1 of the previous year.

(3) CONTENTS OF NOTICE.—At a minimum, the submission required by paragraph (2) shall include for each such facility—

(A) identification of a facility identified or intended to be identified in an approved or pending generic drug submission;

(B) whether the facility manufactures active pharmaceutical ingredients or finished dosage forms, or both;

(C) whether or not the facility is located within the United States and its territories and possessions;

(D) whether the facility manufactures positron emission tomography drugs solely, or in addition to other drugs; and

(E) whether the facility manufactures drugs that are not generic drugs.

(4) CERTAIN SITES AND ORGANIZATIONS.—

(A) IN GENERAL.—Any person that owns or operates a site or organization described in subparagraph (B) shall submit to the Secretary information concerning the ownership, name, and address of the site or organization.

(B) SITES AND ORGANIZATIONS.—A site or organization is described in this subparagraph if it is identified in a generic drug submission and is—

(i) a site in which a bioanalytical study is conducted;

(ii) a clinical research organization;

(iii) a contract analytical testing site; or

(iv) a contract repackager site.

(C) NOTICE.—The Secretary may, by notice published in the Federal Register, specify the means and format for submission of the information under subparagraph (A) and

may specify, as necessary for purposes of this section, any additional information to be submitted.

(D) INSPECTION AUTHORITY.—The Secretary's inspection authority under section 704(a)(1) shall extend to all such sites and organizations.

(g) EFFECT OF FAILURE TO PAY FEES.—

(1) GENERIC DRUG BACKLOG FEE.—Failure to pay the fee under subsection (a)(1) shall result in the Secretary placing the person that owns the abbreviated new drug application subject to that fee on an arrears list, such that no new abbreviated new drug applications or supplement submitted on or after October 1, 2012, from that person, or any affiliate of that person, will be received within the meaning of section 505(j)(5)(A) until such outstanding fee is paid.

(2) DRUG MASTER FILE FEE.—

(A) Failure to pay the fee under subsection (a)(2) within 20 calendar days after the applicable due date under subparagraph (E) of such subsection (as described in subsection (a)(2)(D)(ii)(I)) shall result in the Type II active pharmaceutical ingredient drug master file not being deemed available for reference.

(B)(i) Any generic drug submission submitted on or after October 1, 2012, that references, by a letter of authorization, a Type II active pharmaceutical ingredient drug master file that has not been deemed available for reference shall not be received within the meaning of section 505(j)(5)(A) unless the condition specified in clause (ii) is met.

(ii) The condition specified in this clause is that the fee established under subsection (a)(2) has been paid within 20 calendar days of the Secretary providing the notification to the sponsor of the abbreviated new drug application or supplement of the failure of the owner of the Type II active pharmaceutical ingredient drug master file to pay the drug master file fee as specified in subparagraph (C).

(C)(i) If an abbreviated new drug application or supplement to an abbreviated new drug application references a Type II active pharmaceutical ingredient drug master file for which a fee under subsection (a)(2)(A) has not been paid by the applicable date under subsection (a)(2)(E), the Secretary shall notify the sponsor of the abbreviated new drug application or supplement of the failure of the owner of the Type II active pharmaceutical ingredient drug master file to pay the applicable fee.

(ii) If such fee is not paid within 20 calendar days of the Secretary providing the notification, the abbreviated new drug application or supplement to an abbreviated new drug application shall not be received within the meaning of 505(j)(5)(A).

(3) ABBREVIATED NEW DRUG APPLICATION FEE AND PRIOR APPROVAL SUPPLEMENT FEE.—Failure to pay a fee under subparagraph (A) or (F) of subsection (a)(3) within 20 calendar days of the applicable due date under subparagraph (C) of such subsection shall result in the abbreviated new drug application or the prior approval supplement to an abbreviated new drug ap-

plication not being received within the meaning of section 505(j)(5)(A) until such outstanding fee is paid.

(4) GENERIC DRUG FACILITY FEE AND ACTIVE PHARMACEUTICAL INGREDIENT FACILITY FEE.—

(A) IN GENERAL.—Failure to pay the fee under subsection (a)(4) within 20 calendar days of the due date as specified in subparagraph (D) of such subsection shall result in the following:

(i) The Secretary shall place the facility on a publicly available arrears list, such that no new abbreviated new drug application or supplement submitted on or after October 1, 2012, from the person that is responsible for paying such fee, or any affiliate of that person, will be received within the meaning of section 505(j)(5)(A).

(ii) Any new generic drug submission submitted on or after October 1, 2012, that references such a facility shall not be received, within the meaning of section 505(j)(5)(A) if the outstanding facility fee is not paid within 20 calendar days of the Secretary providing the notification to the sponsor of the failure of the owner of the facility to pay the facility fee under subsection (a)(4)(C).

(iii) All drugs or active pharmaceutical ingredients manufactured in such a facility or containing an ingredient manufactured in such a facility shall be deemed misbranded under section 502(aa).

(B) APPLICATION OF PENALTIES.—The penalties under this paragraph shall apply until the fee established by subsection (a)(4) is paid or the facility is removed from all generic drug submissions that refer to the facility.

(C) NONRECEIVAL FOR NONPAYMENT.—

(i) NOTICE.—If an abbreviated new drug application or supplement to an abbreviated new drug application submitted on or after October 1, 2012, references a facility for which a facility fee has not been paid by the applicable date under subsection (a)(4)(C), the Secretary shall notify the sponsor of the generic drug submission of the failure of the owner of the facility to pay the facility fee.

(ii) NONRECEIVAL.—If the facility fee is not paid within 20 calendar days of the Secretary providing the notification under clause (i), the abbreviated new drug application or supplement to an abbreviated new drug application shall not be received within the meaning of section 505(j)(5)(A).

(h) LIMITATIONS.—

(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 2012, unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2009 (excluding the amount of fees appropriated for such fiscal year)

multiplied by the adjustment factor (as defined in section 744A) applicable to the fiscal year involved.

(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year 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 Type II active pharmaceutical ingredient drug master files, abbreviated new drug applications and prior approval supplements, and generic drug facilities and active pharmaceutical ingredient facilities at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(i) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, subject to paragraph (2). 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 human generic drug activities.

(2) COLLECTIONS AND APPROPRIATION ACTS.—

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

(i) subject to subparagraphs (C) and (D), shall be collected and available 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 a fiscal year beginning after fiscal year 2012 to defray the costs of human generic drug activities (including such costs for an additional number of full-time equivalent positions in the Department of Health and HumanServices to be engaged in such activities), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than $97,000,000 multiplied by the adjustment factor defined in section 744A(3) applicable to the fiscal year involved.

(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for human generic activities are not more than 10 percent below the level specified in such subparagraph.

(C) FEE COLLECTION DURING FIRST PROGRAM YEAR.—Until the date of enactment of an Act making appropriations through September 30, 2013 for the salaries and expenses account of the Food and Drug Administration, fees authorized by this section for fiscal year 2013, may be collected and shall be credited to such account and remain available until expended.

(D) PROVISION FOR EARLY PAYMENTS IN SUBSEQUENT YEARS.—Payment of fees authorized under this section for

a fiscal year (after fiscal year 2013), prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2013 through 2017, there is authorized to be appropriated for fees under this section an amount equivalent to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted under subsection (c), if applicable, or as otherwise affected under paragraph (2) of this subsection.

(j) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 calendar days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

(k) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in human generic drug activities, be reduced to offset the number of officers, employees, and advisory committees so engaged.

(l) POSITRON EMISSION TOMOGRAPHY DRUGS.—

(1) EXEMPTION FROM FEES.—Submission of an application for a positron emission tomography drug or active pharmaceutical ingredient for a positron emission tomography drug shall not require the payment of any fee under this section. Facilities that solely produce positron emission tomography drugs shall not be required to pay a facility fee as established in subsection (a)(4).

(2) IDENTIFICATION REQUIREMENT.—Facilities that produce positron emission tomography drugs or active pharmaceutical ingredients of such drugs are required to be identified pursuant to subsection (f).

(m) DISPUTES CONCERNING FEES.—To qualify for the return of a fee claimed to have been paid in error under this section, a person shall submit to the Secretary a written request justifying such return within 180 calendar days after such fee was paid.

(n) SUBSTANTIALLY COMPLETE APPLICATIONS.—An abbreviated new drug application that is not considered to be received within the meaning of section 505(j)(5)(A) because of failure to pay an applicable fee under this provision within the time period specified in subsection (g) shall be deemed not to have been "substantially complete" on the date of its submission within the meaning of section 505(j)(5)(B)(iv)(II)(cc). An abbreviated new drug application that is not substantially complete on the date of its submission solely because of failure to pay an applicable fee under the preceding sentence shall be deemed substantially complete and received within the meaning of section 505(j)(5)(A) as of the date such applicable fee is received.

SEC. 744C. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) PERFORMANCE REPORT.—

(1) IN GENERAL.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this part, 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 301(b) of the Generic Drug User Fee Amendments of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(2) REGULATORY SCIENCE ACCOUNTABILITY METRICS.—The report required by paragraph (1) shall describe the amounts spent, data generated, and activities undertaken, including any FDA Advisory Committee consideration, by the Secretary for each of the local acting bioequivalence topics (Topics 1–3) in the Regulatory Science Plan described in the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2012.

(b) FISCAL REPORT.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this part, 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) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

(d) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals, and plans for meeting the goals, for human generic drug activities for the first 5 fiscal years after fiscal year 2017, 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 generic drug industry.

(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the generic drug industry on the reauthorization of this part, the Secretary shall—

(A) publish a notice in the Federal Register requesting public input on the reauthorization;

(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

(D) publish the comments on the Food and Drug Administration's Internet Web site.

(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the generic drug industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the generic drug industry, the Secretary shall—

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

(B) publish such recommendations in the Federal Register;

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

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

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

(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2017, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), 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.

(6) MINUTES OF NEGOTIATION MEETINGS.—

(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the generic drug industry.

(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

[Effective October 1, 2017, section 304(a) of H.R. 5651 provides for a repeal of sections 744A and 744B (as added by the bill).]

[SEC. 744A. DEFINITIONS.

[For purposes of this part:

[(1) The term "abbreviated new drug application"—

[(A) means an application submitted under section 505(j), an abbreviated application submitted under section 507 (as in effect on the day before the date of enactment of the Food and Drug Administration Modernization Act of 1997), or an abbreviated new drug application submitted pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984; and

[(B) does not include an application for a positron emission tomography drug.

[(2) The term "active pharmaceutical ingredient" means—

[(A) a substance, or a mixture when the substance is unstable or cannot be transported on its own, intended—

[(i) to be used as a component of a drug; and

[(ii) to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the human body; or

[(B) a substance intended for final crystallization, purification, or salt formation, or any combination of those activities, to become a substance or mixture described in subparagraph (A).

[(3) The term "adjustment factor" means a factor applicable to a fiscal year that is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 2011.

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

[(A) one business entity controls, or has the power to control, the other business entity; or

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

[(5)(A) The term "facility"—

[(i) means a business or other entity—

[(I) under one management, either direct or indirect; and

[(II) at one geographic location or address engaged in manufacturing or processing an active pharmaceutical ingredient or a finished dosage form; and

[(ii) does not include a business or other entity whose only manufacturing or processing activities are one or more of the following: repackaging, relabeling, or testing.

[(B) For purposes of subparagraph (A), separate buildings within close proximity are considered to be at one geographic location or address if the activities in them are—

[(i) closely related to the same business enterprise;

[(ii) under the supervision of the same local management; and

[(iii) capable of being inspected by the Food and Drug Administration during a single inspection.

[(C) If a business or other entity would meet the definition of a facility under this paragraph but for being under multiple management, the business or other entity is deemed to constitute multiple facilities, one per management entity, for purposes of this paragraph.

[(6) The term "finished dosage form" means—

[(A) a drug product in the form in which it will be administered to a patient, such as a tablet, capsule, solution, or topical application;

[(B) a drug product in a form in which reconstitution is necessary prior to administration to a patient, such as oral suspensions or lyophilized powders; or

[(C) any combination of an active pharmaceutical ingredient with another component of a drug product for pur-

poses of production of a drug product described in subparagraph (A) or (B).

