AM	ENDMENT NO Calendar No
Pu	pose: In the nature of a substitute.
IN	THE SENATE OF THE UNITED STATES—112th Cong., 2d Sess.
	S
То	amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.
R	eferred to the Committee on and ordered to be printed
	Ordered to lie on the table and to be printed
	MENDMENT IN THE NATURE OF A SUBSTITUTE intended be proposed by Mr. Harkin (for himself and Mr. Enzi)
Viz	
1	Strike all after the enacting clause and insert the fol-
2	lowing:
3	SECTION 1. SHORT TITLE.
4	This Act may be cited as the "Food and Drug Ad-
5	ministration Safety and Innovation Act".
6	SEC. 2. TABLE OF CONTENTS; REFERENCES IN ACT.
7	(a) Table of Contents.—The table of contents of
8	this Act is as follows:
	Sec. 1. Short title. Sec. 2. Table of contents; references in Act.

TITLE I—FEES RELATING TO DRUGS

- Sec. 101. Short title; finding.
- Sec. 102. Definitions.
- Sec. 103. Authority to assess and use drug fees.
- Sec. 104. Reauthorization; reporting requirements.
- Sec. 105. Sunset dates.
- Sec. 106. Effective date.
- Sec. 107. Savings clause.

#### TITLE II—FEES RELATING TO DEVICES

- Sec. 201. Short title; findings.
- Sec. 202. Definitions.
- Sec. 203. Authority to assess and use device fees.
- Sec. 204. Reauthorization; reporting requirements.
- Sec. 205. Savings clause.
- Sec. 206. Effective date.
- Sec. 207. Sunset dates.
- Sec. 208. Streamlined hiring authority to support activities related to the process for the review of device applications.

#### TITLE III—FEES RELATING TO GENERIC DRUGS

- Sec. 301. Short title.
- Sec. 302. Authority to assess and use human generic drug fees.
- Sec. 303. Reauthorization; reporting requirements.
- Sec. 304. Sunset dates.
- Sec. 305. Effective date.
- Sec. 306. Amendment with respect to misbranding.
- Sec. 307. Streamlined hiring authority of the Food and Drug Administration to support activities related to human generic drugs.

# TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

- Sec. 401. Short title; finding.
- Sec. 402. Fees relating to biosimilar biological products.
- Sec. 403. Reauthorization; reporting requirements.
- Sec. 404. Sunset dates.
- Sec. 405. Effective date.
- Sec. 406. Savings clause.
- Sec. 407. Conforming amendment.

### TITLE V—PEDIATRIC DRUGS AND DEVICES

- Sec. 501. Permanence.
- Sec. 502. Written requests.
- Sec. 503. Communication with Pediatric Review Committee.
- Sec. 504. Access to data.
- Sec. 505. Ensuring the completion of pediatric studies.
- Sec. 506. Pediatric study plans.
- Sec. 507. Reauthorizations.
- Sec. 508. Report.
- Sec. 509. Technical amendments.
- Sec. 510. Relationship Between Pediatric Labeling and New Clinical Investigation Exclusivity.

### TITLE VI—MEDICAL DEVICE REGULATORY IMPROVEMENTS

- Sec. 601. Reclassification procedures.
- Sec. 602. Condition of approval studies.
- Sec. 603. Postmarket surveillance.
- Sec. 604. Sentinel.
- Sec. 605. Recalls.
- Sec. 606. Clinical holds on investigational device exemptions.
- Sec. 607. Unique device identifier.
- Sec. 608. Clarification of least burdensome standard.
- Sec. 609. Custom devices.
- Sec. 610. Agency documentation and review of certain decisions regarding devices.
- Sec. 611. Good guidance practices relating to devices.
- Sec. 612. Modification of de novo application process.
- Sec. 613. Humanitarian use device exemptions.
- Sec. 614. Reauthorization of third-party review and inspections.
- Sec. 615. 510(k) device modifications.

#### TITLE VII—DRUG SUPPLY CHAIN

- Sec. 701. Registration of domestic drug establishments.
- Sec. 702. Registration of foreign establishments.
- Sec. 703. Identification of drug excipient information with product listing.
- Sec. 704. Electronic system for registration and listing.
- Sec. 705. Risk-based inspection frequency.
- Sec. 706. Records for inspection.
- Sec. 707. Failure to allow foreign inspection.
- Sec. 708. Exchange of information.
- Sec. 709. Enhancing the safety and quality of the drug supply.
- Sec. 710. Accreditation of third-party auditors for drug establishments.
- Sec. 711. Standards for admission of imported drugs.
- Sec. 712. Notification.
- Sec. 713. Destruction of unsafe drugs.
- Sec. 714. Protection against intentional adulteration.
- Sec. 715. Enhanced criminal penalty for counterfeiting drugs.
- Sec. 716. Extraterritorial jurisdiction.
- Sec. 717. Compliance with international agreements.

#### TITLE VIII—GENERATING ANTIBIOTIC INCENTIVES NOW

- Sec. 801. Extension of exclusivity period for drugs.
- Sec. 802. Priority review.
- Sec. 803. Fast track product.
- Sec. 804. GAO study.
- Sec. 805. Clinical trials.
- Sec. 806. Regulatory certainty and predictability.

### TITLE IX—DRUG APPROVAL AND PATIENT ACCESS

- Sec. 901. Enhancement of accelerated patient access to new medical treatments.
- Sec. 902. Breakthrough therapies.
- Sec. 903. Consultation with external experts on rare diseases, targeted therapies, and genetic targeting of treatments.
- Sec. 904. Accessibility of information on prescription drug container labels by visually-impaired and blind consumers.
- Sec. 905. Risk-benefit framework.

Sec. 906. Independent study on medical innovation inducement model.

### TITLE X—DRUG SHORTAGES

Sec. 1001. Drug shortages.

# TITLE XI—OTHER PROVISIONS

#### Subtitle A—Reauthorizations

- Sec. 1101. Reauthorization of provision relating to exclusivity of certain drugs containing single enantiomers.
- Sec. 1102. Reauthorization of the Critical Path Public-Private Partnerships.

### Subtitle B—Medical Gas Regulation

- Sec. 1111. Regulation of medical gases.
- Sec. 1112. Regulations.
- Sec. 1113. Applicability.

#### Subtitle C—Miscellaneous Provisions

- Sec. 1121. Advisory committee conflicts of interest.
- Sec. 1122. Guidance document regarding product promotion using the Internet.
- Sec. 1123. Electronic submission of applications.
- Sec. 1124. Combating prescription drug abuse.
- Sec. 1125. Tanning bed labeling.
- Sec. 1126. Optimizing global clinical trials.
- Sec. 1127. Advancing regulatory science to promote public health innovation.
- Sec. 1128. Information technology.
- Sec. 1129. Reporting requirements.
- Sec. 1130. Strategic integrated management plan.
- Sec. 1131. Drug development and bioequivalence testing.
- 1 (b) References in Act.—Except as otherwise spec-
- 2 ified, amendments made by this Act to a section or other
- 3 provision of law are amendments to such section or other
- 4 provision of the Federal Food, Drug, and Cosmetic Act
- 5 (21 U.S.C. 301 et seq.).

# 6 TITLE I—FEES RELATING TO

# 7 **DRUGS**

- 8 SEC. 101. SHORT TITLE; FINDING.
- 9 (a) Short Title.—This title may be cited as the
- 10 "Prescription Drug User Fee Amendments of 2012".

1	(b) FINDING.—The Congress finds that the fees au-
2	thorized by the amendments made in this title will be dedi-
3	cated toward expediting the drug development process and
4	the process for the review of human drug applications, in-
5	cluding postmarket drug safety activities, as set forth in
6	the goals identified for purposes of part 2 of subchapter
7	C of chapter VII of the Federal Food, Drug, and Cosmetic
8	Act, in the letters from the Secretary of Health and
9	Human Services to the Chairman of the Committee on
10	Health, Education, Labor, and Pensions of the Senate and
11	the Chairman of the Committee on Energy and Commerce
12	of the House of Representatives, as set forth in the Con-
13	gressional Record.
14	SEC. 102. DEFINITIONS.
15	Paragraph (7) of section 735 (21 U.S.C. 379g) is
16	amended, in the matter preceding subparagraph (A), by
17	striking "incurred".
18	SEC. 103. AUTHORITY TO ASSESS AND USE DRUG FEES.
19	Section 736 (21 U.S.C. 379h) is amended—
20	(1) in subsection (a)—
21	(A) in the matter preceding paragraph (1),
22	by striking "fiscal year 2008" and inserting
23	"fiscal year 2013";
24	(B) in paragraph (1), in clauses (i) and (ii)
25	of subparagraph (A), by striking "subsection

1	(c)(5)" each place such term appears and in-
2	serting "subsection (c)(4)";
3	(C) in the matter following clause (ii) in
4	paragraph (2)(A)—
5	(i) by striking "subsection (c)(5)" and
6	inserting "subsection (c)(4)"; and
7	(ii) by striking "payable on or before
8	October 1 of each year" and inserting
9	"due on the later of the first business day
10	on or after October 1 of each fiscal year or
11	the first business day after the enactment
12	of an appropriations Act providing for the
13	collection and obligation of fees for such
14	fiscal year under this section"; and
15	(D) in paragraph (3)—
16	(i) in subparagraph (A)—
17	(I) by striking "subsection
18	(c)(5)" and inserting "subsection
19	(c)(4)"; and
20	(II) by striking "payable on or
21	before October 1 of each year." and
22	inserting "due on the later of the first
23	business day on or after October 1 of
24	each fiscal year or the first business
25	day after the enactment of an appro-

1	priations Act providing for the collec-
2	tion and obligation of fees for such
3	fiscal year under this section."; and
4	(ii) by amending subparagraph (B) to
5	read as follows:
6	"(B) Exception.—A prescription drug
7	product shall not be assessed a fee under sub-
8	paragraph (A) if such product is—
9	"(i) identified on the list compiled
10	under section 505(j)(7)(A) with a potency
11	described in terms of per 100 mL;
12	"(ii) the same product as another
13	product that—
14	"(I) was approved under an ap-
15	plication filed under section 505(b) or
16	505(j); and
17	"(II) is not in the list of discon-
18	tinued products compiled under sec-
19	tion $505(j)(7)$ ;
20	"(iii) the same product as another
21	product that was approved under an abbre-
22	viated application filed under section 507
23	(as in effect on the day before the date of
24	enactment of the Food and Drug Adminis-
25	tration Modernization Act of 1997); or

1	(iv) the same product as another
2	product that was approved under an abbre-
3	viated new drug application pursuant to
4	regulations in effect prior to the implemen-
5	tation of the Drug Price Competition and
6	Patent Term Restoration Act of 1984.";
7	(2) in subsection (b)—
8	(A) in paragraph (1)—
9	(i) in the matter preceding subpara-
10	graph (A), by striking "fiscal years 2008
11	through 2012" and inserting "fiscal years
12	2013 through 2017";
13	(ii) in subparagraph (A), by striking
14	"\$392,783,000; and" and inserting
15	"\$693,099,000;"; and
16	(iii) by striking subparagraph (B) and
17	inserting the following:
18	"(B) the dollar amount equal to the infla-
19	tion adjustment for fiscal year 2013 (as deter-
20	mined under paragraph (3)(A)); and
21	"(C) the dollar amount equal to the work-
22	load adjustment for fiscal year 2013 (as deter-
23	mined under paragraph (3)(B))."; and
24	(B) by striking paragraphs (3) and (4) and
25	inserting the following:

1	"(3) Fiscal Year 2013 Inflation and Work-
2	LOAD ADJUSTMENTS.—For purposes of paragraph
3	(1), the dollar amount of the inflation and workload
4	adjustments for fiscal year 2013 shall be determined
5	as follows:
6	"(A) Inflation adjustment.—The infla-
7	tion adjustment for fiscal year 2013 shall be
8	the sum of—
9	"(i) \$652,709,000 multiplied by the
10	result of an inflation adjustment calcula-
11	tion determined using the methodology de-
12	scribed in subsection $(c)(1)(B)$ ; and
13	"(ii) \$652,709,000 multiplied by the
14	result of an inflation adjustment calcula-
15	tion determined using the methodology de-
16	scribed in subsection $(c)(1)(C)$ .
17	"(B) Workload adjustment.—Subject
18	to subparagraph (C), the workload adjustment
19	for fiscal 2013 shall be—
20	"(i) \$652,709,000 plus the amount of
21	the inflation adjustment calculated under
22	subparagraph (A); multiplied by
23	"(ii) the amount (if any) by which a
24	percentage workload adjustment for fiscal
25	year 2013, as determined using the meth-

1	odology described in subsection $(c)(2)(A)$ ,
2	would exceed the percentage workload ad-
3	justment (as so determined) for fiscal year
4	2012, if both such adjustment percentages
5	were calculated using the 5-year base pe-
6	riod consisting of fiscal years 2003
7	through 2007.
8	"(C) Limitation.—Under no cir-
9	cumstances shall the adjustment under sub-
10	paragraph (B) result in fee revenues for fiscal
11	year 2013 that are less than the sum of the
12	amount under paragraph (1)(A) and the
13	amount under paragraph (1)(B).";
14	(3) by striking subsection (c) and inserting the
15	following:
16	"(c) Adjustments.—
17	"(1) Inflation adjustment.—For fiscal year
18	2014 and subsequent fiscal years, the revenues es-
19	tablished in subsection (b) shall be adjusted by the
20	Secretary by notice, published in the Federal Reg-
21	ister, for a fiscal year by the amount equal to the
22	sum of—
23	"(A) one;
24	"(B) the average annual change in the
25	cost, per full-time equivalent position of the

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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 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.

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"(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.

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"(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 1

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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 paragraph shall not be made.

1	"(4) Annual fee setting.—The Secretary
2	shall, not later than 60 days before the start of each
3	fiscal year that begins after September 30, 2012, es-
4	tablish, for the next fiscal year, application, product,
5	and establishment fees under subsection (a), based
6	on the revenue amounts established under subsection
7	(b) and the adjustments provided under this sub-
8	section.
9	"(5) Limit.—The total amount of fees charged,
10	as adjusted under this subsection, for a fiscal year
11	may not exceed the total costs for such fiscal year
12	for the resources allocated for the process for the re-
13	view of human drug applications."; and
14	(4) in subsection (g)—
15	(A) in paragraph (1), by striking "Fees
16	authorized" and inserting "Subject to para-
17	graph (2)(C), fees authorized";
18	(B) in paragraph (2)—
19	(i) in subparagraph (A)—
20	(I) in clause (i), by striking
21	"shall be retained" and inserting
22	"subject to subparagraph (C), shall be
23	collected and available"; and

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1	(II) in clause (ii), by striking
2	"shall only be collected and available"
3	and inserting "shall be available"; and
4	(ii) by adding at the end the following
5	new subparagraph:
6	"(C) Provision for Early Payments.—
7	Payment of fees authorized under this section
8	for a fiscal year, prior to the due date for such
9	fees, may be accepted by the Secretary in ac-
10	cordance with authority provided in advance in
11	a prior year appropriations Act.";
12	(C) in paragraph (3), by striking "fiscal
13	years 2008 through 2012" and inserting "fiscal
14	years 2013 through 2017"; and
15	(D) in paragraph (4)—
16	(i) by striking "fiscal years 2008
17	through 2010" and inserting "fiscal years
18	2013 through 2015";
19	(ii) by striking "fiscal year 2011" and
20	inserting "fiscal year 2016";
21	(iii) by striking "fiscal years 2008
22	though 2011" and inserting "fiscal years
23	2013 through 2016"; and
24	(iv) by striking "fiscal year 2012"
25	and inserting "fiscal year 2017".

1	SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENTS.
2	Section 736B (21 U.S.C. 379h–2) is amended—
3	(1) by amending subsection (a) to read as fol-
4	lows:
5	"(a) Performance Report.—Beginning with fiscal
6	year 2013, not later than 120 days after the end of each
7	fiscal year for which fees are collected under this part,
8	the Secretary shall prepare and submit to the Committee
9	on Energy and Commerce of the House of Representatives
10	and the Committee on Health, Education, Labor, and
11	Pensions of the Senate a report concerning the progress
12	of the Food and Drug Administration in achieving the
13	goals identified in the letters described in section 101(b)
14	of the Prescription Drug User Fee Amendments of 2012
15	during such fiscal year and the future plans of the Food
16	and Drug Administration for meeting the goals. The re-
17	port under this subsection for a fiscal year shall include
18	information on all previous cohorts for which the Sec-
19	retary has not given a complete response on all human
20	drug applications and supplements in the cohort.";
21	(2) in subsection (b), by striking "2008" and
22	inserting "2013"; and
23	(3) in subsection (d), by striking "2012" each
24	place it appears and inserting "2017".

### 1 SEC. 105. SUNSET DATES.

- 2 (a) AUTHORIZATION.—Sections 735 and 736 of the
- 3 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g;
- 4 379h) shall cease to be effective October 1, 2017.
- 5 (b) Reporting Requirements.—Section 736B of
- 6 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
- 7 379h-2) shall cease to be effective January 31, 2018.
- 8 (c) Previous Sunset Provision.—The Prescrip-
- 9 tion Drug User Fee Amendments of 2007 is amended by
- 10 striking section 106.

### 11 SEC. 106. EFFECTIVE DATE.

- The amendments made by this title shall take effect
- 13 on October 1, 2012, or the date of the enactment of this
- 14 Act, whichever is later, except that fees under part 2 of
- 15 subchapter C of chapter VII of the Federal Food, Drug,
- 16 and Cosmetic Act shall be assessed for all human drug
- 17 applications received on or after October 1, 2012, regard-
- 18 less of the date of the enactment of this Act.

# 19 SEC. 107. SAVINGS CLAUSE.

- Notwithstanding the amendments made by this title,
- 21 part 2 of subchapter C of chapter VII of the Federal Food,
- 22 Drug, and Cosmetic Act, as in effect on the day before
- 23 the date of the enactment of this title, shall continue to
- 24 be in effect with respect to human drug applications and
- 25 supplements (as defined in such part as of such day) that
- 26 on or after October 1, 2007, but before October 1, 2012,

- 1 were accepted by the Food and Drug Administration for
- 2 filing with respect to assessing and collecting any fee re-
- 3 quired by such part for a fiscal year prior to fiscal year
- 4 2012.

# 5 TITLE II—FEES RELATING TO

# 6 **DEVICES**

- 7 SEC. 201. SHORT TITLE; FINDINGS.
- 8 (a) Short Title.—This title may be cited as the
- 9 "Medical Device User Fee Amendments of 2012".
- 10 (b) FINDINGS.—The Congress finds that the fees au-
- 11 thorized under the amendments made by this title will be
- 12 dedicated toward expediting the process for the review of
- 13 device applications and for assuring the safety and effec-
- 14 tiveness of devices, as set forth in the goals identified for
- 15 purposes of part 3 of subchapter C of chapter VII of the
- 16 Federal Food, Drug, and Cosmetic Act in the letters from
- 17 the Secretary of Health and Human Services to the Chair-
- 18 man of the Committee on Health, Education, Labor, and
- 19 Pensions of the Senate and the Chairman of the Com-
- 20 mittee on Energy and Commerce of the House of Rep-
- 21 resentatives, as set forth in the Congressional Record.
- 22 SEC. 202. DEFINITIONS.
- 23 Section 737 (21 U.S.C. 379i) is amended—
- 24 (1) in paragraph (9), by striking "incurred"
- after "expenses";

1	(2) in paragraph (10), by striking "October
2	2001" and inserting "October 2011"; and
3	(3) in paragraph (13), by striking "is required
4	to register" and all that follows through the end of
5	paragraph (13) and inserting the following: "is reg-
6	istered (or is required to register) with the Secretary
7	under section 510 because such establishment is en-
8	gaged in the manufacture, preparation, propagation,
9	compounding, or processing of a device.".
10	SEC. 203. AUTHORITY TO ASSESS AND USE DEVICE FEES.
11	(a) Types of Fees.—Section 738(a) (21 U.S.C.
12	379j(a)) is amended—
13	(1) in paragraph (1), by striking "fiscal year
14	2008" and inserting "fiscal year 2013";
15	(2) in paragraph $(2)(A)$ —
16	(A) in the matter preceding clause (i)—
17	(i) by striking "subsections (d) and
18	(e)" and inserting "subsections (d), (e),
19	and (f)";
20	(ii) by striking "October 1, 2002" and
21	inserting "October 1, 2012"; and
22	(iii) by striking "subsection (c)(1)"
23	and inserting "subsection (c)"; and
24	(B) in clause (viii), by striking "1.84" and
25	inserting "2"; and

1	(3) in paragraph (3)—
2	(A) in subparagraph (A)—
3	(i) by inserting "and subsection (f)"
4	after "subparagraph (B)"; and
5	(ii) by striking "2008" and inserting
6	"2013"; and
7	(B) in subparagraph (C), by striking "ini-
8	tial registration" and all that follows through
9	"section 510." and inserting "later of—
10	"(i) the initial or annual registration
11	(as applicable) of the establishment under
12	section 510; or
13	"(ii) the first business day after the
14	date of enactment of an appropriations Act
15	providing for the collection and obligation
16	of fees for such year under this section.".
17	(b) FEE Amounts.—Section 738(b) (21 U.S.C.
18	379j(b)) is amended to read as follows:
19	"(b) Fee Amounts.—
20	"(1) In general.—Subject to subsections (c),
21	(d), (e), (f), and (i), for each of fiscal years 2013
22	through 2017, fees under subsection (a) shall be de-
23	rived from the base fee amounts specified in para-
24	graph (2), to generate the total revenue amounts
25	specified in paragraph (3).

"(2) Base fee amounts.—For purposes of 1 2 paragraph (1), the base fee amounts specified in this 3 paragraph are as follows:

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Fee Type	Year 2013	Year 2014	Year 2015	Year 2016	Year 2017
Premarket Application Establishment Registration	\$248,000 \$2,575	\$252,960 \$3,200	\$258,019 \$3,750	\$263,180 \$3,872	\$268,443 \$3,872
"(3) Total	REVE	NUE A	MOUNTS	s.—For	· pur-
poses of paragrap	h (1),	the tot	tal reve	enue an	nounts
specified in this pa	aragrap	oh are a	s follow	rs:	
"(A) \$97	7,722,3	01 for f	iscal ye	ear 201	3.
"(B) \$11	12,580,	497 for	fiscal	year 20	14.
"(C) \$12	25,767,	107 for	fiscal y	vear 20	15.
"(D) \$12	29,339,	,949 for	fiscal	year 20	16.
"(E) \$15	30,184,	,348 for	r fiscal	year 2	017.".
(c) Annual Fee S	SETTIN	ig; Adj	USTMEN	NTS.—S	Section
738(c) (21 U.S.C. 379j	(c)) is a	amende	d—		
(1) in the su	absectio	on head	ling, by	insert	ing ";
Adjustments" at	fter "S	ETTING	";		

- (2) by striking paragraphs (1) and (2);
- (3) by redesignating paragraphs (3) and (4) as 18 paragraphs (4) and (5), respectively; and
- 19 (4) by inserting before paragraph (4), as so re-20 designated, the following:
- 21 "(1) IN GENERAL.—The Secretary shall, 60 22 days before the start of each fiscal year after Sep-

1	tember 30, 2012, establish fees under subsection (a),
2	based on amounts specified under subsection (b) and
3	the adjustments provided under this subsection, and
4	publish such fees, and the rationale for any adjust-
5	ments to such fees, in the Federal Register.
6	"(2) Inflation adjustments.—
7	"(A) Adjustment to total revenue
8	AMOUNTS.—For fiscal year 2014 and each sub-
9	sequent fiscal year, the Secretary shall adjust
10	the total revenue amount specified in subsection
l 1	(b)(3) for such fiscal year by multiplying such
12	amount by the applicable inflation adjustment
13	under subparagraph (B) for such year.
14	"(B) APPLICABLE INFLATION ADJUST-
15	MENT TO TOTAL REVENUE AMOUNTS.—The ap-
16	plicable inflation adjustment for a fiscal year
17	is—
18	"(i) for fiscal year 2014, the base in-
19	flation adjustment under subparagraph (C)
20	for such fiscal year; and
21	"(ii) for fiscal year 2015 and each
22	subsequent fiscal year, the product of—
23	"(I) the base inflation adjust-
24	ment under subparagraph (C) for
25	such fiscal year; and

1	"( $\Pi$ ) the product of the base in-
2	flation adjustment under subpara-
3	graph (C) for each of the fiscal years
4	preceding such fiscal year, beginning
5	with fiscal year 2014.
6	"(C) Base inflation adjustment to
7	TOTAL REVENUE AMOUNTS.—
8	"(i) In general.—Subject to further
9	adjustment under clause (ii), the base in-
10	flation adjustment for a fiscal year is the
11	sum of one plus—
12	"(I) the average annual change
13	in the cost, per full-time equivalent
14	position of the Food and Drug Ad-
15	ministration, of all personnel com-
16	pensation and benefits paid with re-
17	spect to such positions for the first 3
18	years of the preceding 4 fiscal years,
19	multiplied by 0.60; and
20	$"(\Pi)$ the average annual change
21	that occurred in the Consumer Price
22	Index for urban consumers (Wash-
23	ington-Baltimore, DC-MD-VA-WV;
24	Not Seasonally Adjusted; All items;
25	Annual Index) for the first 3 years of

1	the preceding 4 years of available data
2	multiplied by 0.40.
3	"(ii) Limitations.—For purposes of
4	subparagraph (B), if the base inflation ad-
5	justment for a fiscal year under clause
6	(i)—
7	"(I) is less than 1, such adjust-
8	ment shall be considered to be equal
9	to 1; or
10	"(II) is greater than 1.04, such
11	adjustment shall be considered to be
12	equal to 1.04.
13	"(D) Adjustment to base fee
14	Amounts.—For each of fiscal years 2014
15	through 2017, the base fee amounts specified in
16	subsection (b)(2) shall be adjusted as needed,
17	on a uniform proportionate basis, to generate
18	the total revenue amounts under subsection
19	(b)(3), as adjusted for inflation under subpara-
20	graph (A).
21	"(3) Volume-based adjustments to estab-
22	LISHMENT REGISTRATION BASE FEES.—For each of
23	fiscal years 2014 through 2017, after the base fee
24	amounts specified in subsection (b)(2) are adjusted
25	under paragraph (2)(D), the base establishment reg-

1	istration fee amounts specified in such subsection
2	shall be further adjusted, as the Secretary estimates
3	is necessary in order for total fee collections for such
4	fiscal year to generate the total revenue amounts, as
5	adjusted under paragraph (2).".
6	(d) Fee Waiver or Reduction.—Section 738 (21
7	U.S.C. 379j) is amended by—
8	(1) redesignating subsections (f) through (k) as
9	subsections (g) through (l), respectively; and
10	(2) by inserting after subsection (e) the fol-
11	lowing new subsection:
12	"(f) FEE WAIVER OR REDUCTION.—
13	"(1) In general.—The Secretary may, at the
14	Secretary's sole discretion, grant a waiver or reduc-
15	tion of fees under subsection (a)(2) or (a)(3) if the
16	Secretary finds that such waiver or reduction is in
17	the interest of public health.
18	"(2) Limitation.—The sum of all fee waivers
19	or reductions granted by the Secretary in any fiscal
20	year under paragraph (1) shall not exceed 2 percent
21	of the total fee revenue amounts established for such
22	year under subsection (c).
23	"(3) Duration.—The authority provided by
24	this subsection terminates October 1, 2017.".

1	(e) Conditions.—Section $738(h)(1)(A)$ (21 U.S.C.
2	379j(h)(1)(A)), as redesignated by subsection (d)(1), is
3	amended by striking "\$205,720,000" and inserting
4	"\$280,587,000".
5	(f) Crediting and Availability of Fees.—Sec-
6	tion 738(i) (21 U.S.C. 379j(i)), as redesignated by sub-
7	section (d)(1), is amended—
8	(1) in paragraph (1), by striking "Fees author-
9	ized" and inserting "Subject to paragraph (2)(C)
10	fees authorized";
11	(2) in paragraph (2)—
12	(A) in subparagraph (A)—
13	(i) in clause (i), by striking "shall be
14	retained" and inserting "subject to sub-
15	paragraph (C), shall be collected and avail-
16	able"; and
17	(ii) in clause (ii)—
18	(I) by striking "collected and"
19	after "shall only be"; and
20	(II) by striking "fiscal year
21	2002" and inserting "fiscal year
22	2009''; and
23	(B) by adding at the end, the following:
24	"(C) Provision for Early Payments.—
25	Payment of fees authorized under this section

1	for a fiscal year, prior to the due date for such
2	fees, may be accepted by the Secretary in ac-
3	cordance with authority provided in advance in
4	a prior year appropriations Act.";
5	(3) by amending paragraph (3) to read as fol-
6	lows:
7	"(3) Authorizations of appropriations.—
8	For each of the fiscal years 2013 through 2017,
9	there is authorized to be appropriated for fees under
10	this section an amount equal to the total revenue
11	amount specified under subsection (b)(3) for the fis-
12	cal year, as adjusted under subsection (c) and, for
13	fiscal year 2017 only, as further adjusted under
14	paragraph (4)."; and
15	(4) in paragraph (4)—
16	(A) by striking "fiscal years 2008, 2009,
17	and 2010" and inserting "fiscal years 2013,
18	2014, and 2015";
19	(B) by striking "fiscal year 2011" and in-
20	serting "fiscal year 2016";
21	(C) by striking "June 30, 2011" and in-
22	serting "June 30, 2016";
23	(D) by striking "the amount of fees speci-
24	fied in aggregate in" and inserting "the cumu-
25	lative amount appropriated pursuant to";

1	(E) by striking "aggregate amount in" be-
2	fore "excess shall be credited"; and
3	(F) by striking "fiscal year 2012" and in-
4	serting "fiscal year 2017".
5	(g) Conforming Amendment.—Section
6	515(c)(4)(A) (21 U.S.C. $360e(c)(4)(A)$ ) is amended by
7	striking "738(g)" and inserting "738(h)".
8	SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENTS
9	(a) Reauthorization.—Section 738A(b) (21
10	U.S.C. 379j-1(b)) is amended—
11	(1) in paragraph (1), by striking "2012" and
12	inserting "2017"; and
13	(2) in paragraph (5), by striking "2012" and
14	inserting "2017".
15	(b) Reports.—Section 738A(a) (21 U.S.C. 379j-
16	1(a)) is amended—
17	(1) by striking "2008 through 2012" each place
18	it appears and inserting "2013 through 2017"; and
19	(2) by striking "section 201(c) of the Food and
20	Drug Administration Amendments Act of 2007" and
21	inserting "section 201(b) of the Medical Device User
22	Fee Amendments of 2012".
23	SEC. 205. SAVINGS CLAUSE.
24	Notwithstanding the amendments made by this title
25	part 3 of subchapter C of chapter VII of the Federal Food

- 1 Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in
- 2 effect on the day before the date of the enactment of this
- 3 title, shall continue to be in effect with respect to pre-
- 4 market applications, premarket reports, premarket notifi-
- 5 cation submissions, and supplements (as defined in such
- 6 part as of such day) that on or after October 1, 2007,
- 7 but before October 1, 2012, were accepted by the Food
- 8 and Drug Administration for filing with respect to assess-
- 9 ing and collecting any fee required by such part for a fiscal
- 10 year prior to fiscal year 2013.

### 11 SEC. 206. EFFECTIVE DATE.

- The amendments made by this title shall take effect
- 13 on October 1, 2012, or the date of the enactment of this
- 14 Act, whichever is later, except that fees under part 3 of
- 15 subchapter C of chapter VII of the Federal Food, Drug,
- 16 and Cosmetic Act shall be assessed for all premarket ap-
- 17 plications, premarket reports, supplements, 30-day no-
- 18 tices, and premarket notification submissions received on
- 19 or after October 1, 2012, regardless of the date of the
- 20 enactment of this Act.

### 21 SEC. 207. SUNSET DATES.

- 22 (a) AUTHORIZATIONS.—Sections 737 and 738 (21
- 23 U.S.C. 739i; 739j) shall cease to be effective October 1,
- 24 2017.

- 1 (b) Reporting Requirements.—Section 738A (21
- 2 U.S.C. 739j-1) shall cease to be effective January 31,
- 3 2018.
- 4 (c) Previous Sunset Provision.—The Food and
- 5 Drug Administration Amendments Act of 2007 is amend-
- 6 ed by striking section 217.
- 7 SEC. 208. STREAMLINED HIRING AUTHORITY TO SUPPORT
- 8 ACTIVITIES RELATED TO THE PROCESS FOR
- 9 THE REVIEW OF DEVICE APPLICATIONS.
- Subchapter A of chapter VII (21 U.S.C. 371 et seq.)
- 11 is amended by inserting after section 713 the following
- 12 new section:
- 13 "SEC. 714. STREAMLINED HIRING AUTHORITY.
- "(a) IN GENERAL.—In addition to any other per-
- 15 sonnel authorities under other provisions of law, the Sec-
- 16 retary may, without regard to the provisions of title 5,
- 17 United States Code, governing appointments in the com-
- 18 petitive service, appoint employees to positions in the Food
- 19 and Drug Administration to perform, administer, or sup-
- 20 port activities described in subsection (b), if the Secretary
- 21 determines that such appointments are needed to achieve
- 22 the objectives specified in subsection (c).
- 23 "(b) Activities Described.—The activities de-
- 24 scribed in this subsection are activities under this Act re-

- 1 lated to the process for the review of device applications
- 2 (as defined in section 737(8)).
- 3 "(c) Objectives Specified.—The objectives speci-
- 4 fied in this subsection are with respect to the activities
- 5 under subsection (b), the goals referred to in section
- 6 738A(a)(1).
- 7 "(d) Internal Controls.—The Secretary shall in-
- 8 stitute appropriate internal controls for appointments
- 9 under this section.
- 10 "(e) Sunset.—The authority to appoint employees
- 11 under this section shall terminate on the date that is three
- 12 years after the date of enactment of this section.".

# 13 TITLE III—FEES RELATING TO

# 14 **GENERIC DRUGS**

- 15 SEC. 301. SHORT TITLE.
- 16 (a) Short Title.—This title may be cited as the
- 17 "Generic Drug User Fee Amendments of 2012".
- 18 (b) FINDING.—The Congress finds that the fees au-
- 19 thorized by the amendments made in this title will be dedi-
- 20 cated to human generic drug activities, as set forth in the
- 21 goals identified for purposes of part 7 of subchapter C
- 22 of chapter VII of the Federal Food, Drug, and Cosmetic
- 23 Act, in the letters from the Secretary of Health and
- 24 Human Services to the Chairman of the Committee on
- 25 Health, Education, Labor, and Pensions of the Senate and

1	the Chairman of the Committee on Energy and Commerce
2	of the House of Representatives, as set forth in the Con-
3	gressional Record.
4	SEC. 302. AUTHORITY TO ASSESS AND USE HUMAN GE-
5	NERIC DRUG FEES.
6	Subchapter C of chapter VII (21 U.S.C. 379f et seq.)
7	is amended by adding at the end the following:
8	"PART 7—FEES RELATING TO GENERIC DRUGS
9	"SEC. 744A. DEFINITIONS.
10	"For purposes of this part:
11	"(1) The term 'abbreviated new drug applica-
12	tion'—
13	"(A) means an application submitted
14	under section 505(j), an abbreviated application
15	submitted under section 507 (as in effect on the
16	day before the date of enactment of the Food
17	and Drug Administration Modernization Act of
18	1997), or an abbreviated new drug application
19	submitted pursuant to regulations in effect
20	prior to the implementation of the Drug Price
21	Competition and Patent Term Restoration Act
22	of 1984; and
23	"(B) does not include an application for a
24	positron emission tomography drug.

1	"(2) The term 'active pharmaceutical ingre-
2	dient' means—
3	"(A) a substance, or a mixture when the
4	substance is unstable or cannot be transported
5	on its own, intended—
6	"(i) to be used as a component of a
7	drug; and
8	"(ii) to furnish pharmacological activ-
9	ity or other direct effect in the diagnosis.
10	cure, mitigation, treatment, or prevention
11	of disease, or to affect the structure or any
12	function of the human body; or
13	"(B) a substance intended for final crys-
14	tallization, purification, or salt formation, or
15	any combination of those activities, to become a
16	substance or mixture described in subparagraph
17	(A).
18	"(3) The term 'adjustment factor' means a fac-
19	tor applicable to a fiscal year that is the Consumer
20	Price Index for all urban consumers (all items
21	United States city average) for October of the pre-
22	ceding fiscal year divided by such Index for October
23	2011.

1	"(4) The term 'affiliate' means a business enti-
2	ty that has a relationship with a second business en-
3	tity if, directly or indirectly—
4	"(A) one business entity controls, or has
5	the power to control, the other business entity;
6	or
7	"(B) a third party controls, or has power
8	to control, both of the business entities.
9	"(5)(A) The term 'facility'—
10	"(i) means a business or other entity—
11	"(I) under one management, either di-
12	rect or indirect; and
13	"(II) at one geographic location or ad-
14	dress engaged in manufacturing or proc-
15	essing an active pharmaceutical ingredient
16	or a finished dosage form; and
17	"(ii) does not include a business or other
18	entity whose only manufacturing or processing
19	activities are one or more of the following: re-
20	packaging, relabeling, or testing.
21	"(B) For purposes of subparagraph (A), sepa-
22	rate buildings within close proximity are considered
23	to be at one geographic location or address if the ac-
24	tivities in them are—

1	"(1) closely related to the same business
2	enterprise;
3	"(ii) under the supervision of the same
4	local management; and
5	"(iii) capable of being inspected by the
6	Food and Drug Administration during a single
7	inspection.
8	"(C) If a business or other entity would meet
9	the definition of a facility under this paragraph but
10	for being under multiple management, the business
11	or other entity is deemed to constitute multiple fa-
12	cilities, one per management entity, for purposes of
13	this paragraph.
14	"(6) The term 'finished dosage form' means—
15	"(A) a drug product in the form in which
16	it will be administered to a patient, such as a
17	tablet, capsule, solution, or topical application;
18	"(B) a drug product in a form in which re-
19	constitution is necessary prior to administration
20	to a patient, such as oral suspensions or
21	lyophilized powders; or
22	"(C) any combination of an active pharma-
23	ceutical ingredient with another component of a
24	drug product for purposes of production of a

1	drug product described in subparagraph (A) or
2	(B).
3	"(7) The term 'generic drug submission' means
4	an abbreviated new drug application, an amendment
5	to an abbreviated new drug application, or a prior
6	approval supplement to an abbreviated new drug ap-
7	plication.
8	"(8) The term 'human generic drug activities'
9	means the following activities of the Secretary asso-
10	ciated with generic drugs and inspection of facilities
11	associated with generic drugs:
12	"(A) The activities necessary for the re-
13	view of generic drug submissions, including re-
14	view of drug master files referenced in such
15	submissions.
16	"(B) The issuance of—
17	"(i) approval letters which approve
18	abbreviated new drug applications or sup-
19	plements to such applications; or
20	"(ii) complete response letters which
21	set forth in detail the specific deficiencies
22	in such applications and, where appro-
23	priate, the actions necessary to place such
24	applications in condition for approval.

1	"(C) The issuance of letters related to
2	Type II active pharmaceutical drug master files
3	which—
4	"(i) set forth in detail the specific de-
5	ficiencies in such submissions, and where
6	appropriate, the actions necessary to re-
7	solve those deficiencies; or
8	"(ii) document that no deficiencies
9	need to be addressed.
10	"(D) Inspections related to generic drugs.
11	"(E) Monitoring of research conducted in
12	connection with the review of generic drug sub-
13	missions and drug master files.
14	"(F) Postmarket safety activities with re-
15	spect to drugs approved under abbreviated new
16	drug applications or supplements, including the
17	following activities:
18	"(i) Collecting, developing, and re-
19	viewing safety information on approved
20	drugs, including adverse event reports.
21	"(ii) Developing and using improved
22	adverse-event data-collection systems, in-
23	cluding information technology systems.
24	"(iii) Developing and using improved
25	analytical tools to assess potential safety

1	problems, including access to external data
2	bases.
3	"(iv) Implementing and enforcing sec-
4	tion 505(o) (relating to postapproval stud-
5	ies and clinical trials and labeling changes)
6	and section 505(p) (relating to risk evalua-
7	tion and mitigation strategies) insofar as
8	those activities relate to abbreviated new
9	drug applications.
10	"(v) Carrying out section 505(k)(5)
11	(relating to adverse-event reports and
12	postmarket safety activities).
13	"(G) Regulatory science activities related
14	to generic drugs.
15	"(9) The term 'positron emission tomography
16	drug' has the meaning given to the term 'com-
17	pounded positron emission tomography drug' in sec-
18	tion 201(ii), except that paragraph (1)(B) of such
19	section shall not apply.
20	"(10) The term 'prior approval supplement'
21	means a request to the Secretary to approve a
22	change in the drug substance, drug product, produc-
23	tion process, quality controls, equipment, or facilities
24	covered by an approved abbreviated new drug appli-
25	cation when that change has a substantial potential

1	to have an adverse effect on the identity, strength,
2	quality, purity, or potency of the drug product as
3	these factors may relate to the safety or effective-
4	ness of the drug product.
5	"(11) The term 'resources allocated for human
6	generic drug activities' means the expenses for—
7	"(A) officers and employees of the Food
8	and Drug Administration, contractors of the
9	Food and Drug Administration, advisory com-
10	mittees, and costs related to such officers and
11	employees and to contracts with such contrac-
12	tors;
13	"(B) management of information, and the
14	acquisition, maintenance, and repair of com-
15	puter resources;
16	"(C) leasing, maintenance, renovation, and
17	repair of facilities and acquisition, maintenance,
18	and repair of fixtures, furniture, scientific
19	equipment, and other necessary materials and
20	supplies; and
21	"(D) collecting fees under subsection (a)
22	and accounting for resources allocated for the
23	review of abbreviated new drug applications and
24	supplements and inspection related to generic
25	drugs.

1	"(12) The term 'Type II active pharmaceutical
2	ingredient drug master file' means a submission of
3	information to the Secretary by a person that in-
4	tends to authorize the Food and Drug Administra-
5	tion to reference the information to support approval
6	of a generic drug submission without the submitter
7	having to disclose the information to the generic
8	drug submission applicant.
9	"SEC. 744B. AUTHORITY TO ASSESS AND USE HUMAN GE-
10	NERIC DRUG FEES.
11	"(a) Types of Fees.—Beginning in fiscal year
12	2013, the Secretary shall assess and collect fees in accord-
13	ance with this section as follows:
14	"(1) One-time backlog fee for abbre-
15	VIATED NEW DRUG APPLICATIONS PENDING ON OC-
16	TOBER 1, 2012.—
17	"(A) IN GENERAL.—Each person that
18	owns an abbreviated new drug application that
19	is pending on October 1, 2012, and that has
20	not received a tentative approval prior to that
21	date, shall be subject to a fee for each such ap-
22	plication, as calculated under subparagraph
23	(B).
24	"(B) METHOD OF FEE AMOUNT CALCULA-
25	TION.—The amount of each one-time backlog

1	tee shall be calculated by dividing \$50,000,000
2	by the total number of abbreviated new drug
3	applications pending on October 1, 2012, that
4	have not received a tentative approval as of that
5	date.
6	"(C) NOTICE.—Not later than October 31,
7	2012, the Secretary shall cause to be published
8	in the Federal Register a notice announcing the
9	amount of the fee required by subparagraph
10	(A).
11	"(D) FEE DUE DATE.—The fee required
12	by subparagraph (A) shall be due no later than
13	30 calendar days after the date of the publica-
14	tion of the notice specified in subparagraph (C).
15	"(2) Drug master file fee.—
16	"(A) IN GENERAL.—Each person that
17	owns a Type II active pharmaceutical ingre-
18	dient drug master file that is referenced on or
19	after October 1, 2012, in a generic drug sub-
20	mission by any initial letter of authorization
21	shall be subject to a drug master file fee.
22	"(B) One-time payment.—If a person
23	has paid a drug master file fee for a Type II
24	active pharmaceutical ingredient drug master
25	file, the person shall not be required to pay a

1	subsequent drug master file fee when that Type
2	II active pharmaceutical ingredient drug master
3	file is subsequently referenced in generic drug
4	submissions.
5	"(C) Notice.—
6	"(i) FISCAL YEAR 2013.—Not later
7	than October 31, 2012, the Secretary shall
8	cause to be published in the Federal Reg-
9	ister a notice announcing the amount of
10	the drug master file fee for fiscal year
11	2013.
12	"(ii) FISCAL YEAR 2014 THROUGH
13	2017.—Not later than 60 days before the
14	start of each of fiscal years 2014 through
15	2017, the Secretary shall cause to be pub-
16	lished in the Federal Register the amount
17	of the drug master file fee established by
18	this paragraph for such fiscal year.
19	"(D) AVAILABILITY FOR REFERENCE.—
20	"(i) In general.—Subject to sub-
21	section (g)(2)(C), for a generic drug sub-
22	mission to reference a Type II active phar-
23	maceutical ingredient drug master file, the
24	drug master file must be deemed available
25	for reference by the Secretary.

1	"(ii) Conditions.—A drug master
2	file shall be deemed available for reference
3	by the Secretary if—
4	"(I) the person that owns a Type
5	II active pharmaceutical ingredient
6	drug master file has paid the fee re-
7	quired under subparagraph (A) within
8	20 calendar days after the applicable
9	due date under subparagraph (E);
10	and
11	"(II) the drug master file has not
12	failed an initial completeness assess-
13	ment by the Secretary, in accordance
14	with criteria to be published by the
15	Secretary.
16	"(iii) List.—The Secretary shall
17	make publicly available on the Internet
18	Web site of the Food and Drug Adminis-
19	tration a list of the drug master file num-
20	bers that correspond to drug master files
21	that have successfully undergone an initial
22	completeness assessment, in accordance
23	with criteria to be published by the Sec-
24	retary, and are available for reference.
25	"(E) FEE DUE DATE.—

1	"(i) In general.—Subject to clause
2	(ii), a drug master file fee shall be due no
3	later than the date on which the first ge-
4	neric drug submission is submitted that
5	references the associated Type II active
6	pharmaceutical ingredient drug master file.
7	"(ii) Limitation.—No fee shall be
8	due under subparagraph (A) for a fiscal
9	year until the later of—
10	"(I) 30 calendar days after publi-
11	cation of the notice provided for in
12	clause (i) or (ii) of subparagraph (C),
13	as applicable; or
14	"(II) 30 calendar days after the
15	date of enactment of an appropria-
16	tions Act providing for the collection
17	and obligation of fees under this sec-
18	tion.
19	"(3) Abbreviated New Drug application
20	AND PRIOR APPROVAL SUPPLEMENT FILING FEE.—
21	"(A) In general.—Each applicant that
22	submits, on or after October 1, 2012, an abbre-
23	viated new drug application or a prior approval
24	supplement to an abbreviated new drug applica-
25	tion shall be subject to a fee for each such sub-

1	mission in the amount established under sub-
2	section (d).
3	"(B) Notice.—
4	"(i) FISCAL YEAR 2013.—Not later
5	than October 31, 2012, the Secretary shall
6	cause to be published in the Federal Reg-
7	ister a notice announcing the amount of
8	the fees under subparagraph (A) for fiscal
9	year 2013.
10	"(ii) FISCAL YEARS 2014 THROUGH
11	2017.—Not later than 60 days before the
12	start of each of fiscal years 2014 through
13	2017, the Secretary shall cause to be pub-
14	lished in the Federal Register the amount
15	of the fees under subparagraph (A) for
16	such fiscal year.
17	"(C) FEE DUE DATE.—
18	"(i) In general.—Except as pro-
19	vided in clause (ii), the fees required by
20	subparagraphs (A) and (F) shall be due no
21	later than the date of submission of the
22	abbreviated new drug application or prior
23	approval supplement for which such fee ap-
24	plies.

1	"(ii) Special rule for 2013.—For
2	fiscal year 2013, such fees shall be due on
3	the later of—
4	"(I) the date on which the fee is
5	due under clause (i);
6	"(II) 30 calendar days after pub-
7	lication of the notice referred to in
8	subparagraph (B)(i); or
9	"(III) if an appropriations Act is
10	not enacted providing for the collec-
11	tion and obligation of fees under this
12	section by the date of submission of
13	the application or prior approval sup-
14	plement for which the fees under sub-
15	paragraphs (A) and (F) apply, 30 cal-
16	endar days after the date that such an
17	appropriations Act is enacted.
18	"(D) Refund of fee if abbreviated
19	NEW DRUG APPLICATION IS NOT CONSIDERED
20	TO HAVE BEEN RECEIVED.—The Secretary
21	shall refund 75 percent of the fee paid under
22	subparagraph (A) for any abbreviated new drug
23	application or prior approval supplement to an
24	abbreviated new drug application that the Sec-
25	retary considers not to have been received with-

1	in the meaning of section $505(j)(5)(A)$ for a
2	cause other than failure to pay fees.
3	"(E) FEE FOR AN APPLICATION THE SEC-
4	RETARY CONSIDERS NOT TO HAVE BEEN RE-
5	CEIVED, OR THAT HAS BEEN WITHDRAWN.—An
6	abbreviated new drug application or prior ap-
7	proval supplement that was submitted on or
8	after October 1, 2012, and that the Secretary
9	considers not to have been received, or that has
10	been withdrawn, shall, upon resubmission of the
11	application or a subsequent new submission fol-
12	lowing the applicant's withdrawal of the appli-
13	cation, be subject to a full fee under subpara-
14	graph (A).
15	"(F) Additional fee for active phar-
16	MACEUTICAL INGREDIENT INFORMATION NOT
17	INCLUDED BY REFERENCE TO TYPE II ACTIVE
18	PHARMACEUTICAL INGREDIENT DRUG MASTER
19	FILE.—An applicant that submits a generic
20	drug submission on or after October 1, 2012
21	shall pay a fee, in the amount determined under
22	subsection (d)(3), in addition to the fee re-
23	quired under subparagraph (A), if—
24	"(i) such submission contains infor-
25	mation concerning the manufacture of an

1	active pharmaceutical ingredient at a facil-
2	ity by means other than reference by a let-
3	ter of authorization to a Type II active
4	pharmaceutical drug master file; and
5	"(ii) a fee in the amount equal to the
6	drug master file fee established in para-
7	graph (2) has not been previously paid
8	with respect to such information.
9	"(4) Generic drug facility fee and active
10	PHARMACEUTICAL INGREDIENT FACILITY FEE.—
11	"(A) In general.—Facilities identified,
12	or intended to be identified, in at least one ge-
13	neric drug submission that is pending or ap-
14	proved to produce a finished dosage form of a
15	human generic drug or an active pharma-
16	ceutical ingredient contained in a human ge-
17	neric drug shall be subject to fees as follows:
18	"(i) GENERIC DRUG FACILITY.—Each
19	person that owns a facility which is identi-
20	fied or intended to be identified in at least
21	one generic drug submission that is pend-
22	ing or approved to produce one or more
23	finished dosage forms of a human generic
24	drug shall be assessed an annual fee for
25	each such facility.

1	"(ii) Active pharmaceutical in-
2	GREDIENT FACILITY.—Each person that
3	owns a facility which produces, or which is
4	pending review to produce, one or more ac-
5	tive pharmaceutical ingredients identified,
6	or intended to be identified, in at least one
7	generic drug submission that is pending or
8	approved or in a Type II active pharma-
9	ceutical ingredient drug master file ref-
10	erenced in such a generic drug submission,
11	shall be assessed an annual fee for each
12	such facility.
13	"(iii) Facilities producing both
14	ACTIVE PHARMACEUTICAL INGREDIENTS
15	AND FINISHED DOSAGE FORMS.—Each
16	person that owns a facility identified, or
17	intended to be identified, in at least one
18	generic drug submission that is pending or
19	approved to produce both one or more fin-
20	ished dosage forms subject to clause (i)
21	and one or more active pharmaceutical in-
22	gredients subject to clause (ii) shall be
23	subject to fees under both such clauses for
24	that facility.

1	"(B) Amount.—The amount of fees estab-
2	lished under subparagraph (A) shall be estab-
3	lished under subsection (d).
4	"(C) Notice.—
5	"(i) FISCAL YEAR 2013.—For fiscal
6	year 2013, the Secretary shall cause to be
7	published in the Federal Register a notice
8	announcing the amount of the fees pro-
9	vided for in subparagraph (A) within the
10	timeframe specified in subsection
11	(d)(1)(B).
12	"(ii) FISCAL YEARS 2014 THROUGH
13	2017.—Within the timeframe specified in
14	subsection (d)(2), the Secretary shall cause
15	to be published in the Federal Register the
16	amount of the fees under subparagraph
17	(A) for such fiscal year.
18	"(D) FEE DUE DATE.—
19	"(i) FISCAL YEAR 2013.—For fiscal
20	year 2013, the fees under subparagraph
21	(A) shall be due on the later of—
22	"(I) not later than 45 days after
23	the publication of the notice under
24	subparagraph (B); or

1	"(II) if an appropriations Act is
2	not enacted providing for the collec-
3	tion and obligation of fees under this
4	section by the date of the publication
5	of such notice, 30 days after the date
6	that such an appropriations Act is en-
7	acted.
8	"(ii) FISCAL YEARS 2014 THROUGH
9	2017.—For each of fiscal years 2014
10	through 2017, the fees under subpara-
11	graph (A) for such fiscal year shall be due
12	on the later of—
13	"(I) the first business day on or
14	after October 1 of each such year; or
15	"(II) the first business day after
16	the enactment of an appropriations
17	Act providing for the collection and
18	obligation of fees under this section
19	for such year.
20	"(5) Date of submission.—For purposes of
21	this Act, a generic drug submission or Type II phar-
22	maceutical master file is deemed to be 'submitted' to
23	the Food and Drug Administration—
24	"(A) if it is submitted via a Food and
25	Drug Administration electronic gateway, on the

l	day when transmission to that electronic gate-
2	way is completed, except that a submission or
3	master file that arrives on a weekend, Federal
4	holiday, or day when the Food and Drug Ad-
5	ministration office that will review that submis-
6	sion is not otherwise open for business shall be
7	deemed to be submitted on the next day when
8	that office is open for business; or
9	"(B) if it is submitted in physical media
10	form, on the day it arrives at the appropriate
11	designated document room of the Food and
12	Drug Administration.
13	"(b) Fee Revenue Amounts.—
14	"(1) In general.—
15	"(A) FISCAL YEAR 2013.—For fiscal year
16	2013, fees under subsection (a) except as pro-
17	vided in subsection (o) (relating to waivers)
18	shall be established to generate a total esti-
19	mated revenue amount under such subsection of
20	\$299,000,000. Of that amount—
21	"(i) \$50,000,000 shall be generated
22	by the one-time backlog fee for generic
23	drug applications pending on October 1,
24	2012, established in subsection (a)(1); and

1	"(11) \$249,000,000 shall be generated
2	by the fees under paragraphs (2) through
3	(4) of subsection (a).
4	"(B) FISCAL YEARS 2014 THROUGH 2017.—
5	For each of the fiscal years 2014 through 2017,
6	fees under paragraphs (2) through (4) of sub-
7	section (a) shall be established to generate a
8	total estimated revenue amount under such sub-
9	section that is equal to \$299,000,000, as ad-
10	justed pursuant to subsection (c).
11	"(2) Types of fees.—In establishing fees
12	under paragraph (1) to generate the revenue
13	amounts specified in paragraph (1)(A)(ii) for fiscal
14	year 2013 and paragraph (1)(B) for each of fiscal
15	years 2014 through 2017, such fees shall be derived
16	from the fees under paragraphs (2) through (4) of
17	subsection (a) as follows:
18	"(A) 6 percent shall be derived from fees
19	under subsection (a)(2) (relating to drug mas-
20	ter files).
21	"(B) 24 percent shall be derived from fees
22	under subsection (a)(3) (relating to abbreviated
23	new drug applications and supplements). The
24	amount of a fee for a prior approval supplement

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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—

15 "(A) one;

"(B) 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 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

1 "(C) the average annual change that oc-2 curred in the Consumer Price Index for urban 3 consumers (Washington-Baltimore, DC-MD-VA–WV; Not Seasonally Adjusted; All items; 4 5 Annual Index) for the first 3 years of the pre-6 ceding 4 years of available data multiplied by 7 the proportion of all costs other than personnel 8 compensation and benefits costs to total costs 9 of human generic drug activities for the first 3 10 years of the preceding 4 fiscal years. 11 The adjustment made each fiscal year under this 12 subsection shall be added on a compounded basis to 13

the sum of all adjustments made each fiscal year after fiscal year 2013 under this subsection.

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"(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 no-

1	tice establishing fee revenues and fees for fiscal year
2	2017. If the Secretary has carryover balances for
3	such activities in excess of 3 months of such oper-
4	ating reserves, the adjustment under this subpara-
5	graph shall not be made.
6	"(d) Annual Fee Setting.—
7	"(1) FISCAL YEAR 2013.—For fiscal year
8	2013—
9	"(A) the Secretary shall establish, by Octo-
10	ber 31, 2012, the one-time generic drug backlog
11	fee for generic drug applications pending on Oc-
12	tober 1, 2012, the drug master file fee, the ab-
13	breviated new drug application fee, and the
14	prior approval supplement fee under subsection
15	(a), based on the revenue amounts established
16	under subsection (b); and
17	"(B) the Secretary shall establish, not
18	later than 45 days after the date to comply
19	with the requirement for identification of facili-
20	ties in subsection (f)(2), the generic drug facil-
21	ity fee and active pharmaceutical ingredient fa-
22	cility fee under subsection (a) based on the rev-
23	enue amounts established under subsection (b).
24	"(2) FISCAL YEARS 2014 THROUGH 2017.—Not
25	more than 60 days before the first day of each of

1	fiscal years 2014 through 2017, the Secretary shall
2	establish the drug master file fee, the abbreviated
3	new drug application fee, the prior approval supple-
4	ment fee, the generic drug facility fee, and the active
5	pharmaceutical ingredient facility fee under sub-
6	section (a) for such fiscal year, based on the revenue
7	amounts established under subsection (b) and the
8	adjustments provided under subsection (c).
9	"(3) FEE FOR ACTIVE PHARMACEUTICAL IN-
10	GREDIENT INFORMATION NOT INCLUDED BY REF-
11	ERENCE TO TYPE II ACTIVE PHARMACEUTICAL IN-
12	GREDIENT DRUG MASTER FILE.—In establishing the
13	fees under paragraphs (1) and (2), the amount of
14	the fee under subsection (a)(3)(F) shall be deter-
15	mined by multiplying—
16	"(A) the sum of—
17	"(i) the total number of such active
18	pharmaceutical ingredients in such submis-
19	sion; and
20	"(ii) for each such ingredient that is
21	manufactured at more than one such facil-
22	ity, the total number of such additional fa-
23	cilities; and

1	"(B) the amount equal to the drug master
2	file fee established in subsection (a)(2) for such
3	submission.
4	"(e) Limit.—The total amount of fees charged, as
5	adjusted under subsection (c), for a fiscal year may not
6	exceed the total costs for such fiscal year for the resources
7	allocated for human generic drug activities.
8	"(f) Identification of Facilities.—
9	"(1) Publication of notice; deadline for
10	COMPLIANCE.—Not later than October 1, 2012, the
11	Secretary shall cause to be published in the Federal
12	Register a notice requiring each person that owns a
13	facility described in subsection (a)(4)(A), or a site or
14	organization required to be identified by paragraph
15	(4), to submit to the Secretary information on the
16	identity of each such facility, site, or organization.
17	The notice required by this paragraph shall specify
18	the type of information to be submitted and the
19	means and format for submission of such informa-
20	tion.
21	"(2) Required submission of facility
22	IDENTIFICATION.—Each person that owns a facility
23	described in subsection (a)(4)(A) or a site or organi-
24	zation required to be identified by paragraph (4)
25	shall submit to the Secretary the information re-

1	quired under this subsection each year. Such infor-
2	mation shall—
3	"(A) for fiscal year 2013, be submitted not
4	later than 60 days after the publication of the
5	notice under paragraph (1); and
6	"(B) for each subsequent fiscal year, be
7	submitted, updated, or reconfirmed on or before
8	June 1 of such year.
9	"(3) Contents of Notice.—At a minimum,
10	the submission required by paragraph (2) shall in-
11	clude for each such facility—
12	"(A) identification of a facility identified or
13	intended to be identified in an approved or
14	pending generic drug submission;
15	"(B) whether the facility manufactures ac-
16	tive pharmaceutical ingredients or finished dos-
17	age forms, or both;
18	"(C) whether or not the facility is located
19	within the United States and its territories and
20	possessions;
21	"(D) whether the facility manufactures
22	positron emission tomography drugs solely, or
23	in addition to other drugs; and
24	"(E) whether the facility manufactures
25	drugs that are not generic drugs.

1	(4) CERTAIN SITES AND ORGANIZATIONS.—
2	"(A) IN GENERAL.—Any person that owns
3	or operates a site or organization described in
4	subparagraph (B) shall submit to the Secretary
5	information concerning the ownership, name,
6	and address of the site or organization.
7	"(B) SITES AND ORGANIZATIONS.—A site
8	or organization is described in this subpara-
9	graph if it is identified in a generic drug sub-
10	mission and is—
11	"(i) a site in which a bioanalytical
12	study is conducted;
13	"(ii) a clinical research organization;
14	"(iii) a contract analytical testing site;
15	or
16	"(iv) a contract repackager site.
17	"(C) NOTICE.—The Secretary may, by no-
18	tice published in the Federal Register, specify
19	the means and format for submission of the in-
20	formation under subparagraph (A) and may
21	specify, as necessary for purposes of this sec-
22	tion, any additional information to be sub-
23	mitted.
24	"(D) Inspection authority.—The Sec-
25	retary's inspection authority under section

1	704(a)(1) shall extend to all such sites and or-
2	ganizations.
3	"(g) Effect of Failure To Pay Fees.—
4	"(1) Generic drug backlog fee.—Failure
5	to pay the fee under subsection (a)(1) shall result in
6	the Secretary placing the person that owns the ab-
7	breviated new drug application subject to that fee on
8	an arrears list, such that no new abbreviated new
9	drug applications or supplement submitted on or
10	after October 1, 2012, from that person, or any af-
11	filiate of that person, will be received within the
12	meaning of section 505(j)(5)(A) until such out-
13	standing fee is paid.
14	"(2) Drug master file fee.—
15	"(A) Failure to pay the fee under sub-
16	section (a)(2) within 20 calendar days after the
17	applicable due date under subparagraph (E) of
18	such subsection (as described in subsection
19	(a)(2)(D)(ii)(I)) shall result in the Type II ac-
20	tive pharmaceutical ingredient drug master file
21	not being deemed available for reference.
22	"(B)(i) Any generic drug submission sub-
23	mitted on or after October 1, 2012, that ref-
24	erences, by a letter of authorization, a Type II
25	active pharmaceutical ingredient drug master

1	file that has not been deemed available for ref-
2	erence shall not be received within the meaning
3	of section $505(j)(5)(A)$ unless the condition
4	specified in clause (ii) is met.
5	"(ii) The condition specified in this clause
6	is that the fee established under subsection
7	(a)(2) has been paid within 20 calendar days or
8	the Secretary providing the notification to the
9	sponsor of the abbreviated new drug application
10	or supplement of the failure of the owner of the
11	Type II active pharmaceutical ingredient drug
12	master file to pay the drug master file fee as
13	specified in subparagraph (C).
14	"(C)(i) If an abbreviated new drug applica-
15	tion or supplement to an abbreviated new drug
16	application references a Type II active pharma-
17	ceutical ingredient drug master file for which $\epsilon$
18	fee under subsection $(a)(2)(A)$ has not been
19	paid by the applicable date under subsection
20	(a)(2)(E), the Secretary shall notify the sponsor
21	of the abbreviated new drug application or sup-
22	plement of the failure of the owner of the Type
23	II active pharmaceutical ingredient drug master
24	file to pay the applicable fee.

1	"(ii) If such fee is not paid within 20 cal-
2	endar days of the Secretary providing the noti-
3	fication, the abbreviated new drug application
4	or supplement to an abbreviated new drug ap-
5	plication shall not be received within the mean-
6	ing of $505(j)(5)(A)$ .
7	"(3) Abbreviated New Drug Application
8	FEE AND PRIOR APPROVAL SUPPLEMENT FEE.—
9	Failure to pay a fee under subparagraph (A) or (F)
10	of subsection (a)(3) within 20 calendar days of the
11	applicable due date under subparagraph (C) of such
12	subsection shall result in the abbreviated new drug
13	application or the prior approval supplement to an
14	abbreviated new drug application not being received
15	within the meaning of section $505(j)(5)(A)$ until
16	such outstanding fee is paid.
17	"(4) Generic drug facility fee and active
18	PHARMACEUTICAL INGREDIENT FACILITY FEE.—
19	"(A) In general.—Failure to pay the fee
20	under subsection (a)(4) within 20 calendar days
21	of the due date as specified in subparagraph
22	(D) of such subsection shall result in the fol-
23	lowing:
24	"(i) The Secretary shall place the fa-
25	cility on a publicly available arrears list,

1	such that no new abbreviated new drug ap-
2	plication or supplement submitted on or
3	after October 1, 2012, from the person
4	that is responsible for paying such fee, or
5	any affiliate of that person, will be received
6	within the meaning of section $505(j)(5)(A)$ .
7	"(ii) Any new generic drug submission
8	submitted on or after October 1, 2012,
9	that references such a facility shall not be
10	received, within the meaning of section
11	505(j)(5)(A) if the outstanding facility fee
12	is not paid within 20 calendar days of the
13	Secretary providing the notification to the
14	sponsor of the failure of the owner of the
15	facility to pay the facility fee under sub-
16	section $(a)(4)(C)$ .
17	"(iii) All drugs or active pharma-
18	ceutical ingredients manufactured in such
19	a facility or containing an ingredient man-
20	ufactured in such a facility shall be deemed
21	misbranded under section 502(aa).
22	"(B) Application of penalties.—The
23	penalties under this paragraph shall apply until
24	the fee established by subsection (a)(4) is paid

1	or the facility is removed from all generic drug
2	submissions that refer to the facility.
3	"(C) Nonreceival for nonpayment.—
4	"(i) Notice.—If an abbreviated new
5	drug application or supplement to an ab-
6	breviated new drug application submitted
7	on or after October 1, 2012, references a
8	facility for which a facility fee has not been
9	paid by the applicable date under sub-
10	section (a)(4)(C), the Secretary shall notify
11	the sponsor of the generic drug submission
12	of the failure of the owner of the facility
13	to pay the facility fee.
14	"(ii) Nonreceival.—If the facility
15	fee is not paid within 20 calendar days of
16	the Secretary providing the notification
17	under clause (i), the abbreviated new drug
18	application or supplement to an abbre-
19	viated new drug application shall not be re-
20	ceived within the meaning of section
21	505(j)(5)(A).
22	"(h) Limitations.—
23	"(1) In general.—Fees under subsection (a)
24	shall be refunded for a fiscal year beginning after
25	fiscal year 2012, unless appropriations for salaries

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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

1	in advance in appropriations Acts, subject to para-
2	graph (2). Such fees are authorized to remain avail-
3	able until expended. Such sums as may be necessary
4	may be transferred from the Food and Drug Admin-
5	istration salaries and expenses appropriation account
6	without fiscal year limitation to such appropriation
7	account for salaries and expenses with such fiscal
8	year limitation. The sums transferred shall be avail-
9	able solely for human generic drug activities.
0	"(2) Collections and Appropriation
1	ACTS.—
2	"(A) In general.—The fees authorized
3	by this section—
4	"(i) subject to subparagraphs (C) and
5	(D), shall be collected and available in each
6	fiscal year in an amount not to exceed the
7	amount specified in appropriation Acts, or
8	otherwise made available for obligation for
9	such fiscal year; and
20	"(ii) shall be available for a fiscal year
21	beginning after fiscal year 2012 to defray
22	the costs of human generic drug activities
23	(including such costs for an additional
24	number of full-time equivalent positions in
25	the Department of Health and Human
15 16 17	(D), shall be collected and available fiscal year in an amount not to excamount specified in appropriation A

1 Services to be engaged in such activities), 2 only if the Secretary allocates for such 3 purpose an amount for such fiscal year 4 (excluding amounts from fees collected 5 under this section) less than no 6 \$97,000,000 multiplied by the adjustment factor defined in subsection (p)(3) applica-7 8 ble to the fiscal year involved. 9 "(B) COMPLIANCE.—The Secretary shall 10 be considered to have met the requirements of 11 subparagraph (A)(ii) in any fiscal year if the 12 costs funded by appropriations and allocated for 13 human generic activities are not more than 10 14 percent below the level specified in such sub-15 paragraph. 16 "(C) FEE COLLECTION DURING FIRST 17 PROGRAM YEAR.—Until the date of enactment 18 of an Act making appropriations through Sep-19 tember 30, 2013 for the salaries and expenses 20 account of the Food and Drug Administration, 21 fees authorized by this section for fiscal year 22 2013, may be collected and shall be credited to 23 such account and remain available until ex-24 pended.

1	"(D) Provision for early payments in
2	SUBSEQUENT YEARS.—Payment of fees author-
3	ized under this section for a fiscal year (after
4	fiscal year 2013), prior to the due date for such
5	fees, may be accepted by the Secretary in ac-
6	cordance with authority provided in advance in
7	a prior year appropriations Act.
8	"(3) Authorization of appropriations.—
9	For each of the fiscal years 2013 through 2017,
10	there is authorized to be appropriated for fees under
11	this section an amount equivalent to the total rev-
12	enue amount determined under subsection (b) for
13	the fiscal year, as adjusted under subsection (c), if
14	applicable, or as otherwise affected under paragraph
15	(2) of this subsection.
16	"(j) Collection of Unpaid Fees.—In any case
17	where the Secretary does not receive payment of a fee as-
18	sessed under subsection (a) within 30 calendar days after
19	it is due, such fee shall be treated as a claim of the United
20	States Government subject to subchapter II of chapter 37
21	of title 31, United States Code.
22	"(k) Construction.—This section may not be con-
23	strued to require that the number of full-time equivalent
24	positions in the Department of Health and Human Serv-
25	ices, for officers, employees, and advisory committees not

- 1 engaged in human generic drug activities, be reduced to
- 2 offset the number of officers, employees, and advisory
- 3 committees so engaged.

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- 4 "(1) 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
- "(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).

established in subsection (a)(4).