[(7) The term "generic drug submission" means an abbreviated new drug application, an amendment to an abbreviated new drug application, or a prior approval supplement to an abbreviated new drug application.

[(8) The term "human generic drug activities" means the following activities of the Secretary associated with generic drugs and inspection of facilities associated with generic drugs:

[(A) The activities necessary for the review of generic drug submissions, including review of drug master files referenced in such submissions.

[(B) The issuance of—

[(i) approval letters which approve abbreviated new drug applications or supplements to such applications; or

[(ii) complete response letters which set forth in detail the specific deficiencies in such applications and, where appropriate, the actions necessary to place such applications in condition for approval.

[(C) The issuance of letters related to Type II active pharmaceutical drug master files which—

[(i) set forth in detail the specific deficiencies in such submissions, and where appropriate, the actions necessary to resolve those deficiencies; or

[(ii) document that no deficiencies need to be addressed.

[(D) Inspections related to generic drugs.

[(E) Monitoring of research conducted in connection with the review of generic drug submissions and drug master files.

[(F) Postmarket safety activities with respect to drugs approved under abbreviated new drug applications 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) insofar as those activities relate to abbreviated new drug applications.

[(v) Carrying out section 505(k)(5) (relating to adverse-event reports and postmarket safety activities).

[(G) Regulatory science activities related to generic drugs.

[(9) The term "positron emission tomography drug" has the meaning given to the term "compounded positron emission to-

mography drug" in section 201(ii), except that paragraph (1)(B) of such section shall not apply.

[(10) The term "prior approval supplement" means a request to the Secretary to approve a change in the drug substance, drug product, production process, quality controls, equipment, or facilities covered by an approved abbreviated new drug application when that change has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.

[(11) The term "resources allocated for human generic drug activities" means the expenses for—

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

[(D) collecting fees under subsection (a) and accounting for resources allocated for the review of abbreviated new drug applications and supplements and inspection related to generic drugs.

[(12) The term "Type II active pharmaceutical ingredient drug master file" means a submission of information to the Secretary by a person that intends to authorize the Food and Drug Administration to reference the information to support approval of a generic drug submission without the submitter having to disclose the information to the generic drug submission applicant.

[SEC. 744B. AUTHORITY TO ASSESS AND USE HUMAN GENERIC DRUG FEES.

[(a) TYPES OF FEES.—Beginning in fiscal year 2013, the Secretary shall assess and collect fees in accordance with this section as follows:

[(1) ONE-TIME BACKLOG FEE FOR ABBREVIATED NEW DRUG APPLICATIONS PENDING ON OCTOBER 1, 2012.—

[(A) IN GENERAL.—Each person that owns an abbreviated new drug application that is pending on October 1, 2012, and that has not received a tentative approval prior to that date, shall be subject to a fee for each such application, as calculated under subparagraph (B).

[(B) METHOD OF FEE AMOUNT CALCULATION.—The amount of each one-time backlog fee shall be calculated by dividing $50,000,000 by the total number of abbreviated new drug applications pending on October 1, 2012, that have not received a tentative approval as of that date.

[(C) NOTICE.—Not later than October 31, 2012, the Secretary shall cause to be published in the Federal Register a notice announcing the amount of the fee required by subparagraph (A).

[(D) FEE DUE DATE.—The fee required by subparagraph (A) shall be due no later than 30 calendar days after the date of the publication of the notice specified in subparagraph (C).

[(2) DRUG MASTER FILE FEE.—

[(A) IN GENERAL.—Each person that owns a Type II active pharmaceutical ingredient drug master file that is referenced on or after October 1, 2012, in a generic drug submission by any initial letter of authorization shall be subject to a drug master file fee.

[(B) ONE-TIME PAYMENT.—If a person has paid a drug master file fee for a Type II active pharmaceutical ingredient drug master file, the person shall not be required to pay a subsequent drug master file fee when that Type II active pharmaceutical ingredient drug master file is subsequently referenced in generic drug submissions.

[(C) NOTICE.—

[(i) FISCAL YEAR 2013.—Not later than October 31, 2012, the Secretary shall cause to be published in the Federal Register a notice announcing the amount of the drug master file fee for fiscal year 2013.

[(ii) FISCAL YEAR 2014 THROUGH 2017.—Not later than 60 days before the start of each of fiscal years 2014 through 2017, the Secretary shall cause to be published in the Federal Register the amount of the drug master file fee established by this paragraph for such fiscal year.

[(D) AVAILABILITY FOR REFERENCE.—

[(i) IN GENERAL.—Subject to subsection (g)(2)(C), for a generic drug submission to reference a Type II active pharmaceutical ingredient drug master file, the drug master file must be deemed available for reference by the Secretary.

[(ii) CONDITIONS.—A drug master file shall be deemed available for reference by the Secretary if—

[(I) the person that owns a Type II active pharmaceutical ingredient drug master file has paid the fee required under subparagraph (A) within 20 calendar days after the applicable due date under subparagraph (E); and

[(II) the drug master file has not failed an initial completeness assessment by the Secretary, in accordance with criteria to be published by the Secretary.

[(iii) LIST.—The Secretary shall make publicly available on the Internet Web site of the Food and Drug Administration a list of the drug master file numbers that correspond to drug master files that have successfully undergone an initial completeness assessment, in accordance with criteria to be published by the Secretary, and are available for reference.

[(E) FEE DUE DATE.—

[(i) IN GENERAL.—Subject to clause (ii), a drug master file fee shall be due no later than the date on which the first generic drug submission is submitted

that references the associated Type II active pharmaceutical ingredient drug master file.

[(ii) LIMITATION.— No fee shall be due under subparagraph (A) for a fiscal year until the later of—

[(I) 30 calendar days after publication of the notice provided for in clause (i) or (ii) of subparagraph (C), as applicable; or

[(II) 30 calendar days after the date of enactment of an appropriations Act providing for the collection and obligation of fees under this section.

[(3) ABBREVIATED NEW DRUG APPLICATION AND PRIOR APPROVAL SUPPLEMENT FILING FEE.—

[(A) IN GENERAL.—Each applicant that submits, on or after October 1, 2012, an abbreviated new drug application or a prior approval supplement to an abbreviated new drug application shall be subject to a fee for each such submission in the amount established under subsection (d).

[(B) NOTICE.—

[(i) FISCAL YEAR 2013.—Not later than October 31, 2012, the Secretary shall cause to be published in the Federal Register a notice announcing the amount of the fees under subparagraph (A) for fiscal year 2013.

[(ii) FISCAL YEARS 2014 THROUGH 2017.—Not later than 60 days before the start of each of fiscal years 2014 through 2017, the Secretary shall cause to be published in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

[(C) FEE DUE DATE.—

[(i) IN GENERAL.—Except as provided in clause (ii), the fees required by subparagraphs (A) and (F) shall be due no later than the date of submission of the abbreviated new drug application or prior approval supplement for which such fee applies.

[(ii) SPECIAL RULE FOR 2013.—For fiscal year 2013, such fees shall be due on the later of—

[(I) the date on which the fee is due under clause (i);

[(II) 30 calendar days after publication of the notice referred to in subparagraph (B)(i); or

[(III) if an appropriations Act is not enacted providing for the collection and obligation of fees under this section by the date of submission of the application or prior approval supplement for which the fees under subparagraphs (A) and (F) apply, 30 calendar days after the date that such an appropriations Act is enacted.

[(D) REFUND OF FEE IF ABBREVIATED NEW DRUG APPLICATION IS NOT CONSIDERED TO HAVE BEEN RECEIVED.—The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any abbreviated new drug application or prior approval supplement to an abbreviated new drug application that the Secretary considers not to have been received within the meaning of section 505(j)(5)(A) for a cause other than failure to pay fees.

[(E) FEE FOR AN APPLICATION THE SECRETARY CONSIDERS NOT TO HAVE BEEN RECEIVED, OR THAT HAS BEEN WITHDRAWN.—An abbreviated new drug application or prior approval supplement that was submitted on or after October 1, 2012, and that the Secretary considers not to have been received, or that has been withdrawn, shall, upon resubmission of the application or a subsequent new submission following the applicant's withdrawal of the application, be subject to a full fee under subparagraph (A).

[(F) ADDITIONAL FEE FOR ACTIVE PHARMACEUTICAL INGREDIENT INFORMATION NOT INCLUDED BY REFERENCE TO TYPE II ACTIVE PHARMACEUTICAL INGREDIENT DRUG MASTER FILE.—An applicant that submits a generic drug submission on or after October 1, 2012, shall pay a fee, in the amount determined under subsection (d)(3), in addition to the fee required under subparagraph (A), if—

[(i) such submission contains information concerning the manufacture of an active pharmaceutical ingredient at a facility by means other than reference by a letter of authorization to a Type II active pharmaceutical drug master file; and

[(ii) a fee in the amount equal to the drug master file fee established in paragraph (2) has not been previously paid with respect to such information.

[(4) GENERIC DRUG FACILITY FEE AND ACTIVE PHARMACEUTICAL INGREDIENT FACILITY FEE.—

[(A) IN GENERAL.—Facilities identified, or intended to be identified, in at least one generic drug submission that is pending or approved to produce a finished dosage form of a human generic drug or an active pharmaceutical ingredient contained in a human generic drug shall be subject to fees as follows:

[(i) GENERIC DRUG FACILITY.—Each person that owns a facility which is identified or intended to be identified in at least one generic drug submission that is pending or approved to produce one or more finished dosage forms of a human generic drug shall be assessed an annual fee for each such facility.

[(ii) ACTIVE PHARMACEUTICAL INGREDIENT FACILITY.—Each person that owns a facility which produces, or which is pending review to produce, one or more active pharmaceutical ingredients identified, or intended to be identified, in at least one generic drug submission that is pending or approved or in a Type II active pharmaceutical ingredient drug master file referenced in such a generic drug submission, shall be assessed an annual fee for each such facility.

[(iii) FACILITIES PRODUCING BOTH ACTIVE PHARMACEUTICAL INGREDIENTS AND FINISHED DOSAGE FORMS.—Each person that owns a facility identified, or intended to be identified, in at least one generic drug submission that is pending or approved to produce both one or more finished dosage forms subject to clause (i) and one or more active pharmaceutical in-

gredients subject to clause (ii) shall be subject to fees under both such clauses for that facility.

[(B) AMOUNT.—The amount of fees established under subparagraph (A) shall be established under subsection (d).

[(C) NOTICE.—

[(i) FISCAL YEAR 2013.—For fiscal year 2013, the Secretary shall cause to be published in the Federal Register a notice announcing the amount of the fees provided for in subparagraph (A) within the timeframe specified in subsection (d)(1)(B).

[(ii) FISCAL YEARS 2014 THROUGH 2017.—Within the timeframe specified in subsection (d)(2), the Secretary shall cause to be published in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

[(D) FEE DUE DATE.—

[(i) FISCAL YEAR 2013.—For fiscal year 2013, the fees under subparagraph (A) shall be due on the later of—

[(I) not later than 45 days after the publication of the notice under subparagraph (B); or

[(II) if an appropriations Act is not enacted providing for the collection and obligation of fees under this section by the date of the publication of such notice, 30 days after the date that such an appropriations Act is enacted.

[(ii) FISCAL YEARS 2014 THROUGH 2017.—For each of fiscal years 2014 through 2017, the fees under subparagraph (A) for such fiscal year shall be due on the later of—

[(I) the first business day on or after October 1 of each such year; or

[(II) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees under this section for such year.

[(5) DATE OF SUBMISSION.—For purposes of this part, a generic drug submission or Type II pharmaceutical master file is deemed to be "submitted" to the Food and Drug Administration—

[(A) if it is submitted via a Food and Drug Administration electronic gateway, on the day when transmission to that electronic gateway is completed, except that a submission or master file that arrives on a weekend, Federal holiday, or day when the Food and Drug Administration office that will review that submission is not otherwise open for business shall be deemed to be submitted on the next day when that office is open for business; and

[(B) if it is submitted in physical media form, on the day it arrives at the appropriate designated document room of the Food and Drug Administration.

[(b) FEE REVENUE AMOUNTS.—

[(1) IN GENERAL.—

[(A) FISCAL YEAR 2013.—For fiscal year 2013, fees under subsection (a) shall be established to generate a total esti-

mated revenue amount under such subsection of $299,000,000. Of that amount—

[(i) $50,000,000 shall be generated by the one-time backlog fee for generic drug applications pending on October 1, 2012, established in subsection (a)(1); and

[(ii) $249,000,000 shall be generated by the fees under paragraphs (2) through (4) of subsection (a).

[(B) FISCAL YEARS 2014 THROUGH 2017.—For each of the fiscal years 2014 through 2017, fees under paragraphs (2) through (4) of subsection (a) shall be established to generate a total estimated revenue amount under such subsection that is equal to $299,000,000, as adjusted pursuant to subsection (c).

[(2) TYPES OF FEES.—In establishing fees under paragraph (1) to generate the revenue amounts specified in paragraph (1)(A)(ii) for fiscal year 2013 and paragraph (1)(B) for each of fiscal years 2014 through 2017, such fees shall be derived from the fees under paragraphs (2) through (4) of subsection (a) as follows:

[(A) 6 percent shall be derived from fees under subsection (a)(2) (relating to drug master files).

[(B) 24 percent shall be derived from fees under subsection (a)(3) (relating to abbreviated new drug applications and supplements). The amount of a fee for a prior approval supplement shall be half the amount of the fee for an abbreviated new drug application.

[(C) 56 percent shall be derived from fees under subsection (a)(4)(A)(i) (relating to generic drug facilities). The amount of the fee for a facility located outside the United States and its territories and possessions shall be not less than $15,000 and not more than $30,000 higher than the amount of the fee for a facility located in the United States and its territories and possessions, as determined by the Secretary on the basis of data concerning the difference in cost between inspections of facilities located in the United States, including its territories and possessions, and those located outside of the United States and its territories and possessions.

[(D) 14 percent shall be derived from fees under subsection (a)(4)(A)(ii) (relating to active pharmaceutical ingredient facilities). The amount of the fee for a facility located outside the United States and its territories and possessions shall be not less than $15,000 and not more than $30,000 higher than the amount of the fee for a facility located in the United States, including its territories and possessions, as determined by the Secretary on the basis of data concerning the difference in cost between inspections of facilities located in the United States and its territories and possessions and those located outside of the United States and its territories and possessions.

[(c) ADJUSTMENTS.—

[(1) INFLATION ADJUSTMENT.— For fiscal year 2014 and subsequent fiscal years, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the

Federal Register, for a fiscal year, by an amount equal to the sum of—

[(A) one;

[(B) the average annual percent 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 3 years of the preceding 4 fiscal years multiplied by the proportion of personnel compensation and benefits costs to total costs of human generic drug activities for the first 3 years of the preceding 4 fiscal years; and

[(C) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of human generic drug activities for the first 3 years of the preceding 4 fiscal years.

The adjustment made each fiscal year under this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2013 under this subsection.

[(2) FINAL YEAR ADJUSTMENT.—For fiscal year 2017, the Secretary may, in addition to adjustments under paragraph (1), further increase the fee revenues and fees established in subsection (b) if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for human generic drug activities for the first 3 months of fiscal year 2018. Such fees may only be used in fiscal year 2018. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2017. If the Secretary has carryover balances for such activities in excess of 3 months of such operating reserves, the adjustment under this subparagraph shall not be made.

[(d) ANNUAL FEE SETTING.—

[(1) FISCAL YEAR 2013.—For fiscal year 2013—

[(A) the Secretary shall establish, by October 31, 2012, the one-time generic drug backlog fee for generic drug applications pending on October 1, 2012, the drug master file fee, the abbreviated new drug application fee, and the prior approval supplement fee under subsection (a), based on the revenue amounts established under subsection (b); and

[(B) the Secretary shall establish, not later than 45 days after the date to comply with the requirement for identification of facilities in subsection (f)(2), the generic drug facility fee and active pharmaceutical ingredient facility fee under subsection (a) based on the revenue amounts established under subsection (b).

[(2) FISCAL YEARS 2014 THROUGH 2017.—Not more than 60 days before the first day of each of fiscal years 2014 through 2017, the Secretary shall establish the drug master file fee, the abbreviated new drug application fee, the prior approval sup-

plement fee, the generic drug facility fee, and the active pharmaceutical ingredient facility fee under subsection (a) for such fiscal year, based on the revenue amounts established under subsection (b) and the adjustments provided under subsection (c).

[(3) FEE FOR ACTIVE PHARMACEUTICAL INGREDIENT INFORMATION NOT INCLUDED BY REFERENCE TO TYPE II ACTIVE PHARMACEUTICAL INGREDIENT DRUG MASTER FILE.—In establishing the fees under paragraphs (1) and (2), the amount of the fee under subsection (a)(3)(F) shall be determined by multiplying—

[(A) the sum of—

[(i) the total number of such active pharmaceutical ingredients in such submission; and

[(ii) for each such ingredient that is manufactured at more than one such facility, the total number of such additional facilities; and

[(B) the amount equal to the drug master file fee established in subsection (a)(2) for such submission.

[(e) LIMIT.— The total amount of fees charged, as adjusted under subsection (c), for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for human generic drug activities.

[(f) IDENTIFICATION OF FACILITIES.—

[(1) PUBLICATION OF NOTICE; DEADLINE FOR COMPLIANCE.— Not later than October 1, 2012, the Secretary shall cause to be published in the Federal Register a notice requiring each person that owns a facility described in subsection (a)(4)(A), or a site or organization required to be identified by paragraph (4), to submit to the Secretary information on the identity of each such facility, site, or organization. The notice required by this paragraph shall specify the type of information to be submitted and the means and format for submission of such information.

[(2) REQUIRED SUBMISSION OF FACILITY IDENTIFICATION.— Each person that owns a facility described in subsection (a)(4)(A) or a site or organization required to be identified by paragraph (4) shall submit to the Secretary the information required under this subsection each year. Such information shall—

[(A) for fiscal year 2013, be submitted not later than 60 days after the publication of the notice under paragraph (1); and

[(B) for each subsequent fiscal year, be submitted, updated, or reconfirmed on or before June 1 of the previous year.

[(3) CONTENTS OF NOTICE.—At a minimum, the submission required by paragraph (2) shall include for each such facility—

[(A) identification of a facility identified or intended to be identified in an approved or pending generic drug submission;

[(B) whether the facility manufactures active pharmaceutical ingredients or finished dosage forms, or both;

[(C) whether or not the facility is located within the United States and its territories and possessions;

[(D) whether the facility manufactures positron emission tomography drugs solely, or in addition to other drugs; and

[(E) whether the facility manufactures drugs that are not generic drugs.

[(4) CERTAIN SITES AND ORGANIZATIONS.—

[(A) IN GENERAL.—Any person that owns or operates a site or organization described in subparagraph (B) shall submit to the Secretary information concerning the ownership, name, and address of the site or organization.

[(B) SITES AND ORGANIZATIONS.—A site or organization is described in this subparagraph if it is identified in a generic drug submission and is—

[(i) a site in which a bioanalytical study is conducted;

[(ii) a clinical research organization;

[(iii) a contract analytical testing site; or

[(iv) a contract repackager site.

[(C) NOTICE.—The Secretary may, by notice published in the Federal Register, specify the means and format for submission of the information under subparagraph (A) and may specify, as necessary for purposes of this section, any additional information to be submitted.

[(D) INSPECTION AUTHORITY.—The Secretary's inspection authority under section 704(a)(1) shall extend to all such sites and organizations.

[(g) EFFECT OF FAILURE TO PAY FEES.—

[(1) GENERIC DRUG BACKLOG FEE.—Failure to pay the fee under subsection (a)(1) shall result in the Secretary placing the person that owns the abbreviated new drug application subject to that fee on an arrears list, such that no new abbreviated new drug applications or supplement submitted on or after October 1, 2012, from that person, or any affiliate of that person, will be received within the meaning of section 505(j)(5)(A) until such outstanding fee is paid.

[(2) DRUG MASTER FILE FEE.—

[(A) Failure to pay the fee under subsection (a)(2) within 20 calendar days after the applicable due date under subparagraph (E) of such subsection (as described in subsection (a)(2)(D)(ii)(I)) shall result in the Type II active pharmaceutical ingredient drug master file not being deemed available for reference.

[(B)(i) Any generic drug submission submitted on or after October 1, 2012, that references, by a letter of authorization, a Type II active pharmaceutical ingredient drug master file that has not been deemed available for reference shall not be received within the meaning of section 505(j)(5)(A) unless the condition specified in clause (ii) is met.

[(ii) The condition specified in this clause is that the fee established under subsection (a)(2) has been paid within 20 calendar days of the Secretary providing the notification to the sponsor of the abbreviated new drug application or supplement of the failure of the owner of the Type II active pharmaceutical ingredient drug master file to pay the drug master file fee as specified in subparagraph (C).

[(C)(i) If an abbreviated new drug application or supplement to an abbreviated new drug application references a

Type II active pharmaceutical ingredient drug master file for which a fee under subsection (a)(2)(A) has not been paid by the applicable date under subsection (a)(2)(E), the Secretary shall notify the sponsor of the abbreviated new drug application or supplement of the failure of the owner of the Type II active pharmaceutical ingredient drug master file to pay the applicable fee.

[(ii) If such fee is not paid within 20 calendar days of the Secretary providing the notification, the abbreviated new drug application or supplement to an abbreviated new drug application shall not be received within the meaning of 505(j)(5)(A).

[(3) ABBREVIATED NEW DRUG APPLICATION FEE AND PRIOR APPROVAL SUPPLEMENT FEE.—Failure to pay a fee under subparagraph (A) or (F) of subsection (a)(3) within 20 calendar days of the applicable due date under subparagraph (C) of such subsection shall result in the abbreviated new drug application or the prior approval supplement to an abbreviated new drug application not being received within the meaning of section 505(j)(5)(A) until such outstanding fee is paid.

[(4) GENERIC DRUG FACILITY FEE AND ACTIVE PHARMACEUTICAL INGREDIENT FACILITY FEE.—

[(A) IN GENERAL.—Failure to pay the fee under subsection (a)(4) within 20 calendar days of the due date as specified in subparagraph (D) of such subsection shall result in the following:

[(i) The Secretary shall place the facility on a publicly available arrears list, such that no new abbreviated new drug application or supplement submitted on or after October 1, 2012, from the person that is responsible for paying such fee, or any affiliate of that person, will be received within the meaning of section 505(j)(5)(A).

[(ii) Any new generic drug submission submitted on or after October 1, 2012, that references such a facility shall not be received, within the meaning of section 505(j)(5)(A) if the outstanding facility fee is not paid within 20 calendar days of the Secretary providing the notification to the sponsor of the failure of the owner of the facility to pay the facility fee under subsection (a)(4)(C).

[(iii) All drugs or active pharmaceutical ingredients manufactured in such a facility or containing an ingredient manufactured in such a facility shall be deemed misbranded under section 502(aa).

[(B) APPLICATION OF PENALTIES.—The penalties under this paragraph shall apply until the fee established by subsection (a)(4) is paid or the facility is removed from all generic drug submissions that refer to the facility.

[(C) NONRECEIVAL FOR NONPAYMENT.—

[(i) NOTICE.—If an abbreviated new drug application or supplement to an abbreviated new drug application submitted on or after October 1, 2012, references a facility for which a facility fee has not been paid by the applicable date under subsection (a)(4)(C),

the Secretary shall notify the sponsor of the generic drug submission of the failure of the owner of the facility to pay the facility fee.

[(ii) NONRECEIVAL.—If the facility fee is not paid within 20 calendar days of the Secretary providing the notification under clause (i), the abbreviated new drug application or supplement to an abbreviated new drug application shall not be received within the meaning of section 505(j)(5)(A).

[(h) LIMITATIONS.—

[(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 2012, unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2009 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor (as defined in section 744A) applicable to the fiscal year involved.

[(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year 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 Type II active pharmaceutical ingredient drug master files, abbreviated new drug applications and prior approval supplements, and generic drug facilities and active pharmaceutical ingredient facilities at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

[(i) CREDITING AND AVAILABILITY OF FEES.—

[(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, subject to paragraph (2). 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 human generic drug activities.