- 18 "(m) Disputes Concerning Fees.—To qualify for
- 19 the return of a fee claimed to have been paid in error
- 20 under this section, a person shall submit to the Secretary
- 21 a written request justifying such return within 180 cal-
- 22 endar days after such fee was paid.
- 23 "(n) Substantially Complete Applications.—
- 24 An abbreviated new drug application that is not consid-
- 25 ered to be received within the meaning of section

- 1 505(j)(5)(A) because of failure to pay an applicable fee
- 2 under this provision within the time period specified in
- 3 subsection (g) shall be deemed not to have been 'substan-
- 4 tially complete' on the date of its submission within the
- 5 meaning of section 505(j)(5)(B)(iv)(II)(cc). An abbre-
- 6 viated new drug application that is not substantially com-
- 7 plete on the date of its submission solely because of failure
- 8 to pay an applicable fee under the preceding sentence shall
- 9 be deemed substantially complete and received within the
- 10 meaning of section 505(j)(5)(A) as of the date such appli-
- 11 cable fee is received.".
- 12 SEC. 303. REAUTHORIZATION; REPORTING REQUIREMENTS.
- Part 7 of subchapter C of chapter VII, as added by
- 14 section 302 of this Act, is amended by inserting after sec-
- 15 tion 744B the following:
- 16 "SEC. 744C. REAUTHORIZATION; REPORTING REQUIRE-
- 17 MENTS.
- 18 "(a) Performance Report.—Beginning with fiscal
- 19 year 2013, not later than 120 days after the end of each
- 20 fiscal year for which fees are collected under this part,
- 21 the Secretary shall prepare and submit to the Committee
- 22 on Energy and Commerce of the House of Representatives
- 23 and the Committee on Health, Education, Labor, and
- 24 Pensions of the Senate a report concerning the progress
- 25 of the Food and Drug Administration in achieving the

- 1 goals identified in the letters described in section 301(b)
- 2 of the Generic Drug User Fee Amendments of 2012 dur-
- 3 ing such fiscal year and the future plans of the Food and
- 4 Drug Administration for meeting the goals.
- 5 "(b) FISCAL REPORT.—Beginning with fiscal year
- 6 2013, not later than 120 days after the end of each fiscal
- 7 year for which fees are collected under this part, the Sec-
- 8 retary shall prepare and submit to the Committee on En-
- 9 ergy and Commerce of the House of Representatives and
- 10 the Committee on Health, Education, Labor, and Pen-
- 11 sions of the Senate a report on the implementation of the
- 12 authority for such fees during such fiscal year and the
- 13 use, by the Food and Drug Administration, of the fees
- 14 collected for such fiscal year.
- 15 "(c) Public Availability.—The Secretary shall
- 16 make the reports required under subsections (a) and (b)
- 17 available to the public on the Internet Web site of the
- 18 Food and Drug Administration.
- 19 "(d) REAUTHORIZATION.—
- 20 "(1) Consultation.—In developing rec-
- ommendations to present to the Congress with re-
- spect to the goals, and plans for meeting the goals,
- for human generic drug activities for the first 5 fis-
- 24 cal years after fiscal year 2017, and for the reau-

1	thorization of this part for such fiscal years, the Sec-
2	retary shall consult with—
3	"(A) the Committee on Energy and Com-
4	merce of the House of Representatives;
5	"(B) the Committee on Health, Education,
6	Labor, and Pensions of the Senate;
7	"(C) scientific and academic experts;
8	"(D) health care professionals;
9	"(E) representatives of patient and con-
10	sumer advocacy groups; and
11	"(F) the generic drug industry.
12	"(2) Prior public input.—Prior to beginning
13	negotiations with the generic drug industry on the
14	reauthorization of this part, the Secretary shall—
15	"(A) publish a notice in the Federal Reg-
16	ister requesting public input on the reauthoriza-
17	tion;
18	"(B) hold a public meeting at which the
19	public may present its views on the reauthoriza-
20	tion, including specific suggestions for changes
21	to the goals referred to in subsection (a);
22	"(C) provide a period of 30 days after the
23	public meeting to obtain written comments from
24	the public suggesting changes to this part; and

1	"(D) publish the comments on the Food
2	and Drug Administration's Internet Web site.
3	"(3) Periodic Consultation.—Not less fre-
4	quently than once every month during negotiations
5	with the generic drug industry, the Secretary shall
6	hold discussions with representatives of patient and
7	consumer advocacy groups to continue discussions of
8	their views on the reauthorization and their sugges-
9	tions for changes to this part as expressed under
10	paragraph (2).
11	"(4) Public Review of Recommenda-
12	TIONS.—After negotiations with the generic drug in-
13	dustry, the Secretary shall—
14	"(A) present the recommendations devel-
15	oped under paragraph (1) to the congressional
16	committees specified in such paragraph;
17	"(B) publish such recommendations in the
18	Federal Register;
19	"(C) provide for a period of 30 days for
20	the public to provide written comments on such
21	recommendations;
22	"(D) hold a meeting at which the public
23	may present its views on such recommenda-
24	tions; and

1	"(E) after consideration of such public
2	views and comments, revise such recommenda-
3	tions as necessary.
4	"(5) Transmittal of recommendations.—
5	Not later than January 15, 2017, the Secretary
6	shall transmit to the Congress the revised rec-
7	ommendations under paragraph (4), a summary of
8	the views and comments received under such para-
9	graph, and any changes made to the recommenda-
10	tions in response to such views and comments.
11	"(6) Minutes of negotiation meetings.—
12	"(A) Public availability.—Before pre-
13	senting the recommendations developed under
14	paragraphs (1) through (5) to the Congress, the
15	Secretary shall make publicly available, on the
16	Internet Web site of the Food and Drug Ad-
17	ministration, minutes of all negotiation meet-
18	ings conducted under this subsection between
19	the Food and Drug Administration and the ge-
20	neric drug industry.
21	"(B) Content.—The minutes described
22	under subparagraph (A) shall summarize any
23	substantive proposal made by any party to the
24	negotiations as well as significant controversies

1 or differences of opinion during the negotiations

2 and their resolution.".

### 3 SEC. 304. SUNSET DATES.

- 4 (a) AUTHORIZATION.—The amendments made by
- 5 section 302 cease to be effective October 1, 2017.
- 6 (b) REPORTING REQUIREMENTS.—The amendments
- 7 made by section 303 cease to be effective January 31,
- 8 2018.

### 9 SEC. 305. EFFECTIVE DATE.

- The amendments made by this title shall take effect
- 11 on October 1, 2012, or the date of the enactment of this
- 12 title, whichever is later, except that fees under section 302
- 13 shall be assessed for all human generic drug submissions
- 14 and Type II active pharmaceutical drug master files re-
- 15 ceived on or after October 1, 2012, regardless of the date
- 16 of enactment of this title.

### 17 SEC. 306. AMENDMENT WITH RESPECT TO MISBRANDING.

- 18 Section 502 (21 U.S.C. 352) is amended by adding
- 19 at the end the following:
- 20 "(aa) If it is a drug, or an active pharmaceutical in-
- 21 gredient, and it was manufactured, prepared, propagated,
- 22 compounded, or processed in a facility for which fees have
- 23 not been paid as required by section 744A(a)(4) or for
- 24 which identifying information required by section 744B(f)
- 25 has not been submitted, or it contains an active pharma-

1	ceutical ingredient that was manufactured, prepared,
2	propagated, compounded, or processed in such a facility.".
3	SEC. 307. STREAMLINED HIRING AUTHORITY OF THE FOOD
4	AND DRUG ADMINISTRATION TO SUPPORT
5	ACTIVITIES RELATED TO HUMAN GENERIC
6	DRUGS.
7	Section 714 of the Federal Food, Drug, and Cosmetic
8	Act, as added by section 208, is amended—
9	(1) in subsection (b)—
10	(A) by striking "are activities" and insert-
11	ing "are—
12	"(1) activities";
13	(B) by striking the period at the end and
14	inserting "; and; and
15	(C) by adding at the end the following:
16	"(2) activities under this Act related to human
17	generic drug activities (as defined in section
18	744A)."; and
19	(2) by amending subsection (c) to read as fol-
20	lows:
21	"(c) Objectives Specified.—The objectives speci-
22	fied in this subsection are—
23	"(1) with respect to the activities under sub-
24	section (b)(1), the goals referred to in section
25	738A(a)(1); and

1 "(2) with respect to the activities under sub2 section (b)(2), the performance goals with respect to
3 section 744A (regarding assessment and use of
4 human generic drug fees), as set forth in the letters
5 described in section 301(b) of the Generic Drug
6 User Fee Amendments of 2012.".

## 7 TITLE IV—FEES RELATING TO

# 8 BIOSIMILAR BIOLOGICAL

### 9 **PRODUCTS**

- 10 SEC. 401. SHORT TITLE; FINDING.
- 11 (a) SHORT TITLE.—This title may be cited as the 12 "Biosimilar User Fee Act of 2012".
- 13 (b) FINDING.—The Congress finds that the fees au-
- 14 thorized by the amendments made in this title will be dedi-
- 15 cated to expediting the process for the review of biosimilar
- 16 biological product applications, including postmarket safe-
- 17 ty activities, as set forth in the goals identified for pur-
- 18 poses of part 8 of subchapter C of chapter VII of the Fed-
- 19 eral Food, Drug, and Cosmetic Act, in the letters from
- 20 the Secretary of Health and Human Services to the Chair-
- 21 man of the Committee on Health, Education, Labor, and
- 22 Pensions of the Senate and the Chairman of the Com-
- 23 mittee on Energy and Commerce of the House of Rep-
- 24 resentatives, as set forth in the Congressional Record

1	SEC. 402. FEES RELATING TO BIOSIMILAR BIOLOGICAL
2	PRODUCTS.
3	Subchapter C of chapter VII (21 U.S.C. 379f et seq.)
4	is amended by inserting after part 7, as added by title
5	III of this Act, the following:
6	"PART 8—FEES RELATING TO BIOSIMILAR
7	BIOLOGICAL PRODUCTS
8	"SEC. 744G. DEFINITIONS.
9	"For purposes of this part:
10	"(1) The term 'adjustment factor' applicable to
11	a fiscal year that is the Consumer Price Index for
12	all urban consumers (Washington-Baltimore, DC-
13	MD-VA-WV; Not Seasonally Adjusted; All items) of
14	the preceding fiscal year divided by such Index for
15	September 2011.
16	"(2) The term 'affiliate' means a business enti-
17	ty that has a relationship with a second business en-
18	tity if, directly or indirectly—
19	"(A) one business entity controls, or has
20	the power to control, the other business entity;
21	or
22	"(B) a third party controls, or has power
23	to control, both of the business entities.
24	"(3) The term 'biosimilar biological product'
25	means a product for which a biosimilar biological
26	product application has been approved.

1	"(4)(A) Subject to subparagraph (B), the term
2	'biosimilar biological product application' means an
3	application for licensure of a biological product
4	under section 351(k) of the Public Health Service
5	Act.
6	"(B) Such term does not include—
7	"(i) a supplement to such an application;
8	"(ii) an application filed under section
9	351(k) of the Public Health Service Act that
10	cites as the reference product a bovine blood
11	product for topical application licensed before
12	September 1, 1992, or a large volume paren-
13	teral drug product approved before such date;
14	"(iii) an application filed under section
15	351(k) of the Public Health Service Act with
16	respect to—
17	"(I) whole blood or a blood component
18	for transfusion;
19	"(II) an allergenic extract product;
20	"(III) an in vitro diagnostic biological
21	product; or
22	"(IV) a biological product for further
23	manufacturing use only; or
24	"(iv) an application for licensure under
25	section 351(k) of the Public Health Service Act

1	that is submitted by a State or Federal Govern-
2	ment entity for a product that is not distributed
3	commercially.
4	"(5) The term 'biosimilar biological product de-
5	velopment meeting' means any meeting, other than
6	a biosimilar initial advisory meeting, regarding the
7	content of a development program, including a pro-
8	posed design for, or data from, a study intended to
9	support a biosimilar biological product application.
10	"(6) The term 'biosimilar biological product de-
11	velopment program' means the program under this
12	part for expediting the process for the review of sub-
13	missions in connection with biosimilar biological
14	product development.
15	"(7)(A) The term 'biosimilar biological product
16	establishment' means a foreign or domestic place of
17	business—
18	"(i) that is at one general physical location
19	consisting of one or more buildings, all of which
20	are within five miles of each other; and
21	"(ii) at which one or more biosimilar bio-
22	logical products are manufactured in final dos-
23	age form.
24	"(B) For purposes of subparagraph (A)(ii), the
25	term 'manufactured' does not include packaging.

1	"(8) The term 'biosimilar initial advisory meet-
2	ing'—
3	"(A) means a meeting, if requested, that is
4	limited to—
5	"(i) a general discussion regarding
6	whether licensure under section 351(k) of
7	the Public Health Service Act may be fea-
8	sible for a particular product; and
9	"(ii) if so, general advice on the ex-
10	pected content of the development pro-
11	gram; and
12	"(B) does not include any meeting that in-
13	volves substantive review of summary data or
14	full study reports.
15	"(9) The term 'costs of resources allocated for
16	the process for the review of biosimilar biological
17	product applications' means the expenses in connec-
18	tion with the process for the review of biosimilar bio-
19	logical product applications for—
20	"(A) officers and employees of the Food
21	and Drug Administration, contractors of the
22	Food and Drug Administration, advisory com-
23	mittees, and costs related to such officers em-
24	ployees and committees and to contracts with
25	such contractors;

1	"(B) management of information, and the
2	acquisition, maintenance, and repair of com-
3	puter resources;
4	"(C) leasing, maintenance, renovation, and
5	repair of facilities and acquisition, maintenance,
6	and repair of fixtures, furniture, scientific
7	equipment, and other necessary materials and
8	supplies; and
9	"(D) collecting fees under section 744H
10	and accounting for resources allocated for the
11	review of submissions in connection with bio-
12	similar biological product development, bio-
13	similar biological product applications, and sup-
14	plements.
15	"(10) The term 'final dosage form' means, with
16	respect to a biosimilar biological product, a finished
17	dosage form which is approved for administration to
18	a patient without substantial further manufacturing
19	(such as lyophilized products before reconstitution).
20	"(11) The term 'financial hold'—
21	"(A) means an order issued by the Sec-
22	retary to prohibit the sponsor of a clinical in-
23	vestigation from continuing the investigation is
24	the Secretary determines that the investigation
25	is intended to support a biosimilar biological

1	product application and the sponsor has failed
2	to pay any fee for the product required under
3	subparagraph (A), (B), or (D) of section
4	744H(a)(1); and
5	"(B) does not mean that any of the bases
6	for a 'clinical hold' under section 505(i)(3) have
7	been determined by the Secretary to exist con-
8	cerning the investigation.
9	"(12) The term 'person' includes an affiliate of
10	such person.
11	"(13) The term 'process for the review of bio-
12	similar biological product applications' means the
13	following activities of the Secretary with respect to
14	the review of submissions in connection with bio-
15	similar biological product development, biosimilar bi-
16	ological product applications, and supplements:
17	"(A) The activities necessary for the re-
18	view of submissions in connection with bio-
19	similar biological product development, bio-
20	similar biological product applications, and sup-
21	plements.
22	"(B) Actions related to submissions in con-
23	nection with biosimilar biological product devel-
24	opment, the issuance of action letters which ap-
25	prove biosimilar biological product applications

1	or which set forth in detail the specific defi-
2	ciencies in such applications, and where appro-
3	priate, the actions necessary to place such ap-
4	plications in condition for approval.
5	"(C) The inspection of biosimilar biological
6	product establishments and other facilities un-
7	dertaken as part of the Secretary's review of
8	pending biosimilar biological product applica-
9	tions and supplements.
10	"(D) Activities necessary for the release of
11	lots of biosimilar biological products under sec-
12	tion 351(k) of the Public Health Service Act.
13	"(E) Monitoring of research conducted in
14	connection with the review of biosimilar biologi-
15	cal product applications.
16	"(F) Postmarket safety activities with re-
17	spect to biologics approved under biosimilar bio-
18	logical product applications or supplements, in-
19	cluding the following activities:
20	"(i) Collecting, developing, and re-
21	viewing safety information on biosimilar bi-
22	ological products, including adverse-event
23	reports.

1	"(ii) Developing and using improved
2	adverse-event data-collection systems, in-
3	cluding information technology systems.
4	"(iii) Developing and using improved
5	analytical tools to assess potential safety
6	problems, including access to external data
7	bases.
8	"(iv) Implementing and enforcing sec-
9	tion 505(o) (relating to postapproval stud-
10	ies and clinical trials and labeling changes)
11	and section 505(p) (relating to risk evalua-
12	tion and mitigation strategies).
13	"(v) Carrying out section 505(k)(5)
14	(relating to adverse-event reports and
15	postmarket safety activities).
16	"(14) The term 'supplement' means a request
17	to the Secretary to approve a change in a biosimilar
18	biological product application which has been ap-
19	proved, including a supplement requesting that the
20	Secretary determine that the biosimilar biological
21	product meets the standards for interchangeability
22	described in section $351(k)(4)$ of the Public Health
23	Service Act.

1	"SEC. 744H. AUTHORITY TO ASSESS AND USE BIOSIMILAR
2	BIOLOGICAL PRODUCT FEES.
3	"(a) Types of Fees.—Beginning in fiscal year
4	2013, the Secretary shall assess and collect fees in accord-
5	ance with this section as follows:
6	"(1) Biosimilar development program
7	FEES.—
8	"(A) Initial biosimilar biological
9	PRODUCT DEVELOPMENT FEE.—
10	"(i) In General.—Each person that
11	submits to the Secretary a meeting request
12	described under clause (ii) or a clinical
13	protocol for an investigational new drug
14	protocol described under clause (iii) shall
15	pay for the product named in the meeting
16	request or the investigational new drug ap-
17	plication the initial biosimilar biological
18	product development fee established under
19	subsection $(b)(1)(A)$ .
20	"(ii) MEETING REQUEST.—The meet-
21	ing request described in this clause is a re-
22	quest for a biosimilar biological product
23	development meeting for a product.
24	"(iii) Clinical protocol for ind.—
25	A clinical protocol for an investigational
26	new drug protocol described in this clause

1	is a clinical protocol consistent with the
2	provisions of section 505(i), including any
3	regulations promulgated under section
4	505(i), (referred to in this section as 'in-
5	vestigational new drug application') de-
6	scribing an investigation that the Secretary
7	determines is intended to support a bio-
8	similar biological product application for a
9	product.
10	"(iv) Due date.—The initial bio-
11	similar biological product development fee
12	shall be due by the earlier of the following
13	"(I) Not later than 5 days after
14	the Secretary grants a request for a
15	biosimilar biological product develop-
16	ment meeting.
17	"(II) The date of submission of
18	an investigational new drug applica-
19	tion describing an investigation that
20	the Secretary determines is intended
21	to support a biosimilar biologica
22	product application.
23	"(v) Transition rule.—Each per-
24	son that has submitted an investigational
25	new drug application prior to the date of

1	enactment of the Biosimilars User Fee Act
2	of 2012 shall pay the initial biosimilar bio-
3	logical product development fee by the ear-
4	lier of the following:
5	"(I) Not later than 60 days after
6	the date of the enactment of the
7	Biosimilars User Fee Act of 2012, if
8	the Secretary determines that the in-
9	vestigational new drug application de-
10	scribes an investigation that is in-
11	tended to support a biosimilar biologi-
12	cal product application.
13	"(II) Not later than 5 days after
14	the Secretary grants a request for a
15	biosimilar biological product develop-
16	ment meeting.
17	"(B) ANNUAL BIOSIMILAR BIOLOGICAL
18	PRODUCT DEVELOPMENT FEE.—
19	"(i) In general.—A person that
20	pays an initial biosimilar biological product
21	development fee for a product shall pay for
22	such product, beginning in the fiscal year
23	following the fiscal year in which the initial
24	biosimilar biological product development
25	fee was paid, an annual fee established

1	under subsection $(b)(1)(B)$ for biosimilar
2	biological product development (referred to
3	in this section as 'annual biosimilar bio-
4	logical product development fee').
5	"(ii) Due date.—The annual bio-
6	similar biological product development pro-
7	gram fee for each fiscal year will be due on
8	the later of—
9	"(I) the first business day on or
10	after October 1 of each such year; or
11	"(II) the first business day after
12	the enactment of an appropriations
13	Act providing for the collection and
14	obligation of fees for such year under
15	this section.
16	"(iii) Exception.—The annual bio-
17	similar development program fee for each
18	fiscal year will be due on the date specified
19	in clause (ii), unless the person has—
20	"(I) submitted a marketing appli-
21	cation for the biological product that
22	was accepted for filing; or
23	"(II) discontinued participation
24	in the biosimilar biological product de-

1	velopment program for the product
2	under subparagraph (C).
3	"(C) DISCONTINUATION OF FEE OBLIGA-
4	TION.—A person may discontinue participation
5	in the biosimilar biological product development
6	program for a product effective October 1 of a
7	fiscal year by, not later than August 1 of the
8	preceding fiscal year—
9	"(i) if no investigational new drug ap-
10	plication concerning the product has been
11	submitted, submitting to the Secretary a
12	written declaration that the person has no
13	present intention of further developing the
14	product as a biosimilar biological product
15	or
16	"(ii) if an investigational new drug
17	application concerning the product has
18	been submitted, by withdrawing the inves-
19	tigational new drug application in accord-
20	ance with part 312 of title 21, Code of
21	Federal Regulations (or any successor reg-
22	ulations).
23	"(D) REACTIVATION FEE.—
24	"(i) In general.—A person that has
25	discontinued participation in the biosimilar

1	biological product development program for
2	a product under subparagraph (C) shall
3	pay a fee (referred to in this section as 're-
4	activation fee') by the earlier of the fol-
5	lowing:
6	"(I) Not later than 5 days after
7	the Secretary grants a request for a
8	biosimilar biological product develop-
9	ment meeting for the product (after
10	the date on which such participation
11	was discontinued).
12	"(II) Upon the date of submis-
13	sion (after the date on which such
14	participation was discontinued) of an
15	investigational new drug application
16	describing an investigation that the
17	Secretary determines is intended to
18	support a biosimilar biological product
19	application for that product.
20	"(ii) Application of Annual
21	FEE.—A person that pays a reactivation
22	fee for a product shall pay for such prod-
23	uct, beginning in the next fiscal year, the
24	annual biosimilar biological product devel-
25	opment fee under subparagraph (B).

1	"(E) Effect of failure to pay bio-
2	SIMILAR DEVELOPMENT PROGRAM FEES.—
3	"(i) No biosimilar biological
4	PRODUCT DEVELOPMENT MEETINGS.—If a
5	person has failed to pay an initial or an-
6	nual biosimilar biological product develop-
7	ment fee as required under subparagraph
8	(A) or (B), or a reactivation fee as re-
9	quired under subparagraph (D), the Sec-
10	retary shall not provide a biosimilar bio-
11	logical product development meeting relat-
12	ing to the product for which fees are owed.
13	"(ii) No receipt of investiga-
14	TIONAL NEW DRUG APPLICATIONS.—Ex-
15	cept in extraordinary circumstances, the
16	Secretary shall not consider an investiga-
17	tional new drug application to have been
18	received under section 505(i)(2) if—
19	"(I) the Secretary determines
20	that the investigation is intended to
21	support a biosimilar biological product
22	application; and
23	"(II) the sponsor has failed to
24	pay an initial or annual biosimilar bio-
25	logical product development fee for

1	the product as required under sub-
2	paragraph (A) or (B), or a reactiva-
3	tion fee as required under subpara-
4	graph (D).
5	"(iii) Financial Hold.—Notwith-
6	standing section 505(i)(2), except in ex-
7	traordinary circumstances, the Secretary
8	shall prohibit the sponsor of a clinical in-
9	vestigation from continuing the investiga-
10	tion if—
11	"(I) the Secretary determines
12	that the investigation is intended to
13	support a biosimilar biological product
14	application; and
15	"(II) the sponsor has failed to
16	pay an initial or annual biosimilar bio-
17	logical product development fee for
18	the product as required under sub-
19	paragraph (A) or (B), or a reactiva-
20	tion fee for the product as required
21	under subparagraph (D).
22	"(iv) No acceptance of biosimilar
23	BIOLOGICAL PRODUCT APPLICATIONS OF
24	SUPPLEMENTS.—If a person has failed to
25	pay an initial or annual biosimilar biologi-

1	cal product development fee as required
2	under subparagraph (A) or (B), or a reac-
3	tivation fee as required under subpara-
4	graph (D), any biosimilar biological prod-
5	uct application or supplement submitted by
6	that person shall be considered incomplete
7	and shall not be accepted for filing by the
8	Secretary until all such fees owed by such
9	person have been paid.
10	"(F) Limits regarding biosimilar de-
11	VELOPMENT PROGRAM FEES.—
12	"(i) No refunds.—The Secretary
13	shall not refund any initial or annual bio-
14	similar biological product development fee
15	paid under subparagraph (A) or (B), or
16	any reactivation fee paid under subpara-
17	graph (D).
18	"(ii) No waivers, exemptions, or
19	REDUCTIONS.—The Secretary shall not
20	grant a waiver, exemption, or reduction of
21	any initial or annual biosimilar biological
22	product development fee due or payable
23	under subparagraph (A) or (B), or any re-
24	activation fee due or payable under sub-
25	paragraph (D).

(2) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-
CATION AND SUPPLEMENT FEE.—
"(A) IN GENERAL.—Each person that sub-
mits, 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 estab-
lished under subsection $(b)(1)(D)$ for
a biosimilar biological product applica-
tion; 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 effective-
ness are not required, that is equal to—
"(I) half of the amount of the fee
established under subsection (b)(1)(D)

1	for a biosimilar biological product ap-
2	plication; minus
3	"(II) the cumulative amount of
4	fees paid, if any, under subparagraphs
5	(A), (B), and (D) of paragraph (1)
6	for that product.
7	"(iii) A fee for a supplement for which
8	clinical data (other than comparative bio-
9	availability studies) with respect to safety
10	or effectiveness are required, that is equal
11	to half of the amount of the fee established
12	under subsection (b)(1)(D) for a biosimilar
13	biological product application.
14	"(B) REDUCTION IN FEES.—Notwith-
15	standing section 404 of the Biosimilars User
16	Fee Act of 2012, any person who pays a fee
17	under subparagraph (A), (B), or (D) of para-
18	graph (1) for a product before October 1, 2017,
19	but submits a biosimilar biological product ap-
20	plication for that product after such date, shall
21	be entitled to the reduction of any biosimilar bi-
22	ological product application fees that may be
23	assessed at the time when such biosimilar bio-
24	logical product application is submitted, by the
25	cumulative amount of fees paid under subpara-

1	graphs (A), (B), and (D) of paragraph (1) for
2	that product.
3	"(C) PAYMENT DUE DATE.—Any fee re-
4	quired by subparagraph (A) shall be due upon
5	submission of the application or supplement for
6	which such fee applies.
7	"(D) Exception for previously filed
8	APPLICATION OR SUPPLEMENT.—If a biosimilar
9	biological product application or supplement
10	was submitted by a person that paid the fee for
11	such application or supplement, was accepted
12	for filing, and was not approved or was with-
13	drawn (without a waiver), the submission of a
14	biosimilar biological product application or a
15	supplement for the same product by the same
16	person (or the person's licensee, assignee, or
17	successor) shall not be subject to a fee under
18	subparagraph (A).
19	"(E) REFUND OF APPLICATION FEE IF AP-
20	PLICATION REFUSED FOR FILING OR WITH-
21	DRAWN BEFORE FILING.—The Secretary shall
22	refund 75 percent of the fee paid under this
23	paragraph for any application or supplement
24	which is refused for filing or withdrawn without
25	a waiver before filing.

"(F) FEES FOR APPLICATIONS PRE-
VIOUSLY REFUSED FOR FILING OR WITHDRAWN
BEFORE FILING.—A biosimilar biological prod-
uct application or supplement that was sub-
mitted but was refused for filing, or was with
drawn before being accepted or refused for fil-
ing, shall be subject to the full fee under sub-
paragraph (A) upon being resubmitted or filed
over protest, unless the fee is waived under sub-
section (c).
"(3) Biosimilar biological product estab-
LISHMENT FEE.—
"(A) In general.—Except as provided in
subparagraph (E), each person that is named
as the applicant in a biosimilar biological prod-
uct 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 biologica
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 fis-

1	uct named in the application is assessed a fee
2	under paragraph (4) unless the biosimilar bio-
3	logical product establishment listed in the appli-
4	cation does not engage in the manufacture of
5	the biosimilar biological product during such
6	fiscal year.
7	"(C) Due date.—The establishment fee
8	for a fiscal year shall be due on the later of—
9	"(i) the first business day on or after
10	October 1 of such fiscal year; or
11	"(ii) the first business day after the
12	enactment of an appropriations Act pro-
13	viding for the collection and obligation of
14	fees for such fiscal year under this section.
15	"(D) Application to establishment.—
16	"(i) Each biosimilar biological product
17	establishment shall be assessed only one
18	fee per biosimilar biological product estab-
19	lishment, notwithstanding the number of
20	biosimilar biological products manufac-
21	tured at the establishment, subject to
22	clause (ii).
23	"(ii) In the event an establishment is
24	listed in a biosimilar biological product ap-
25	plication by more than one applicant, the

1	establishment fee for the fiscal year shall
2	be divided equally and assessed among the
3	applicants whose biosimilar biological prod-
4	ucts are manufactured by the establish-
5	ment during the fiscal year and assessed
6	biosimilar biological product fees under
7	paragraph (4).
8	"(E) EXCEPTION FOR NEW PRODUCTS.—
9	If, during the fiscal year, an applicant initiates
10	or causes to be initiated the manufacture of a
11	biosimilar biological product at an establish-
12	ment listed in its biosimilar biological product
13	application—
14	"(i) that did not manufacture the bio-
15	similar biological product in the previous
16	fiscal year; and
17	"(ii) for which the full biosimilar bio-
18	logical product establishment fee has been
19	assessed in the fiscal year at a time before
20	manufacture of the biosimilar biological
21	product was begun,
22	the applicant shall not be assessed a share of
23	the biosimilar biological product establishment
24	fee for the fiscal year in which the manufacture
25	of the product began.

1	"(4) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—
2	"(A) In general.—Each person who is
3	named as the applicant in a biosimilar biologi-
4	cal product application shall pay for each such
5	biosimilar biological product the annual fee es-
6	tablished under subsection $(b)(1)(F)$ .
7	"(B) Due date.—The biosimilar biologi-
8	cal product fee for a fiscal year shall be due on
9	the later of—
10	"(i) the first business day on or after
11	October 1 of each such year; or
12	"(ii) the first business day after the
13	enactment of an appropriations Act pro-
14	viding for the collection and obligation of
15	fees for such year under this section.
16	"(C) One fee per product per year.—
17	The biosimilar biological product fee shall be
18	paid only once for each product for each fiscal
19	year.
20	"(b) FEE SETTING AND AMOUNTS.—
21	"(1) In General.—Subject to paragraph (2),
22	the Secretary shall, 60 days before the start of each
23	fiscal year that begins after September 30, 2012, es-
24	tablish, for the next fiscal year, the fees under sub-

1	section (a). Except as provided in subsection (c),
2	such fees shall be in the following amounts:
3	"(A) Initial biosimilar biological
4	PRODUCT DEVELOPMENT FEE.—The initial bio-
5	similar biological product development fee under
6	subsection (a)(1)(A) for a fiscal year shall be
7	equal to 10 percent of the amount established
8	under section $736(c)(4)$ for a human drug ap-
9	plication described in section 736(a)(1)(A)(i)
10	for that fiscal year.
11	"(B) ANNUAL BIOSIMILAR BIOLOGICAL
12	PRODUCT DEVELOPMENT FEE.—The annual
13	biosimilar biological product development fee
14	under subsection (a)(1)(B) for a fiscal year
15	shall be equal to 10 percent of the amount es-
16	tablished under section 736(c)(4) for a human
17	drug application described in section
18	736(a)(1)(A)(i) for that fiscal year.
19	"(C) Reactivation fee.—The reactiva-
20	tion fee under subsection $(a)(1)(D)$ for a fiscal
21	year shall be equal to 20 percent of the amount
22	of the fee established under section $736(c)(4)$
23	for a human drug application described in sec-
24	tion 736(a)(1)(A)(i) for that fiscal year.

1	"(D) BIOSIMILAR BIOLOGICAL PRODUCT
2	APPLICATION FEE.—The biosimilar biological
3	product application fee under subsection (a)(2)
4	for a fiscal year shall be equal to the amount
5	established under section $736(c)(4)$ for a
6	human drug application described in section
7	736(a)(1)(A)(i) for that fiscal year.
8	"(E) BIOSIMILAR BIOLOGICAL PRODUCT
9	ESTABLISHMENT FEE.—The biosimilar biologi-
10	cal product establishment fee under subsection
11	(a)(3) for a fiscal year shall be equal to the
12	amount established under section $736(c)(4)$ for
13	a prescription drug establishment for that fiscal
14	year.
15	"(F) BIOSIMILAR BIOLOGICAL PRODUCT
16	FEE.—The biosimilar biological product fee
17	under subsection $(a)(4)$ for a fiscal year shall be
18	equal to the amount established under section
19	736(c)(4) for a prescription drug product for
20	that fiscal year.
21	"(2) Limit.—The total amount of fees charged
22	for a fiscal year under this section may not exceed
23	the total amount for such fiscal year of the costs of
24	resources allocated for the process for the review of
25	biosimilar biological product applications.

1	"(c) Application Fee Waiver for Small Busi-
2	NESS.—
3	"(1) WAIVER OF APPLICATION FEE.—The Sec-
4	retary shall grant to a person who is named in a bio-
5	similar biological product application a waiver from
6	the application fee assessed to that person under
7	subsection (a)(2)(A) for the first biosimilar biologi-
8	cal product application that a small business or its
9	affiliate submits to the Secretary for review. After a
10	small business or its affiliate is granted such a waiv-
11	er, the small business or its affiliate shall pay—
12	"(A) application fees for all subsequent
13	biosimilar biological product applications sub-
14	mitted to the Secretary for review in the same
15	manner as an entity that is not a small busi-
16	ness; and
17	"(B) all supplement fees for all supple-
18	ments to biosimilar biological product applica-
19	tions submitted to the Secretary for review in
20	the same manner as an entity that is not a
21	small business.
22	"(2) Considerations.—In determining wheth-
23	er to grant a waiver of a fee under paragraph (1),
24	the Secretary shall consider only the circumstances

1 and assets of the applicant involved and any affiliate 2 of the applicant. 3 "(3) SMALL BUSINESS DEFINED.—In this sub-4 section, the term 'small business' means an entity 5 that has fewer than 500 employees, including em-6 ployees of affiliates, and does not have a drug prod-7 uct that has been approved under a human drug ap-8 plication (as defined in section 735) or a biosimilar 9 biological product application (as defined in section 10 744G(4)) and introduced or delivered for introduc-11 tion into interstate commerce. 12 "(d) Effect of Failure To Pay Fees.—A bio-13 similar biological product application or supplement submitted by a person subject to fees under subsection (a) 14 15 shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such per-16 17 son have been paid. 18 "(e) Crediting and Availability of Fees.— 19 "(1) In General.—Subject to paragraph (2), 20 fees authorized under subsection (a) shall be col-21 lected and available for obligation only to the extent 22 and in the amount provided in advance in appropria-23 tions Acts. Such fees are authorized to remain avail-24 able until expended. Such sums as may be necessary 25 may be transferred from the Food and Drug Admin-

1	istration salaries and expenses appropriation account
2	without fiscal year limitation to such appropriation
3	account for salaries and expenses with such fiscal
4	year limitation. The sums transferred shall be avail-
5	able solely for the process for the review of bio-
6	similar biological product applications.
7	"(2) Collections and Appropriation
8	ACTS.—
9	"(A) In general.—Subject to subpara-
10	graphs (C) and (D), the fees authorized by this
11	section shall be collected and available in each
12	fiscal year in an amount not to exceed the
13	amount specified in appropriation Acts, or oth-
14	erwise made available for obligation for such
15	fiscal year.
16	"(B) Use of fees and limitation.—
17	The fees authorized by this section shall be
18	available for a fiscal year beginning after fiscal
19	year 2012 to defray the costs of the process for
20	the review of biosimilar biological product appli-
21	cations (including such costs for an additional
22	number of full-time equivalent positions in the
23	Department of Health and Human Services to
24	be engaged in such process), only if the Sec-
25	retary allocates for such purpose an amount for

1	such fiscal year (excluding amounts from fees
2	collected under this section) no less than
3	\$20,000,000, multiplied by the adjustment fac-
4	tor applicable to the fiscal year involved.
5	"(C) FEE COLLECTION DURING FIRST
6	PROGRAM YEAR.—Until the date of enactment
7	of an Act making appropriations through Sep-
8	tember 30, 2013, for the salaries and expenses
9	account of the Food and Drug Administration,
10	fees authorized by this section for fiscal year
11	2013 may be collected and shall be credited to
12	such account and remain available until ex-
13	pended.
14	"(D) Provision for Early Payments in
15	SUBSEQUENT YEARS.—Payment of fees author-
16	ized under this section for a fiscal year (after
17	fiscal year 2013), prior to the due date for such
18	fees, may be accepted by the Secretary in ac-
19	cordance with authority provided in advance in
20	a prior year appropriations Act.
21	"(3) Authorization of appropriations.—
22	For each of fiscal years 2013 through 2017, there
23	is authorized to be appropriated for fees under this
24	section an amount equivalent to the total amount of
25	fees assessed for such fiscal year under this section.

- 1 "(f) Collection of Unpaid Fees.—In any case
- 2 where the Secretary does not receive payment of a fee as-
- 3 sessed under subsection (a) within 30 days after it is due,
- 4 such fee shall be treated as a claim of the United States
- 5 Government subject to subchapter II of chapter 37 of title
- 6 31, United States Code.
- 7 "(g) Written Requests for Waivers and Re-
- 8 FUNDS.—To qualify for consideration for a waiver under
- 9 subsection (c), or for a refund of any fee collected in ac-
- 10 cordance with subsection (a)(2)(A), a person shall submit
- 11 to the Secretary a written request for such waiver or re-
- 12 fund not later than 180 days after such fee is due.
- 13 "(h) Construction.—This section may not be con-
- 14 strued to require that the number of full-time equivalent
- 15 positions in the Department of Health and Human Serv-
- 16 ices, for officers, employers, and advisory committees not
- 17 engaged in the process of the review of biosimilar biologi-
- 18 cal product applications, be reduced to offset the number
- 19 of officers, employees, and advisory committees so en-
- 20 gaged.".
- 21 SEC. 403. REAUTHORIZATION; REPORTING REQUIREMENTS.
- 22 Part 8 of subchapter C of chapter VII, as added by
- 23 section 402, is further amended by inserting after section
- 24 744H the following:

1	"SEC.	744I.	REAUTHORIZATION;	REPORTING	REQUIRE-

MENTS.

- 3 "(a) Performance Report.—Beginning with fiscal
- 4 year 2013, not later than 120 days after the end of each
- 5 fiscal year for which fees are collected under this part,
- 6 the Secretary shall prepare and submit to the Committee
- 7 on Energy and Commerce of the House of Representatives
- 8 and the Committee on Health, Education, Labor, and
- 9 Pensions of the Senate a report concerning the progress
- 10 of the Food and Drug Administration in achieving the
- 11 goals identified in the letters described in section 401(b)
- 12 of the Biosimilar User Fee Act of 2012 during such fiscal
- 13 year and the future plans of the Food and Drug Adminis-
- 14 tration for meeting such goals. The report for a fiscal year
- 15 shall include information on all previous cohorts for which
- 16 the Secretary has not given a complete response on all
- 17 biosimilar biological product applications and supplements
- 18 in the cohort.

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- 19 "(b) FISCAL REPORT.—Not later than 120 days after
- 20 the end of fiscal year 2013 and each subsequent fiscal year
- 21 for which fees are collected under this part, the Secretary
- 22 shall prepare and submit to the Committee on Energy and
- 23 Commerce of the House of Representatives and the Com-
- 24 mittee on Health, Education, Labor, and Pensions of the
- 25 Senate a report on the implementation of the authority
- 26 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
- 4 make the reports required under subsections (a) and (b)
- 5 available to the public on the Internet Web site of the
- 6 Food and Drug Administration.
- 7 "(d) Study.—

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- 6 "(1) IN GENERAL.—The Secretary shall con-9 tract with an independent accounting or consulting 10 firm to study the workload volume and full costs as-11 sociated with the process for the review of biosimilar 12 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).
- 21 "(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 Com-
merce 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 con-
sumer advocacy groups; and
"(F) the regulated industry.
"(2) Public Review of Recommenda-
TIONS.—After negotiations with the regulated indus-
try, the Secretary shall—
"(A) present the recommendations devel-
oped 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;

1	"(D) hold a meeting at which the public
2	may present its views on such recommenda-
3	tions; and
4	"(E) after consideration of such public
5	views and comments, revise such recommenda-
6	tions as necessary.
7	"(3) Transmittal of recommendations.—
8	Not later than January 15, 2017, the Secretary
9	shall transmit to the Congress the revised rec-
10	ommendations under paragraph (2), a summary of
11	the views and comments received under such para-
12	graph, and any changes made to the recommenda-
13	tions in response to such views and comments.".
14	SEC. 404. SUNSET DATES.
15	(a) AUTHORIZATION.—The amendment made by sec-
16	tion 402 shall cease to be effective October 1, 2017.
17	(b) REPORTING REQUIREMENTS.—The amendment
18	made by section 403 shall cease to be effective January
19	31, 2018.
20	SEC. 405. EFFECTIVE DATE.
21	(a) In General.—Except as provided under sub-
22	section (b), the amendments made by this title shall take
23	effect on the later of—
24	(1) October 1, 2012; or
25	(2) the date of the enactment of this title.

- 1 (b) Exception.—Fees under part 8 of subchapter
- 2 C of chapter VII of the Federal Food, Drug, and Cosmetic
- 3 Act, as added by this title, shall be assessed for all bio-
- 4 similar biological product applications received on or after
- 5 October 1, 2012, regardless of the date of the enactment
- 6 of this title.

## 7 SEC. 406. SAVINGS CLAUSE.

- 8 Notwithstanding the amendments made by this title,
- 9 part 2 of subchapter C of chapter VII of the Federal Food,
- 10 Drug, and Cosmetic Act, as in effect on the day before
- 11 the date of the enactment of this title, shall continue to
- 12 be in effect with respect to human drug applications and
- 13 supplements (as defined in such part as of such day) that
- 14 were accepted by the Food and Drug Administration for
- 15 filing on or after October 1, 2007, but before October 1,
- 16 2012, with respect to assessing and collecting any fee re-
- 17 quired by such part for a fiscal year prior to fiscal year
- 18 2013.

## 19 SEC. 407. CONFORMING AMENDMENT.

- 20 Section 735(1)(B) (21 U.S.C. 379g(1)(B)) is amend-
- 21 ed by striking "or (k)".

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2	AND DEVICES
3	SEC. 501. PERMANENCE.
4	(a) Pediatric Studies of Drugs.—Subsection (q)
5	of section 505A (21 U.S.C. 355a) is amended—
6	(1) in the subsection heading, by striking
7	"Sunset" and inserting "Permanence";
8	(2) in paragraph (1), by striking "on or before
9	October 1, 2012,"; and
10	(3) in paragraph (2), by striking "on or before
11	October 1, 2012,".
12	(b) RESEARCH INTO PEDIATRIC USES FOR DRUGS
13	AND BIOLOGICAL PRODUCTS.—Section 505B (21 U.S.C.
14	355c) is amended—
15	(1) by striking subsection (m); and
16	(2) by redesignating subsection (n) as sub-
17	section (m).
18	SEC. 502. WRITTEN REQUESTS.
19	(a) Federal Food, Drug, and Cosmetic Act.—
20	Subsection (h) of section 505A (21 U.S.C. 355a) is
21	amended to read as follows:
22	"(h) Relationship to Pediatric Research Re-
23	QUIREMENTS.—Exclusivity under this section shall only be
24	granted for the completion of a study or studies that are
25	the subject of a written request and for which reports are

- 1 submitted and accepted in accordance with subsection
- 2 (d)(3). Written requests under this section may consist of
- 3 a study or studies required under section 505B.".
- 4 (b) Public Health Service Act.—Section
- 5 351(m)(1) of the Public Health Service Act (42 U.S.C.
- 6 262(m)(1)) is amended by striking "(f), (i), (j), (k), (l),
- 7 (p), and (q)" and inserting "(f), (h), (i), (j), (k), (l), and
- 8 (p)".

## 9 SEC. 503. COMMUNICATION WITH PEDIATRIC REVIEW COM-

- 10 MITTEE.
- 11 Not later than 1 year after the date of enactment
- 12 of this Act, the Secretary of Health and Human Services
- 13 (referred to in this title as the "Secretary") shall issue
- 14 internal standard operating procedures that provide for
- 15 the review by the internal review committee established
- 16 under section 505C of the Federal Food, Drug, and Cos-
- 17 metic Act (21 U.S.C. 355d) of any significant modifica-
- 18 tions to initial pediatric study plans, agreed pediatric
- 19 study plans, and written requests under sections 505A and
- 20 505B of the Federal Food, Drug, and Cosmetic Act (21
- 21 U.S.C. 355c). Such internal standard operating proce-
- 22 dures shall be made publicly available on the Internet
- 23 website of the Food and Drug Administration.

## 1 SEC. 504. ACCESS TO DATA.

2	Not later than 3 years after the date of enactment
3	of this Act, the Secretary shall make available to the pub-
4	lic, including through posting on the Internet Web site of
5	the Food and Drug Administration, the medical, statis-
6	tical, and clinical pharmacology reviews of, and cor-
7	responding written requests issued to an applicant, spon-
8	sor, or holder for, pediatric studies submitted between
9	January 4, 2002 and September 27, 2007 under sub-
10	section (b) or (c) of section 505A of the Federal Food,
11	Drug, and Cosmetic Act (21 U.S.C. 355a) for which 6
12	months of market exclusivity was granted and that re-
13	sulted in a labeling change. The Secretary shall make pub-
14	lic the information described in the preceding sentence in
15	a manner consistent with how the Secretary releases infor-
16	mation under section 505A(k) of the Federal Food, Drug,
17	and Cosmetic Act (21 U.S.C. 355a(k)).
18	SEC. 505. ENSURING THE COMPLETION OF PEDIATRIC
19	STUDIES.
20	(a) Extension of Deadline for Deferred
21	Studies.—Section 505B (21 U.S.C. 355c) is amended—
22	(1) in subsection (a)(3)—
23	(A) by redesignating subparagraph (B) as
24	subparagraph (C);
25	(B) by inserting after subparagraph (A)
26	the following:

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1	"(B) Deferral extension.—
2	"(i) In general.—On the initiative
3	of the Secretary or at the request of the
4	applicant, the Secretary may grant an ex-
5	tension of a deferral approved under sub-
6	paragraph (A) for submission of some or
7	all assessments required under paragraph
8	(1) if—
9	"(I) the Secretary determines
10	that the conditions described in sub-
11	clause (II) or (III) of subparagraph
12	(A)(i) continue to be met; and
13	"(II) the applicant submits a new
14	timeline under subparagraph
15	(A)(ii)(IV) and any significant up-
16	dates to the information required
17	under subparagraph (A)(ii).
18	"(ii) Timing and information.—If
19	the deferral extension under this subpara-
20	graph is requested by the applicant, the
21	applicant shall submit the deferral exten-
22	sion request containing the information de-
23	scribed in this subparagraph not less than
24	90 days prior to the date that the deferral
25	would expire. The Secretary shall respond

to such request not later than 45 days
after the receipt of such letter. If the Sec-
retary grants such an extension, the speci-
fied date shall be considered the extended
date. The sponsor of the required assess-
ment under paragraph (1) shall not be
issued a letter described in subsection (d)
unless the specified or extended date of
submission for such required studies has
passed or if the request for an extension is
pending. For a deferral that has expired
prior to the date of enactment of the Food
and Drug Administration Safety and Inno-
vation Act or that will expire prior to 270
days after the date of enactment of such
Act, a deferral extension shall be requested
by an applicant not later than 180 days
after the date of enactment of such Act.
The Secretary shall respond to any such
request as soon as practicable, but not
later than 1 year after the date of enact-
ment of such Act. Nothing in this clause
shall prevent the Secretary from updating
the status of a study or studies publicly if

1	components of such study or studies are
2	late or delayed."; and
3	(C) in subparagraph (C), as so redesig-
4	nated—
5	(i) in clause (i), by adding at the end
6	the following:
7	"(III) Projected completion date
8	for pediatric studies.
9	"(IV) The reason or reasons why
10	a deferral or deferral extension con-
11	tinues to be necessary."; and
12	(ii) in clause (ii)—
13	(I) by inserting ", as well as the
14	date of each deferral or deferral ex-
15	tension, as applicable," after "clause
16	(i)"; and
17	(II) by inserting "not later than
18	90 days after submission to the Sec-
19	retary or with the next routine quar-
20	terly update" after "Administration"
21	and
22	(2) in subsection (f)—
23	(A) in the subsection heading, by inserting
24	"Deferral Extensions," after "Defer-
25	RALS,";

1	(B) in paragraph (1), by inserting ", defer-
2	ral extension," after "deferral"; and
3	(C) in paragraph (4), by inserting ", defer-
4	ral extensions," after "deferrals".
5	(b) Tracking of Extensions; Annual Informa-
6	TION.—Section $505B(f)(6)(D)$ (21 U.S.C. $355e(f)(6)(D)$ )
7	is amended to read as follows:
8	"(D) aggregated on an annual basis—
9	"(i) the total number of deferrals and
10	deferral extensions requested and granted
11	under this section and, if granted, the rea-
12	sons for each such deferral or deferral ex-
13	tension;
14	"(ii) the timeline for completion of the
15	assessments; and
16	"(iii) the number of assessments com-
17	pleted and pending;".
18	(c) Action on Failure to Complete Studies.—
19	(1) Issuance of Letter.—Subsection (d) of
20	section 505B (21 U.S.C. 355c) is amended to read
21	as follows:
22	"(d) Submission of Assessments.—If a person
23	fails to submit a required assessment described in sub-
24	section (a)(2), fails to meet the applicable requirements
25	in subsection (a)(3), or fails to submit a request for ap-

1 proval of a pediatric formulation described in subsection

2 (a) or (b), in accordance with applicable provisions of sub-

3 sections (a) and (b), the following shall apply:

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"(1) Beginning 270 days after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall issue a letter to such person informing them of such failure to submit or meet the applicable subsection. Such letter shall require the person to respond in writing within 45 calendar days of issuance of such letter. Such response may include the person's request for a deferral extension if applicable. Such letter and the person's written response to such letter shall be made publicly available on the Internet web site of the Food and Drug Administration 45 calendar days after issuance, with redactions for any trade secrets and confidential commercial information. If the Secretary determines that the letter was issued in error, the requirements of this paragraph shall not apply.

"(2) The drug or biological product that is the subject of an assessment described in subsection (a)(2), applicable requirements in subsection (a)(3), or request for approval of a pediatric formulation, may be considered misbranded solely because of that failure and subject to relevant enforcement action

1	(except that the drug or biological product shall not
2	be subject to action under section 303), but such
3	failure shall not be the basis for a proceeding—
4	"(A) to withdraw approval for a drug
5	under section 505(e); or
6	"(B) to revoke the license for a biological
7	product under section 351 of the Public Health
8	Service Act.".
9	(2) Tracking of letters issued.—Subpara-
10	graph (D) of section $505B(f)(6)$ (21 U.S.C.
11	355c(f)(6)), as amended by subsection (b), is further
12	amended—
13	(A) in clause (ii), by striking "; and and
14	inserting a semicolon;
15	(B) in clause (iii), by adding "and" at the
16	end; and
17	(C) by adding at the end the following:
18	"(iv) the number of postmarket non-
19	compliance letters issued pursuant to sub-
20	section (d), and the recipients of such let-
21	ters;".
22	SEC. 506. PEDIATRIC STUDY PLANS.
23	(a) In General.—Subsection (e) of section 505B
24	(21 U.S.C. 355c) is amended to read as follows:
25	"(e) Pediatric Study Plans.—

1	"(1) In General.—An applicant subject to
2	subsection (a) shall submit to the Secretary an ini-
3	tial pediatric study plan prior to the submission of
4	the assessments described under subsection $(a)(2)$ .
5	"(2) Timing; content; meeting.—
6	"(A) Timing.—An applicant shall submit
7	an initial pediatric study plan to the Secretary
8	not later than 60 calendar days after the date
9	of the end of phase II meeting or such other
10	equivalent time agreed upon between the Sec-
11	retary and the applicant. Nothing in this para-
12	graph shall preclude the Secretary from accept-
13	ing the submission of an initial pediatric study
14	plan earlier than the date described under the
15	preceding sentence.
16	"(B) CONTENT OF INITIAL PLAN.—The
17	initial pediatric study plan shall include—
18	"(i) an outline of the pediatric study
19	or studies that the applicant plans to con-
20	duct (including, to the extent practicable
21	study objectives and design, age groups,
22	relevant endpoints, and statistical ap-
23	proach);
24	"(ii) any request for a deferral, partial
25	waiver, or waiver under this section, if ap-

1	plicable, along with any supporting infor-
2	mation; and
3	"(iii) other information specified in
4	the regulations promulgated under para-
5	graph (4).
6	"(C) Meeting.—The Secretary—
7	"(i) shall meet with the applicant to
8	discuss the initial pediatric study plan not
9	later than 60 calendar days after the re-
10	ceipt of such plan under subparagraph (A)
11	"(ii) may determine that a written re-
12	sponse to the initial pediatric study plan is
13	sufficient to communicate comments on the
14	initial pediatric study plan, and that no
15	meeting is necessary; and
16	"(iii) if the Secretary determines that
17	no meeting is necessary, shall so notify the
18	applicant and provide written comments of
19	the Secretary not later than 60 calendar
20	days after the receipt of the initial pedi-
21	atric study plan.
22	"(3) AGREED PEDIATRIC STUDY PLAN.—The
23	applicant shall document agreement on the initial
24	pediatric study plan in a submission to the Secretary
25	marked 'Agreed Pediatric Study Plan', and the Sec-

retary shall confirm such agreement to the applicant in writing not later than 30 calendar days of receipt of such agreed pediatric study plan.

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

"(5) AMENDMENTS TO THE PLAN.—At the initiative of the Secretary or the applicant, the agreed pediatric study plan may be amended at any time. The requirements of paragraph (2)(C) shall apply to any such proposed amendment in the same manner and to the same extent as such requirements apply to an initial pediatric study plan under paragraph (1). The requirements of paragraphs (3) and (4) 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 study plan.

"(6) Internal committee.—The Secretary shall consult the internal committee under section

1	505C on the review of the initial pediatric plan,
2	agreed pediatric plan, and any significant amend-
3	ments to such plans.
4	"(7) REQUIRED RULEMAKING.—Not later than
5	1 year after the date of enactment of the Food and
6	Drug Administration Safety and Innovation Act, the
7	Secretary shall promulgate proposed regulations and
8	issue proposed guidance to implement the provisions
9	of this subsection.".
10	(b) Conforming Amendments.—Section 505B (21
11	U.S.C. 355c)is amended—
12	(1) by amending subclause (II) of subsection
13	(a)(3)(A)(ii) to read as follows:
14	"(II) a pediatric study plan as
15	described in subsection (e);"; and
16	(2) in subsection (f)—
17	(A) in the subsection heading, by striking
18	"Pediatric Plans," and inserting "Pedi-
19	ATRIC STUDY PLANS,";
20	(B) in paragraph (1), by striking "all pedi-
21	atric plans" and inserting "initial pediatric
22	study plans, agreed pediatric study plans,"; and
23	(C) in paragraph (4)—

1	(i) in the paragraph heading, by strik-
2	ing "Pediatric Plans," and inserting
3	"PEDIATRIC STUDY PLANS,"; and
4	(ii) by striking "pediatric plans" and
5	inserting "initial pediatric study plans,
6	agreed pediatric study plans,".
7	(c) Effective Dates.—
8	(1) Pediatric study plans.—Subsection (e)
9	of section 505B of the Federal Food, Drug, and
10	Cosmetic Act (other than paragraph (4) of such sub-
11	section), as amended by subsection (a), shall take ef-
12	fect 180 days after the date of enactment of this
13	Act, without regard to whether the Secretary has
14	promulgated final regulations under paragraph (4)
15	of such subsection by such date.
16	(2) Conforming amendments.—The amend-
17	ments made by subsection (b) shall take effect 180
18	days after the date of enactment of this Act.
19	SEC. 507. REAUTHORIZATIONS.
20	(a) Pediatric Advisory Committee.—Section
21	14(d) of the Best Pharmaceuticals for Children Act (42
22	U.S.C. 284m note) is amended by striking "Notwith-
23	standing section 14 of the Federal Advisory Committee
24	Act, the advisory committee shall continue to operate dur-
25	ing the five-year period beginning on the date of the enact-

- 1 ment of the Best Pharmaceuticals for Children Act of
- 2 2007" and inserting "Section 14 of the Federal Advisory
- 3 Committee Act shall not apply to the advisory committee".
- 4 (b) Pediatric Subcommittee of the Oncologic
- 5 Drugs Advisory Committee.—Section 15(a)(3) of the
- 6 Best Pharmaceuticals for Children Act (42 U.S.C. 284m
- 7 note) is amended by striking "during the five-year period
- 8 beginning on the date of the enactment of the Best Phar-
- 9 maceuticals for Children Act of 2007" and inserting "for
- 10 the duration of the operation of the Oncologic Drugs Advi-
- 11 sory Committee".
- 12 (c) Humanitarian Device Exemption Exten-
- 13 SION.—Section 520(m)(6)(A)(iv) of the Federal Food,
- 14 Drug, and Cosmetic Act (21 U.S.C. 360j(m)(6)(A)(iv)) is
- 15 amended by striking "2012" and inserting "2017".
- 16 (d) Demonstration Grants to Improve Pedi-
- 17 ATRIC DEVICE AVAILABILITY.—Section 305(e) of Pedi-
- 18 atric Medical Device Safety and Improvement Act (Public
- 19 Law 110–85; 42 U.S.C. 282 note)) is amended by striking
- 20 "\$6,000,000 for each of fiscal years 2008 through 2012"
- 21 and inserting "\$4,500,000 for each of fiscal years 2013
- 22 through 2017".
- (e) Program for Pediatric Study of Drugs in
- 24 PHSA.—Section 409I(e)(1)(B) of the Public Health Serv-
- 25 ice Act (42 U.S.C. 284m((e)(1)(B)) is amended by strik-

1	ing "of the four succeeding fiscal years" and inserting
2	"succeeding fiscal year".
3	SEC. 508. REPORT.
4	(a) In General.—Not later than January 1, 2016,
5	and at the end of each subsequent 5-year period, the Sec-
6	retary of Health and Human Services shall submit to Con-
7	gress a report that evaluates the effectiveness of sections
8	505A and 505B of the Federal Food, Drug, and Cosmetic
9	Act (21 U.S.C. 355a, 355c) and section 409I of the Public
10	Health Service Act (42 U.S.C. 284m) in ensuring that
11	medicines used by children are tested in pediatric popu-
12	lations and properly labeled for use in children.
13	(b) Contents.—The report under subsection (a)
14	shall include—
15	(1) the number and importance of drugs and
16	biological products for children that are being tested
17	(as of the date of such report) under 505A and
18	505B of the Federal Food, Drug, and Cosmetic Act
19	(21 U.S.C. 355a, 355c) and section 409I of the
20	Public Health Service Act (42 U.S.C. 284m), includ-
21	ing—
22	(A) the number of labeling changes made
23	to drugs and biological products pursuant to
24	such sections since the date of enactment of
25	this Act; and

1	(B) the importance of such drugs and bio-
2	logical products in the improvement of the
3	health of children;
4	(2) the number of requirements under such sec-
5	tions 505A and 505B that have not met by the ini-
6	tial deadline provided under such sections, includ-
7	ing—
8	(A) the number of deferrals and deferral
9	extensions granted and the reasons such exten-
10	sions were granted;
11	(B) the number of waivers and partial
12	waivers granted; and
13	(C) the number of letters issued under
14	subsection (d) of such section 505B;
15	(3) the number of written requests issued, de-
16	clined, and referred to the National Institutes of
17	Health under such section 505A since the date of
18	enactment of this Act (including the reasons for
19	such declination), and a description and status of re-
20	ferrals made under subsection (n) of such section
21	505A;
22	(4) the number of proposed pediatric plans sub-
23	mitted and agreed to as identified in the marketing
24	application under such section 505B;

1	(b) any labeling changes recommended by the
2	Pediatric Advisory Committee as a result of the re-
3	view by such Committee of adverse events reports;
4	(6) the number and current status of pediatric
5	postmarketing requirements;
6	(7) the number and importance of drugs and
7	biological products for children that are not being
8	tested for use in pediatric populations, notwith-
9	standing the existence of the programs under such
10	sections 505A and 505B and section 409I of the
11	Public Health Service Act;
12	(8) the possible reasons for the lack of testing
13	reported under paragraph (7);
14	(9) the number of drugs and biological products
15	for which testing is being done (as of the date of the
16	report) and for which a labeling change is required
17	under the programs described in paragraph (7), in-
18	cluding—
19	(A) the date labeling changes are made;
20	(B) which labeling changes required the
21	use of the dispute resolution process; and
22	(C) for labeling changes that required such
23	dispute resolution process, a description of—
24	(i) the disputes;

1	(ii) the recommendations of the Pedi-
2	atric Advisory Committee; and
3	(iii) the outcomes of such process; and
4	(D) an assessment of the effectiveness in
5	improving information about pediatric uses of
6	drugs and biological products;
7	(10)(A) the efforts made by the Secretary to in-
8	crease the number of studies conducted in the neo-
9	natal population (including efforts made to encour-
10	age the conduct of appropriate studies in neonates
11	by companies with products that have sufficient
12	safety and other information to make the conduct of
13	the studies ethical and safe); and
14	(B) the results of such efforts;
15	(11)(A) the number and importance of drugs
16	and biological products for children with cancer that
17	are being tested as a result of the programs de-
18	scribed in paragraph (7); and
19	(B) any recommendations for modifications to
20	such programs that would lead to new and better
21	therapies for children with cancer, including a de-
22	tailed rationale for each recommendation;
23	(12) an assessment of progress made in ad-
24	dressing the recommendations and findings of any
25	prior report issued by the Comptroller General re-

garding the topics addressed in the report under this
section, including with respect to—
(A) improving public access to information
from pediatric studies conducted under such
sections 505A and 505B; and
(B) improving the timeliness of pediatric
studies and pediatric study planning under such
sections 505A and 505B;
(13) any recommendations for modification to
the programs that would improve pediatric drug re-
search and increase pediatric labeling of drugs and
biological products; and
(14) an assessment of the successes of and limi-
tations to studying drugs for rare diseases under
such sections 505A and 505B.
(e) Consultation on Recommendations.—At
least 180 days before the report is due under subsection
(a), and no sooner than 4 years after the date of enact-
ment of this Act, the Secretary of Health and Human
Services shall consult with representatives of patient
groups, including pediatric patient groups, consumer
groups, regulated industry, scientific and medical commu-
nities, academia, and other interested parties to obtain
any recommendations or information relevant to the effec-

1	tiveness of the programs described in subsection $(b)(7)$ ,
2	including suggestions for modifications to such programs.
3	SEC. 509. TECHNICAL AMENDMENTS.
4	(a) Pediatric Studies of Drugs in FFDCA.—
5	Section 505A (21 U.S.C. 355a) is amended—
6	(1) in subsection (k)(2), by striking "subsection
7	(f)(3)(F)" and inserting "subsection $(f)(6)(F)$ ";
8	(2) in subsection (n)—
9	(A) in the subsection heading, by striking
10	"Completed" and inserting "Submitted";
11	and
12	(B) in paragraph (1)—
13	(i) in the matter preceding subpara-
14	graph (A), by striking "have not been com-
15	pleted" and inserting "have not been sub-
16	mitted by the date specified in the written
17	request issued or if the applicant or holder
18	does not agree to the request";
19	(ii) in subparagraph (A)—
20	(I) in the first sentence, by in-
21	serting ", or for which a period of ex-
22	clusivity eligible for extension under
23	subsection $(b)(1)$ or $(c)(1)$ of this sec-
24	tion or under subsection $(m)(2)$ or
25	(m)(3) of section 351 of the Public

1	Health Service Act has not ended
2	after "expired"; and
3	(II) by striking "Prior to" and
4	all that follows through the period at
5	the end; and
6	(iii) in subparagraph (B), by striking
7	"no listed patents or has 1 or more listed
8	patents that have expired," and inserting
9	"no unexpired listed patents and for which
10	no unexpired periods of exclusivity eligible
11	for extension under subsection $(b)(1)$ or
12	(e)(1) of this section or under subsection
13	(m)(2) or $(m)(3)$ of section 351 of the
14	Public Health Service Act apply"; and
15	(3) in subsection $(0)(2)$ , by amendment sub-
16	paragraph (B) to read as follows:
17	"(B) a statement of any appropriate pedi-
18	atric contraindications, warnings, precautions,
19	or other information that the Secretary con-
20	siders necessary to assure safe use.".
21	(b) Research Into Pediatric Uses for Drugs
22	AND BIOLOGICAL PROJECTS IN FFDCA.—Section 505B
23	(21 U.S.C. 355c) is amended—
24	(1) in subsection (a)—
25	(A) in paragraph (1)—

1	(i) in the matter preceding subpara-
2	graph (A), by inserting "for a drug" after
3	"(or supplement to an application)";
4	(ii) in subparagraph (A), by striking
5	"for a" and inserting ", including, with re-
6	spect to a drug, an application (or supple-
7	ment to an application) for a";
8	(iii) in subparagraph (B), by striking
9	"for a" and inserting ", including, with re-
10	spect to a drug, an application (or supple-
11	ment to an application) for a"; and
12	(iv) in the matter following subpara-
13	graph (B), by inserting "(or supplement)"
14	after "application"; and
15	(B) in paragraph (4)(C)—
16	(i) in the first sentence, by inserting
17	"partial" before "waiver is granted"; and
18	(ii) in the second sentence, by striking
19	"either a full or" and inserting "such a";
20	(2) in subsection $(b)(1)$ , in the matter pre-
21	ceding subparagraph (A), by striking "After pro-
22	viding notice" and all that follows through "studies),
23	the" and inserting "The";
24	(3) in subsection (g)—

1	(A) in paragraph (1)(A), by inserting
2	"that receives a priority review or 330 days
3	after the date of the submission of an applica-
4	tion or supplement that receives a standard re-
5	view" after "after the date of the submission of
6	the application or supplement"; and
7	(B) in paragraph (2), by striking "the
8	label of such product" and inserting "the label-
9	ing of such product"; and
10	(4) in subsection $(h)(1)$ —
11	(A) by inserting "an application (or sup-
12	plement to an application) that contains" after
13	"date of submission of"; and
14	(B) by inserting ", if the application (or
15	supplement) receives a priority review, or not
16	later than 330 days after the date of submis-
17	sion of an application (or supplement to an ap-
18	plication) that contains a pediatric assessment
19	under this section, if the application (or supple-
20	ment) receives a standard review," after "under
21	this section,".
22	(c) Internal Review Committee.—The heading of
23	section 505C (21 U.S.C. 355d) is amended by inserting
24	"AND DEFERRAL EXTENSIONS" after "DEFERRALS".

1	(d) Program for Pediatric Studies of Drugs.—
2	Section 409I(c) of the Public Health Service Act (42
3	U.S.C. 284m(c)) is amended—
4	(1) in paragraph (1)—
5	(A) in the matter preceding subparagraph
6	(A), by inserting "or section 351(m) of this
7	Act," after "Cosmetic Act,";
8	(B) in subparagraph (A)(i), by inserting
9	"or section 351(k) of this Act" after "Cosmetic
10	Act"; and
11	(C) by amending subparagraph (B) to read
12	as follows:
13	"(B) there remains no patent listed pursu-
14	ant to section 505(b)(1) of the Federal Food,
15	Drug, and Cosmetic Act, and every three-year
16	and five-year period referred to in subsection
17	(e)(3)(E)(ii), $(e)(3)(E)(iii),$ $(e)(3)(E)(iv),$
18	(j)(5)(F)(ii), (j)(5)(F)(iii), or (j)(5)(F)(iv) of
19	section 505 of the Federal Food, Drug, and
20	Cosmetic Act, or applicable twelve-year period
21	referred to in section 351(k)(7) of this Act, and
22	any seven-year period referred to in section 527
23	of the Federal Food, Drug, and Cosmetic Act
24	has ended for at least one form of the drug;
25	and"; and

1	(2) in paragraph (2)—
2	(A) in the paragraph heading, by striking
3	"FOR DRUGS LACKING EXCLUSIVITY"; and
4	(B) by striking "under section 505 of the
5	Federal Food, Drug, and Cosmetic Act"; and
6	(C) by striking "505A of such Act" and
7	inserting "505A of the Federal Food, Drug,
8	and Cosmetic Act or section 351(m) of this
9	Act".
10	(e) Pediatric Subcommittee of the Oncologic
11	Advisory Committee.—Section 15(a) of the Best Phar-
12	maceuticals for Children Act (Public Law 107–109), as
13	amended by section 502(e) of the Food and Drug Admin-
14	istration Amendments Act of 2007 (Public Law 110–85),
15	is amended in paragraph (1)(D), by striking "section
16	505B(f)" and inserting "'section $505C$ '".
17	(f) Foundation of National Institutes of
18	Health.—Section 499(c)(1)(C) of the Public Health
19	Service Act (42 U.S.C. 290b(c)(1)(C)) is amended by
20	striking "for which the Secretary issues a certification in
21	the affirmative under section 505A(n)(1)(A) of the Fed-
22	eral Food, Drug, and Cosmetic Act".
23	(g) Application.—Notwithstanding any provision of
24	section 505A and 505B of the Federal Food, Drug, and
25	Cosmetic Act (21 U.S.C. 355a, 355c) stating that a provi-

- 1 sion applies beginning on the date of the enactment of the
- 2 Best Pharmaceuticals for Children Act of 2007 or the date
- 3 of the enactment of the Pediatric Research Equity Act of
- 4 2007, any amendment made by this title to such a provi-
- 5 sion applies beginning on the date of the enactment of this
- 6 Act.
- 7 SEC. 510. RELATIONSHIP BETWEEN PEDIATRIC LABELING
- 8 AND NEW CLINICAL INVESTIGATION EXCLU-
- 9 **SIVITY.**
- 10 (a) IN GENERAL.—Section 505 (21 U.S.C. 351) is
- 11 amended by adding at the end the following:
- 12 "(w) Relationship Between Pediatric Label-
- 13 ING AND NEW CLINICAL INVESTIGATION EXCLUSIVITY.—
- 14 The period of market exclusivity described in clauses (iii)
- 15 and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv)
- 16 of subsection (j)(5)(F) shall not apply to a pediatric study
- 17 conducted under section 505A or 505B that results, pur-
- 18 suant to section 505B(g)(2), in the inclusion in the label-
- 19 ing of the product a determination that the product is not
- 20 indicated for use in pediatric populations or subpopula-
- 21 tions or information indicating that the results of a study
- 22 were inconclusive or did not demonstrate that the product
- 23 is safe or effective in pediatric populations or subpopula-
- 24 tions.".