[(2) COLLECTIONS AND APPROPRIATION ACTS.—

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

[(i) subject to subparagraphs (C) and (D), shall be collected and available 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 a fiscal year beginning after fiscal year 2012 to defray the costs of human generic drug activities (including such costs for an additional number of full-time equivalent positions in the Department of Health and HumanServices to be engaged in such activities), only if the Secretary allocates for such purpose an amount for such fiscal year

(excluding amounts from fees collected under this section) no less than $97,000,000 multiplied by the adjustment factor defined in section 744A(3) applicable to the fiscal year involved.

[(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for human generic activities are not more than 10 percent below the level specified in such subparagraph.

[(C) FEE COLLECTION DURING FIRST PROGRAM YEAR.—Until the date of enactment of an Act making appropriations through September 30, 2013 for the salaries and expenses account of the Food and Drug Administration, fees authorized by this section for fiscal year 2013, may be collected and shall be credited to such account and remain available until expended.

[(D) PROVISION FOR EARLY PAYMENTS IN SUBSEQUENT YEARS.—Payment of fees authorized under this section for a fiscal year (after fiscal year 2013), prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

[(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2013 through 2017, there is authorized to be appropriated for fees under this section an amount equivalent to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted under subsection (c), if applicable, or as otherwise affected under paragraph (2) of this subsection.

[(j) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 calendar days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

[(k) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in human generic drug activities, be reduced to offset the number of officers, employees, and advisory committees so engaged.

[(l) POSITRON EMISSION TOMOGRAPHY DRUGS.—

[(1) EXEMPTION FROM FEES.—Submission of an application for a positron emission tomography drug or active pharmaceutical ingredient for a positron emission tomography drug shall not require the payment of any fee under this section. Facilities that solely produce positron emission tomography drugs shall not be required to pay a facility fee as established in subsection (a)(4).

[(2) IDENTIFICATION REQUIREMENT.—Facilities that produce positron emission tomography drugs or active pharmaceutical ingredients of such drugs are required to be identified pursuant to subsection (f).

[(m) DISPUTES CONCERNING FEES.—To qualify for the return of a fee claimed to have been paid in error under this section, a person shall submit to the Secretary a written request justifying such return within 180 calendar days after such fee was paid.

[(n) SUBSTANTIALLY COMPLETE APPLICATIONS.—An abbreviated new drug application that is not considered to be received within the meaning of section 505(j)(5)(A) because of failure to pay an applicable fee under this provision within the time period specified in subsection (g) shall be deemed not to have been "substantially complete" on the date of its submission within the meaning of section 505(j)(5)(B)(iv)(II)(cc). An abbreviated new drug application that is not substantially complete on the date of its submission solely because of failure to pay an applicable fee under the preceding sentence shall be deemed substantially complete and received within the meaning of section 505(j)(5)(A) as of the date such applicable fee is received.]

[Effective January 31, 2018, section 304(b) of H.R. 5651 provides for a repeal of section 744C (as added by the bill).]

[SEC. 744C. REAUTHORIZATION; REPORTING REQUIREMENTS.

[(a) PERFORMANCE REPORT.—

[(1) IN GENERAL.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this part, 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 301(b) of the Generic Drug User Fee Amendments of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

[(2) REGULATORY SCIENCE ACCOUNTABILITY METRICS.—The report required by paragraph (1) shall describe the amounts spent, data generated, and activities undertaken, including any FDA Advisory Committee consideration, by the Secretary for each of the local acting bioequivalence topics (Topics 1–3) in the Regulatory Science Plan described in the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2012.

[(b) FISCAL REPORT.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this part, 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) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

[(d) REAUTHORIZATION.—

[(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals, and plans for meeting the goals, for human generic drug activities for the first 5 fiscal years after fiscal year 2017, 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 generic drug industry.

[(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the generic drug industry on the reauthorization of this part, the Secretary shall—

[(A) publish a notice in the Federal Register requesting public input on the reauthorization;

[(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

[(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

[(D) publish the comments on the Food and Drug Administration's Internet Web site.

[(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the generic drug industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

[(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the generic drug industry, the Secretary shall—

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

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

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

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

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

[(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2017, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), 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.

[(6) MINUTES OF NEGOTIATION MEETINGS.—

[(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings con-

ducted under this subsection between the Food and Drug Administration and the generic drug industry.

[(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.]

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PART 8—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

SEC. 744G. DEFINITIONS.

For purposes of this part:

(1) The term "adjustment factor" applicable to a fiscal year that is the Consumer Price Index for all urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items) of the preceding fiscal year divided by such Index for September 2011.

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

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

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

(3) The term "biosimilar biological product" means a product for which a biosimilar biological product application has been approved.

(4)(A) Subject to subparagraph (B), the term "biosimilar biological product application" means an application for licensure of a biological product under section 351(k) of the Public Health Service Act.

(B) Such term does not include—

(i) a supplement to such an application;

(ii) an application filed under section 351(k) of the Public Health Service Act that cites as the reference product a bovine blood product for topical application licensed before September 1, 1992, or a large volume parenteral drug product approved before such date;

(iii) an application filed under section 351(k) of the Public Health Service Act with respect to—

(I) whole blood or a blood component for transfusion;

(II) an allergenic extract product;

(III) an in vitro diagnostic biological product; or

(IV) a biological product for further manufacturing use only; or

(iv) an application for licensure under section 351(k) of the Public Health Service Act that is submitted by a State or Federal Government entity for a product that is not distributed commercially.

(5) The term "biosimilar biological product development meeting" means any meeting, other than a biosimilar initial advisory meeting, regarding the content of a development program,

including a proposed design for, or data from, a study intended to support a biosimilar biological product application.

(6) The term "biosimilar biological product development program" means the program under this part for expediting the process for the review of submissions in connection with biosimilar biological product development.

(7)(A) The term "biosimilar biological product establishment" means a foreign or domestic place of business—

(i) that is at one general physical location consisting of one or more buildings, all of which are within five miles of each other; and

(ii) at which one or more biosimilar biological products are manufactured in final dosage form.

(B) For purposes of subparagraph (A)(ii), the term "manufactured" does not include packaging.

(8) The term "biosimilar initial advisory meeting"—

(A) means a meeting, if requested, that is limited to—

(i) a general discussion regarding whether licensure under section 351(k) of the Public Health Service Act may be feasible for a particular product; and

(ii) if so, general advice on the expected content of the development program; and

(B) does not include any meeting that involves substantive review of summary data or full study reports.

(9) The term "costs of resources allocated for the process for the review of biosimilar biological product applications" means the expenses in connection with the process for the review of biosimilar biological product applications for—

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

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

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

(D) collecting fees under section 744H and accounting for resources allocated for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

(10) The term "final dosage form" means, with respect to a biosimilar biological product, a finished dosage form which is approved for administration to a patient without substantial further manufacturing (such as lyophilized products before reconstitution).

(11) The term "financial hold"—

(A) means an order issued by the Secretary to prohibit the sponsor of a clinical investigation from continuing the investigation if the Secretary determines that the investigation is intended to support a biosimilar biological product application and the sponsor has failed to pay any fee for

the product required under subparagraph (A), (B), or (D) of section 744H(a)(1); and

(B) does not mean that any of the bases for a "clinical hold" under section 505(i)(3) have been determined by the Secretary to exist concerning the investigation.

(12) The term "person" includes an affiliate of such person.

(13) The term "process for the review of biosimilar biological product applications" means the following activities of the Secretary with respect to the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements:

(A) The activities necessary for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

(B) Actions related to submissions in connection with biosimilar biological product development, the issuance of action letters which approve biosimilar biological product applications or which set forth in detail the specific deficiencies in such applications, and where appropriate, the actions necessary to place such applications in condition for approval.

(C) The inspection of biosimilar biological product establishments and other facilities undertaken as part of the Secretary's review of pending biosimilar biological product applications and supplements.

(D) Activities necessary for the release of lots of biosimilar biological products under section 351(k) of the Public Health Service Act.

(E) Monitoring of research conducted in connection with the review of biosimilar biological product applications.

(F) Postmarket safety activities with respect to biologics approved under biosimilar biological product applications or supplements, including the following activities:

(i) Collecting, developing, and reviewing safety information on biosimilar biological products, 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) Carrying out section 505(k)(5) (relating to adverse-event reports and postmarket safety activities).

(14) The term "supplement" means a request to the Secretary to approve a change in a biosimilar biological product application which has been approved, including a supplement requesting that the Secretary determine that the biosimilar biological product meets the standards for interchangeability described in section 351(k)(4) of the Public Health Service Act.

SEC. 744H. AUTHORITY TO ASSESS AND USE BIOSIMILAR BIOLOGICAL PRODUCT FEES.

(a) TYPES OF FEES.—Beginning in fiscal year 2013, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) BIOSIMILAR DEVELOPMENT PROGRAM FEES.—

(A) INITIAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—

(i) IN GENERAL.—Each person that submits to the Secretary a meeting request described under clause (ii) or a clinical protocol for an investigational new drug protocol described under clause (iii) shall pay for the product named in the meeting request or the investigational new drug application the initial biosimilar biological product development fee established under subsection (b)(1)(A).

(ii) MEETING REQUEST.—The meeting request defined in this clause is a request for a biosimilar biological product development meeting for a product.

(iii) CLINICAL PROTOCOL FOR IND.—A clinical protocol for an investigational new drug protocol described in this clause is a clinical protocol consistent with the provisions of section 505(i), including any regulations promulgated under section 505(i), (referred to in this section as "investigational new drug application") describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for a product.

(iv) DUE DATE.—The initial biosimilar biological product development fee shall be due by the earlier of the following:

(I) Not later than 5 days after the Secretary grants a request for a biosimilar biological product development meeting.

(II) The date of submission of an investigational new drug application describing an investigation that the Secretary determines is intended to support a biosimilar biological product application.

(v) TRANSITION RULE.—Each person that has submitted an investigational new drug application prior to the date of enactment of the Biosimilars User Fee Act of 2012 shall pay the initial biosimilar biological product development fee by the earlier of the following:

(I) Not later than 60 days after the date of the enactment of the Biosimilars User Fee Act of 2012, if the Secretary determines that the investigational new drug application describes an investigation that is intended to support a biosimilar biological product application.

(II) Not later than 5 days after the Secretary grants a request for a biosimilar biological product development meeting.

(B) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—

(i) IN GENERAL.—A person that pays an initial biosimilar biological product development fee for a product shall pay for such product, beginning in the fiscal year following the fiscal year in which the initial biosimilar biological product development fee was paid, an annual fee established under subsection (b)(1)(B) for biosimilar biological product development (referred to in this section as "annual biosimilar biological product development fee").

(ii) DUE DATE.—The annual biosimilar biological product development program fee for each fiscal year will be due on the later of—

(I) the first business day on or after October 1 of each such year; or

(II) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

(iii) EXCEPTION.—The annual biosimilar development program fee for each fiscal year will be due on the date specified in clause (ii), unless the person has—

(I) submitted a marketing application for the biological product that was accepted for filing; or

(II) discontinued participation in the biosimilar biological product development program for the product under subparagraph (C).

(C) DISCONTINUATION OF FEE OBLIGATION.—A person may discontinue participation in the biosimilar biological product development program for a product effective October 1 of a fiscal year by, not later than August 1 of the preceding fiscal year—

(i) if no investigational new drug application concerning the product has been submitted, submitting to the Secretary a written declaration that the person has no present intention of further developing the product as a biosimilar biological product; or

(ii) if an investigational new drug application concerning the product has been submitted, by withdrawing the investigational new drug application in accordance with part 312 of title 21, Code of Federal Regulations (or any successor regulations).

(D) REACTIVATION FEE.—

(i) IN GENERAL.—A person that has discontinued participation in the biosimilar biological product development program for a product under subparagraph (C) shall pay a fee (referred to in this section as "reactivation fee") by the earlier of the following:

(I) Not later than 5 days after the Secretary grants a request for a biosimilar biological product development meeting for the product (after the date on which such participation was discontinued).