1	(b) Pediatric Studies of Drugs.—Section
2	505A(m) (21 U.S.C. 355a(m)) is amended—
3	(1) by striking "(m) Clarification of Inter-
4	ACTION OF MARKET EXCLUSIVITY UNDER THIS
5	SECTION AND MARKET EXCLUSIVITY AWARDED TO
6	An Applicant for Approval of A Drug Under
7	SECTION 505(j).—If a" and all that follows through
8	the end of the matter that precedes paragraph (1)
9	and inserting the following:
10	"(m) Clarification of Interaction of Market
11	EXCLUSIVITY UNDER THIS SECTION AND MARKET EX-
12	CLUSIVITY AWARDED TO AN APPLICATION OR SUPPLE-
13	MENT UNDER SUBSECTION (C) OR (J) OF SECTION 505.—
14	"(1) 180-day exclusivity period.—If a 180-
15	day period under section $505(j)(5)(B)(iv)$ overlaps
16	with a 6-month exclusivity period under this section,
17	so that the applicant for approval of a drug under
18	section 505(j) entitled to the 180-day period under
19	that section loses a portion of the 180-day period to
20	which the applicant is entitled for the drug, the 180-
21	day period shall be extended from—";
22	(2) by redesignating paragraphs (1) and (2) as
23	subparagraphs (A) and (B) and moving such sub-
24	paragraphs, as so redesignated, 2 ems to the right;
25	and

1	(3) by adding at the end the following:
2	"(2) 3-YEAR EXCLUSIVITY PERIOD.—The 3-year
3	period of exclusivity under clauses (iii) and (iv) of
4	subsection 505(c)(3)(E) and clauses (iii) and (iv) or
5	subsection $505(j)(5)(F)$ are not available for ap
6	proval of applications or supplements to applications
7	based on reports of pediatric studies conducted
8	under sections 505A or 505B that resulted, pursu
9	ant to section $505B(g)(2)$ , in the inclusion in the la
10	beling of the product a determination that the prod
11	uct is not indicated for use in pediatric populations
12	or subpopulations or information indicating that the
13	results of an assessment were inconclusive or did no
14	demonstrate that the product is safe or effective in
15	pediatric populations or subpopulation.".
16	(c) Prompt Approval of Drugs.—Section 505A(o)
17	(21 U.S.C. 355a(o)) is amended—
18	(1) in the heading, by striking "Section
19	505(J)" and inserting "Subsections (c) and (J
20	of Section 505";
21	(2) in paragraph (1), by striking "under section
22	505(j)" and inserting "under subsection (b)(2), (c)
23	or (j) of section 505";
24	(3) in paragraph (2)—

1	(A) in the matter preceding subparagraph
2	(A), by inserting "clauses (iii) and (iv) of sec-
3	tion 505(e)(3)(E) or" after "Notwithstanding";
4	and
5	(B) in subparagraph (B), by striking "or
6	precautions that the Secretary considers nec-
7	essary" and inserting "precautions, or other in-
8	formation that the Secretary considers nec-
9	essary to ensure safe use"; and
10	(4) in paragraph (3)—
11	(A) in subparagraph (B), by inserting
12	"that differ from adult formulations" before the
13	semicolon at the end; and
14	(B) in subparagraph (C)—
15	(i) by striking "under section 505(j)"
16	and inserting "under subsection (c) or (j)
17	of section 505"; and
18	(ii) by inserting "clauses (iii) or (iv)
19	of section $505(c)(3)(E)$ or" after "exclu-
20	sivity under".
21	TITLE VI—MEDICAL DEVICE
22	REGULATORY IMPROVEMENTS
23	SEC. 601. RECLASSIFICATION PROCEDURES.
24	(a) Classification Changes.—

1	(1) In General.—Section $513(e)(1)$ (21)
2	U.S.C. $360c(e)(1)$ ) is amended to read as follows:
3	``(e)(1)(A) Based on new information respecting a de-
4	vice, the Secretary may, upon the initiative of the Sec-
5	retary or upon petition of an interested person, change
6	the classification of such device, and revoke, on account
7	of the change in classification, any regulation or require-
8	ment in effect under section 514 or 515 with respect to
9	such device, by administrative order published in the Fed-
10	eral Register following publication of a proposed reclassi-
11	fication order in the Federal Register, a meeting of a de-
12	vice classification panel described in subsection (b), and
13	consideration of comments to a public docket, notwith-
14	standing subchapter II of Chapter $5$ of title $5$ of the
15	United States Code. An order under this subsection
16	changing the classification of a device from class III to
17	class II may provide that such classification shall not take
18	effect until the effective date of a performance standard
19	established under section 514 for such device.
20	"(B) Authority to issue such administrative order
21	shall not be delegated below the Commissioner. The Com-
22	missioner shall issue such an order as proposed by the Di-
23	rector of the Center for Devices and Radiological Health
24	unless the Commissioner, in consultation with the Office
25	of the Secretary of Health and Human Services, concludes

1	that the order exceeds the legal authority of the Food and
2	Drug Administration or that the order would be lawful,
3	but unlikely to advance the public health.".
4	(2) Technical and conforming amend-
5	MENTS.—
6	(A) Section 513(e)(2) (21 U.S.C.
7	360c(e)(2)) is amended by striking "regulation
8	promulgated" and inserting "an order issued".
9	(B) Section 514(a)(1) (21 U.S.C.
10	360d(a)(1)) is amended by striking "under a
11	regulation under section 513(e) but such regu-
12	lation" and inserting "under an administrative
13	order under section 513(e) (or a regulation pro-
14	mulgated under such section prior to the date
15	of enactment of the Food and Drug Adminis-
16	tration Safety and Innovation Act) but such
17	order (or regulation)";
18	(C) Section 517(a)(1) (21 U.S.C.
19	360g(a)(1)) is amended by striking "or chang-
20	ing the classification of a device to class I" and
21	inserting ", an administrative order changing
22	the classification of a device to class I,".
23	(3) Devices reclassified prior to the
24	DATE OF ENACTMENT OF THIS ACT.—

1	(A) IN GENERAL.—The amendments made
2	by this subsection shall have no effect on a reg-
3	ulation promulgated with respect to the classi-
4	fication of a device under section 513(e) of the
5	Federal Food, Drug, and Cosmetic Act prior to
6	the date of enactment of this Act.
7	(B) Applicability of other provi-
8	SIONS.—In the case of a device reclassified
9	under section 513(e) of the Federal Food,
10	Drug, and Cosmetic Act by regulation prior to
11	the date of enactment of this Act, section
12	517(a)(1) of the Federal Food, Drug, and Cos-
13	metic Act (21 U.S.C. 360g(a)(1)) shall apply to
14	such regulation promulgated under section
15	513(e) of such Act with respect to such device
16	in the same manner such section 517(a)(1) ap-
17	plies to an administrative order issued with re-
18	spect to a device reclassified after the date of
19	enactment of this Act.
20	(b) Devices Marketed Before May 28, 1976.—
21	(1) Premarket approval.—Section 515 (21
22	U.S.C. 360e) is amended—
23	(A) in subsection (a), by striking "regula-
24	tion promulgated under subsection (b)" and in-
25	serting "an order issued under subsection (b)

1	(or a regulation promulgated under such sub-
2	section prior to the date of enactment of the
3	Food and Drug Administration Safety and In-
4	novation Act)";
5	(B) in subsection (b)—
6	(i) in paragraph (1)—
7	(I) in the heading, by striking
8	"Regulation" and inserting "Order";
9	and
10	(II) in the matter following sub-
11	paragraph (B)—
12	(aa) by striking "by regula-
13	tion, promulgated in accordance
14	with this subsection" and insert-
15	ing "by administrative order fol-
16	lowing publication of a proposed
17	order in the Federal Register, a
18	meeting of a device classification
19	panel described in section 513(b),
20	and consideration of comments
21	from all affected stakeholders, in-
22	cluding patients, payors, and pro-
23	viders, notwithstanding sub-
24	chapter II of chapter 5 of title 5,
25	United States Code"; and

1	(bb) by adding at the end
2	the following:
3	"Authority to issue such administrative order shall not be
4	delegated below the Commissioner. Before publishing such
5	administrative order, the Commissioner shall consult with
6	the Office of the Secretary. The Commissioner shall issue
7	such an order as proposed by the Director of the Center
8	for Devices and Radiological Health unless the Commis-
9	sioner, in consultation with the Office of the Secretary,
10	concludes that the order exceeds the legal authority of the
11	Food and Drug Administration or that the order would
12	be lawful, but unlikely to advance the public health.";
13	(ii) in paragraph (2)—
14	(I) by striking subparagraph (B);
15	and
16	(II) in subparagraph (A)—
17	(aa) by striking "(2)(A) A
18	proceeding for the promulgation
19	of a regulation under paragraph
20	(1) respecting a device shall be
21	initiated by the publication in the
22	Federal Register of a notice of
23	proposed rulemaking. Such notice
24	shall contain—" and inserting
25	"(2) A proposed order required

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1	under paragraph (1) shall con-
2	tain—";
3	(bb) by redesignating
4	clauses (i) through (iv) as sub-
5	paragraphs (A) through (D), re-
6	spectively;
7	(cc) in subparagraph (A), as
8	so redesignated, by striking "reg-
9	ulation" and inserting "order";
10	and
11	(dd) in subparagraph (C), as
12	so redesignated, by striking "reg-
13	ulation" and inserting "order";
14	(iii) in paragraph (3)—
15	(I) by striking "proposed regula-
16	tion" each place such term appears
17	and inserting "proposed order";
18	(II) by striking "paragraph (2)
19	and after" and inserting "paragraph
20	(2),";
21	(III) by inserting "and a meeting
22	of a device classification panel de-
23	scribed in section 513(b)," after "such
24	proposed regulation and findings,";

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1	(IV) by striking "(A) promulgate
2	such regulation" and inserting "(A)
3	issue an administrative order under
4	paragraph (1)";
5	(V) by striking "paragraph
6	(2)(A)(ii)" and inserting "paragraph
7	(2)(B)"; and
8	(VI) by striking "promulgation of
9	the regulation" and inserting
10	"issuance of the administrative
11	order"; and
12	(iv) by striking paragraph (4); and
13	(C) in subsection (i)—
14	(i) in paragraph (2)—
15	(I) in the matter preceding sub-
16	paragraph (A)—
17	(aa) by striking "December
18	1, 1995" and inserting "the date
19	that is 2 years after the date of
20	enactment of the Food and Drug
21	Administration Safety and Inno-
22	vation Act"; and
23	(bb) by striking "publish a
24	regulation in the Federal Reg-
25	ister" and inserting "issue an ad-

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1	ministrative order following pub-
2	lication of a proposed order in
3	the Federal Register, a meeting
4	of a device classification panel
5	described in section 513(b), and
6	consideration of comments from
7	all affected stakeholders, includ-
8	ing patients, payors, and pro-
9	viders, notwithstanding sub-
10	chapter II of chapter 5 of title 5,
11	United States Code,";
12	(II) in subparagraph (B), by
13	striking "final regulation has been
14	promulgated under section 515(b)"
15	and inserting "administrative order
16	has been issued under subsection (b)
17	(or no regulation has been promul-
18	gated under such subsection prior to
19	the date of enactment of the Food
20	and Drug Administration Safety and
21	Innovation Act)";
22	(III) in the matter following sub-
23	paragraph (B), by striking "regula-
24	tion requires" and inserting "adminis-

1	trative order issued under this para-
2	graph requires"; and
3	(IV) by striking the third and
4	fourth sentences; and
5	(ii) in paragraph (3)—
6	(I) by striking "regulation requir-
7	ing" each place such term appears
8	and inserting "order requiring"; and
9	(II) by striking "promulgation of
10	a section 515(b) regulation" and in-
11	serting "issuance of an administrative
12	order under subsection (b)".
13	(2) Technical and conforming amend-
14	MENTS.—Section 501(f) (21 U.S.C. 351(f)) is
15	amended—
16	(A) in subparagraph (1)(A)—
17	(i) in subclause (i), by striking "a reg-
18	ulation promulgated" and inserting "an
19	order issued"; and
20	(ii) in subclause (ii), by striking "pro-
21	mulgation of such regulation" and insert-
22	ing "issuance of such order";
23	(B) in subparagraph (2)(B)—

1	(i) by striking "a regulation promul-
2	gated" and inserting "an order issued"
3	and
4	(ii) by striking "promulgation of such
5	regulation" and inserting "issuance of
6	such order"; and
7	(C) by adding at the end the following:
8	"(3) In the case of a device with respect to which
9	a regulation was promulgated under section 515(b) prior
10	to the date of enactment of the Food and Drug Adminis-
11	tration Safety and Innovation Act, a reference in this sub-
12	section to an order issued under section 515(b) shall be
13	deemed to include such regulation.".
14	(3) Approval by regulation prior to the
15	DATE OF ENACTMENT OF THIS ACT.—The amend-
16	ments made by this subsection shall have no effect
17	on a regulation that was promulgated prior to the
18	date of enactment of this Act requiring that a device
19	have an approval under section 515 of the Federal
20	Food, Drug, and Cosmetic Act (21 U.S.C. 360e) of
21	an application for premarket approval.
22	(c) Reporting.—The Secretary of Health and
23	Human Services shall annually post on the Internet web
24	site of the Food and Drug Administration—

1	(1) the number and type of class I and class II
2	devices reclassified as class II or class III in the pre-
3	vious calendar year under section 513(e)(1) of the
4	Federal Food, Drug, and Cosmetic Act (21 U.S.C.
5	360c(e)(1));
6	(2) the number and type of class II and class
7	III devices reclassified as class I or class II in the
8	previous calendar year under such section 513(e)(1);
9	and
10	(3) the number and type of devices reclassified
11	in the previous calendar year under section 515 of
12	the Federal Food, Drug, and Cosmetic Act (21
13	U.S.C. 360e).
14	SEC. 602. CONDITION OF APPROVAL STUDIES.
15	Section $515(d)(1)(B)(ii)$ (21 U.S.C.
16	360e(d)(1)(B)(ii)) is amended—
17	(1) by striking "(ii)" and inserting "(ii)(I)";
18	and
19	(2) by adding at the end the following:
20	"(II) An order approving an application for a device
21	may require as a condition to such approval that the appli-
22	cant conduct a postmarket study regarding the device.".
23	SEC. 603. POSTMARKET SURVEILLANCE.
24	Section 522 (21 U.S.C. 360l) is amended—

1	(1) in subsection (a)(1)(A), in the matter pre-
2	ceding clause (i), by inserting ", at the time of ap-
3	proval or clearance of a device or at any time there-
4	after," after "by order"; and
5	(2) in subsection $(b)(1)$ , by inserting "The
6	manufacturer shall commence surveillance under this
7	section not later than 15 months after the day on
8	which the Secretary issues an order under this sec-
9	tion." after the second sentence.
10	SEC. 604. SENTINEL.
11	Section 519 (21 U.S.C. 360i) is amended by adding
12	at the end the following:
13	"(h) Inclusion of Devices in the Postmarket
14	RISK IDENTIFICATION AND ANALYSIS SYSTEM.—
15	"(1) In General.—
16	"(A) APPLICATION TO DEVICES.—The Sec-
17	retary shall amend the procedures established
18	and maintained under clauses (i), (ii), (iii), and
19	(v) of section 505(k)(3)(C) in order to expand
20	the postmarket risk identification and analysis
21	system established under such section to include
22	and apply to devices.
23	"(B) Exception.—Clause (i)(II) of sec-
24	tion $505(k)(3)(C)$ shall not apply to devices.

1	"(C) CLARIFICATION.—With respect to de-
2	vices, the private sector health-related electronic
3	data provided under section
4	505(k)(3)(C)(i)(III)(bb) may include medical
5	device utilization data, health insurance claims
6	data, and procedure and device registries.
7	"(2) Data.—In expanding the system as de-
8	scribed in paragraph (1)(A), the Secretary shall use
9	relevant data with respect to devices cleared under
10	section 510(k) or approved under section 515, in-
11	cluding claims data, patient survey data, and any
12	other data deemed appropriate by the Secretary.
13	"(3) Stakeholder input.—To help ensure ef-
14	fective implementation of the system described in
15	paragraph (1)(A), the Secretary shall engage outside
16	stakeholders in development of the system through a
17	public hearing, advisory committee meeting, public
18	docket, or other like public measures, as appro-
19	priate.
20	"(4) Voluntary surveys.—Chapter 35 of
21	title 44, United States Code, shall not apply to the
22	collection of voluntary information from health care
23	providers, such as voluntary surveys or question-
24	naires, initiated by the Secretary for purposes of
25	postmarket risk identification for devices.".

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1	SEC. 605.	RECALLS.
2	(a)	Assessment of Device Recall Informa
3	TION.—	
4		(1) In general.—
5		(A) ASSESSMENT PROGRAM.—The Sec
6		retary of Health and Human Services (referred
7		to in this section as the "Secretary") shall en
8		hance the Food and Drug Administration's re
9		call program to routinely and systematically as
10		sess—
11		(i) information submitted to the Sec
12		retary pursuant to a device recall order
13		under section 518(e) of the Federal Food
14		Drug, and Cosmetic Act (21 U.S.C
15		360h(e)); and
16		(ii) information required to be re
17		ported to the Secretary regarding a correc
18		tion or removal of a device under section
19		519(g) of such Act (21 U.S.C. $360i(g)$ ).
20		(B) Use.—The Secretary shall use the as
21		sessment of information described under sub
22		paragraph (A) to proactively identify strategies
23		for mitigating health risks presented by defec
24		tive or unsafe devices.
25		(2) DESIGN—The program under paragraph

(1) shall, at a minimum, identify—

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1	(A) trends in the numbers and types of de-
2	vice recalls;
3	(B) the types of devices in each device
4	class that are most frequently recalled;
5	(C) the causes of device recalls; and
6	(D) any other information as the Secretary
7	determines appropriate.
8	(b) Audit Check Procedures.—The Secretary
9	shall clarify procedures for conducting device recall audit
10	checks to improve the ability of investigators to perform
11	these checks in a consistent manner.
12	(c) Assessment Criteria.—The Secretary shall de-
13	velop explicit criteria for assessing whether a person sub-
14	ject to a recall order under section 518(e) of the Federal
15	Food, Drug, and Cosmetic Act (21 U.S.C. 360h(e)) or to
16	a requirement under section 519(g) of such Act (21
17	U.S.C. 360i(g)) has performed an effective correction or
18	removal action under such section 519(g).
19	(d) TERMINATION OF RECALLS.—The Secretary shall
20	document the basis for the termination by the Food and
21	Drug Administration of—
22	(1) an individual device recall ordered under
23	section 518(e) of the Federal Food, Drug, and Cos-
24	metic Act (21 U.S.C. 360h(e)); and

1	(2) any correction or removal action for which
2	a report is required to be submitted to the Secretary
3	under section 519(g) of such Act (21 U.S.C.
4	360i(g)).
5	SEC. 606. CLINICAL HOLDS ON INVESTIGATIONAL DEVICE
6	EXEMPTIONS.
7	Section 520(g) (21 U.S.C. 360j(g)) is amended by
8	adding at the end the following:
9	"(8)(A) At any time, the Secretary may prohibit the
10	sponsor of an investigation from conducting the investiga-
11	tion (referred to in this paragraph as a 'clinical hold') if
12	the Secretary makes a determination described in sub-
13	paragraph (B). The Secretary shall specify the basis for
14	the clinical hold, including the specific information avail-
15	able to the Secretary which served as the basis for such
16	clinical hold, and confirm such determination in writing.
17	"(B) For purposes of subparagraph (A), a determina-
18	tion described in this subparagraph with respect to a clin-
19	ical hold is that—
20	"(i) the device involved represents an unreason-
21	able risk to the safety of the persons who are the
22	subjects of the clinical investigation, taking into ac-
23	count the qualifications of the clinical investigators,
24	information about the device, the design of the clin-
25	ical investigation, the condition for which the device

1	is to be investigated, and the health status of the
2	subjects involved; or
3	"(ii) the clinical hold should be issued for such
4	other reasons as the Secretary may by regulation es-
5	tablish.
6	"(C) Any written request to the Secretary from the
7	sponsor of an investigation that a clinical hold be removed
8	shall receive a decision, in writing and specifying the rea-
9	sons therefor, within 30 days after receipt of such request.
10	Any such request shall include sufficient information to
11	support the removal of such clinical hold.".
12	SEC. 607. UNIQUE DEVICE IDENTIFIER.
13	Section 519(f) (21 U.S.C. 360i(f)) is amended—
14	(1) by striking "The Secretary shall promul-
15	gate" and inserting "Not later than December 31,
16	2012, the Secretary shall issue proposed"; and
17	(2) by adding at the end the following:
18	"The Secretary shall finalize the proposed regulations not
19	later than 6 months after the close of the comment period
20	and shall implement the final regulations with respect to
21	devices that are implantable, life-saving, and life sus-
22	taining not later than 2 years after the regulations are
23	finalized.".

1	SEC. 608. CLARIFICATION OF LEAST BURDENSOME STAND-
2	ARD.
3	(a) Premarket Approval.—Section 513(a)(3)(D)
4	(21 U.S.C. 360c(a)(3)(D)) is amended—
5	(1) by redesignating clause (iii) as clause (v);
6	and
7	(2) by inserting after clause (ii) the following:
8	"(iii) For purposes of clause (ii) , the term 'nec-
9	essary' means the minimum required information that
10	would support a determination by the Secretary that an
11	application provides reasonable assurance of the effective-
12	ness of the device.
13	"(iv) Nothing in this subparagraph shall alter the cri-
14	teria for evaluating an application for premarket approval
15	of a device.".
16	(b) Premarket Notification Under Section
17	510(K).—Section $513(i)(1)(D)$ (21 U.S.C. $360c(i)(1)(D)$ )
18	is amended—
19	(1) by striking "(D) Whenever" and inserting
20	"(D)(i) Whenever"; and
21	(2) by adding at the end the following:
22	"(ii) For purposes of clause (i), the term 'necessary'
23	means the minimum required information that would sup-
24	port a determination of substantial equivalence between
25	a new device and a predicate device.

1	"(iii) Nothing in this subparagraph shall alter the
2	standard for determining substantial equivalence between
3	a new device and a predicate device.".
4	SEC. 609. CUSTOM DEVICES.
5	Section 520(b) (21 U.S.C. 360j) is amended to read
6	as follows:
7	"(b) Custom Devices.—
8	"(1) In general.—The requirements of sec-
9	tions 514 and 515 shall not apply to a device that—
10	"(A) is created or modified in order to
11	comply with the order of an individual physician
12	or dentist (or any other specially qualified per-
13	son designated under regulations promulgated
14	by the Secretary after an opportunity for an
15	oral hearing);
16	"(B) in order to comply with an order de-
17	scribed in subparagraph (A), necessarily devi-
18	ates from an otherwise applicable performance
19	standard under section 514 or requirement
20	under section 515;
21	"(C) is not generally available in the
22	United States in finished form through labeling
23	or advertising by the manufacturer, importer,
24	or distributor for commercial distribution;

1	"(D) is designed to treat a unique pathol-
2	ogy or physiological condition that no other de-
3	vice is domestically available to treat;
4	"(E)(i) is intended to meet the special
5	needs of such physician or dentist (or other spe-
6	cially qualified person so designated) in the
7	course of the professional practice of such phy-
8	sician or dentist (or other specially qualified
9	person so designated); or
10	"(ii) is intended for use by an individual
11	patient named in such order of such physician
12	or dentist (or other specially qualified person so
13	designated);
14	"(F) is assembled from components or
15	manufactured and finished on a case-by-case
16	basis to accommodate the unique needs de-
17	scribed in clause (i) or (ii) of subparagraph (E);
18	and
19	"(G) may have common, standardized de-
20	sign characteristics, chemical and material com-
21	positions, and manufacturing processes as com-
22	mercially distributed devices.
23	"(2) Limitations.—Paragraph (1) shall apply
24	to a device only if—

1	"(A) such device is for the purpose of
2	treating a sufficiently rare condition, such that
3	conducting clinical investigations on such device
4	would be impractical; and
5	"(B) production of such device under para-
6	graph (1) is limited to no more than 5 units per
7	year of a particular device type, provided that
8	such replication otherwise complies with this
9	section.
10	"(3) Exception.—Paragraph (1) shall not
11	apply to oral facial devices.
12	"(4) Guidance.—Not later than 2 years after
13	the date of enactment of this section, the Secretary
14	shall issue final guidance on replication of multiple
15	devices described in paragraph (2)(B).
16	"(5) Notification to the secretary.—The
17	manufacturer of a device created or modified as de-
18	scribed in paragraph (1) shall notify the Secretary,
19	in a manner prescribed by the Secretary, of the
20	manufacture of such device.".
21	SEC. 610. AGENCY DOCUMENTATION AND REVIEW OF CER-
22	TAIN DECISIONS REGARDING DEVICES.
23	Chapter V (21 U.S.C. 351 et seq.) is amended by
24	inserting after section 517 the following:

1	"SEC. 517A. AGENCY DOCUMENTATION AND REVIEW OF
2	CERTAIN DECISIONS REGARDING DEVICES.
3	"(a) Documentation of Rationale for De-
4	NIAL.—If the Secretary renders a final decision to deny
5	clearance of a premarket notification under section 510(k)
6	or approval of a premarket application under section 515,
7	or when the Secretary disapproves an application for an
8	investigational exemption under 520(g), the written cor-
9	respondence to the applicant communicating that decision
10	shall provide a substantive summary of the scientific and
11	regulatory rationale for the decision.
12	"(b) Review of Denial.—
13	"(1) IN GENERAL.—A person who has sub-
14	mitted a report under section 510(k), an application
15	under section 515, or an application for an exemp-
16	tion under section 520(g) and for whom clearance of
17	the report or approval of the application is denied
18	may request a supervisory review of the decision to
19	deny such clearance or approval. Such review shall
20	be conducted by an individual at the organizational
21	level above the organization level at which the deci-
22	sion to deny the clearance of the report or approval
23	of the application is made.
24	"(2) Submission of request.—A person re-
25	questing a supervisory review under paragraph (1)
26	shall submit such request to the Secretary not later

than 30 days after such denial 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 involve consultation with experts outside of the Food and Drug Administration, or in cases in which the sponsor seeks to introduce evidence not already in the administrative record at the time the denial decision was made.".

1	SEC. 611. GOOD GUIDANCE PRACTICES RELATING TO DE-
2	VICES.
3	Subparagraph (C) of section 701(h)(1) (21 U.S.C.
4	371(h)(1)) is amended—
5	(1) by striking "(C) For guidance documents"
6	and inserting "(C)(i) For guidance documents"; and
7	(2) by adding at the end the following:
8	"(ii) With respect to devices, if a notice to in-
9	dustry guidance letter, a notice to industry advisory
10	letter, or any similar notice sets forth initial inter-
11	pretations of a regulation or policy or sets forth
12	changes in interpretation or policy, such notice shall
13	be treated as a guidance document for purposes of
14	this subparagraph.".
15	SEC. 612. MODIFICATION OF DE NOVO APPLICATION PROC-
16	ESS.
17	(a) In General.—Section 513(f)(2) (21 U.S.C.
18	360e(f)(2)) is amended—
19	(1) by redesignating subparagraphs (B) and
20	(C) as subparagraphs (C) and (D), respectively;
21	(2) by amending subparagraph (A) to read as
22	follows:
23	"(A) In the case of a type of device that has not pre-
24	viously been classified under this Act, a person may do
25	one of the following:

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"(i) Submit a report under section 510(k), and, if the device is classified into class III under paragraph (1), such person may request, not later than 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) Submit a request for initial classification of the device under this subparagraph, if the person declares that there is no legally marketed device upon which to base a substantial equivalence determination as that term is defined in subsection (i). Subject to subparagraph (B), the Secretary shall classify the device under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1). The person submitting the request for classification under this subparagraph may recommend to the Secretary a classification for the device and shall 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. Requests
under this clause shall be subject to the electronic
copy requirements of section 745A(b).";
(3) by inserting after subparagraph (A) the fol-
lowing:
"(B) The Secretary may decline to undertake a clas-
sification request submitted under clause $(2)(A)(ii)$ if the
Secretary identifies a legally marketed device that could
provide a reasonable basis for review of substantial equiva-
lence under paragraph (1), or when the Secretary deter-
mines that the device submitted is not of low-moderate
risk or that special controls to mitigate the risks cannot
be developed."; and
(4) in subparagraph (C), as so redesignated—
(A) in clause (i), by striking "Not later
than 60 days after the date of the submission
of the request under subparagraph (A)," and
inserting "Not later than 120 days after the
date of the submission of the request under
subparagraph (A)(i) or 150 days after the date
of the submission of the request under subpara-
graph (A)(ii),"; and

1	(B) in clause (ii), by inserting "or is classi-
2	fied in" after "remains in".
3	(b) GAO REPORT.—Not later than 2 years after the
4	date of enactment of this Act, the Comptroller General
5	of the United States shall complete a study and submit
6	to Congress a report on the effectiveness of the review
7	pathway under section 513(f)(2)(A) of the Federal Food,
8	Drug, and Cosmetic Act, as amended by this Act.
9	(c) Conforming Amendment.—Section
10	513(f)(1)(B) (21 U.S.C. 360c(f)(1)(B)) is amended by in-
11	serting "a request under paragraph (2) or" after "re-
12	sponse to".
13	SEC. 613. HUMANITARIAN USE DEVICE EXEMPTIONS.
14	(a) In General.—Section 520(m) (21 U.S.C.
15	360j(m)) is amended—
16	(1) in paragraph (6)—
17	(A) in subparagraph (A)—
18	(i) in the matter preceding clause (i),
19	by striking "subparagraph (D)" and in-
20	serting "subparagraph (C)";
21	(ii) by striking clause (i) and inserting
22	the following:
23	"(i) The device with respect to which the ex-
24	emption is granted—

1	"(I) is intended for the treatment or diag-
2	nosis of a disease or condition that occurs in
3	pediatric patients or in a pediatric subpopula-
4	tion, and such device is labeled for use in pedi-
5	atric patients or in a pediatric subpopulation in
6	which the disease or condition occurs; or
7	"(II) is intended for the treatment or diag-
8	nosis of a disease or condition that does not
9	occur in pediatric patients or that occurs in pe-
10	diatric patients in such numbers that the devel-
11	opment of the device for such patients is impos-
12	sible, highly impracticable, or unsafe."; and
13	(iii) by striking clause (ii) and insert-
14	ing the following:
15	"(ii) During any calendar year, the number of
16	such devices distributed during that year under each
17	exemption granted under this subsection does not
18	exceed the number of such devices needed to treat,
19	diagnose, or cure a population of 4,000 individuals
20	in the United States (referred to in this paragraph
21	as the 'annual distribution number').";
22	(B) by striking subparagraph (C);
23	(C) by redesignating subparagraphs (D)
24	and (E) as subparagraphs (C) and (D), respec-
25	tively; and

1	(D) in subparagraph (C), as so redesig-
2	nated, by striking "and modified under sub-
3	paragraph (C), if applicable,";
4	(2) in paragraph (7), by striking "regarding a
5	device" and inserting "regarding a device described
6	in paragraph $(6)(A)(i)(I)$ "; and
7	(3) in paragraph (8), by striking "of all devices
8	described in paragraph (6)" and inserting "of all de-
9	vices described in paragraph (6)(A)(i)(I)".
10	(b) APPLICABILITY TO EXISTING DEVICES.—A spon-
11	sor of a device for which an exemption was approved under
12	paragraph (2) of section 520(m) of the Federal Food,
13	Drug, and Cosmetic Act (21 U.S.C. 360j(m)) before the
14	date of enactment of this Act may seek a determination
15	under subclause (I) or (II) of section $520(m)(6)(A)(i)$ (as
16	amended by subsection (a)). If the Secretary determines
17	that such subclause (I) or (II) applies with respect to a
18	device, clauses (ii), (iii), and (iv) of subparagraph (A) and
19	subparagraphs (B), (C), and (D) of paragraph (6) of such
20	section 520(m) shall apply to such device.
21	(c) Report.—Not later than January 1, 2017, the
22	Comptroller General of the United States shall submit to
23	Congress a report that evaluates and describes—
24	(1) the effectiveness of the amendments made
25	by subsection (a) in stimulating innovation with re-

1	spect to medical devices, including any favorable of
2	adverse impact on pediatric device development;
3	(2) the impact of such amendments on pediatric
4	device approvals for devices that received a humani-
5	tarian use designation under section 520(m) of the
6	Federal Food, Drug, and Cosmetic Act (21 U.S.C
7	360j(m)) prior to the date of enactment of this Act
8	(3) the status of public and private insurance
9	coverage of devices granted an exemption under
10	paragraph (2) of such section 520(m) (as amended
11	by subsection (a)) and costs to patients of such de-
12	vices;
13	(4) the impact that paragraph (4) of such sec-
14	tion 520(m) has had on access to and insurance cov-
15	erage of devices granted an exemption under para-
16	graph (2) of such section 520(m); and
17	(5) the effect of the amendments made by sub-
18	section (a) on patients described in such section
19	520(m).
20	SEC. 614. REAUTHORIZATION OF THIRD-PARTY REVIEW
21	AND INSPECTIONS.
22	(a) Third Party Review.—Section 523(c) (21
23	U.S.C. 360m(c)) is amended by striking "2012" and in-
24	serting "2017".

1	(b) Third Party Inspections.—Section
2	704(g)(11) (21 U.S.C. 374(g)(11)) is amended by striking
3	"2012" and inserting "2017".
4	SEC. 615. 510(K) DEVICE MODIFICATIONS.
5	Having acknowledged to Congress potential unin-
6	tended consequences that may result from the implemen-
7	tation of the Food and Drug Administration guidance en-
8	titled "Guidance for Industry and FDA Staff—510(k) De-
9	vice Modifications: Deciding When to Submit a 510(k) for
10	a Change to an Existing Device", the Secretary of Health
11	and Human Services shall withdraw such guidance
12	promptly and ensure that, before any future guidance doc-
13	ument on this issue is made final, affected stakeholders
14	are provided with an opportunity to comment.
15	TITLE VII—DRUG SUPPLY CHAIN
16	SEC. 701. REGISTRATION OF DOMESTIC DRUG ESTABLISH-
17	MENTS.
18	Section 510 (21 U.S.C. 360) is amended—
19	(1) in subsection (b)—
20	(A) in paragraph (1), by striking "On or
21	before" and all that follows through the period
22	at the end and inserting the following: "During
23	the period beginning on October 1 and ending
24	on December 31 of each year, every person who
25	owns or operates any establishment in any

1	State engaged in the manufacture, preparation
2	propagation, compounding, or processing of a
3	drug or drugs shall register with the Sec-
4	retary—
5	"(A) the name of such person, places of busi-
6	ness of such person, all such establishments, the
7	unique facility identifier of each such establishment
8	and a point of contact e-mail address; and
9	"(B) the name and place of business of each
10	drug importer that takes physical possession of a
11	drug (other than an excipient), with which the per-
12	son conducts business, including all establishments
13	of each such drug importer, the unique facility iden-
14	tifier of each such establishment, and a point of con-
15	tact e-mail address for each such drug importer."
16	and
17	(B) by adding at the end the following:
18	"(3) The Secretary may specify the unique facility
19	identifier system that shall be used by registrants under
20	paragraph (1)."; and
21	(2) in subsection (c), by striking "with the Sec-
22	retary his name, place of business, and such estab-
23	lishment" and inserting "with the Secretary—
24	"(1) with respect to drugs, the information de-
25	scribed under subsection (b)(1); and

1	"(2) with respect to devices, the information de-
2	scribed under subsection (b)(2).".
3	SEC. 702. REGISTRATION OF FOREIGN ESTABLISHMENTS.
4	(a) Enforcement of Registration of Foreign
5	ESTABLISHMENTS.—Section 502(o) (21 U.S.C. 352(o)) is
6	amended by striking "in any State".
7	(b) Registration of Foreign Drug Establish-
8	MENTS.—Section 510(i) (U.S.C. 360(i)) is amended—
9	(1) in paragraph (1)—
10	(A) by amending the matter preceding sub-
11	paragraph (A) to read as follows: "Every per-
12	son who owns or operates any establishment
13	within any foreign country engaged in the man-
14	ufacture, preparation, propagation,
15	compounding, or processing of a drug or device
16	that is imported or offered for import into the
17	United States shall, through electronic means
18	in accordance with the criteria of the Sec-
19	retary—'';
20	(B) by amending subparagraph (A) to read
21	as follows:
22	"(A) upon first engaging in any such activity,
23	immediately submit a registration to the Secretary
24	that includes—

1	"(i) with respect to drugs, the name and
2	place of business of such person, all such estab-
3	lishments, the unique facility identifier of each
4	such establishment, a point of contact e-mail
5	address, the name of the United States agent of
6	each such establishment, the name and place of
7	business of each drug importer with which such
8	person conducts business, including all estab-
9	lishments of each such drug importer, the
10	unique facility identifier of each such establish-
11	ment, and a point of contact e-mail address for
12	each such drug importer; and
13	"(ii) with respect to devices, the name and
14	place of business of the establishment, the name
15	of the United States agent for the establish-
16	ment, the name of each importer of such device
17	in the United States that is known to the estab-
18	lishment, and the name of each person who im-
19	ports or offers for import such device to the
20	United States for purposes of importation;
21	and"; and
22	(C) by amending subparagraph (B) to read
23	as follows:
24	"(B) each establishment subject to the require-
25	ments of subparagraph (A) shall thereafter register

1	with the Secretary during the period beginning on
2	October 1 and ending on December 31 of each
3	year."; and
4	(2) by adding at the end the following:
5	"(4) The Secretary may specify the unique facility
6	identifier system that shall be used by registrants under
7	paragraph (1) with respect to drugs.".
8	SEC. 703. IDENTIFICATION OF DRUG EXCIPIENT INFORMA-
9	TION WITH PRODUCT LISTING.
10	Section $510(j)(1)$ (21 U.S.C. $360(j)(1)$ ) is amend-
11	ed—
12	(1) in subparagraph (C), by striking "; and"
13	and inserting a semicolon;
14	(2) in subparagraph (D), by striking the period
15	at the end and inserting "; and; and
16	(3) by adding at the end the following:
17	"(E) in the case of a drug contained in the ap-
18	plicable list and subject to section 505 or 512, the
19	name and place of business of each manufacturer of
20	an excipient of the drug with which the person so
21	registered conducts business, including all establish-
22	ments used in the production of such excipient, the
23	unique facility identifier of each such establishment,
24	and a point of contact e-mail address for each such
25	excipient manufacturer.".

1	SEC. 704. ELECTRONIC SYSTEM FOR REGISTRATION AND
2	LISTING.
3	Section 510(p) (21 U.S.C. 360(p)) is amended—
4	(1) by striking "(p) Registrations and listings"
5	and inserting the following:
6	"(p) Electronic Registration and Listing.—
7	"(1) In general.—Registration and listing";
8	and
9	(2) by adding at the end the following:
10	"(2) Electronic database.—Not later than
11	2 years after the Secretary specifies a unique facility
12	identifier system under subsections (b) and (i), the
13	Secretary shall maintain an electronic database,
14	which shall not be subject to inspection under sub-
15	section (f), populated with the information submitted
16	as described under paragraph (1) that—
17	"(A) enables personnel of the Food and
18	Drug Administration to search the database by
19	any field of information submitted in a registra-
20	tion described under paragraph (1), or com-
21	bination of such fields; and
22	"(B) uses the unique facility identifier sys-
23	tem to link with other relevant databases within
24	the Food and Drug Administration, including
25	the database for submission of information
26	under section 801(r).

1	"(3) Risk-based information and coordi-
2	NATION.—The Secretary shall ensure the accuracy
3	and coordination of relevant Food and Drug Admin-
4	istration databases in order to identify and inform
5	risk-based inspections under section 510(h).".
6	SEC. 705. RISK-BASED INSPECTION FREQUENCY.
7	Section 510(h) (21 U.S.C. 360(h)) is amended to
8	read as follows:
9	"(h) Inspections.—
10	"(1) In general.—Every establishment that is
11	required to be registered with the Secretary under
12	this section shall be subject to inspection pursuant
13	to section 704.
14	"(2) RISK-BASED SCHEDULE.—The Secretary,
15	acting through one or more officers or employees
16	duly designated by the Secretary, shall inspect estab-
17	lishments described in paragraph (1) that are en-
18	gaged in the manufacture, preparation, propagation,
19	compounding, or processing of a drug or drugs (re-
20	ferred to in this subsection as 'drug establishments')
21	in accordance with a risk-based schedule established
22	by the Secretary.
23	"(3) RISK FACTORS.—In establishing the risk-
24	based scheduled under paragraph (2), the Secretary
25	shall inspect establishments according to the known

1	safety risks of such establishments, which shall be
2	based on the following factors:
3	"(A) The compliance history of the estab-
4	lishment.
5	"(B) The record, history, and nature of re-
6	calls linked to the establishment.
7	"(C) The inherent risk of the drug manu-
8	factured, prepared, propagated, compounded, or
9	processed at the establishment.
10	"(D) The certifications described under
11	sections 801(r) and 809 for the establishment.
12	"(E) Whether the establishment has been
13	inspected in the preceding 4-year period.
14	"(F) Any other criteria deemed necessary
15	and appropriate by the Secretary for purposes
16	of allocating inspection resources.
17	"(4) Effect of Status.—In determining the
18	risk associated with an establishment for purposes of
19	establishing a risk-based schedule under paragraph
20	(2), the Secretary shall not consider whether the
21	drugs manufactured, prepared, propagated, com-
22	pounded, or processed by such establishment are
23	drugs described in section 503(b).
24	"(5) Annual report on inspections of es-
25	TABLISHMENTS.—Not later than February 1 of each

1	year, the Secretary shall submit a report to Con-
2	gress regarding—
3	"(A)(i) the number of domestic and foreign
4	establishments registered pursuant to this sec-
5	tion in the previous fiscal year; and
6	"(ii) the number of such domestic estab-
7	lishments and the number of such foreign es-
8	tablishments that the Secretary inspected in the
9	previous fiscal year;
10	"(B) with respect to establishments that
11	manufacture, prepare, propagate, compound, or
12	process an active ingredient of a drug, a fin-
13	ished drug product, or an excipient of a drug
14	the number of each such type of establishment
15	and
16	"(C) the percentage of the budget of the
17	Food and Drug Administration used to fund
18	the inspections described under subparagraph
19	(A).
20	"(6) Public availability of annual re-
21	PORTS.—The Secretary shall make the report re-
22	quired under paragraph (5) available to the public
23	on the Internet Web site of the Food and Drug Ad-
24	ministration.".

## 1 SEC. 706. RECORDS FOR INSPECTION.

- 2 Section 704(a) (21 U.S.C. 374(a)) is amended by
- 3 adding at the end the following:
- 4 "(4)(A) Any records or other information that the
- 5 Secretary is entitled to request under this section from
- 6 a person that owns or operates an establishment that is
- 7 engaged in the manufacture, preparation, propagation,
- 8 compounding, or processing of a drug shall, upon the re-
- 9 quest of the Secretary, be provided to the Secretary by
- 10 such person within a reasonable time frame, within rea-
- 11 sonable limits and in a reasonable manner, and in elec-
- 12 tronic form, at the expense of such person. The Sec-
- 13 retary's request shall include a clear description of the
- 14 records requested.
- 15 "(B) Upon receipt of the records requested under
- 16 subparagraph (A), the Secretary shall provide to the per-
- 17 son confirmation of the receipt of such records.
- 18 "(C) Nothing in this paragraph supplants the author-
- 19 ity of the Secretary to conduct inspections otherwise per-
- 20 mitted under this Act in order to ensure compliance by
- 21 an establishment with this Act.".

## 22 SEC. 707. FAILURE TO ALLOW FOREIGN INSPECTION.

- 23 Section 801(a) (21 U.S.C. 381(a)) is amended by
- 24 adding at the end the following: "Notwithstanding any
- 25 other provision of this subsection, the Secretary of Home-
- 26 land Security shall, upon request from the Secretary of

- 1 Health and Human Services refuse to admit into the
- 2 United States any article if the article was manufactured,
- 3 prepared, propagated, compounded, processed, or held at
- 4 an establishment that has refused to permit the Secretary
- 5 of Health and Human Services to enter or inspect the es-
- 6 tablishment in the same manner and to the same extent
- 7 as the Secretary may inspect establishments under section
- 8 704.".

## 9 SEC. 708. EXCHANGE OF INFORMATION.

- 10 Section 708 (21 U.S.C. 379) is amended—
- 11 (1) by striking "CONFIDENTIAL INFORMATION"
- and all that follows through "The Secretary" and in-
- serting "CONFIDENTIAL INFORMATION.
- 14 "(a) CONTRACTORS.—The Secretary"; and
- 15 (2) by adding at the end the following:
- 16 "(b) Ability to Receive and Protect Confiden-
- 17 TIAL INFORMATION.—The Secretary shall not be required
- 18 to disclose under section 552 of title 5, United States
- 19 Code, or any other provision of law, any information relat-
- 20 ing to drugs obtained from a Federal, State or local gov-
- 21 ernment agency, or from a foreign government agency, if
- 22 the agency has requested that the information be kept con-
- 23 fidential, except pursuant to an order of a court of the
- 24 United States. For purposes of section 552 of title 5,

1 United States Code, this subsection shall be considered a

- 2 statute described in section 552(b)(3)(B).
- 3 "(c) Authority to Enter Into Memoranda of
- 4 Understanding for Purposes of Information Ex-
- 5 CHANGE.—The Secretary may enter into written agree-
- 6 ments regarding the exchange of information referenced
- 7 in section 301(j) subject to the following criteria:

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- 9 enter into written agreements under this subsection 10 with foreign governments that the Secretary has cer-11 tified as having the authority and demonstrated abil-12 ity to protect trade secret information from disclo-13 sure. Responsibility for this certification shall not be 14 delegated to any officer or employee other than the
  - "(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.

1	"(3) Information exchange.—The Secretary
2	may provide to a foreign government that has been
3	certified under paragraph (1) and that has executed
4	a written agreement under paragraph (2) informa-
5	tion referenced in section 301(j) in the following cir-
6	cumstances:
7	"(A) Information concerning the inspection
8	of a facility may be provided if—
9	"(i) the Secretary reasonably believes,
10	or that the written agreement described in
11	paragraph (2) establishes, that the govern-
12	ment has authority to otherwise obtain
13	such information; and
14	"(ii) the written agreement executed
15	under paragraph (2) limits the recipient's
16	use of the information to the recipient's
17	civil regulatory purposes.
18	"(B) Information not described in sub-
19	paragraph (A) may be provided as part of an
20	investigation, or to alert the foreign government
21	to the potential need for an investigation, if the
22	Secretary has reasonable grounds to believe
23	that a drug has a reasonable probability of
24	causing serious adverse health consequences or
25	death to humans or animals.

1	"(4) Effect of subsection.—Nothing in this
2	subsection affects the ability of the Secretary to
3	enter into any written agreement authorized by
4	other provisions of law to share confidential informa-
5	tion.".
6	SEC. 709. ENHANCING THE SAFETY AND QUALITY OF THE
7	DRUG SUPPLY.
8	Section 501 (21 U.S.C. 351) is amended by adding
9	at the end the following flush text:
10	"For purposes of subsection (a)(2)(B), the term 'current
11	good manufacturing practice' includes the implementation
12	of oversight and controls over the manufacture of drugs
13	to ensure quality, including managing the risk of and es-
14	tablishing the safety of raw materials, materials used in
15	the manufacturing of drugs, and finished drug products.".
16	SEC. 710. ACCREDITATION OF THIRD-PARTY AUDITORS FOR
17	DRUG ESTABLISHMENTS.
18	(a) IN CHARDAI Charter WIII (91 II C.C. 991 at
	(a) IN GENERAL.—Chapter VIII (21 U.S.C. 381 et
19	seq.) is amended by adding at the end the following:
	•
20	seq.) is amended by adding at the end the following:
20 21	seq.) is amended by adding at the end the following:  "SEC. 809. ACCREDITATION OF THIRD-PARTY AUDITORS
20 21 22	seq.) is amended by adding at the end the following:  "SEC. 809. ACCREDITATION OF THIRD-PARTY AUDITORS  FOR DRUG ESTABLISHMENTS.
19 20 21 22 23 24	seq.) is amended by adding at the end the following:  "SEC. 809. ACCREDITATION OF THIRD-PARTY AUDITORS  FOR DRUG ESTABLISHMENTS.  "(a) DEFINITIONS.—In this section:

1	"(2) Accredited third-party auditor.—
2	The term 'accredited third-party auditor' means a
3	third-party auditor (which may be an individual) ac-
4	credited by an accreditation body to conduct drug
5	safety and quality audits.
6	"(3) Audit agent"—The term 'audit agent'
7	means an individual who is an employee or agent of
8	an accredited third-party auditor and, although not
9	individually accredited, is qualified to conduct drug
10	safety and quality audits on behalf of an accredited
11	third-party auditor.
12	"(4) Consultative audit.—The term 'con-
13	sultative audit' means an audit of an eligible entity
14	intended for internal purposes only to determine
15	whether an establishment is in compliance with the
16	provisions of this Act and applicable industry prac-
17	tices, or any other such service.
18	"(5) Drug safety and quality audit.—The
19	term 'drug safety and quality audit'—
20	"(A) means an audit of an eligible entity
21	to certify that the eligible entity meets the re-
22	quirements of this Act applicable to drugs, in-
23	cluding the requirements of section 501 with re-
24	spect to drugs; and
25	"(B) is not a consultative audit.

1	"(6) ELIGIBLE ENTITY.—The term 'eligible en-
2	tity' means an entity, including a foreign drug estab-
3	lishment registered under section 510(c), in the drug
4	supply chain that chooses to be audited by an ac-
5	credited third-party auditor or the audit agent of
6	such accredited third-party auditor.
7	"(7) Third-party auditor.—The term 'third-
8	party auditor' means a foreign government, agency
9	of a foreign government or any other third party
10	(which may be an individual), as the Secretary de-
11	termines appropriate in accordance with the criteria
12	described in subsection $(c)(1)$ , that is eligible to be
13	considered for accreditation to conduct drug safety
14	and quality audits.
15	"(b) Accreditation System.—
16	"(1) Recognition of accreditation bod-
17	IES.—
18	"(A) In general.—Not later than 2 years
19	after date of enactment of the Food and Drug
20	Administration Safety and Innovation Act, the
21	Secretary shall establish a system for the rec-
22	ognition of accreditation bodies that accredit
23	third-party auditors to conduct drug safety and
24	quality audits.
25	"(B) DIRECT ACCREDITATION.—

1	"(i) IN GENERAL.—If, by the date
2	that is 2 years after the date of establish-
3	ment of the system described in subpara-
4	graph (A), the Secretary has not identified
5	and recognized an accreditation body to
6	meet the requirements of this section, the
7	Secretary may directly accredit third-party
8	auditors.
9	"(ii) Certain direct accredita-
10	TIONS.—Notwithstanding subparagraph
11	(A) or clause (i), the Secretary may di-
12	rectly accredit any foreign government or
13	any agency of a foreign government as a
14	third-party auditor at any time after the
15	date of enactment of the Food and Drug
16	Administration Safety and Innovation Act.
17	"(2) Notification.—Each accreditation body
18	recognized by the Secretary shall submit to the Sec-
19	retary—
20	"(A) a list of all accredited third-party
21	auditors accredited by such body (including the
22	name, contact information, and scope and dura-
23	tion of accreditation for each such auditor), and
24	the audit agents of such auditors; and

1	"(B) updated lists as needed to ensure the
2	list held by the Secretary is accurate.
3	"(3) REVOCATION OF RECOGNITION AS AN AC-
4	CREDITATION BODY.—The Secretary shall promptly
5	revoke, after the opportunity for an informal hear-
6	ing, the recognition of any accreditation body found
7	not to be in compliance with the requirements of this
8	section.
9	"(4) Reinstatement.—The Secretary shall es-
10	tablish procedures to reinstate recognition of an ac-
11	creditation body if the Secretary determines, based
12	on evidence presented by such accreditation body,
13	that revocation was inappropriate or that the body
14	meets the requirements for recognition under this
15	section.
16	"(5) Model accreditation standards.—
17	"(A) In General.—Not later than 18
18	months after the date of enactment of the Food
19	and Drug Administration Safety and Innova-
20	tion Act, the Secretary shall develop model
21	standards, including standards for drug safety
22	and quality audit results, reports, and certifi-
23	cations, and each recognized accreditation body
24	shall ensure that third-party auditors and audit
25	agents of such auditors meet such standards in

1	order to qualify such third-party auditors as ac-
2	credited third-party auditors under this section
3	"(B) CONTENT.—The standards developed
4	under subparagraph (A) may—
5	"(i) include a description of required
6	standards relating to the training proce-
7	dures, competency, management respon-
8	sibilities, quality control, and conflict of in-
9	terest requirements of accredited third-
10	party auditors; and
11	"(ii) set forth procedures for the peri-
12	odic renewal of the accreditation of accred-
13	ited third-party auditors.
14	"(C) Requirement to provide results
15	AND REPORTS TO THE SECRETARY.—An ac-
16	creditation body (or, in the case of direct ac-
17	creditation under subsection (b)(1)(B), the Sec-
18	retary) may not accredit a third-party auditor
19	unless such third-party auditor agrees to pro-
20	vide to the Secretary, upon request, the results
21	and reports of any drug safety and quality
22	audit conducted pursuant to the accreditation
23	provided under this section.
24	"(6) DISCLOSURE.—The Secretary shall main-
25	tain on the Internet Web site of the Food and Drug

1	Administration a list of recognized accreditation
2	bodies and accredited third-party auditors under this
3	section.
4	"(c) Accredited Third-party Auditors.—
5	"(1) Requirements for accreditation as a
6	THIRD-PARTY AUDITOR.—
7	"(A) Foreign governments.—Prior to
8	accrediting a foreign government or an agency
9	of a foreign government as an accredited third-
10	party auditor, the accreditation body (or, in the
11	case of direct accreditation under subsection
12	(b)(1)(B), the Secretary) shall perform such re-
13	views and audits of drug safety programs, sys-
14	tems, and standards of the government or agen-
15	cy of the government as the Secretary deems
16	necessary, including requirements under the
17	standards developed under subsection (b)(5), to
18	determine that the foreign government or agen-
19	cy of the foreign government is capable of ade-
20	quately ensuring that eligible entities or drugs
21	certified by such government or agency meet
22	the requirements of this Act.
23	"(B) Other third parties.—Prior to
24	accrediting any other third party to be an ac-
25	credited third-party auditor, the accreditation

1 body (or, in the case of direct accreditation 2 under subsection (b)(1)(B), the Secretary) shall 3 perform such reviews and audits of the training 4 and qualifications of audit agents used by that 5 party and conduct such reviews of internal sys-6 tems and such other investigation of the party 7 as the Secretary deems necessary, including re-8 quirements under the standards developed 9 under subsection (b)(5), to determine that the 10 third-party auditor is capable of adequately en-11 suring that an eligible entity or drug certified 12 by such third-party auditor meets the require-13 ments of this Act. 14 "(2) Use of audit agents.—An accredited 15 third-party auditor may conduct drug safety and 16 quality audits and may employ or use audit agents 17 to conduct drug safety and quality audits, but must 18 ensure that such audit agents comply with all re-19 quirements the Secretary deems necessary, including 20 requirements under paragraph (1) and subsection 21 (b)(5).22 "(3) Revocation of accreditation.— "(A) IN GENERAL.—The Secretary shall 23

promptly revoke, after the opportunity for an

24

1	informal hearing, the accreditation of an ac-
2	credited third-party auditor—
3	"(i) if, following an evaluation, the
4	Secretary finds that the accredited third-
5	party auditor is not in compliance with the
6	requirements of this section; or
7	"(ii) following a refusal to allow
8	United States officials to conduct such au-
9	dits and investigations as may be necessary
10	to determine compliance with the require-
11	ments set forth in this section.
12	"(B) Additional basis for revocation
13	OF ACCREDITATION.—The Secretary may re-
14	voke accreditation from an accredited third-
15	party auditor in the case that such third-party
16	auditor is accredited by an accreditation body
17	for which recognition as an accreditation body
18	under subsection (b)(3) is revoked, if the Sec-
19	retary determines that there is good cause for
20	the revocation of accreditation.
21	"(4) Reaccreditation.—The Secretary shall
22	establish procedures to reinstate the accreditation of
23	a third-party auditor for which accreditation has
24	been revoked under paragraph (3)—

1	"(A) if the Secretary determines, based on
2	evidence presented, that—
3	"(i) the third-party auditor satisfies
4	the requirements of this section; and
5	"(ii) adequate grounds for revocation
6	no longer exist; and
7	"(B) in the case of a third-party auditor
8	accredited by an accreditation body for which
9	recognition as an accreditation body is revoked
10	under subsection (b)(3)—
11	"(i) if the third-party auditor becomes
12	accredited not later than 1 year after rev-
13	ocation of accreditation under paragraph
14	(3), through direct accreditation under
15	subsection (b)(1)(B), or by an accredita-
16	tion body in good standing; or
17	"(ii) under such other conditions as
18	the Secretary may require.
19	"(5) Requirement to issue certification
20	OF ELIGIBLE ENTITIES FOR COMPLIANCE WITH CUR-
21	RENT GOOD MANUFACTURING PRACTICE.—
22	"(A) IN GENERAL.—An accreditation body
23	(or, in the case of direct accreditation under
24	subsection (b)(1)(B), the Secretary) may not
25	accredit a third-party auditor unless such third-

1	party auditor agrees to issue a written and, as
2	appropriate, electronic, document or certifi-
3	cation, as the Secretary may require under this
4	Act, regarding compliance with section 501.
5	The Secretary may consider any such document
6	or certification to satisfy requirements under
7	section 801(r) and to target inspection re-
8	sources under section 510(h).
9	"(B) Requirements for issuing cer-
10	TIFICATION.—
11	"(i) In GENERAL.—An accredited
12	third-party auditor shall issue a drug cer-
13	tification described in subparagraph (A)
14	only after conducting a drug safety and
15	quality audit and such other activities that
16	may be necessary to establish compliance
17	with the provisions of section 501.
18	"(ii) Provision of Certification.—
19	Only an accredited third-party auditor or
20	the Secretary may provide a drug certifi-
21	cation described in subparagraph (A).
22	"(C) Records.—Following any accredita-
23	tion of a third-party auditor, the Secretary
24	may, at any time, require the accredited third-
25	party auditor or any audit agent of such audi-

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and quality audit report and such other reports or documents required as part of the drug safety and quality audit process, for any eligible entity for which the accredited third-party auditor or audit agent of such auditor performed a drug safety and quality audit. The Secretary may require documentation that the eligible entity is in compliance with any applicable registration requirements.

"(D) LIMITATION.—The requirement under subparagraph (C) shall not include any report or other documents resulting from a consultative audit, except that the Secretary may access the results of a consultative audit in accordance with section 704.

"(E) DECLARATION OF AUDIT TYPE.—Before an accredited third-party auditor begins
any audit or provides any consultative service to
an eligible entity, both the accredited thirdparty auditor and eligible entity shall establish
in writing whether the audit is intended to be
a drug safety and quality audit. Any audit, inspection, or consultative service of any type provided by an accredited third-party auditor on

1	behalf of an eligible entity shall be presumed to
2	be a drug safety and quality audit in the ab-
3	sence of such a written agreement. Once a drug
4	safety and quality audit is initiated, it shall be
5	subject to the requirements of this section, and
6	no person may withhold from the Secretary any
7	document subject to subparagraph (C) on the
8	grounds that the audit was a consultative audit
9	or otherwise not a drug safety and quality
10	audit.
11	"(F) Rule of construction.—Nothing
12	in this section shall be construed to limit the
13	authority of the Secretary under section 704.
14	"(6) Requirements regarding serious
15	RISKS TO THE PUBLIC HEALTH.—If, at any time
16	during a drug safety and quality audit, an accredited
17	third-party auditor or an audit agent of such auditor
18	discovers a condition that could cause or contribute
19	to a serious risk to the public health, such auditor
20	shall immediately notify the Secretary of—
21	"(A) the identity and location of the eligi-
22	ble entity subject to the drug safety and quality
23	audit; and
24	"(B) such condition.
25	"(7) Limitations.—

1	"(A) In general.—An audit agent of an
2	accredited third-party auditor may not perform
3	a drug safety and quality audit of an eligible
4	entity if such audit agent has performed a drug
5	safety and quality audit or consultative audit of
6	such eligible entity during the previous 13-
7	month period.
8	"(B) Waiver.—The Secretary may waive
9	the application of subparagraph (A) if the Sec-
10	retary determines that there is insufficient ac-
11	cess to accredited third-party auditors in a
12	country or region or that the use of the same
13	audit agent or accredited third-party auditor is
14	otherwise necessary.
15	"(8) Conflicts of interest.—
16	"(A) Accreditation bodies.—A recog-
17	nized accreditation body shall—
18	"(i) not be owned, managed, or con-
19	trolled by any person that owns or operates
20	a third-party auditor to be accredited by
21	such body;
22	"(ii) in carrying out accreditation of
23	third-party auditors under this section,
24	have procedures to ensure against the use
25	of any officer or employee of such body

1	that has a financial conflict of interest re-
2	garding a third-party auditor to be accred-
3	ited by such body; and
4	"(iii) annually make available to the
5	Secretary disclosures of the extent to
6	which such body and the officers and em-
7	ployees of such body have maintained com-
8	pliance with clauses (i) and (ii) relating to
9	financial conflicts of interest.
10	"(B) Accredited third-party audi-
11	TORS.—An accredited third-party auditor
12	shall—
13	"(i) not be owned, managed, or con-
14	trolled by any person that owns or operates
15	an eligible entity to be certified by such
16	auditor;
17	"(ii) in carrying out drug safety and
18	quality audits of eligible entities under this
19	section, have procedures to ensure against
20	the use of any officer or employee of such
21	auditor that has a financial conflict of in-
22	terest regarding an eligible entity to be
23	certified by such auditor; and
24	"(iii) annually make available to the
25	Secretary disclosures of the extent to

1	which such auditor and the officers and
2	employees of such auditor have maintained
3	compliance with clauses (i) and (ii) relat-
4	ing to financial conflicts of interest.
5	"(C) Audit agent agent
6	shall—
7	"(i) not own or operate an eligible en-
8	tity to be audited by such agent;
9	"(ii) in carrying out audits of eligible
10	entities under this section, have procedures
11	to ensure that such agent does not have a
12	financial conflict of interest regarding an
13	eligible entity to be audited by such agent;
14	and
15	"(iii) annually make available to the
16	Secretary disclosures of the extent to
17	which such agent has maintained compli-
18	ance with clauses (i) and (ii) relating to fi-
19	nancial conflicts of interest.
20	"(d) False Statements.—Any statement or rep-
21	resentation made—
22	"(1) by an employee or agent of an eligible enti-
23	ty to an accredited third-party auditor or audit
24	agent; or

1	"(2) by an accreditation body, accredited third-
2	party auditor, or audit agent of such auditor to the
3	Secretary, shall be subject to section 1001 of title
4	18, United States Code.
5	"(e) Monitoring.—To ensure compliance with the
6	requirements of this section, the Secretary—
7	"(1) shall periodically, or at least once every 4
8	years, reevaluate the accreditation bodies described
9	in subsection (b)(1);
10	"(2) shall periodically, or at least once every 4
11	years, evaluate the performance of each accredited
12	third-party auditor, through the review of regulatory
13	audit reports by such auditors, the compliance his-
14	tory as available of eligible entities certified by such
15	auditors, and any other measures deemed necessary
16	by the Secretary;
17	"(3) may at any time, conduct an onsite audit
18	of any eligible entity certified by an accredited third-
19	party auditor, with or without the auditor present;
20	and
21	"(4) shall take any other measures deemed nec-
22	essary by the Secretary.
23	"(f) Effect of Audit.—The results of a drug safe-
24	ty and quality audit by an accredited third-party auditor
25	under this section—

1	"(1) may be used by the eligible entity—
2	"(A) as documentation of compliance with
3	section 501(a)(2)(B) or section 801(r); and
4	"(B) for other purposes as determined ap-
5	propriate by the Secretary; and
6	"(2) shall be used by the Secretary in estab-
7	lishing the risk-based inspection schedules under sec-
8	tion 510(h).
9	"(g) Costs.—
10	"(1) Authorized fees of secretary.—The
11	Secretary may assess fees on accreditation bodies
12	and accredited third-party auditors in such an
13	amount necessary to establish and administer the
14	recognition and accreditation program under this
15	section. The Secretary may require accredited third-
16	party auditors and audit agents to reimburse the
17	Food and Drug Administration for the work per-
18	formed to carry out this section. The Secretary shall
19	not generate surplus revenue from such a reimburse-
20	ment mechanism. Fees authorized under this para-
21	graph shall be collected and available for obligation
22	only to the extent and in the amount provided in ad-
23	vance in appropriation Acts. Such fees are author-
24	ized to remain available until expended.

1	"(2) Authorized fees for recognized ac-
2	CREDITATION BODIES.—An accreditation body rec-
3	ognized by the Secretary under subsection (b) may
4	assess a reasonable fee to accredit third-party audi-
5	tors.
6	"(h) Limitations.—
7	"(1) No effect on section 704 inspec-
8	TIONS.—The drug safety and quality audits per-
9	formed under this section shall not be considered in-
10	spections under section 704.
11	"(2) No effect on inspection author-
12	ITY.—Nothing in this section affects the authority of
13	the Secretary to inspect any eligible entity pursuant
14	to this Act.
15	"(i) Regulations.—
16	"(1) In general.—Not later than 18 months
17	after the date of enactment of the Food and Drug
18	Administration Safety and Innovation Act, the Sec-
19	retary shall adopt final regulations implementing
20	this section.
21	"(2) Procedure.—In promulgating the regula-
22	tions implementing this section, the Secretary
23	shall—
24	"(A) issue a notice of proposed rulemaking
25	that includes the proposed regulation;

1	"(B) provide a period of not less than 60
2	days for comments on the proposed regulation;
3	and
4	"(C) publish the final regulation not less
5	than 30 days before the effective date of the
6	regulation.
7	"(3) Content.—Such regulations shall in-
8	clude—
9	"(A) requirements that, to the extent prac-
10	ticable, drug safety and quality audits per-
11	formed under this section be unannounced;
12	"(B) a structure to decrease the potential
13	for conflicts of interest, including timing and
14	public disclosure, for fees paid by eligible enti-
15	ties to accredited third-party auditors; and
16	"(C) appropriate limits on financial affili-
17	ations between an accredited third-party audi-
18	tor or audit agents of such auditor and any per-
19	son that owns or operates an eligible entity to
20	be audited by such auditor, as described in sub-
21	paragraphs (A) and (B).
22	"(4) Restrictions.—Notwithstanding any
23	other provision of law, the Secretary shall promul-
24	gate regulations implementing this section only as
25	described in paragraph (2).".

1	(b) Report on Accredited Third-party Audi-
2	TORS.—Not later than January 20, 2017, the Comptroller
3	General of the United States shall submit to Congress a
4	report that addresses the following, with respect to the pe-
5	riod beginning on the date of implementation of section
6	809 of the Federal Food, Drug, and Cosmetic Act (as
7	added by subsection (a)) and ending on the date of such
8	report:
9	(1) The extent to which drug safety and quality
10	audits completed by accredited third-party auditors
11	under such section 809 are being used by the Sec-
12	retary of Health and Human Services (referred to in
13	this subsection as the "Secretary") in establishing or
14	applying the risk-based inspection schedules under
15	section 510(h) of such Act (as amended by section
16	705).
17	(2) The extent to which drug safety and quality
18	audits completed by accredited third-party auditors
19	or agents are assisting the Food and Drug Adminis-
20	tration in evaluating compliance with sections
21	501(a)(2)(B) of such Act (21 U.S.C. 351(a)(2)(B))
22	and 801(r) of such Act (as added by section 711).
23	(3) Whether the Secretary has been able to ac-
24	cess drug safety and quality audit reports completed

1	by accredited third-party auditors under such section
2	809.
3	(4) Whether accredited third-party auditors ac-
4	credited under such section 809 have adhered to the
5	conflict of interest provisions set forth in such sec-
6	tion.
7	(5) The extent to which the Secretary has au-
8	dited recognized accreditation bodies or accredited
9	third-party auditors to ensure compliance with the
10	requirements of such section 809.
11	(6) The number of waivers under subsection
12	(c)(7)(B) of such section 809 issued during the most
13	recent 12-month period and the official justification
14	by the Secretary for each determination that there
15	was insufficient access to an accredited third-party
16	auditor.
17	(7) The number of times a manufacturer has
18	used the same accredited third-party auditor for 2 or
19	more consecutive drug safety and quality audits
20	under such section 809.
21	(8) Recommendations to Congress regarding
22	the accreditation program under such section 809,
23	including whether Congress should continue, modify,
24	or terminate the program.

1	SEC. 711. STANDARDS FOR ADMISSION OF IMPORTED
2	DRUGS.
3	Section 801 (21 U.S.C. 381) is amended—
4	(1) in subsection (o), by striking "drug or";
5	and
6	(2) by adding at the end the following:
7	"(r)(1) The Secretary may require, as a condition of
8	granting admission to a drug imported or offered for im-
9	port into the United States, that the importer electroni-
10	cally submit information demonstrating that the drug
11	complies with applicable requirements of this Act.
12	"(2) The information described under paragraph (1)
13	may include—
14	"(A) information demonstrating the regulatory
15	status of the drug, such as the new drug application,
16	abbreviated new drug application, or investigational
17	new drug or drug master file number;
18	"(B) facility information, such as proof of reg-
19	istration and the unique facility identifier;
20	"(C) indication of compliance with current good
21	manufacturing practice, testing results, certifications
22	relating to satisfactory inspections, and compliance
23	with the country of export regulations; and
24	"(D) any other information deemed necessary
25	and appropriate by the Secretary to assess compli-
26	ance of the article being offered for import.

1	"(3) Information requirements referred to in para-
2	graph (2)(C) may, at the discretion of the Secretary, be
3	satisfied—
4	"(A) by certifications from accredited third par-
5	ties, as described under section 809;
6	"(B) through representation by a foreign gov-
7	ernment, if such inspection is conducted using
8	standards and practices as agreed to by the Sec-
9	retary; or
10	"(C) other appropriate documentation or evi-
11	dence as described by the Secretary.
12	"(4)(A) Not later than 18 months after the date of
13	enactment of the Food and Drug Administration Safety
14	and Innovation Act, the Secretary shall adopt final regula-
15	tions implementing this subsection. Such requirements
16	shall be appropriate for the type of import, such as wheth-
17	er the drug is for import into the United States for use
18	in preclinical research or in a clinical investigation under
19	an investigational new drug exemption under 505(i).
20	"(B) In promulgating the regulations implementing
21	this subsection, the Secretary shall—
22	"(i) issue a notice of proposed rulemaking that
23	includes the proposed regulation;
24	"(ii) provide a period of not less than 60 days
25	for comments on the proposed regulation; and

1	"(iii) publish the final regulation not less than
2	30 days before the effective date of the regulation.
3	"(C) Notwithstanding any other provision of law, the
4	Secretary shall promulgate regulations implementing this
5	subsection only as described in subparagraph (B).".
6	SEC. 712. NOTIFICATION.
7	(a) Prohibited Acts.—Section 301 (21 U.S.C.
8	331) is amended by adding at the end the following:
9	"(aaa) The failure to notify the Secretary in violation
10	of section 568.".
11	(b) Notification.—
12	(1) In general.—Subchapter E of chapter V
13	(21 U.S.C. 360bbb et seq.) is amended by adding at
14	the end the following:
15	"SEC. 568. NOTIFICATION.
16	"(a) Notification to Secretary.—With respect
17	to a drug, the Secretary may require notification to the
18	Secretary by a covered person if the covered person
19	knows—
20	"(1) of a substantial loss or theft of such drug;
21	or
22	"(2) that such drug—
23	"(A) has been or is being counterfeited;
24	and

1	"(B)(i) is the counterfeit product in com-
2	merce in the United States; or
3	"(ii) is offered for import into the United
4	States.
5	"(b) Manner of Notification.—Notification
6	under this section shall be made in a reasonable time, in
7	such reasonable manner, and by such reasonable means
8	as the Secretary may require by regulation or specify in
9	guidance.
10	"(c) Definition.—In this section, the term 'covered
11	person' means—
12	"(1) a person who is required to register under
13	section 510 with respect to an establishment en-
14	gaged in the manufacture, preparation, propagation
15	compounding, or processing of a drug; or
16	"(2) a person engaged in the wholesale distribu-
17	tion (as defined in section 503(e)(3)(B)) of a drug."
18	(2) Applicability.—Notifications under sec-
19	tion 568 of the Federal Food, Drug, and Cosmetic
20	Act (as added by paragraph (1)) apply to losses
21	thefts, or counterfeiting, as described in subsection
22	(a) of such section 568, that occur on or after the
23	date of enactment of this Act.

## 1 SEC. 713. DESTRUCTION OF UNSAFE DRUGS.

- 2 (a) In General.—The sixth sentence of section
- 3 801(a) (21 U.S.C. 381(a)) is amended by inserting before
- 4 the period at the end the following: ", except that the Sec-
- 5 retary of Health and Human Services, in collaboration
- 6 with the Secretary of Homeland Security, may cause the
- 7 destruction, without the opportunity for export, of any
- 8 drug refused admission that has reasonable probability of
- 9 causing serious adverse health consequences or death to
- 10 humans or animals, as determined by the Secretary of
- 11 Health and Human Services, or that is valued at an
- 12 amount that is \$2,000 or less (or such higher amount as
- 13 the Secretary of Homeland Security may set by regulation
- 14 pursuant to section 1498 of title 19, United States
- 15 Code)".
- 16 (b) Notice.—Subsection (a) of section 801 (21
- 17 U.S.C. 381), as amended by subsection (a), is further
- 18 amended by inserting after the sixth sentence the fol-
- 19 lowing: "The Secretary of Health and Human Services
- 20 shall issue regulations providing for notice and an oppor-
- 21 tunity to appear before the Secretary of Health and
- 22 Human Services and introduce testimony, as described in
- 23 the first sentence of this subsection, on destruction of a
- 24 drug under the sixth sentence of this subsection. The regu-
- 25 lations shall provide notice and an opportunity for an in-

- 1 formal hearing to the owner or consignee before the de-
- 2 struction occurs.".
- 3 (c) APPLICABILITY.—The amendment made by sub-
- 4 section (a) shall apply beginning on the effective date of
- 5 the regulations promulgated under the amendment made
- 6 by subsection (b).