(II) Upon the date of submission (after the date on which such participation was discontinued) of an investigational new drug application describing an investigation that the Secretary determines is

intended to support a biosimilar biological product application for that product.

(ii) APPLICATION OF ANNUAL FEE.—A person that pays a reactivation fee for a product shall pay for such product, beginning in the next fiscal year, the annual biosimilar biological product development fee under subparagraph (B).

(E) EFFECT OF FAILURE TO PAY BIOSIMILAR DEVELOPMENT PROGRAM FEES.—

(i) NO BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT MEETINGS.—If a person has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), the Secretary shall not provide a biosimilar biological product development meeting relating to the product for which fees are owed.

(ii) NO RECEIPT OF INVESTIGATIONAL NEW DRUG APPLICATIONS.—Except in extraordinary circumstances, the Secretary shall not consider an investigational new drug application to have been received under section 505(i)(2) if—

(I) the Secretary determines that the investigation is intended to support a biosimilar biological product application; and

(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee for the product as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D).

(iii) FINANCIAL HOLD.—Notwithstanding section 505(i)(2), except in extraordinary circumstances, the Secretary shall prohibit the sponsor of a clinical investigation from continuing the investigation if—

(I) the Secretary determines that the investigation is intended to support a biosimilar biological product application; and

(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee for the product as required under subparagraph (A) or (B), or a reactivation fee for the product as required under subparagraph (D).

(iv) NO ACCEPTANCE OF BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS OR SUPPLEMENTS.—If a person has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), any biosimilar biological product application or supplement submitted by that person shall be considered incomplete and shall not be accepted for filing by the Secretary until all such fees owed by such person have been paid.

(F) LIMITS REGARDING BIOSIMILAR DEVELOPMENT PROGRAM FEES.—

(i) NO REFUNDS.—The Secretary shall not refund any initial or annual biosimilar biological product development fee paid under subparagraph (A) or (B), or any reactivation fee paid under subparagraph (D).

(ii) NO WAIVERS, EXEMPTIONS, OR REDUCTIONS.—The Secretary shall not grant a waiver, exemption, or reduction of any initial or annual biosimilar biological product development fee due or payable under subparagraph (A) or (B), or any reactivation fee due or payable under subparagraph (D).

(2) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION AND SUPPLEMENT FEE.—

(A) IN GENERAL.—Each person that submits, on or after October 1, 2012, a biosimilar biological product application or a supplement shall be subject to the following fees:

(i) A fee for a biosimilar biological product application that is equal to—

(I) the amount of the fee established under subsection (b)(1)(D) for a biosimilar biological product application; minus

(II) the cumulative amount of fees paid, if any, under subparagraphs (A), (B), and (D) of paragraph (1) for the product that is the subject of the application.

(ii) A fee for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are not required, that is equal to—

(I) half of the amount of the fee established under subsection (b)(1)(D) for a biosimilar biological product application; minus

(II) the cumulative amount of fees paid, if any, under subparagraphs (A), (B), and (D) of paragraph (1) for that product.

(iii) A fee for a supplement for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required, that is equal to half of the amount of the fee established under subsection (b)(1)(D) for a biosimilar biological product application.

(B) REDUCTION IN FEES.—Notwithstanding section 404 of the Biosimilars User Fee Act of 2012, any person who pays a fee under subparagraph (A), (B), or (D) of paragraph (1) for a product before October 1, 2017, but submits a biosimilar biological product application for that product after such date, shall be entitled to the reduction of any biosimilar biological product application fees that may be assessed at the time when such biosimilar biological product application is submitted, by the cumulative amount of fees paid under subparagraphs (A), (B), and (D) of paragraph (1) for that product.

(C) PAYMENT DUE DATE.—Any fee required by subparagraph (A) shall be due upon submission of the application or supplement for which such fee applies.

(D) EXCEPTION FOR PREVIOUSLY FILED APPLICATION OR SUPPLEMENT.—If a biosimilar biological product application or supplement was submitted by a person that paid the fee for such application or supplement, was accepted for filing, and was not approved or was withdrawn (without a waiver), the submission of a biosimilar biological product application or a supplement for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

(E) REFUND OF APPLICATION FEE IF APPLICATION REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—The Secretary shall refund 75 percent of the fee paid under this paragraph for any application or supplement which is refused for filing or withdrawn without a waiver before filing.

(F) FEES FOR APPLICATIONS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—A biosimilar biological product 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 under subsection (c).

(3) BIOSIMILAR BIOLOGICAL PRODUCT ESTABLISHMENT FEE.—

(A) IN GENERAL.—Except as provided in subparagraph (E), each person that is named as the applicant in a biosimilar biological product application shall be assessed an annual fee established under subsection (b)(1)(E) for each biosimilar biological product establishment that is listed in the approved biosimilar biological product application as an establishment that manufactures the biosimilar biological product named in such application.

(B) ASSESSMENT IN FISCAL YEARS.—The establishment fee shall be assessed in each fiscal year for which the biosimilar biological product named in the application is assessed a fee under paragraph (4) unless the biosimilar biological product establishment listed in the application does not engage in the manufacture of the biosimilar biological product during such fiscal year.

(C) DUE DATE.—The establishment fee for a fiscal year shall be due on the later of—

(i) the first business day on or after October 1 of such fiscal year; or

(ii) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section.

(D) APPLICATION TO ESTABLISHMENT.—

(i) Each biosimilar biological product establishment shall be assessed only one fee per biosimilar biological product establishment, notwithstanding the number of biosimilar biological products manufactured at the establishment, subject to clause (ii).

(ii) In the event an establishment is listed in a biosimilar biological product application by more than one applicant, the establishment fee for the fiscal year

shall be divided equally and assessed among the applicants whose biosimilar biological products are manufactured by the establishment during the fiscal year and assessed biosimilar biological product fees under paragraph (4).

(E) EXCEPTION FOR NEW PRODUCTS.—If, during the fiscal year, an applicant initiates or causes to be initiated the manufacture of a biosimilar biological product at an establishment listed in its biosimilar biological product application—

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

(ii) for which the full biosimilar biological product establishment fee has been assessed in the fiscal year at a time before manufacture of the biosimilar biological product was begun,

the applicant shall not be assessed a share of the biosimilar biological product establishment fee for the fiscal year in which the manufacture of the product began.

(4) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—

(A) IN GENERAL.—Each person who is named as the applicant in a biosimilar biological product application shall pay for each such biosimilar biological product the annual fee established under subsection (b)(1)(F).

(B) DUE DATE.—The biosimilar biological product fee for a fiscal year shall be due on the later of—

(i) the first business day on or after October 1 of each such year; or

(ii) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

(C) ONE FEE PER PRODUCT PER YEAR.—The biosimilar biological product fee shall be paid only once for each product for each fiscal year.

(b) FEE SETTING AND AMOUNTS.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall, 60 days before the start of each fiscal year that begins after September 30, 2012, establish, for the next fiscal year, the fees under subsection (a). Except as provided in subsection (c), such fees shall be in the following amounts:

(A) INITIAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—The initial biosimilar biological product development fee under subsection (a)(1)(A) for a fiscal year shall be equal to 10 percent of the amount established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

(B) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—The annual biosimilar biological product development fee under subsection (a)(1)(B) for a fiscal year shall be equal to 10 percent of the amount established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

(C) REACTIVATION FEE.—The reactivation fee under subsection (a)(1)(D) for a fiscal year shall be equal to 20 percent of the amount of the fee established under section

736(c)(4) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

(D) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION FEE.—The biosimilar biological product application fee under subsection (a)(2) for a fiscal year shall be equal to the amount established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

(E) BIOSIMILAR BIOLOGICAL PRODUCT ESTABLISHMENT FEE.—The biosimilar biological product establishment fee under subsection (a)(3) for a fiscal year shall be equal to the amount established under section 736(c)(4) for a prescription drug establishment for that fiscal year.

(F) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—The biosimilar biological product fee under subsection (a)(4) for a fiscal year shall be equal to the amount established under section 736(c)(4) for a prescription drug product for that fiscal year.

(2) LIMIT.—The total amount of fees charged for a fiscal year under this section may not exceed the total amount for such fiscal year of the costs of resources allocated for the process for the review of biosimilar biological product applications.

(c) APPLICATION FEE WAIVER FOR SMALL BUSINESS.—

(1) WAIVER OF APPLICATION FEE.—The Secretary shall grant to a person who is named in a biosimilar biological product application a waiver from the application fee assessed to that person under subsection (a)(2)(A) for the first biosimilar biological product application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay—

(A) application fees for all subsequent biosimilar biological product applications submitted to the Secretary for review in the same manner as an entity that is not a small business; and

(B) all supplement fees for all supplements to biosimilar biological product applications submitted to the Secretary for review in the same manner as an entity that is not a small business.

(2) CONSIDERATIONS.—In determining whether to grant a waiver 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.

(3) SMALL BUSINESS DEFINED.—In this subsection, the term "small business" means an entity that has fewer than 500 employees, including employees of affiliates, and does not have a drug product that has been approved under a human drug application (as defined in section 735) or a biosimilar biological product application (as defined in section 744G(4)) and introduced or delivered for introduction into interstate commerce.

(d) EFFECT OF FAILURE TO PAY FEES.—A biosimilar biological product application or supplement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid.

(e) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—Subject to paragraph (2), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of biosimilar biological product applications.

(2) COLLECTIONS AND APPROPRIATION ACTS.—

(A) IN GENERAL.—Subject to subparagraphs (C) and (D), the fees authorized by this section shall be collected and available 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.

(B) USE OF FEES AND LIMITATION.—The fees authorized by this section shall be available for a fiscal year beginning after fiscal year 2012 to defray the costs of the process for the review of biosimilar biological product applications (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than $20,000,000, multiplied by the adjustment factor applicable to the fiscal year involved.

(C) FEE COLLECTION DURING FIRST PROGRAM YEAR.—Until the date of enactment of an Act making appropriations through September 30, 2013, for the salaries and expenses account of the Food and Drug Administration, fees authorized by this section for fiscal year 2013 may be collected and shall be credited to such account and remain available until expended.

(D) PROVISION FOR EARLY PAYMENTS IN SUBSEQUENT YEARS.—Payment of fees authorized under this section for a fiscal year (after fiscal year 2013), prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(3) AUTHORIZATION OF APPROPRIATIONS.—For each of fiscal years 2013 through 2017, there is authorized to be appropriated for fees under this section an amount equivalent to the total amount of fees assessed for such fiscal year under this section.

(f) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

(g) WRITTEN REQUESTS FOR WAIVERS AND REFUNDS.—To qualify for consideration for a waiver under subsection (c), or for a refund of any fee collected in accordance with subsection (a)(2)(A), a person

shall submit to the Secretary a written request for such waiver or refund not later than 180 days after such fee is due.

(h) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in the process of the review of biosimilar biological product applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

SEC. 744I. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) PERFORMANCE REPORT.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this part, 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 401(b) of the Biosimilar User Fee Act of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting such goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all biosimilar biological product applications and supplements in the cohort.

(b) FISCAL REPORT.—Not later than 120 days after the end of fiscal year 2013 and each subsequent fiscal year for which fees are collected under this part, 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) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

(d) STUDY.—

(1) IN GENERAL.—The Secretary shall contract with an independent accounting or consulting firm to study the workload volume and full costs associated with the process for the review of biosimilar biological product applications.

(2) INTERIM RESULTS.—Not later than June 1, 2015, the Secretary shall publish, for public comment, interim results of the study described under paragraph (1).

(3) FINAL RESULTS.—Not later than September 30, 2016, the Secretary shall publish, for public comment, the final results of the study described under paragraph (1).

(e) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals described in subsection (a), and plans for meeting the goals, for the process for the review of biosimilar biological product applications for the first 5 fiscal years after fiscal year 2017, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

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

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

(C) scientific and academic experts;

(D) health care professionals;

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

(F) the regulated industry.

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

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

(B) publish such recommendations in the Federal Register;

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

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

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

(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2017, the Secretary shall transmit to the 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.

[Effective October 1, 2017, section 404(a) of H.R. 5651 provides for a repeal of sections 744G and 744H (as added by the bill).]

[SEC. 744G. DEFINITIONS.

[For purposes of this part:

[(1) The term "adjustment factor" applicable to a fiscal year that is the Consumer Price Index for all urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items) of the preceding fiscal year divided by such Index for September 2011.

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

[(A) one business entity controls, or has the power to control, the other business entity; or

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

[(3) The term "biosimilar biological product" means a product for which a biosimilar biological product application has been approved.

[(4)(A) Subject to subparagraph (B), the term "biosimilar biological product application" means an application for licensure of a biological product under section 351(k) of the Public Health Service Act.

[(B) Such term does not include—

[(i) a supplement to such an application;

[(ii) an application filed under section 351(k) of the Public Health Service Act that cites as the reference product a bovine blood product for topical application licensed be-

fore September 1, 1992, or a large volume parenteral drug product approved before such date;

[(iii) an application filed under section 351(k) of the Public Health Service Act with respect to—

[(I) whole blood or a blood component for transfusion;

[(II) an allergenic extract product;

[(III) an in vitro diagnostic biological product; or

[(IV) a biological product for further manufacturing use only; or

[(iv) an application for licensure under section 351(k) of the Public Health Service Act that is submitted by a State or Federal Government entity for a product that is not distributed commercially.

[(5) The term "biosimilar biological product development meeting" means any meeting, other than a biosimilar initial advisory meeting, regarding the content of a development program, including a proposed design for, or data from, a study intended to support a biosimilar biological product application.

[(6) The term "biosimilar biological product development program" means the program under this part for expediting the process for the review of submissions in connection with biosimilar biological product development.

[(7)(A) The term "biosimilar biological product establishment" means a foreign or domestic place of business—

[(i) that is at one general physical location consisting of one or more buildings, all of which are within five miles of each other; and

[(ii) at which one or more biosimilar biological products are manufactured in final dosage form.

[(B) For purposes of subparagraph (A)(ii), the term "manufactured" does not include packaging.

[(8) The term "biosimilar initial advisory meeting"—

[(A) means a meeting, if requested, that is limited to—

[(i) a general discussion regarding whether licensure under section 351(k) of the Public Health Service Act may be feasible for a particular product; and

[(ii) if so, general advice on the expected content of the development program; and

[(B) does not include any meeting that involves substantive review of summary data or full study reports.

[(9) The term "costs of resources allocated for the process for the review of biosimilar biological product applications" means the expenses in connection with the process for the review of biosimilar biological product applications for—

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

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

[(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fix-

tures, furniture, scientific equipment, and other necessary materials and supplies; and

[(D) collecting fees under section 744H and accounting for resources allocated for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

[(10) The term "final dosage form" means, with respect to a biosimilar biological product, a finished dosage form which is approved for administration to a patient without substantial further manufacturing (such as lyophilized products before reconstitution).

[(11) The term "financial hold"—

[(A) means an order issued by the Secretary to prohibit the sponsor of a clinical investigation from continuing the investigation if the Secretary determines that the investigation is intended to support a biosimilar biological product application and the sponsor has failed to pay any fee for the product required under subparagraph (A), (B), or (D) of section 744H(a)(1); and

[(B) does not mean that any of the bases for a "clinical hold" under section 505(i)(3) have been determined by the Secretary to exist concerning the investigation.

[(12) The term "person" includes an affiliate of such person.

[(13) The term "process for the review of biosimilar biological product applications" means the following activities of the Secretary with respect to the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements:

[(A) The activities necessary for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

[(B) Actions related to submissions in connection with biosimilar biological product development, the issuance of action letters which approve biosimilar biological product applications or which set forth in detail the specific deficiencies in such applications, and where appropriate, the actions necessary to place such applications in condition for approval.

[(C) The inspection of biosimilar biological product establishments and other facilities undertaken as part of the Secretary's review of pending biosimilar biological product applications and supplements.

[(D) Activities necessary for the release of lots of biosimilar biological products under section 351(k) of the Public Health Service Act.

[(E) Monitoring of research conducted in connection with the review of biosimilar biological product applications.

[(F) Postmarket safety activities with respect to biologics approved under biosimilar biological product applications or supplements, including the following activities:

[(i) Collecting, developing, and reviewing safety information on biosimilar biological products, 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) Carrying out section 505(k)(5) (relating to adverse-event reports and postmarket safety activities).

[(14) The term "supplement" means a request to the Secretary to approve a change in a biosimilar biological product application which has been approved, including a supplement requesting that the Secretary determine that the biosimilar biological product meets the standards for interchangeability described in section 351(k)(4) of the Public Health Service Act.

[SEC. 744H. AUTHORITY TO ASSESS AND USE BIOSIMILAR BIOLOGICAL PRODUCT FEES.

[(a) TYPES OF FEES.—Beginning in fiscal year 2013, the Secretary shall assess and collect fees in accordance with this section as follows:

[(1) BIOSIMILAR DEVELOPMENT PROGRAM FEES.—

[(A) INITIAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—

[(i) IN GENERAL.—Each person that submits to the Secretary a meeting request described under clause (ii) or a clinical protocol for an investigational new drug protocol described under clause (iii) shall pay for the product named in the meeting request or the investigational new drug application the initial biosimilar biological product development fee established under subsection (b)(1)(A).

[(ii) MEETING REQUEST.—The meeting request defined in this clause is a request for a biosimilar biological product development meeting for a product.

[(iii) CLINICAL PROTOCOL FOR IND.—A clinical protocol for an investigational new drug protocol described in this clause is a clinical protocol consistent with the provisions of section 505(i), including any regulations promulgated under section 505(i), (referred to in this section as "investigational new drug application") describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for a product.

[(iv) DUE DATE.—The initial biosimilar biological product development fee shall be due by the earlier of the following:

[(I) Not later than 5 days after the Secretary grants a request for a biosimilar biological product development meeting.

[(II) The date of submission of an investigational new drug application describing an investigation that the Secretary determines is intended

to support a biosimilar biological product application.

[(v) TRANSITION RULE.—Each person that has submitted an investigational new drug application prior to the date of enactment of the Biosimilars User Fee Act of 2012 shall pay the initial biosimilar biological product development fee by the earlier of the following:

[(I) Not later than 60 days after the date of the enactment of the Biosimilars User Fee Act of 2012, if the Secretary determines that the investigational new drug application describes an investigation that is intended to support a biosimilar biological product application.

[(II) Not later than 5 days after the Secretary grants a request for a biosimilar biological product development meeting.

[(B) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—

[(i) IN GENERAL.—A person that pays an initial biosimilar biological product development fee for a product shall pay for such product, beginning in the fiscal year following the fiscal year in which the initial biosimilar biological product development fee was paid, an annual fee established under subsection (b)(1)(B) for biosimilar biological product development (referred to in this section as "annual biosimilar biological product development fee").

[(ii) DUE DATE.—The annual biosimilar biological product development program fee for each fiscal year will be due on the later of—

[(I) the first business day on or after October 1 of each such year; or

[(II) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

[(iii) EXCEPTION.—The annual biosimilar development program fee for each fiscal year will be due on the date specified in clause (ii), unless the person has—

[(I) submitted a marketing application for the biological product that was accepted for filing; or

[(II) discontinued participation in the biosimilar biological product development program for the product under subparagraph (C).

[(C) DISCONTINUATION OF FEE OBLIGATION.—A person may discontinue participation in the biosimilar biological product development program for a product effective October 1 of a fiscal year by, not later than August 1 of the preceding fiscal year—

[(i) if no investigational new drug application concerning the product has been submitted, submitting to the Secretary a written declaration that the person

has no present intention of further developing the product as a biosimilar biological product; or

[(ii) if an investigational new drug application concerning the product has been submitted, by withdrawing the investigational new drug application in accordance with part 312 of title 21, Code of Federal Regulations (or any successor regulations).

[(D) REACTIVATION FEE.—

[(i) IN GENERAL.—A person that has discontinued participation in the biosimilar biological product development program for a product under subparagraph (C) shall pay a fee (referred to in this section as "reactivation fee") by the earlier of the following:

[(I) Not later than 5 days after the Secretary grants a request for a biosimilar biological product development meeting for the product (after the date on which such participation was discontinued).

[(II) Upon the date of submission (after the date on which such participation was discontinued) of an investigational new drug application describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for that product.

[(ii) APPLICATION OF ANNUAL FEE.—A person that pays a reactivation fee for a product shall pay for such product, beginning in the next fiscal year, the annual biosimilar biological product development fee under subparagraph (B).

[(E) EFFECT OF FAILURE TO PAY BIOSIMILAR DEVELOPMENT PROGRAM FEES.—

[(i) NO BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT MEETINGS.—If a person has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), the Secretary shall not provide a biosimilar biological product development meeting relating to the product for which fees are owed.

[(ii) NO RECEIPT OF INVESTIGATIONAL NEW DRUG APPLICATIONS.—Except in extraordinary circumstances, the Secretary shall not consider an investigational new drug application to have been received under section 505(i)(2) if—

[(I) the Secretary determines that the investigation is intended to support a biosimilar biological product application; and

[(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee for the product as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D).

[(iii) FINANCIAL HOLD.—Notwithstanding section 505(i)(2), except in extraordinary circumstances, the

Secretary shall prohibit the sponsor of a clinical investigation from continuing the investigation if—

[(I) the Secretary determines that the investigation is intended to support a biosimilar biological product application; and

[(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee for the product as required under subparagraph (A) or (B), or a reactivation fee for the product as required under subparagraph (D).

[(iv) NO ACCEPTANCE OF BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS OR SUPPLEMENTS.—If a person has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), any biosimilar biological product application or supplement submitted by that person shall be considered incomplete and shall not be accepted for filing by the Secretary until all such fees owed by such person have been paid.

[(F) LIMITS REGARDING BIOSIMILAR DEVELOPMENT PROGRAM FEES.—

[(i) NO REFUNDS.—The Secretary shall not refund any initial or annual biosimilar biological product development fee paid under subparagraph (A) or (B), or any reactivation fee paid under subparagraph (D).

[(ii) NO WAIVERS, EXEMPTIONS, OR REDUCTIONS.—The Secretary shall not grant a waiver, exemption, or reduction of any initial or annual biosimilar biological product development fee due or payable under subparagraph (A) or (B), or any reactivation fee due or payable under subparagraph (D).

[(2) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION AND SUPPLEMENT FEE.—

[(A) IN GENERAL.—Each person that submits, on or after October 1, 2012, a biosimilar biological product application or a supplement shall be subject to the following fees:

[(i) A fee for a biosimilar biological product application that is equal to—

[(I) the amount of the fee established under subsection (b)(1)(D) for a biosimilar biological product application; minus

[(II) the cumulative amount of fees paid, if any, under subparagraphs (A), (B), and (D) of paragraph (1) for the product that is the subject of the application.

[(ii) A fee for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are not required, that is equal to—

[(I) half of the amount of the fee established under subsection (b)(1)(D) for a biosimilar biological product application; minus

[(II) the cumulative amount of fees paid, if any, under subparagraphs (A), (B), and (D) of paragraph (1) for that product.

[(iii) A fee for a supplement for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required, that is equal to half of the amount of the fee established under subsection (b)(1)(D) for a biosimilar biological product application.

[(B) REDUCTION IN FEES.—Notwithstanding section 404 of the Biosimilars User Fee Act of 2012, any person who pays a fee under subparagraph (A), (B), or (D) of paragraph (1) for a product before October 1, 2017, but submits a biosimilar biological product application for that product after such date, shall be entitled to the reduction of any biosimilar biological product application fees that may be assessed at the time when such biosimilar biological product application is submitted, by the cumulative amount of fees paid under subparagraphs (A), (B), and (D) of paragraph (1) for that product.

[(C) PAYMENT DUE DATE.—Any fee required by subparagraph (A) shall be due upon submission of the application or supplement for which such fee applies.

[(D) EXCEPTION FOR PREVIOUSLY FILED APPLICATION OR SUPPLEMENT.—If a biosimilar biological product application or supplement was submitted by a person that paid the fee for such application or supplement, was accepted for filing, and was not approved or was withdrawn (without a waiver), the submission of a biosimilar biological product application or a supplement for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

[(E) REFUND OF APPLICATION FEE IF APPLICATION REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—The Secretary shall refund 75 percent of the fee paid under this paragraph for any application or supplement which is refused for filing or withdrawn without a waiver before filing.