### 7 SEC. 714. PROTECTION AGAINST INTENTIONAL ADULTERA-

- 8 TION.
- 9 Section 303(b) (21 U.S.C. 333(b)) is amended by
- 10 adding at the end the following:
- 11 "(7) Notwithstanding subsection (a)(2), any person
- 12 that knowingly and intentionally adulterates a drug such
- 13 that the drug is adulterated under subsection (a)(1), (b),
- 14 (c), or (d) of section 501 and has a reasonable probability
- 15 of causing serious adverse health consequences or death
- 16 to humans or animals shall be imprisoned for not more
- 17 than 20 years or fined not more than \$1,000,000, or
- 18 both.".

#### 19 SEC. 715. ENHANCED CRIMINAL PENALTY FOR COUNTER-

- 20 **FEITING DRUGS.**
- 21 Section 303(b) (21 U.S.C. 333(b)), as amended by
- 22 section 714, is further amended by adding at the end the
- 23 following:
- 24 "(8) Notwithstanding subsection (a)(2), any person
- 25 who knowingly and intentionally violates section 301(i)

- 1 shall be imprisoned for not more than 20 years or fined
- 2 not more than \$4,000,000 or both.".
- 3 SEC. 716. EXTRATERRITORIAL JURISDICTION.
- 4 Chapter III (21 U.S.C. 331 et seq.) is amended by
- 5 adding at the end the following:
- 6 "SEC. 311. EXTRATERRITORIAL JURISDICTION.
- 7 "There is extraterritorial jurisdiction over any viola-
- 8 tion of this Act relating to any article regulated under this
- 9 Act if such article was intended for import into the United
- 10 States or if any act in furtherance of the violation was
- 11 committed in the United States.".
- 12 SEC. 717. COMPLIANCE WITH INTERNATIONAL AGREE-
- 13 MENTS.
- 14 The provisions of this title (and the amendments
- 15 made by this title) shall be applied in a manner that the
- 16 Secretary of Health and Human Services, in consultation
- 17 with the United States Trade Representative, considers
- 18 necessary to comply with the obligations of the United
- 19 States under international agreements.

# 20 TITLE VIII—GENERATING

# 21 ANTIBIOTIC INCENTIVES NOW

- 22 SEC. 801. EXTENSION OF EXCLUSIVITY PERIOD FOR DRUGS.
- 23 (a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.)
- 24 is amended by inserting after section 505D the following:

1	"SEC. 505E. EXTENSION OF EXCLUSIVITY PERIOD FOR NEW
2	QUALIFIED INFECTIOUS DISEASE PRODUCTS.
3	"(a) Extension.—If the Secretary approves an ap-
4	plication pursuant to section 505 for a drug that has been
5	designated as a qualified infectious disease product under
6	subsection (d), the 4- and 5-year periods described in sub-
7	sections $(c)(3)(E)(ii)$ and $(j)(5)(F)(ii)$ of section 505, the
8	3-year periods described in clauses (iii) and (iv) of sub-
9	section (c)(3)(E) and clauses (iii) and (iv) of subsection
10	(j)(5)(F) of section 505, or the 7-year period described
11	in section 527, as applicable, shall be extended by 5 years.
12	"(b) Relation to Pediatric Exclusivity.—Any
13	extension under subsection (a) of a period shall be in addi-
14	tion to any extension of the period under section 505A
15	with respect to the drug.
16	"(c) Limitations.—Subsection (a) does not apply to
17	the approval of—
18	"(1) a supplement to an application under sec-
19	tion 505(b) for any qualified infectious disease prod-
20	uct for which an extension described in subsection
21	(a) is in effect or has expired;
22	"(2) a subsequent application filed with respect
23	to a product approved under section 505 for a
24	change that results in a new indication, route of ad-
25	ministration, dosing schedule, dosage form, delivery
26	system, delivery device, or strength; or

1	"(3) an application for a product that is not ap-
2	proved for the use for which it received a designa-
3	tion under subsection (d).
4	"(d) Designation.—
5	"(1) In general.—The manufacturer or spon-
6	sor of a drug may request the Secretary to designate
7	a drug as a qualified infectious disease product at
8	any time before the submission of an application
9	under section 505(b) for such drug. The Secretary
10	shall, not later than 60 days after the submission of
11	such a request, determine whether the drug is a
12	qualified infectious disease product.
13	"(2) Limitation.—Except as provided in para-
14	graph (3), a designation under this subsection shall
15	not be withdrawn for any reason, including modifica-
16	tions to the list of qualifying pathogens under sub-
17	section $(f)(2)(C)$ .
18	"(3) Revocation of Designation.—The Sec-
19	retary may revoke a designation of a drug as a
20	qualified infectious disease product if the Secretary
21	finds that the request for such designation contained
22	an untrue statement of material fact.
23	"(e) Regulations.—
24	"(1) In general.—Not later than 2 years
25	after the date of enactment of the Food and Drug

1	Administration Safety and Innovation Act, the Sec-
2	retary shall adopt final regulations implementing
3	this section.
4	"(2) Procedure.—In promulgating a regula-
5	tion implementing this section, the Secretary shall—
6	"(A) issue a notice of proposed rulemaking
7	that includes the proposed regulation;
8	"(B) provide a period of not less than 60
9	days for comments on the proposed regulation;
10	and
11	"(C) publish the final regulation not less
12	than 30 days before the effective date of the
13	regulation.
14	"(3) Restrictions.—Notwithstanding any
15	other provision of law, the Secretary shall promul-
16	gate regulations implementing this section only as
17	described in paragraph (2), except that the Sec-
18	retary may issue interim guidance for sponsors seek-
19	ing designation under subsection (d) prior to the
20	promulgation of such regulations.
21	"(4) Designation prior to regulations.—
22	The Secretary may designate drugs as qualified in-
23	fectious disease products under subsection (d) prior
24	to the promulgation of regulations under this sub-
25	section.

1	"(f) Qualifying Pathogen.—
2	"(1) Definition.—In this section, the term
3	'qualifying pathogen' means a pathogen identified
4	and listed by the Secretary under paragraph (2) that
5	has the potential to pose a serious threat to public
6	health, such as—
7	"(A) resistant gram positive pathogens, in-
8	cluding methicillin-resistant Staphylococcus
9	aureus, vancomycin-resistant Staphylococcus
10	aureus, and vancomycin-resistant enterococcus;
11	"(B) multi-drug resistant gram negative
12	bacteria, including Acinetobacter, Klebsiella,
13	Pseudomonas, and E. coli species;
14	"(C) multi-drug resistant tuberculosis; and
15	"(D) Clostridium difficile.
16	"(2) List of qualifying pathogens.—
17	"(A) IN GENERAL.—The Secretary shall
18	establish and maintain a list of qualifying
19	pathogens, and shall make public the method-
20	ology for developing such list.
21	"(B) Considerations.—In establishing
22	and maintaining the list of pathogens described
23	under this section the Secretary shall—
24	"(i) consider—

1	"(I) the impact on the public
2	health due to drug-resistant orga-
3	nisms in humans;
4	"(II) the rate of growth of drug-
5	resistant organisms in humans;
6	"(III) the increase in resistance
7	rates in humans; and
8	"(IV) the morbidity and mor-
9	tality in humans; and
10	"(ii) consult with experts in infectious
11	diseases and antibiotic resistance, includ-
12	ing the Centers for Disease Control and
13	Prevention, the Food and Drug Adminis-
14	tration, medical professionals, and the clin-
15	ical research community.
16	"(C) Review.—Every 5 years, or more
17	often as needed, the Secretary shall review, pro-
18	vide modifications to, and publish the list of
19	qualifying pathogens under subparagraph (A)
20	and shall by regulation revise the list as nec-
21	essary, in accordance with subsection (e).
22	"(g) Qualified Infectious Disease Product.—
23	The term 'qualified infectious disease product' means an
24	antibacterial or antifungal drug for human use intended

- 1 to treat serious or life-threatening infections, including
- 2 those caused by—
- 3 "(1) an antibacterial or antifungal resistant
- 4 pathogen, including novel or emerging infectious
- 5 pathogens; or
- 6 "(2) qualifying pathogens listed by the Sec-
- 7 retary under subsection (f).".
- 8 (b) Application.—Section 505E of the Federal
- 9 Food, Drug, and Cosmetic Act, as added by subsection
- 10 (a), applies only with respect to a drug that is first ap-
- 11 proved under section 505(c) of such Act (21 U.S.C.
- 12 355(c)) on or after the date of the enactment of this Act.
- 13 SEC. 802. PRIORITY REVIEW.
- 14 (a) AMENDMENT.—Chapter V (21 U.S.C. 351 et
- 15 seq.) is amended by inserting after section 524 the fol-
- 16 lowing:
- 17 "SEC. 524A. PRIORITY REVIEW FOR QUALIFIED INFECTIOUS
- 18 **DISEASE PRODUCTS.**
- 19 "If the Secretary designates a drug under section
- 20 505E(d) as a qualified infectious disease product, then the
- 21 Secretary shall give priority review to any application sub-
- 22 mitted for approval for such drug under section 505(b).".
- 23 (b) Application.—Section 524A of the Federal
- 24 Food, Drug, and Cosmetic Act, as added by subsection
- 25 (a), applies only with respect to an application that is sub-

1	mitted under section 505(b) of such Act (21 U.S.C
2	355(b)) on or after the date of the enactment of this Act
3	SEC. 803. FAST TRACK PRODUCT.
4	Section 506(a)(1) (21 U.S.C. 356(a)(1)), as amended
5	by section 901(b), is amended by inserting ", or if the
6	Secretary designates the drug as a qualified infectious dis-
7	ease product under section 505E(d)" before the period at
8	the end of the first sentence.
9	SEC. 804. GAO STUDY.
10	(a) In General.—The Comptroller General of the
11	United States shall—
12	(1) conduct a study—
13	(A) on the need for, and public impact of
14	incentives to encourage the research, develop-
15	ment, and marketing of qualified infectious dis-
16	ease biological products and antifungal prod-
17	ucts; and
18	(B) consistent with trade and confiden-
19	tiality data protections, assessing, for all anti-
20	bacterial and antifungal drugs, including bio-
21	logical products, the average or aggregate—
22	(i) costs of all clinical trials for each
23	phase;
24	(ii) percentage of success or failure at
25	each phase of clinical trials; and

1	(iii) public versus private funding lev-
2	els of the trials for each phase; and
3	(2) not later than 1 year after the date of en-
4	actment of this Act, submit a report to Congress or
5	the results of such study, including any rec-
6	ommendations of the Comptroller General on appro-
7	priate incentives for addressing such need.
8	(b) CONTENTS.—The part of the study described in
9	subsection (a)(1)(A) shall include—
10	(1) an assessment of any underlying regulatory
11	issues related to qualified infectious disease prod-
12	ucts, including qualified infectious disease biological
13	products;
14	(2) an assessment of the management by the
15	Food and Drug Administration of the review of
16	qualified infectious disease products, including quali-
17	fied infectious disease biological products and the
18	regulatory certainty of related regulatory pathways
19	for such products;
20	(3) a description of any regulatory impediments
21	to the clinical development of new qualified infec-
22	tious disease products, including qualified infectious
23	disease biological products, and the efforts of the
24	Food and Drug Administration to address such im-
25	pediments; and

1	(4) recommendations with respect to—
2	(A) improving the review and predictability
3	of regulatory pathways for such products; and
4	(B) overcoming any regulatory impedi-
5	ments identified in paragraph (3).
6	(c) Definitions.—In this section:
7	(1) The term "biological product" has the
8	meaning given to such term in section 351 of the
9	Public Health Service Act (42 U.S.C. 262).
10	(2) The term "qualified infectious disease bio-
11	logical product" means a biological product intended
12	to treat a serious or life-threatening infection de-
13	scribed in section 505E(g) of the Federal Food
14	Drug, and Cosmetic Act, as added by section 801.
15	(3) The term "qualified infectious disease prod-
16	uct" has the meaning given such term in section
17	505E(g) of the Federal Food, Drug, and Cosmetic
18	Act, as added by section 801.
19	SEC. 805. CLINICAL TRIALS.
20	(a) Review and Revision of Guidance Docu-
21	MENTS.—
22	(1) In General.—The Secretary of Health and
23	Human Services (referred to in this section as the
24	"Secretary") shall review and, as appropriate, revise

1	not fewer than 3 guidance documents per year.
2	which shall include—
3	(A) reviewing the guidance documents of
4	the Food and Drug Administration for the con-
5	duct of clinical trials with respect to antibiotic
6	and antifungal drugs; and
7	(B) as appropriate, revising such guidance
8	documents to reflect developments in scientific
9	and medical information and technology and to
10	ensure clarity regarding the procedures and re-
11	quirements for approval of antibiotic and
12	antifungal drugs under chapter V of the Fed-
13	eral Food, Drug, and Cosmetic Act (21 U.S.C.
14	351 et seq.).
15	(2) Issues for review.—At a minimum, the
16	review under paragraph (1) shall address the appro-
17	priate animal models of infection, in vitro tech-
18	niques, valid micro-biological surrogate markers, the
19	use of non-inferiority versus superiority trials, trial
20	enrollment, data requirements, and appropriate delta
21	values for non-inferiority trials.
22	(3) Rule of construction.—Except to the
23	extent to which the Secretary makes revisions under
24	paragraph (1)(B), nothing in this section shall be

1 construed to repeal or otherwise affect the guidance 2 documents of the Food and Drug Administration.

### (b) Recommendations for Investigations.—

(1) Request.—The sponsor of a drug intended to be designated as a qualified infectious disease product may request that the Secretary provide written recommendations for nonclinical and clinical investigations which the Secretary believes may be necessary to be conducted with the drug before such drug may be approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in treating, detecting, preventing, or identifying a qualifying pathogen, as defined in section 505E of such Act.

(2) RECOMMENDATIONS.—If the Secretary has reason to believe that a drug for which a request is made under this subsection is a qualified infectious disease product, the Secretary shall provide the person making the request written recommendations for the nonclinical and clinical investigations which the Secretary believes, on the basis of information available to the Secretary at the time of the request, would be necessary for approval under section 505 of the Federal Food, Drug, and Cosmetic Act (21)

1	U.S.C. 355) of such drug for the use described in
2	paragraph (1).
3	(c) GAO STUDY.—Not later than January 1, 2016
4	the Comptroller General of the United States shall submit
5	to Congress a report—
6	(1) regarding the review and revision of the
7	clinical trial guidance documents required under
8	subsection (a) and the impact such review and revi-
9	sion has had on the review and approval of qualified
10	infectious disease products;
11	(2) assessing—
12	(A) the effectiveness of the results-oriented
13	metrics managers employ to ensure that review-
14	ers of such products are familiar with, and con-
15	sistently applying, clinical trial guidance docu-
16	ments; and
17	(B) the predictability of related regulatory
18	pathways and review;
19	(3) identifying any outstanding regulatory im-
20	pediments to the clinical development of qualified in-
21	fectious disease products;
22	(4) reporting on the progress the Food and
23	Drug Administration has made in addressing the im-
24	pediments identified under paragraph (3); and

1	(5) containing recommendations regarding how
2	to improve the review of, and regulatory pathway
3	for, such products.
4	(d) Qualified Infectious Disease Product.—
5	For purposes of this section, the term "qualified infectious
6	disease product" has the meaning given such term in sec-
7	tion 505E(g) of the Federal Food, Drug, and Cosmetic
8	Act, as added by section 801.
9	SEC. 806. REGULATORY CERTAINTY AND PREDICTABILITY.
10	(a) Initial Strategy and Implementation
11	PLAN.—Not later than 1 year after the date of enactment
12	of this Act, the Secretary of Health and Human Services
13	(referred to in this section as the "Secretary") shall sub-
14	mit to Congress a strategy and implementation plan with
15	respect to the requirements of this Act. The strategy and
16	implementation plan shall include—
17	(1) a description of the regulatory challenges to
18	clinical development, approval, and licensure of
19	qualified infectious disease products;
20	(2) the regulatory and scientific priorities of the
21	Secretary with respect to such challenges; and
22	(3) the steps the Secretary will take to ensure
23	regulatory certainty and predictability with respect
24	to qualified infectious disease products, including
25	steps the Secretary will take to ensure managers and

1	reviewers are familiar with related regulatory path-
2	ways, requirements of the Food and Drug Adminis-
3	tration, guidance documents related to such prod-
4	ucts, and applying such requirements consistently.
5	(b) Subsequent Report.—Not later than 3 years
6	after the date of enactment of this Act, the Secretary shall
7	submit to Congress a report on—
8	(1) the progress made toward the priorities
9	identified under subsection (a)(2);
10	(2) the number of qualified infectious disease
11	products that have been submitted for approval or li-
12	censure on or after the date of enactment of this
13	Act;
14	(3) a list of qualified infectious disease products
15	with information on the types of exclusivity granted
16	for each product, consistent with the information
17	published under section $505(j)(7)(A)(iii)$ of the Fed-
18	eral Food, Drug, and Cosmetic Act (21 U.S.C.
19	355(j)(7)(A)(iii));
20	(4) the number of such qualified infectious dis-
21	ease products and that have been approved or li-
22	censed on or after the date of enactment of this Act;
23	and
24	(5) the number of calendar days it took for the
25	approval or licensure of the qualified infectious dis-

1	ease products approved or licensed on or after the
2	date of enactment of this Act.
3	(c) Qualified Infectious Disease Product.—
4	For purposes of this section, the term "qualified infectious
5	disease product" has the meaning given such term in sec-
6	tion 505E(g) of the Federal Food, Drug, and Cosmetic
7	Act, as added by section 801.
8	TITLE IX—DRUG APPROVAL AND
9	PATIENT ACCESS
10	SEC. 901. ENHANCEMENT OF ACCELERATED PATIENT AC-
11	CESS TO NEW MEDICAL TREATMENTS.
12	(a) Findings; Sense of Congress.—
13	(1) FINDINGS.—Congress finds as follows:
14	(A) The Food and Drug Administration
15	(referred to in this section as the "FDA")
16	serves a critical role in helping to assure that
17	new medicines are safe and effective. Regu-
18	latory innovation is 1 element of the Nation's
19	strategy to address serious and life-threatening
20	diseases or conditions by promoting investment
21	in and development of innovative treatments for
22	unmet medical needs.
23	(B) During the 2 decades following the es-
24	tablishment of the accelerated approval mecha-
25	nism, advances in medical sciences, including

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genomics, molecular biology, and bioinformatics, have provided an unprecedented understanding of the underlying biological mechanism and pathogenesis of disease. A new generation of modern, targeted medicines is under development to treat serious and life-threatening diseases, some applying drug development strategies based on biomarkers or pharmacogenomics, predictive toxicology, clinical trial enrichment techniques, and novel clinical trial designs, such as adaptive clinical trials.

entific and medical advances, the FDA should be encouraged to implement more broadly effective processes for the expedited development and review of innovative new medicines intended to address unmet medical needs for serious or life-threatening diseases or conditions, including those for rare diseases or conditions, using a broad range of surrogate or clinical endpoints and modern scientific tools earlier in the drug development cycle when appropriate. This may result in fewer, smaller, or shorter clinical trials for the intended patient population or targeted subpopulation without com-

1	promising or altering the high standards of the
2	FDA for the approval of drugs.
3	(D) Patients benefit from expedited access
4	to safe and effective innovative therapies to
5	treat unmet medical needs for serious or life-
6	threatening diseases or conditions.
7	(E) For these reasons, the statutory au-
8	thority in effect on the day before the date of
9	enactment of this Act governing expedited ap-
10	proval of drugs for serious or life-threatening
11	diseases or conditions should be amended in
12	order to enhance the authority of the FDA to
13	consider appropriate scientific data, methods,
14	and tools, and to expedite development and ac-
15	cess to novel treatments for patients with a
16	broad range of serious or life-threatening dis-
17	eases or conditions.
18	(2) Sense of congress.—It is the sense of
19	Congress that the Food and Drug Administration
20	should apply the accelerated approval and fast track
21	provisions set forth in section 506 of the Federal
22	Food, Drug, and Cosmetic Act (21 U.S.C. 356), as
23	amended by this section, to help expedite the devel-
24	opment and availability to patients of treatments for
25	serious or life-threatening diseases or conditions

1	while maintaining safety and effectiveness standards
2	for such treatments.
3	(b) Expedited Approval of Drugs for Serious
4	OR LIFE-THREATENING DISEASES OR CONDITIONS.—Sec-
5	tion 506 (21 U.S.C. 356) is amended to read as follows:
6	"SEC. 506. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS
7	OR LIFE-THREATENING DISEASES OR CONDI-
8	TIONS.
9	"(a) Designation of Drug as Fast Track Prod-
10	UCT.—
11	"(1) IN GENERAL.—The Secretary shall, at the
12	request of the sponsor of a new drug, facilitate the
13	development and expedite the review of such drug if
14	it is intended, whether alone or in combination with
15	one or more other drugs, for the treatment of a seri-
16	ous or life-threatening disease or condition, and it
17	demonstrates the potential to address unmet medical
18	needs for such a disease or condition. (In this sec-
19	tion, such a drug is referred to as a 'fast track prod-
20	uct'.)
21	"(2) Request for designation.—The spon-
22	sor of a new drug may request the Secretary to des-
23	ignate the drug as a fast track product. A request
24	for the designation may be made concurrently with
25	or at any time after, submission of an application

1	for the investigation of the drug under section 505(i)
2	or section 351(a)(3) of the Public Health Service
3	Act.
4	"(3) Designation.—Within 60 calendar days
5	after the receipt of a request under paragraph (2),
6	the Secretary shall determine whether the drug that
7	is the subject of the request meets the criteria de-
8	scribed in paragraph (1). If the Secretary finds that
9	the drug meets the criteria, the Secretary shall des-
10	ignate the drug as a fast track product and shall
11	take such actions as are appropriate to expedite the
12	development and review of the application for ap-
13	proval of such product.
14	"(b) Accelerated Approval of a Drug for a
15	SERIOUS OR LIFE-THREATENING DISEASE OR CONDI-
16	TION, INCLUDING A FAST TRACK PRODUCT.—
17	"(1) In general.—
18	"(A) ACCELERATED APPROVAL.—The Sec-
19	retary may approve an application for approval
20	of a product for a serious or life-threatening
21	disease or condition, including a fast track
22	product, under section 505(c) or section 351(a)
23	of the Public Health Service Act upon a deter-
24	mination that the product has an effect on a
25	surrogate endpoint that is reasonably likely to

1	predict clinical benefit, or on a clinical endpoint
2	that can be measured earlier than irreversible
3	morbidity or mortality, that is reasonably likely
4	to predict an effect on irreversible morbidity or
5	mortality or other clinical benefit, taking into
6	account the severity, rarity, or prevalence of the
7	condition and the availability or lack of alter-
8	native treatments. The approval described in
9	the preceding sentence is referred to in this sec-
10	tion as 'accelerated approval'.
11	"(B) EVIDENCE.—The evidence to support
12	that an endpoint is reasonably likely to predict
13	clinical benefit under subparagraph (A) may in-
14	clude epidemiological, pathophysiological, thera-
15	peutic, pharmacologic, or other evidence devel-
16	oped using biomarkers, for example, or other
17	scientific methods or tools.
18	"(2) Limitation.—Approval of a product
19	under this subsection may be subject to 1 or both
20	of the following requirements:
21	"(A) That the sponsor conduct appropriate
22	post-approval studies to verify and describe the
23	predicted effect on irreversible morbidity or
24	mortality or other clinical benefit.

1	"(B) That the sponsor submit copies of all
2	promotional materials related to the product
3	during the preapproval review period and, fol-
4	lowing approval and for such period thereafter
5	as the Secretary determines to be appropriate,
6	at least 30 days prior to dissemination of the
7	materials.
8	"(3) Expedited withdrawal of Ap-
9	PROVAL.—The Secretary may withdraw approval of
10	a product approved under accelerated approval using
11	expedited procedures (as prescribed by the Secretary
12	in regulations which shall include an opportunity for
13	an informal hearing) if—
14	"(A) the sponsor fails to conduct any re-
15	quired post-approval study of the drug with due
16	diligence;
17	"(B) a study required to verify and de-
18	scribe the predicted effect on irreversible mor-
19	bidity or mortality or other clinical benefit of
20	the product fails to verify and describe such ef-
21	fect or benefit;
22	"(C) other evidence demonstrates that the
23	product is not safe or effective under the condi-
24	tions of use; or

1	"(D) the sponsor disseminates false or
2	misleading promotional materials with respect
3	to the product.
4	"(c) Review of Incomplete Applications for
5	APPROVAL OF A FAST TRACK PRODUCT.—
6	"(1) In General.—If the Secretary deter-
7	mines, after preliminary evaluation of clinical data
8	submitted by the sponsor, that a fast track product
9	may be effective, the Secretary shall evaluate for fil-
10	ing, and may commence review of portions of, an ap-
11	plication for the approval of the product before the
12	sponsor submits a complete application. The Sec-
13	retary shall commence such review only if the appli-
14	eant—
15	"(A) provides a schedule for submission of
16	information necessary to make the application
17	complete; and
18	"(B) pays any fee that may be required
19	under section 736.
20	"(2) Exception.—Any time period for review
21	of human drug applications that has been agreed to
22	by the Secretary and that has been set forth in goals
23	identified in letters of the Secretary (relating to the
24	use of fees collected under section 736 to expedite
25	the drug development process and the review of

1 human drug applications) shall not apply to an ap-2 plication submitted under paragraph (1) until the 3 date on which the application is complete. "(d) AWARENESS EFFORTS.—The Secretary shall— 4 5 "(1) develop and disseminate to physicians, pa-6 tient organizations, pharmaceutical and bio-7 technology companies, and other appropriate persons 8 a description of the provisions of this section appli-9 cable to accelerated approval and fast track prod-10 ucts; and 11 "(2) establish a program to encourage the de-12 velopment of surrogate and clinical endpoints, in-13 cluding biomarkers, and other scientific methods and 14 tools that can assist the Secretary in determining 15 whether the evidence submitted in an application is 16 reasonably likely to predict clinical benefit for seri-17 ous or life-threatening conditions for which signifi-18 cant unmet medical needs exist. 19 "(e) Construction.— 20 "(1) Purpose.—The amendments made by the 21 Food and Drug Administration Safety and Innova-22 tion Act to this section are intended to encourage 23 the Secretary to utilize innovative and flexible ap-24 proaches to the assessment of products under accel-25 erated approval for treatments for patients with seriKER12278 S.L.C.

ous or life-threatening diseases or conditions and unmet medical needs.

"(2) Construction.—Nothing in this section shall be construed to alter the standards of evidence under subsection (c) or (d) of section 505 (including the substantial evidence standard in section 505(d)) of this Act or under section 351(a) of the Public Health Service Act. Such sections and standards of evidence apply to the review and approval of products under this section, including whether a product is safe and effective. Nothing in this section alters the ability of the Secretary to rely on evidence that does not come from adequate and well-controlled investigations for the purpose of determining whether an endpoint is reasonably likely to predict clinical benefit as described in subsection (b)(1)(B).".

### (c) Guidance; Amended Regulations.—

(1) DRAFT GUIDANCE.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall issue draft guidance to implement the amendments made by this section. In developing such guidance, the Secretary shall specifically consider issues arising under the accelerated approval and fast track processes

under section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b), for drugs designated for a rare disease or condition under section 526 of such Act (21 U.S.C. 360bb) and shall also consider any unique issues associated with very rare diseases.

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- (2) FINAL GUIDANCE.—Not later than 1 year after the issuance of draft guidance under paragraph (1), and after an opportunity for public comment, the Secretary shall issue final guidance.
- (3) Conforming changes.—The Secretary shall issue, as necessary, conforming amendments to the applicable regulations under title 21, Code of Federal Regulations, governing accelerated approval.
- (4) No effect of inaction on requests.—

  If the Secretary fails to issue final guidance or amended regulations as required by this subsection, such failure shall not preclude the review of, or action on, a request for designation or an application for approval submitted pursuant to section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b).
- 23 (d) INDEPENDENT REVIEW.—The Secretary may, in 24 conjunction with other planned reviews, contract with an 25 independent entity with expertise in assessing the quality

and efficiency of biopharmaceutical development and regu-2 latory review programs to evaluate the Food and Drug Ad-3 ministration's application of the processes described in 4 section 506 of the Federal Food, Drug, and Cosmetic Act, 5 as amended by subsection (b), and the impact of such 6 processes on the development and timely availability of innovative treatments for patients suffering from serious or 8 life-threatening conditions. Any such evaluation shall in-9 clude consultation with regulated industries, patient advo-10 cacy and disease research foundations, and relevant aca-11 demic medical centers. 12 SEC. 902. BREAKTHROUGH THERAPIES. 13 (a) IN GENERAL.—Section 506 (21 U.S.C. 356), as 14 amended by section 901, is further amended— 15 (1) by redesignating subsections (a) through (c) 16 as subsections (b) through (d), respectively; 17 (2) by redesignating subsection (d) as sub-18 section (f); 19 (3) by inserting before subsection (b), as so re-20 designated, the following: 21 "(a) Designation of a Drug as a Breakthrough 22 THERAPY.— 23 "(1) IN GENERAL.—The Secretary shall, at the 24 request of the sponsor of a drug, expedite the devel-25 opment and review of such drug if the drug is inKER12278 S.L.C.

tended, 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

1	drug as a breakthrough therapy and shall take
2	such actions as are appropriate to expedite the
3	development and review of the application for
4	approval of such drug.
5	"(B) Actions.—The actions to expedite
6	the development and review of an application
7	under subparagraph (A) may include, as appro-
8	priate—
9	"(i) holding meetings with the sponsor
10	and the review team throughout the devel-
11	opment of the drug;
12	"(ii) providing timely advice to, and
13	interactive communication with, the spon-
14	sor regarding the development of the drug
15	to ensure that the development program to
16	gather the non-clinical and clinical data
17	necessary for approval is as efficient as
18	practicable;
19	"(iii) involving senior managers and
20	experienced review staff, as appropriate, in
21	a collaborative, cross-disciplinary review;
22	"(iv) assigning a cross-disciplinary
23	project lead for the Food and Drug Ad-
24	ministration review team to facilitate an
25	efficient review of the development pro-

1	gram and to serve as a scientific liaison be-
2	tween the review team and the sponsor;
3	and
4	"(v) taking steps to ensure that the
5	design of the clinical trials is as efficient as
6	practicable, when scientifically appropriate,
7	such as by minimizing the number of pa-
8	tients exposed to a potentially less effica-
9	cious treatment.";
10	(4) in subsection (f)(1), as so redesignated, by
11	striking "applicable to accelerated approval" and in-
12	serting "applicable to breakthrough therapies, accel-
13	erated approval, and"; and
14	(5) by adding at the end the following:
15	"(g) Report.—Beginning in fiscal year 2013, the
16	Secretary shall annually prepare and submit to the Com-
17	mittee on Health, Education, Labor, and Pensions of the
18	Senate and the Committee on Energy and Commerce of
19	the House of Representatives, and make publicly available,
20	with respect to this section for the previous fiscal year—
21	"(1) the number of drugs for which a sponsor
22	requested designation as a breakthrough therapy;
23	"(2) the number of products designated as a
24	breakthrough therapy; and

1	(3) for each product designated as a break-
2	through therapy, a summary of the actions taken
3	under subsection (a)(3).".
4	(b) Guidance; Amended Regulations.—
5	(1) In general.—
6	(A) GUIDANCE.—Not later than 18
7	months after the date of enactment of this Act,
8	the Secretary of Health and Human Services
9	(referred to in this section as the "Secretary")
10	shall issue draft guidance on implementing the
11	requirements with respect to breakthrough
12	therapies, as set forth in section 506(a) of the
13	Federal Food, Drug, and Cosmetic Act (21
14	U.S.C. 356(a)), as amended by this section.
15	The Secretary shall issue final guidance not
16	later than 1 year after the close of the comment
17	period for the draft guidance.
18	(B) Amended regulations.—
19	(i) IN GENERAL.—If the Secretary de-
20	termines that it is necessary to amend the
21	regulations under title 21, Code of Federal
22	Regulations in order to implement the
23	amendments made by this section to sec-
24	tion 506(a) of the Federal Food, Drug,
25	and Cosmetic Act, the Secretary shall

1	amend such regulations not later than 2
2	years after the date of enactment of this
3	Act.
4	(ii) Procedure.—In amending regu-
5	lations under clause (i), the Secretary
6	shall—
7	(I) issue a notice of proposed
8	rulemaking that includes the proposed
9	regulation;
10	(II) provide a period of not less
11	than 60 days for comments on the
12	proposed regulation; and
13	(III) publish the final regulation
14	not less than 30 days before the effec-
15	tive date of the regulation.
16	(iii) Restrictions.—Notwithstanding
17	any other provision of law, the Secretary
18	shall promulgate regulations implementing
19	the amendments made by section only as
20	described in clause (ii).
21	(2) Requirements.—Guidance issued under
22	this section shall—
23	(A) specify the process and criteria by
24	which the Secretary makes a designation under

1	section 506(a)(3) of the Federal Food, Drug
2	and Cosmetic Act; and
3	(B) specify the actions the Secretary shall
4	take to expedite the development and review of
5	a breakthrough therapy pursuant to such des-
6	ignation under such section 506(a)(3), includ-
7	ing updating good review management practices
8	to reflect breakthrough therapies.
9	(c) Independent Review.—Not later than 3 years
10	after the date of enactment of this Act, the Comptroller
11	General of the United States, in consultation with appro-
12	priate experts, shall assess the manner by which the Food
13	and Drug Administration has applied the processes de-
14	scribed in section 506(a) of the Federal Food, Drug, and
15	Cosmetic Act, as amended by this section, and the impact
16	of such processes on the development and timely avail-
17	ability of innovative treatments for patients affected by se-
18	rious or life-threatening conditions. Such assessment shall
19	be made publicly available upon completion.
20	(d) Conforming Amendments.—Section 506B(e)
21	(21 U.S.C. 356b) is amended by striking "section
22	506(b)(2)(A)" each place such term appears and inserting
23	"section 506(c)(2)(A)".

1	SEC. 903. CONSULTATION WITH EXTERNAL EXPERTS ON
2	RARE DISEASES, TARGETED THERAPIES, AND
3	GENETIC TARGETING OF TREATMENTS.
4	Subchapter E of chapter V (21 U.S.C. 360bbb et
5	seq.), as amended by section 712, is further amended by
6	adding at the end the following:
7	"SEC. 569. CONSULTATION WITH EXTERNAL EXPERTS ON
8	RARE DISEASES, TARGETED THERAPIES, AND
9	GENETIC TARGETING OF TREATMENTS.
10	"(a) In General.—For the purpose of promoting
11	the efficiency of and informing the review by the Food
12	and Drug Administration of new drugs and biological
13	products for rare diseases and drugs and biological prod-
14	ucts that are genetically targeted, the following shall
15	apply:
16	"(1) Consultation with stakeholders.—
17	Consistent with sections X.C and IX.E.4 of the
18	PDUFA Reauthorization Performance Goals and
19	Procedures Fiscal Years 2013 through 2017, as ref-
20	erenced in the letters described in section 101(b) of
21	the Prescription Drug User Fee Amendments of
22	2012, the Secretary shall ensure that opportunities
23	exist, at a time the Secretary determines appro-
24	priate, for consultations with stakeholders on the
25	topics described in subsection (c).