[(F) FEES FOR APPLICATIONS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—A biosimilar biological product 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 under subsection (c).

[(3) BIOSIMILAR BIOLOGICAL PRODUCT ESTABLISHMENT FEE.—

[(A) IN GENERAL.—Except as provided in subparagraph (E), each person that is named as the applicant in a biosimilar biological product application shall be assessed an annual fee established under subsection (b)(1)(E) for each biosimilar biological product establishment that is listed in the approved biosimilar biological product application as an establishment that manufactures the biosimilar biological product named in such application.

[(B) ASSESSMENT IN FISCAL YEARS.—The establishment fee shall be assessed in each fiscal year for which the biosimilar biological product named in the application is assessed a fee under paragraph (4) unless the biosimilar biological product establishment listed in the application does not engage in the manufacture of the biosimilar biological product during such fiscal year.

[(C) DUE DATE.—The establishment fee for a fiscal year shall be due on the later of—

[(i) the first business day on or after October 1 of such fiscal year; or

[(ii) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section.

[(D) APPLICATION TO ESTABLISHMENT.—

[(i) Each biosimilar biological product establishment shall be assessed only one fee per biosimilar biological product establishment, notwithstanding the number of biosimilar biological products manufactured at the establishment, subject to clause (ii).

[(ii) In the event an establishment is listed in a biosimilar biological product application by more than one applicant, the establishment fee for the fiscal year shall be divided equally and assessed among the applicants whose biosimilar biological products are manufactured by the establishment during the fiscal year and assessed biosimilar biological product fees under paragraph (4).

[(E) EXCEPTION FOR NEW PRODUCTS.—If, during the fiscal year, an applicant initiates or causes to be initiated the manufacture of a biosimilar biological product at an establishment listed in its biosimilar biological product application—

[(i) that did not manufacture the biosimilar biological product in the previous fiscal year; and

[(ii) for which the full biosimilar biological product establishment fee has been assessed in the fiscal year at a time before manufacture of the biosimilar biological product was begun,

the applicant shall not be assessed a share of the biosimilar biological product establishment fee for the fiscal year in which the manufacture of the product began.

[(4) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—

[(A) IN GENERAL.—Each person who is named as the applicant in a biosimilar biological product application shall pay for each such biosimilar biological product the annual fee established under subsection (b)(1)(F).

[(B) DUE DATE.—The biosimilar biological product fee for a fiscal year shall be due on the later of—

[(i) the first business day on or after October 1 of each such year; or

[(ii) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

[(C) ONE FEE PER PRODUCT PER YEAR.—The biosimilar biological product fee shall be paid only once for each product for each fiscal year.

[(b) FEE SETTING AND AMOUNTS.—

[(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall, 60 days before the start of each fiscal year that begins after September 30, 2012, establish, for the next fiscal year, the fees under subsection (a). Except as provided in subsection (c), such fees shall be in the following amounts:

[(A) INITIAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—The initial biosimilar biological product development fee under subsection (a)(1)(A) for a fiscal year shall be equal to 10 percent of the amount established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

[(B) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—The annual biosimilar biological product development fee under subsection (a)(1)(B) for a fiscal year shall be equal to 10 percent of the amount established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

[(C) REACTIVATION FEE.—The reactivation fee under subsection (a)(1)(D) for a fiscal year shall be equal to 20 percent of the amount of the fee established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

[(D) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION FEE.—The biosimilar biological product application fee under subsection (a)(2) for a fiscal year shall be equal to the amount established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

[(E) BIOSIMILAR BIOLOGICAL PRODUCT ESTABLISHMENT FEE.—The biosimilar biological product establishment fee under subsection (a)(3) for a fiscal year shall be equal to the amount established under section 736(c)(4) for a prescription drug establishment for that fiscal year.

[(F) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—The biosimilar biological product fee under subsection (a)(4) for a fiscal year shall be equal to the amount established under section 736(c)(4) for a prescription drug product for that fiscal year.

[(2) LIMIT.—The total amount of fees charged for a fiscal year under this section may not exceed the total amount for such fiscal year of the costs of resources allocated for the process for the review of biosimilar biological product applications.

[(c) APPLICATION FEE WAIVER FOR SMALL BUSINESS.—

[(1) WAIVER OF APPLICATION FEE.—The Secretary shall grant to a person who is named in a biosimilar biological product application a waiver from the application fee assessed to that person under subsection (a)(2)(A) for the first biosimilar biological product application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay—

[(A) application fees for all subsequent biosimilar biological product applications submitted to the Secretary for review in the same manner as an entity that is not a small business; and

[(B) all supplement fees for all supplements to biosimilar biological product applications submitted to the Secretary for review in the same manner as an entity that is not a small business.

[(2) CONSIDERATIONS.—In determining whether to grant a waiver 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.

[(3) SMALL BUSINESS DEFINED.—In this subsection, the term "small business" means an entity that has fewer than 500 employees, including employees of affiliates, and does not have a drug product that has been approved under a human drug application (as defined in section 735) or a biosimilar biological product application (as defined in section 744G(4)) and introduced or delivered for introduction into interstate commerce.

[(d) EFFECT OF FAILURE TO PAY FEES.—A biosimilar biological product application or supplement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid.

[(e) CREDITING AND AVAILABILITY OF FEES.—

[(1) IN GENERAL.—Subject to paragraph (2), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of biosimilar biological product applications.

[(2) COLLECTIONS AND APPROPRIATION ACTS.—

[(A) IN GENERAL.—Subject to subparagraphs (C) and (D), the fees authorized by this section shall be collected and available 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.

[(B) USE OF FEES AND LIMITATION.—The fees authorized by this section shall be available for a fiscal year beginning after fiscal year 2012 to defray the costs of the process for the review of biosimilar biological product applications (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than $20,000,000, multiplied by the adjustment factor applicable to the fiscal year involved.

[(C) FEE COLLECTION DURING FIRST PROGRAM YEAR.—Until the date of enactment of an Act making appropria-

tions through September 30, 2013, for the salaries and expenses account of the Food and Drug Administration, fees authorized by this section for fiscal year 2013 may be collected and shall be credited to such account and remain available until expended.

[(D) PROVISION FOR EARLY PAYMENTS IN SUBSEQUENT YEARS.—Payment of fees authorized under this section for a fiscal year (after fiscal year 2013), prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

[(3) AUTHORIZATION OF APPROPRIATIONS.—For each of fiscal years 2013 through 2017, there is authorized to be appropriated for fees under this section an amount equivalent to the total amount of fees assessed for such fiscal year under this section.

[(f) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

[(g) WRITTEN REQUESTS FOR WAIVERS AND REFUNDS.—To qualify for consideration for a waiver under subsection (c), or for a refund of any fee collected in accordance with subsection (a)(2)(A), a person shall submit to the Secretary a written request for such waiver or refund not later than 180 days after such fee is due.

[(h) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in the process of the review of biosimilar biological product applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.]

[Effective January 31, 2018, section 404(b) of H.R. 5651 provides for a repeal of section 744I (as added by the bill).]

[SEC. 744I. REAUTHORIZATION; REPORTING REQUIREMENTS.

[(a) PERFORMANCE REPORT.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this part, 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 401(b) of the Biosimilar User Fee Act of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting such goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all biosimilar biological product applications and supplements in the cohort.

[(b) FISCAL REPORT.—Not later than 120 days after the end of fiscal year 2013 and each subsequent fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Rep-

resentatives 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) PUBLIC AVAILABILITY.— The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

[(d) STUDY.—

[(1) IN GENERAL.—The Secretary shall contract with an independent accounting or consulting firm to study the workload volume and full costs associated with the process for the review of biosimilar biological product applications.

[(2) INTERIM RESULTS.—Not later than June 1, 2015, the Secretary shall publish, for public comment, interim results of the study described under paragraph (1).

[(3) FINAL RESULTS.—Not later than September 30, 2016, the Secretary shall publish, for public comment, the final results of the study described under paragraph (1).

[(e) REAUTHORIZATION.—

[(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals described in subsection (a), and plans for meeting the goals, for the process for the review of biosimilar biological product applications for the first 5 fiscal years after fiscal year 2017, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

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

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

[(C) scientific and academic experts;

[(D) health care professionals;

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

[(F) the regulated industry.

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

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

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

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

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

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

[(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2017, the Secretary shall transmit to the 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.]

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SUBCHAPTER D—INFORMATION AND EDUCATION

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SEC. 745A. ELECTRONIC FORMAT FOR SUBMISSIONS.

(a) DRUGS AND BIOLOGICS.—

(1) IN GENERAL.—Beginning no earlier than 24 months after the issuance of a final guidance issued after public notice and opportunity for comment, submissions under subsection (b), (i), or (j) of section 505 of this Act or subsection (a) or (k) of section 351 of the Public Health Service Act shall be submitted in such electronic format as specified by the Secretary in such guidance.

(2) GUIDANCE CONTENTS.—In the guidance under paragraph (1), the Secretary may—

(A) provide a timetable for establishment by the Secretary of further standards for electronic submission as required by such paragraph; and

(B) set forth criteria for waivers of and exemptions from the requirements of this subsection.

(3) EXCEPTION.—This subsection shall not apply to submissions described in section 561.

(b) DEVICES.—

(1) IN GENERAL.—Beginning after the issuance of final guidance implementing this paragraph, pre-submissions and submissions for devices under section 510(k), 513(f)(2)(A), 515(c), 515(d), 515(f), 520(g), 520(m), or 564 of this Act or section 351 of the Public Health Service Act, and any supplements to such pre-submissions or submissions, shall include an electronic copy of such pre-submissions or submissions.

(2) GUIDANCE CONTENTS.—In the guidance under paragraph (1), the Secretary may—

(A) provide standards for the electronic copy required under such paragraph; and

(B) set forth criteria for waivers of and exemptions from the requirements of this subsection.

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CHAPTER VIII—IMPORTS AND EXPORTS

IMPORTS AND EXPORTS

SEC. 801. (a) The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon his request, samples of food, drugs, devices, tobacco products, and cosmetics which are being imported or offered for import into the United States, giving notice thereof*, except as otherwise described in the sixth and seventh sentences of this subsection,* to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. The Secretary of Health and Human Services shall furnish to the Secretary of the Treasury a list of establishments registered pursuant to subsection (i) of section 510 or section 905(h) and shall request that if any drugs, de-

vices, or tobacco products manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such drugs, devices, or tobacco products be delivered to the Secretary of Health and Human Services, with notice of such delivery to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions or, in the case of a device, the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 520(f), or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 505, or prohibited from introduction or delivery for introduction into interstate commerce under section 301(ll), or (4) the recordkeeping requirements under section 204 of the FDA Food Safety Modernization Act (other than the requirements under subsection (f) of such section) have not been complied with regarding such article, *or (5) for an article that is a drug, the appropriate unique facility identifiers under subsection (s) (relating to commercial importers) and section 510(i) (relating to foreign establishments), as specified by the Secretary, are not provided,* then such article shall be refused admission, except as provided in subsection (b) of this section. With respect to an article of food, if importation of such food is subject to, but not compliant with, the requirement under subsection (q) that such food be accompanied by a certification or other assurance that the food meets applicable requirements of this Act, then such article shall be refused admission. If such article is subject to a requirement under section 760 or 761 and if the Secretary has credible evidence or information indicating that the responsible person (as defined in such section 760 or 761) has not complied with a requirement of such section 760 or 761 with respect to any such article, or has not allowed access to records described in such section 760 or 761, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations*, except that the Secretary of Health and Human Services, in consultation with the Secretary of Homeland Security, may cause the destruction, without the opportunity for export, of any drug refused admission that has reasonable probability of causing serious adverse health consequences or death, as determined by the Secretary of Health and Human Services, or that is valued at an amount that is $2,000 or less (or such higher amount as the Secretary of Homeland Security may set by regulation pursuant to section 1498 of title 19, United States Code). The Secretary of Health and Human Services shall issue regulations providing for notice and an opportunity for a hearing on the destruction of a drug under the previous sentence. For a drug with a value less than and or equal to $2,000 (or, as described in the sixth sentence of this sub-*

section, such higher amount as the Secretary of Homeland Security may set by regulation pursuant to section 1498 of title 19, United States Code) the regulations under the previous sentence shall provide for prompt notice and an opportunity for a hearing for the owner or consignee before or after the destruction has occurred. For a drug with a value greater than $2,000 (or, as described in the sixth sentence of this subsection, such higher amount as the Secretary of Homeland Security may set by regulation pursuant to section 1498 of title 19, United States Code) that has reasonable probability of causing serious adverse health consequences or death as determined by the Secretary of Health and Human Services, the regulations under the seventh sentence of this subsection shall provide for notice and an opportunity for a hearing to the owner or consignee before the destruction occurs. Clause (2) of the third sentence of this paragraph shall not be construed to prohibit the admission of narcotic drugs the importation of which is permitted under the Controlled Substances Import and Export Act.

* * * * * * *

(r) DOCUMENTATION.—

(1) SUBMISSION.—The Secretary may require, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection as determined appropriate by the Secretary, the submission of documentation or other information for a drug that is imported or offered for import into the United States.

(2) REFUSAL OF ADMISSION.—A drug imported or offered for import into the United States shall be refused admission unless all documentation and information the Secretary requires under this Act, the Public Health Service Act, or both, as appropriate, for such article is submitted.

(3) REGULATIONS.—

(A) DOCUMENTS AND INFORMATION.—The Secretary shall issue a regulation to specify the documentation or other information that is described in paragraph (1). Such information may include—

(i) information demonstrating the regulatory status of the drug, such as the new drug application, abbreviated new drug application, or investigational new drug or Drug Master File number;

(ii) facility information, such as proof of registration and the unique facility identifier; and

(iii) indication of compliance with current good manufacturing practice, such as satisfactory testing results, certifications relating to satisfactory inspections, and compliance with the country of export regulations.

(B) EXEMPTION.—The Secretary may, by regulation, exempt drugs imported for research purposes only and other types of drug imports from some or all of the requirements of this subsection.

(4) EFFECTIVE DATE.—The final rule under paragraph (3)(A) shall take effect not less than 180 days after the Secretary promulgates such final rule.

(s) REGISTRATION OF COMMERCIAL IMPORTERS.—

(1) REGISTRATION.—The Secretary shall require a commercial importer of drugs—

(A) to be registered with the Secretary in a form and manner specified by the Secretary; and

(B) consistent with the guidance under section 510(q), to submit, at the time of registration, a unique identifier for the principal place of business for which the importer is required to register under this subsection.

(2) REGULATIONS.—

(A) IN GENERAL.—The Secretary, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection, shall promulgate regulations to establish good importer practices that specify the measures an importer shall take to ensure imported drugs are in compliance with the requirements of this Act and the Public Health Service Act.

(B) EXPEDITED CLEARANCE FOR CERTAIN IMPORTERS.—In promulgating good importer practice regulations under subparagraph (A), the Secretary may, as appropriate, take into account differences among importers and types of imports, and, based on the level of risk posed by the imported drug, provide for expedited clearance for those importers that volunteer to participate in partnership programs for highly compliant companies.

(3) DISCONTINUANCE OF REGISTRATION.—The Secretary shall discontinue the registration of any commercial importer of drugs that fails to comply with the regulations promulgated under this subsection.

(4) EXEMPTIONS.—The Secretary, by notice in the Federal Register, may establish exemptions from the requirements of this subsection.

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OFFICE OF INTERNATIONAL RELATIONS

SEC. 803. (a) * * *

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(c)(1) * * *

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(3)*(A)* The Secretary shall regularly participate in meetings with representatives of other foreign governments to discuss and reach agreement on methods and approaches to harmonize regulatory requirements.

(B) In carrying out subparagraph (A), the Secretary may participate in appropriate fora, including the International Medical Device Regulators Forum, and may—

(i) provide guidance to such fora on strategies, policies, directions, membership, and other activities of a forum as appropriate;

(ii) to the extent appropriate, solicit, review, and consider comments from industry, academia, health care professionals, and patient groups regarding the activities of such fora; and

(iii) to the extent appropriate, inform the public of the Secretary's activities within such fora, and share with the public any documentation relating to a forum's strategies, policies, and other activities of such fora.

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

(4) With respect to devices, the Secretary may, when appropriate, enter into arrangements with nations regarding methods and approaches to harmonizing regulatory requirements for activities, including inspections and common international labeling symbols

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PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

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TITLE I—PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

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[SEC. 106. SUNSET DATES.

[(a) AUTHORIZATION.—The amendments made by sections 102, 103, and 104 cease to be effective October 1, 2012.

[(b) REPORTING REQUIREMENTS.—The amendment made by section 105 ceases to be effective January 31, 2013.]

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SECTION 508 OF THE PRESCRIPTION DRUG USER FEE AMENDMENTS ACT OF 2002

[SEC. 508. EFFECTIVE DATE.

[The amendments made by this subtitle shall take effect October 1, 2002.]

SECTION 107 OF THE FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT OF 1997

[SEC. 107. TERMINATION OF EFFECTIVENESS.

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

SECTION 105 OF THE PRESCRIPTION DRUG USER FEE ACT OF 1992

[SEC. 105. SUNSET.

[The amendments made by section 103 shall not be in effect after October 1, 1997 and section 104 shall not be in effect after 120 days after such date.]

MEDICAL DEVICE USER FEE AMENDMENTS OF 2007

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TITLE II—MEDICAL DEVICE USER FEE AMENDMENTS OF 2007

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Subtitle A—Fees Related to Medical Devices

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[SEC. 217. SUNSET CLAUSE.

[The amendments made by this subtitle cease to be effective October 1, 2012, except that section 738A of the Federal Food, Drug, and Cosmetic Act (regarding annual performance and financial reports) ceases to be effective January 31, 2013.]

MEDICAL DEVICE USER FEE AND MODERNIZATION ACT OF 2002

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TITLE I—FEES RELATED TO MEDICAL DEVICES

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[SEC. 107. SUNSET CLAUSE.

[The amendments made by this title cease to be effective October 1, 2007, except that section 103 with respect to annual reports ceases to be effective January 31, 2008.]

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PUBLIC HEALTH SERVICE ACT

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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PART F—LICENSING—BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES

Subpart 1—Biological Products

REGULATION OF BIOLOGICAL PRODUCTS

SEC. 351. (a) * * *

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(m) PEDIATRIC STUDIES.—

(1) APPLICATION OF CERTAIN PROVISIONS.—The provisions of subsections (a), (d), (e), [(f), (i), (j), (k), (l), (p), and (q)] *(f), (h), (i), (j), (k), (l), (n), and (p)* of section 505A of the Federal Food, Drug, and Cosmetic Act shall apply with respect to the extension of a period under paragraphs (2) and (3) to the same extent and in the same manner as such provisions apply with respect to the extension of a period under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act.

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TITLE IV—NATIONAL RESEARCH INSTITUTES

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PART B—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

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

(a) * * *

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(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, *or section 351(m) of this 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 section 351(k) of this Act*; or

* * * * * * *

[(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]

(B)(i) there remains no patent listed pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act; and

(ii) every three-year and five-year period referred to in subsection (c)(3)(E)(ii), (c)(3)(E)(iii), (c)(3)(E(iv), (j)(5)(F)(ii), (j)(5)(F)(iii), or (j)(5)(F)(iv) of section 505 of the Federal Food, Drug and Cosmetic Act, or applicable twelve-year period referred to in section 351(k)(7) of this Act, and any seven-year period referred to in section 527 of the Federal

Food, Drug, and Cosmetic Act, has ended for at least one form of the drug; and

* * * * * * *

(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] *505A of the Federal Food, Drug, and Cosmetic Act or section 351(m) of this 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.

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(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.] *$25,000,000 for each of fiscal years 2013 through 2017.*

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PART I—FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH

SEC. 499. ESTABLISHMENT AND DUTIES OF FOUNDATION.

(a) * * *

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(c) CERTAIN ACTIVITIES OF FOUNDATION.—

(1) IN GENERAL.—In carrying out subsection (b), the Foundation may solicit and accept gifts, grants, and other donations, establish accounts, and invest and expend funds in support of the following activities with respect to the purpose described in such subsection:

(A) * * *

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(C) A program to collect funds for pediatric pharmacologic research and studies [for which the Secretary issues a certification in the affirmative under section

505A(n)(1)(A) of the Federal Food, Drug, and Cosmetic Act].

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BEST PHARMACEUTICALS FOR CHILDREN ACT

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SEC. 6. OFFICE OF PEDIATRIC THERAPEUTICS.

(a) * * *

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(c) STAFF.—The staff of the Office of Pediatric Therapeutics shall coordinate with employees of the Department of Health and Human Services who exercise responsibilities relating to pediatric therapeutics and shall include—

(1) one or more additional individuals with expertise concerning ethical issues presented by the conduct of clinical research in the pediatric population; [and]

(2) one or more additional individuals with expertise in neonatology;

(3) one or more additional individuals with expertise in pediatric epidemiology; and

[(2)] *(4)* one or more additional individuals with expertise in pediatrics as may be necessary to perform the activities described in subsection (b).

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SEC. 14. PEDIATRIC ADVISORY COMMITTEE.

(a) * * *

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(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] *to carry out the advisory committee's responsibilities under sections 505A, 505B, and 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c, and 360j(m))*.

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SEC. 15. PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC DRUGS ADVISORY COMMITTEE.

(a) CLARIFICATION OF AUTHORITIES.—

(1) IN GENERAL.—The Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (referred to in this section as the "Subcommittee"), in carrying out the mission of reviewing and evaluating the data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pediatric cancers, shall—

(A) * * *

* * * * * * *

(D) provide recommendations to the internal review committee created under [section 505B(f)] *section 505C* 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.

* * * * * * *

(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] *to carry out the Subcommittee's responsibilities under this section*.

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SECTION 305 OF THE PEDIATRIC MEDICAL DEVICE SAFETY AND IMPROVEMENT ACT OF 2007

SEC. 305. DEMONSTRATION GRANTS FOR IMPROVING PEDIATRIC DEVICE AVAILABILITY.

(a) * * *

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(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] *2013 through 2017*.

ORPHAN DRUG ACT

* * * * * * *

GRANTS AND CONTRACTS FOR DEVELOPMENT OF DRUGS FOR RARE DISEASES AND CONDITIONS

SEC. 5. (a) * * *

(b) For purposes of subsection (a):

(1) The term "qualified testing" means—

(A) human clinical testing—

(i) * * *

(ii) which occurs [after the date such drug is designated under section 526 of such Act and] before the date on which an application with respect to such drug is submitted under section 505(b) of such Act or under section 351 of the Public Health Service Act; and

* * * * * * *

[(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.]

(c) AUTHORIZATION OF APPROPRIATIONS.—For grants and contracts under subsection (a), there is authorized to be appropriated $30,000,000 for each of fiscal years 2013 through 2017.

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CONTROLLED SUBSTANCES ACT

TITLE II—CONTROL AND ENFORCEMENT

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PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES; PIPERIDINE REPORTING

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QUOTAS APPLICABLE TO CERTAIN SUBSTANCES

SEC. 306. (a) * * *

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(h)(1) Not later than 30 days after the receipt of a request described in paragraph (2), the Attorney General shall—

(A) complete review of such request; and

(B)(i) as necessary to address a shortage of a controlled substance, increase the aggregate and individual production quotas under this section applicable to such controlled substance and any ingredient therein to the level requested; or

(ii) if the Attorney General determines that the level requested is not necessary to address a shortage of a controlled substance, the Attorney General shall provide a written response detailing the basis for the Attorney General's determination.

The Secretary shall make the written response provided under subparagraph (B)(ii) available to the public on the Web site of the Food and Drug Administration.

(2) A request is described in this paragraph if—

(A) the request pertains to a controlled substance on the list of drugs in shortage maintained under section 506D of the Federal Food, Drug, and Cosmetic Act;

(B) the request is submitted by the manufacturer of the controlled substance; and

(C) the controlled substance is in schedule II.

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