1	(2) Consultation with external ex-
2	PERTS.—The Secretary shall develop and maintain a
3	list of external experts who, because of their special
4	expertise, are qualified to provide advice on rare dis-
5	ease issues, including topics described in subsection
6	(c). The Secretary may, when appropriate to address
7	a specific regulatory question, consult such external
8	experts on issues related to the review of new drugs
9	and biological products for rare diseases and drugs
10	and biological products that are genetically targeted,
11	including the topics described in subsection (e),
12	when such consultation is necessary because the Sec-
13	retary lacks specific scientific, medical, or technical
14	expertise necessary for the performance of its regu-
15	latory responsibilities and the necessary expertise
16	can be provided by the external experts.
17	"(b) External Experts.—For purposes of sub-
18	section (a)(2), external experts are those who possess sci-
19	entific or medical training that the Secretary lacks with
20	respect to one or more rare diseases.
21	"(c) Topics for Consultation.—Topics for con-
22	sultation pursuant to this section may include—
23	"(1) rare diseases;
24	"(2) the severity of rare diseases:

1	"(3) the unmet medical need associated with
2	rare diseases;
3	"(4) the willingness and ability of individuals
4	with a rare disease to participate in clinical trials;
5	"(5) an assessment of the benefits and risks of
6	therapies to treat rare diseases;
7	"(6) the general design of clinical trials for rare
8	disease populations and subpopulations; and
9	"(7) demographics and the clinical description
10	of patient populations.
11	"(d) Classification as Special Government Em-
12	PLOYEES.—The external experts who are consulted under
13	this section may be considered special government employ-
14	ees, as defined under section 202 of title 18, United States
15	Code.
16	"(e) Protection of Proprietary Informa-
17	TION.—Nothing in this section shall be construed to alter
18	the protections offered by laws, regulations, and policies
19	governing disclosure of confidential commercial or trade
20	secret information, and any other information exempt
21	from disclosure pursuant to section 552(b) of title 5,
22	United States Code, as such provisions would be applied
23	to consultation with individuals and organizations prior to
24	the date of enactment of this section.

1	(f) OTHER CONSULTATION.—Nothing in this sec-
2	tion shall be construed to limit the ability of the Secretary
3	to consult with individuals and organizations as authorized
4	prior to the date of enactment of this section.
5	"(g) No Right or Obligation.—Nothing in this
6	section shall be construed to create a legal right for a con-
7	sultation on any matter or require the Secretary to meet
8	with any particular expert or stakeholder. Nothing in this
9	section shall be construed to alter agreed upon goals and
10	procedures identified in the letters described in section
11	101(b) of the Prescription Drug User Fee Amendments
12	of 2012. Nothing in this section is intended to increase
13	the number of review cycles as in effect before the date
14	of enactment of this section.".
15	SEC. 904. ACCESSIBILITY OF INFORMATION ON PRESCRIP-
16	TION DRUG CONTAINER LABELS BY VIS-
17	UALLY-IMPAIRED AND BLIND CONSUMERS.
18	(a) Establishment of Working Group.—
19	(1) In General.—The Architectural and
20	Transportation Barriers Compliance Board (referred
21	to in this section as the "Access Board") shall con-
22	vene a stakeholder working group (referred to in this
23	section as the "working group") to develop best
24	practices on access to information on prescription

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drug container labels for individuals who are blind or visually impaired.

(2) Members.—The working group shall be comprised of representatives of national organizations representing blind and visually-impaired individuals, national organizations representing the elderly, and industry groups representing stakeholders, including retail, mail order, and independent community pharmacies, who would be impacted by such best practices. Representation within the working group shall be divided equally between consumer and industry advocates.

## (3) Best practices.—

- (A) IN GENERAL.—The working group shall develop, not later than 1 year after the date of the enactment of this Act, best practices for pharmacies to ensure that blind and visually-impaired individuals have safe, consistent, reliable, and independent access to the information on prescription drug container labels.
- (B) PUBLIC AVAILABILITY.—The best practices developed under subparagraph (A) may be made publicly available, including through the Internet Web sites of the working group participant organizations, and through

1	other means, in a manner that provides access
2	to interested individuals, including individuals
3	with disabilities.
4	(C) Limitations.—The best practices de-
5	veloped under subparagraph (A) shall not be
6	construed as accessibility guidelines or stand-
7	ards of the Access Board, and shall not confer
8	any rights or impose any obligations on working
9	group participants or other persons. Nothing in
10	this section shall be construed to limit or condi-
11	tion any right, obligation, or remedy available
12	under the Americans with Disabilities Act of
13	1990 (42 U.S.C. 12101 et seq.) or any other
14	Federal or State law requiring effective commu-
15	nication, barrier removal, or nondiscrimination
16	on the basis of disability.
17	(4) Considerations.—In developing and
18	issuing the best practices under paragraph (3)(A),
19	the working group shall consider—
20	(A) the use of—
21	(i) Braille;
22	(ii) auditory means, such as—
23	(I) "talking bottles" that provide
24	audible container label information;

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1	(II) digital voice recorders at-
2	tached to the prescription drug con-
3	tainer; and
4	(III) radio frequency identifica-
5	tion tags;
6	(iii) enhanced visual means, such as—
7	(I) large font labels or large font
8	"duplicate" labels that are affixed or
9	matched to a prescription drug con-
10	tainer;
11	(II) high-contrast printing; and
12	(III) sans-serf font; and
13	(iv) other relevant alternatives as de-
14	termined by the working group;
15	(B) whether there are technical, financial,
16	manpower, or other factors unique to phar-
17	macies with 20 or fewer retail locations which
18	may pose significant challenges to the adoption
19	of the best practices; and
20	(C) such other factors as the working
21	group determines to be appropriate.
22	(5) Information campaign.—Upon comple-
23	tion of development of the best practices under sub-
24	section (a)(3), the National Council on Disability, in
25	consultation with the working group, shall conduct

- an informational and educational campaign designed to inform individuals with disabilities, pharmacists, and the public about such best practices.
  - (6) FACA WAIVER.—The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the working group.

## (b) GAO STUDY.—

- (1) In General.—Beginning 18 months after the completion of the development of best practices under subsection (a)(3)(A), the Comptroller General of the United States shall conduct a review of the extent to which pharmacies are utilizing such best practices, and the extent to which barriers to accessible information on prescription drug container labels for blind and visually-impaired individuals continue.
- (2) Report.—Not later than September 30, 2016, the Comptroller General of the United States shall submit to Congress a report on the review conducted under paragraph (1). Such report shall include recommendations about how best to reduce the barriers experienced by blind and visually-impaired individuals to independently accessing information on prescription drug container labels.
- (c) Definitions.—In this section—

1	(1) the term "pharmacy" includes a pharmacy
2	that receives prescriptions and dispenses prescription
3	drugs through an Internet Web site or by mail;
4	(2) the term "prescription drug" means a drug
5	subject to section 503(b)(1) of the Federal Food,
6	Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)); and
7	(3) the term "prescription drug container label"
8	means the label with the directions for use that is
9	affixed to the prescription drug container by the
10	pharmacist and dispensed to the consumer.
11	SEC. 905. RISK-BENEFIT FRAMEWORK.
12	Section 505(d) (21 U.S.C. 355(d)) is amended by
13	adding at the end the following: "The Secretary shall im-
14	plement a structured risk-benefit assessment framework
15	in the new drug approval process to facilitate the balanced
16	consideration of benefits and risks, a consistent and sys-
17	tematic approach to the discussion and regulatory deci-
18	sionmaking, and the communication of the benefits and
19	risks of new drugs. Nothing in the preceding sentence
20	shall alter the criteria for evaluating an application for
21	premarket approval of a drug.".
22	SEC. 906. INDEPENDENT STUDY ON MEDICAL INNOVATION
23	INDUCEMENT MODEL.
24	(a) In General.—The Secretary of Health and
25	Human Services shall enter into an agreement with the

1	National Academies to provide expert consultation and
2	conduct a study that evaluates the feasibility and possible
3	consequences of the use of innovation inducement prizes
4	to reward successful medical innovations. Under the
5	agreement, the National Academies shall submit to such
6	Secretary a report on such study not later than 15 months
7	after the date of enactment of this Act.
8	(b) Requirements.—
9	(1) In general.—The study conducted under
10	subsection (a) shall model at least 3 separate seg-
11	ments on the medical technologies market as can-
12	didate targets for the new incentive system and con-
13	sider different medical innovation inducement prize
14	design issues, including the challenges presented in
15	the implementation of prizes for end products, open
16	source dividend prizes, and prizes for upstream re-
17	search.
18	(2) Market segments.—The segments on the
19	medical technologies market that shall be considered
20	under paragraph (1) include—
21	(A) all pharmaceutical and biologic drugs
22	and vaccines;
23	(B) drugs and vaccines used solely for the
24	treatment of HIV/AIDS; and
25	(C) antibiotics.

1	(c) Elements.—The study conducted under sub-
2	section (a) shall include consideration of each of the fol-
3	lowing:
4	(1) Whether a system of large innovation in-
5	ducement prizes could work as a replacement for the
6	existing product monopoly/patent-based system, as
7	in effect on the date of enactment of this Act.
8	(2) How big large innovation prize funds would
9	have to be in order to induce at least as much re-
10	search and development investment in innovation as
11	is induced under the current system of time-limited
12	market exclusivity, as in effect on the date of enact-
13	ment of this Act.
14	(3) Whether a system of large innovation in-
15	ducement prizes would be more or less expensive
16	than such current system of time-limited market ex-
17	clusivity, calculated over different time periods.
18	(4) Whether a system of large innovation in-
19	ducement prizes would expand access to new prod-
20	ucts and improve health outcomes.
21	(5) The type of information and decisionmaking
22	skills that would be necessary to manage end prod-
23	uct prizes.

1	(6) Whether there would there be major advan-
2	tages in rewarding the incremental impact of innova-
3	tions, as benchmarked against existing products.
4	(7) How open-source dividend prizes could be
5	managed, and whether such prizes would increase
6	access to knowledge, materials, data and tech-
7	nologies.
8	(8) Whether a system of competitive inter-
9	mediaries for interim research prizes would provide
10	an acceptable solution to the valuation challenges for
11	interim prizes.
12	TITLE X—DRUG SHORTAGES
13	SEC. 1001. DRUG SHORTAGES.
14	(a) In General.—Section 506C (21 U.S.C. 356c)
15	is amended to read as follows:
16	"SEC. 506C. DISCONTINUANCE OR INTERRUPTION IN THE
17	PRODUCTION OF LIFE-SAVING DRUGS.
18	"(a) In General.—A manufacturer of a drug—
19	"(1) that is—
20	"(A) life-supporting;
21	"(B) life-sustaining;
22	"(C) intended for use in the prevention of
23	a debilitating disease or condition;
24	"(D) a sterile injectable product; or

1	"(E) used in emergency medical care or
2	during surgery; and
3	"(2) that is not a radio pharmaceutical drug
4	product, a human tissue replaced by a recombinant
5	product, a product derived from human plasma pro-
6	tein, or any other product as designated by the Sec-
7	retary,
8	shall notify the Secretary, in accordance with subsection
9	(b), of a permanent discontinuance in the manufacture of
10	the drug or an interruption of the manufacture of the drug
11	that could lead to a meaningful disruption in the supply
12	of that drug in the United States.
13	"(b) Timing.—A notice required under subsection (a)
14	shall be submitted to the Secretary—
15	"(1) at least 6 months prior to the date of the
16	discontinuance or interruption; or
17	"(2) if compliance with paragraph (1) is not
18	possible, as soon as practicable.
19	"(c) Expedited Inspections and Reviews.—If,
20	based on notifications described in subsection (a) or any
21	other relevant information, the Secretary concludes that
22	there is, or is likely to be, a drug shortage of a drug de-
23	scribed in subsection (a), the Secretary may—
24	"(1) expedite the review of a supplement to a
25	new drug application submitted under section

1	505(b), an abbreviated new drug application sub-
2	mitted under section 505(j), or a supplement to such
3	an application submitted under section 505(j) that
4	could help mitigate or prevent such shortage; or
5	"(2) expedite an inspection or reinspection of
6	an establishment that could help mitigate or prevent
7	such drug shortage.
8	"(d) Coordination.—
9	"(1) TASK FORCE AND STRATEGIC PLAN.—
10	"(A) In general.—
11	"(i) Task force.—As soon as prac-
12	ticable after the date of enactment of the
13	Food and Drug Administration Safety and
14	Innovation Act, the Secretary shall estab-
15	lish a Task Force to develop and imple-
16	ment a strategic plan for enhancing the
17	Secretary's response to preventing and
18	mitigating drug shortages.
19	"(ii) Strategic Plan.—The strategic
20	plan described in clause (i) shall include—
21	"(I) plans for enhanced inter-
22	agency and intraagency coordination,
23	communication, and decisionmaking;
24	"(II) plans for ensuring that
25	drug shortages are considered when

1	the Secretary initiates a regulatory
2	action that could precipitate a drug
3	shortage or exacerbate an existing
4	drug shortage;
5	"(III) plans for effective commu-
6	nication with outside stakeholders, in-
7	cluding who the Secretary should alert
8	about potential or actual drug short-
9	ages, how the communication should
10	occur, and what types of information
11	should be shared; and
12	"(IV) plans for considering the
13	impact of drug shortages on research
14	and clinical trials.
15	"(iii) Consultation.—In carrying
16	out this subparagraph, the Task Force
17	shall ensure consultation with the appro-
18	priate offices within the Food and Drug
19	Administration, including the Office of the
20	Commissioner, the Center for Drug Eval-
21	uation and Research, the Office of Regu-
22	latory Affairs, and employees within the
23	Department of Health and Human Serv-
24	ices with expertise regarding drug short-

1	ages. The Secretary shall engage external
2	stakeholders and experts as appropriate.
3	"(B) Timing.—Not later than 1 year after
4	the date of enactment Food and Drug Adminis-
5	tration Safety and Innovation Act, the Task
6	Force shall—
7	"(i) publish the strategic plan de-
8	scribed in subparagraph (A); and
9	"(ii) submit such plan to Congress.
10	"(2) COMMUNICATION.—The Secretary shall
11	ensure that, prior to any enforcement action or
12	issuance of a warning letter that the Secretary de-
13	termines could reasonably be anticipated to lead to
14	a meaningful disruption in the supply in the United
15	States of a drug described under subsection (a)
16	there is communication with the appropriate office
17	of the Food and Drug Administration with expertise
18	regarding drug shortages regarding whether the ac-
19	tion or letter could cause, or exacerbate, a shortage
20	of the drug.
21	"(3) Action.—If the Secretary determines,
22	after the communication described in paragraph (2).
23	that an enforcement action or a warning letter could
24	reasonably cause or exacerbate a shortage of a drug
25	described under subsection (a), then the Secretary

1	shall evaluate the risks associated with the impact of
2	such shortage upon patients and those risks associ-
3	ated with the violation involved before taking such
4	action or issuing such letter, unless there is immi-
5	nent risk of serious adverse health consequences or
6	death to humans.
7	"(4) Reporting by other entities.—The
8	Secretary shall identify or establish a mechanism by
9	which healthcare providers and other third-party or-
10	ganizations may report to the Secretary evidence of
11	a drug shortage.
12	"(5) REVIEW AND CONSTRUCTION.—No deter-
13	mination, finding, action, or omission of the Sec-
14	retary under this subsection shall—
15	"(A) be subject to judicial review; or
16	"(B) be construed to establish a defense to
17	an enforcement action by the Secretary.
18	"(e) Recordkeeping and Reporting.—
19	"(1) Recordkeeping.—The Secretary shall
20	maintain records related to drug shortages, includ-
21	ing with respect to each of the following:
22	"(A) The number of manufacturers that
23	submitted a notification to the Secretary under
24	subsection (a) in each calendar year.

1	(B) The number of drug shortages that
2	occurred in each calendar year and a list of
3	drug names, drug types, and classes that were
4	the subject of such shortages.
5	"(C) A list of the known factors contrib-
6	uting to the drug shortages described in sub-
7	paragraph (B).
8	"(D)(i) A list of major actions taken by
9	the Secretary to prevent or mitigate the drug
10	shortages described in subparagraph (B).
11	"(ii) The Secretary shall include in the list
12	under clause (i) the following:
13	"(I) The number of applications for
14	which the Secretary expedited review under
15	subsection $(c)(1)$ in each calendar year.
16	"(II) The number of establishment in-
17	spections or reinspections that the Sec-
18	retary expedited under subsection $(c)(2)$ in
19	each calendar year.
20	"(E) The number of notifications sub-
21	mitted to the Secretary under subsection (a) in
22	each calendar year.
23	"(F) The names of manufacturers that the
24	Secretary has learned did not comply with the

l	notification requirement under subsection (a) in
2	each calendar year.
3	"(G) The number of times in each cal-
4	endar year that the Secretary determined under
5	subsection (d)(3) that an enforcement action or
6	a warning letter could reasonably cause or exac-
7	erbate a shortage of a drug described under
8	subsection (a), but did not evaluate the risks
9	associated with the impact of such shortage
10	upon patients and those risks associated with
11	the violation involved before taking such action
12	or issuing such letter on the grounds that there
13	was imminent risk of serious adverse health
14	consequences or death to humans, and a sum-
15	mary of the determinations.
16	"(H) A summary of the communications
17	made and actions taken under subsection (d) in
18	each calendar year.
19	"(I) Any other information the Secretary
20	deems appropriate to better prevent and miti-
21	gate drug shortages.
22	"(2) Trend analysis.—The Secretary is au-
23	thorized to retain a third party to conduct a study,
24	if the Secretary believes such a study would help

1	clarify the causes, trends, or solutions related to
2	drug shortages.
3	"(3) ANNUAL SUMMARY.—Not later than 18
4	months after the date of enactment of the Food and
5	Drug Administration Safety and Innovation Act, and
6	annually thereafter, the Secretary shall submit to
7	the Committee on Health, Education, Labor, and
8	Pensions of the Senate and the Committee on En-
9	ergy and Commerce of the House of Representatives
10	a report summarizing, with respect to the 1-year pe-
11	riod preceding such report, the information de-
12	scribed in paragraph (1). Such report shall not in-
13	clude any information that is exempt from disclosure
14	under subsection (a) of section 552 of title 5, United
15	States Code, by reason of subsection (b)(4) of such
16	section.
17	"(f) Definitions.—For purposes of this section—
18	"(1) the term 'drug'—
19	"(A) means a drug (as defined in section
20	201(g)) that is intended for human use; and
21	"(B) does not include biological products
22	(as defined in section 351 of the Public Health
23	Service Act), unless otherwise provided by the
24	Secretary in the regulations promulgated under
25	subsection (h);

1	"(2) the term 'drug shortage' or 'shortage',
2	with respect to a drug, means a period of time when
3	the demand or projected demand for the drug within
4	the United States exceeds the supply of the drug;
5	and
6	"(3) the term 'meaningful disruption'—
7	"(A) means a change in production that is
8	reasonably likely to lead to a reduction in the
9	supply of a drug by a manufacturer that is
10	more than negligible and impacts the ability of
11	the manufacturer to fill orders or meet expected
12	demand for its product; and
13	"(B) does not include interruptions in
14	manufacturing due to matters such as routine
15	maintenance or insignificant changes in manu-
16	facturing so long as the manufacturer expects
17	to resume operations in a short period of time.
18	"(g) DISTRIBUTION.—To the maximum extent prac-
19	ticable, the Secretary may distribute information on drug
20	shortages and on the permanent discontinuation of the
21	drugs described in this section to appropriate provider and
22	patient organizations, except that any such distribution
23	shall not include any information that is exempt from dis-
24	closure under section 552 of title 5, United States Code,
25	by reason of subsection (b)(4) of such section.

1	"(h) Regulations.—
2	"(1) In general.—Not later than 18 months
3	after the date of enactment of the Food and Drug
4	Administration Safety and Innovation Act, the Sec-
5	retary shall adopt a final regulation implementing
6	this section.
7	"(2) Inclusion of Biological Products.—
8	"(A) IN GENERAL.—The Secretary may by
9	regulation apply this section to biological prod-
10	ucts (as defined in section 351 of the Public
11	Health Service Act) if the Secretary determines
12	such inclusion would benefit the public health.
13	"(B) RULE FOR VACCINES.—If the Sec-
14	retary applies this section to vaccines pursuant
15	to subparagraph (A), the Secretary shall—
16	"(i) consider whether the notification
17	requirement under subsection (a) may be
18	satisfied by submitting a notification to the
19	Centers for Disease Control and Preven-
20	tion under the vaccine shortage notification
21	program of such Centers; and
22	"(ii) explain the determination made
23	by the Secretary under clause (i) in the
24	regulation.

1	"(3) Procedure.—In promulgating a regula-
2	tion implementing this section, the Secretary shall—
3	"(A) issue a notice of proposed rulemaking
4	that includes the proposed regulation;
5	"(B) provide a period of not less than 60
6	days for comments on the proposed regulation;
7	and
8	"(C) publish the final regulation not less
9	than 30 days before the regulation's effective
10	date.
11	"(4) Restrictions.—Notwithstanding any
12	other provision of Federal law, in implementing this
13	section, the Secretary shall only promulgate regula-
14	tions as described in paragraph (3).".
15	(b) Effect of Notification.—The submission of
16	a notification to the Secretary of Health and Human Serv-
17	ices (referred to in this section as the "Secretary") for
18	purposes of complying with the requirement in section
19	506C(a) of the Federal Food, Drug, and Cosmetic Act (as
20	amended by subsection (a)) shall not be construed—
21	(1) as an admission that any product that is
22	the subject of such notification violates any provision
23	of the Federal Food, Drug, and Cosmetic Act (21
24	U.S.C. 301 et seq.); or

1	(2) as evidence of an intention to promote or
2	market the product for an indication or use for
3	which the product has not been approved by the Sec-
4	retary.
5	(c) Internal Review.—Not later than 2 years after
6	the date of enactment of this Act, the Secretary shall—
7	(1) analyze and review the regulations promul-
8	gated under the Federal Food, Drug, and Cosmetic
9	Act (21 U.S.C. 301 et seq.), the guidances or poli-
10	cies issued under such Act related to drugs intended
11	for human use, and the practices of the Food and
12	Drug Administration regarding enforcing such Act
13	related to manufacturing of such drugs, to identify
14	any such regulations, guidances, policies, or prac-
15	tices that cause, exacerbate, prevent, or mitigate
16	drug shortages (as defined in section 506C of the
17	Federal Food, Drug, and Cosmetic Act (as amended
18	by subsection (a)); and
19	(2) determine how regulations, guidances, poli-
20	cies, or practices identified under paragraph (1)
21	should be modified, streamlined, expanded, or dis-
22	continued in order to reduce or prevent such drug
23	shortages, taking into consideration the effect of any
24	changes on the public health.

1	(d) STUDY ON MARKET FACTORS CONTRIBUTING TO
2	Drug Shortages and Stockpiling.—
3	(1) IN GENERAL.—Not later than 1 year after
4	the date of enactment of this Act, the Comptroller
5	General of the United States, in consultation with
6	the Secretary, the Department of Health and
7	Human Services Office of the Inspector General, the
8	Attorney General, and Chairman of the Federal
9	Trade Commission, shall publish a report reviewing
10	any findings that drug shortages (as so defined)
11	have led market participants to stockpile affected
12	drugs or sell them at significantly increased prices,
13	the impact of such activities on Federal revenue, and
14	any economic factors that have exacerbated or cre-
15	ated a market for such actions.
16	(2) Content.—The report under paragraph
17	(1) shall include—
18	(A) an analysis of the incidence of any of
19	the activities described in paragraph (1) and
20	the effect of such activities on the public health;
21	(B) an evaluation of whether in such cases
22	there is a correlation between drugs in shortage
23	and—
24	(i) the number of manufacturers pro-
25	ducing such drugs;

1	(ii) the pricing structure, including
2	Federal reimbursements, for such drugs
3	before such drugs were in shortage, and to
4	the extent possible, revenue received by
5	each such manufacturer of such drugs;
6	(iii) pricing structure and revenue, to
7	the extent possible, for the same drugs
8	when sold under the conditions described
9	in paragraph (1); and
10	(iv) the impact of contracting prac-
11	tices by market participants (including
12	manufacturers, distributors, group pur-
13	chasing organizations, and providers) on
14	competition, access to drugs, and pricing
15	of drugs;
16	(C) whether the activities described in
17	paragraph (1) are consistent with applicable
18	law; and
19	(D) recommendations to Congress on what
20	if any, additional reporting or enforcement ac-
21	tions are necessary.
22	(3) Trade secret and confidential infor-
23	MATION.—Nothing in this subsection alters or
24	amends section 1905 of title 18, United States Code
25	or section 552(b)(4) of title 5, United States Code

1	(e) Guidance Regarding Repackaging.—Not
2	later than 1 year after the date of enactment of this Act,
3	the Secretary shall issue guidance that clarifies the policy
4	of the Food and Drug Administration regarding hospital
5	pharmacies repackaging and safely transferring repack-
6	aged drugs among hospitals within a common health sys-
7	tem during a drug shortage, as identified by the Secretary.
8	TITLE XI—OTHER PROVISIONS
9	Subtitle A—Reauthorizations
10	SEC. 1101. REAUTHORIZATION OF PROVISION RELATING TO
11	EXCLUSIVITY OF CERTAIN DRUGS CON-
12	TAINING SINGLE ENANTIOMERS.
13	Section $505(u)(4)$ (21 U.S.C. $355(u)(4)$ ) is amended
14	by striking "2012" and inserting "2017".
15	SEC. 1102. REAUTHORIZATION OF THE CRITICAL PATH
16	PUBLIC-PRIVATE PARTNERSHIPS.
17	Section 566(f) (21 U.S.C. 360bbb–5(f)) is amended
18	by striking "2012" and inserting "2017".
19	Subtitle B—Medical Gas
20	Regulation
21	SEC. 1111. REGULATION OF MEDICAL GASES.
22	(a) Regulation.—Chapter V (21 U.S.C. 351 et

1	"Subchapter G—Medical Gases
2	"SEC. 575. DEFINITIONS.
3	"In this subchapter:
4	"(1) The term 'designated medical gas' means
5	any of the following:
6	"(A) Oxygen, that meets the standards set
7	forth in an official compendium.
8	"(B) Nitrogen, that meets the standards
9	set forth in an official compendium.
10	"(C) Nitrous oxide, that meets the stand-
11	ards set forth in an official compendium.
12	"(D) Carbon dioxide, that meets the stand-
13	ards set forth in an official compendium.
14	"(E) Helium, that meets the standards set
15	forth in an official compendium.
16	"(F) Carbon monoxide, that meets the
17	standards set forth in an official compendium.
18	"(G) Medical air, that meets the standards
19	set forth in an official compendium.
20	"(H) Any other medical gas deemed appro-
21	priate by the Secretary, unless any period of ex-
22	clusivity under section $505(e)(3)(E)(ii)$ or
23	505(j)(5)(F)(ii), or the extension of any such
24	period under section 505A, applicable to such
25	medical gas has not expired.

1	"(2) The term 'medical gas' means a drug
2	that—
3	"(A) is manufactured or stored in a lique-
4	fied, nonliquefied, or cryogenic state; and
5	"(B) is administered as a gas.
6	"SEC. 576. REGULATION OF MEDICAL GASES.
7	"(a) Certification of Designated Medical
8	Gases.—
9	"(1) Submission.—
10	"(A) IN GENERAL.—Beginning on the date
11	of enactment of this section, any person may
12	file with the Secretary a request for a certifi-
13	cation of a designated medical gas.
14	"(B) Content.—A request under sub-
15	paragraph (A) shall contain—
16	"(i) a description of the medical gas;
17	"(ii) the name and address of the
18	sponsor;
19	"(iii) the name and address of the fa-
20	cility or facilities where the gas is or will
21	be manufactured; and
22	"(iv) any other information deemed
23	appropriate by the Secretary to determine
24	whether the medical gas is a designated
25	medical gas.

1	"(2) GRANT OF CERTIFICATION.—A certifi-
2	cation described under paragraph (1)(A) shall be de-
3	termined to have been granted unless, not later than
4	60 days after the filing of a request under para-
5	graph (1), the Secretary finds that—
6	"(A) the medical gas subject to the certifi-
7	cation is not a designated medical gas;
8	"(B) the request does not contain the in-
9	formation required under paragraph (1) or oth-
10	erwise lacks sufficient information to permit the
11	Secretary to determine that the gas is a des-
12	ignated medical gas; or
13	"(C) granting the request would be con-
14	trary to public health.
15	"(3) Effect of Certification.—
16	"(A) In General.—
17	"(i) Approved uses.—A designated
18	medical gas for which a certification is
19	granted under paragraph (2) is deemed,
20	alone or in combination with another des-
21	ignated gas or gases as medically appro-
22	priate, to have in effect an approved appli-
23	cation under section 505 or 512, subject to
24	all applicable postapproval requirements,
25	for the following indications for use:

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1	"(1) Oxygen for the treatment or
2	prevention of hypoxemia or hypoxia.
3	"(II) Nitrogen for use in hypoxic
4	challenge testing.
5	"(III) Nitrous oxide for analge-
6	sia.
7	"(IV) Carbon dioxide for use in
8	extracorporeal membrane oxygenation
9	therapy or respiratory stimulation.
10	"(V) Helium for the treatment of
11	upper airway obstruction or increased
12	airway resistance.
13	"(VI) Medical air to reduce the
14	risk of hyperoxia.
15	"(VII) Carbon monoxide for use
16	in lung diffusion testing.
17	"(VIII) Any other indication for
18	use for a designated medical gas or
19	combination of designated medical
20	gases deemed appropriate by the Sec-
21	retary, unless any period of exclusivity
22	under clause (iii) or (iv) of section
23	505(c)(3)(E), under clause (iii) or (iv)
24	of section $505(j)(5)(F)$ , or under sec-
25	tion 527, or the extension of any such

1	period under section 505A, applicable
2	to such indication for use for such gas
3	or combination of gases has not ex-
4	pired.
5	"(ii) Labeling.—The requirements
6	established in sections 503(b)(4) and
7	502(f) shall be deemed to have been met
8	for a designated medical gas if the labeling
9	on final use containers of such gas bears
10	the information required by section
11	503(b)(4) and a warning statement con-
12	cerning the use of the gas, as determined
13	by the Secretary by regulation, as well as
14	appropriate directions and warnings con-
15	cerning storage and handling.
16	"(B) Inapplicability of exclusivity
17	PROVISIONS.—
18	"(i) Effect on ineligibility.—No
19	designated medical gas deemed under
20	paragraph (3)(A)(i) to have in effect an
21	approved application shall be eligible for
22	any periods of exclusivity under sections
23	505(c), 505(j), or 527, or the extension of
24	any such period under section 505A, on
25	the basis of such deemed approval.

1	"(ii) Effect on certification.—
2	No period of exclusivity under sections
3	505(c), 505(j), or section 527, or the ex-
4	tension of any such period under section
5	505A, with respect to an application for a
6	drug shall prohibit, limit, or otherwise af-
7	fect the submission, grant, or effect of a
8	certification under this section, except as
9	provided in paragraph (3)(A)(i)(VIII).
10	"(4) WITHDRAWAL, SUSPENSION, OR REVOCA-
11	TION OF APPROVAL.—
12	"(A) In General.—Nothing in this sub-
13	chapter limits the authority of the Secretary to
14	withdraw or suspend approval of a drug, includ-
15	ing a designated medical gas deemed under this
16	section to have in effect an approved applica-
17	tion, under section 505 or section 512.
18	"(B) REVOCATION.—The Secretary may
19	revoke the grant of a certification under this
20	section if the Secretary determines that the re-
21	quest for certification contains any material
22	omission or falsification.
23	"(b) Prescription Requirement.—
24	"(1) In general.—A designated medical gas
25	shall be subject to section 503(b)(1) unless the Sec-

1	retary exercises the authority provided in section
2	503(b)(3) to remove such gas from the requirements
3	of section $503(b)(1)$ .
4	"(2) Exception for oxygen.—
5	"(A) In general.—Notwithstanding para-
6	graph (1), oxygen may be provided without a
7	prescription for the following uses:
8	"(i) The use in the event of depres-
9	surization or other environmental oxygen
10	deficiency.
11	"(ii) The use in the event of oxygen
12	deficiency or use in emergency resuscita-
13	tion, when administered by properly
14	trained personnel.
15	"(B) Labeling.—For oxygen provided
16	pursuant to subparagraph (A), the require-
17	ments established in section 503(b)(4) shall be
18	deemed to have been met if the labeling of the
19	oxygen bears a warning that the medical gas
20	can be used for emergency use only and for all
21	other medical applications a prescription is re-
22	quired.
23	"(c) Inapplicability of Drugs Fees to Des-
24	IGNATED MEDICAL GASES.—A designated medical gas
25	deemed under this section to have in effect an approved

- 1 application shall not be assessed fees under section 736(a)
- 2 on the basis of such deemed approval.".

## 3 SEC. 1112. REGULATIONS.

- 4 (a) Review of Regulations.—Not later than 18
- 5 months after the date of enactment of this Act, the Sec-
- 6 retary of Health and Human Services (referred to in this
- 7 section as the "Secretary") shall, after obtaining input
- 8 from medical gas manufacturers, and any other interested
- 9 members of the public, submit a report to the Committee
- 10 on Health, Education, Labor, and Pensions of the Senate
- 11 and the Committee on Energy and Commerce of the
- 12 House of Representatives regarding any changes to the
- 13 Federal drug regulations in title 21, Code of Federal Reg-
- 14 ulations that the Secretary determines to be necessary
- 15 pursuant to the amendments made by section 811.
- 16 (b) Amended Regulations.—If the Secretary de-
- 17 termines that changes to the Federal drug regulations in
- 18 title 21, Code of Federal Regulations are necessary under
- 19 subsection (a), the Secretary shall issue final regulations
- 20 implementing such changes not later than 4 years after
- 21 the date of enactment of this Act.
- 22 SEC. 1113. APPLICABILITY.
- Nothing in this subtitle or the amendments made by
- 24 this subtitle shall apply to—

1	(1) a drug that is covered by an application
2	under section 505 or 512 of the Federal Food,
3	Drug, and Cosmetic Act (21 U.S.C. 355, 360b) ap-
4	proved prior to May 1, 2012; or
5	(2) any of the gases listed in subparagraphs (A)
6	through (G) of section 575(1) of such Act (as added
7	by section 1111), or any mixture of any such gases,
8	for an indication that—
9	(A) is not included in, or is different from,
10	those specified in subclauses (I) through (VII)
11	of section 576(a)(3)(i) of such Act (as added by
12	section 1111); and
13	(B) is approved on or after May 1, 2012,
14	pursuant to an application submitted under sec-
15	tion 505 or 512 of such Act.
16	Subtitle C—Miscellaneous
17	Provisions
18	SEC. 1121. ADVISORY COMMITTEE CONFLICTS OF INTER-
19	EST.
20	Section 712 (21 U.S.C. 379d–1) is amended—
21	(1) in subsection (b)—
22	(A) by striking paragraph (2); and
23	(B) in paragraph (1)—
24	(i) by redesignating subparagraph (B)
25	as paragraph (2) and moving such para-

1	graph, as so redesignated, 2 ems to the
2	left;
3	(ii) in subparagraph (A), by redesig-
4	nating clauses (i) through (iii) as subpara-
5	graphs (A) through (C), respectively, and
6	moving such subparagraphs, as so redesig-
7	nated, 2 ems to the left;
8	(iii) in subparagraph (A), as so redes-
9	ignated, by inserting ", including strategies
10	to increase the number of special Govern-
11	ment employees across medical and sci-
12	entific specialties in areas where the Sec-
13	retary would benefit from specific sci-
14	entific, medical, or technical expertise nec-
15	essary for the performance of its regu-
16	latory responsibilities" before the semicolon
17	at the end;
18	(iv) by striking "(1) Recruitment.—
19	" and inserting "(1) RECRUITMENT IN
20	GENERAL.—The Secretary shall—";
21	(v) by striking "(A) In General.—
22	The Secretary shall—";
23	(vi) by redesignating clauses (i)
24	through (iii) of paragraph (2) (as so redes-
25	ignated) as subparagraphs (A) through

1	(C), respectively, and moving such sub-
2	paragraphs, as so redesignated, 2 ems to
3	the left;
4	(vii) in paragraph (2) (as so redesig-
5	nated), in the matter before subparagraph
6	(A) (as so redesignated), by striking "sub-
7	paragraph (A)" and inserting "paragraph
8	(1)"; and
9	(viii) by adding at the end the fol-
10	lowing:
11	"(3) Recruitment through referrals.—In
12	carrying out paragraph (1), the Secretary shall, in
13	order to further the goal of including in advisory
14	committees the most qualified and specialized ex-
15	perts in the specific diseases to be considered by
16	such advisory committees, at least every 180 days,
17	request referrals from a variety of stakeholders, in-
18	cluding the Institute of Medicine, the National Insti-
19	tutes of Health, product developers, patient groups,
20	disease advocacy organizations, professional soci-
21	eties, medical societies, including the American
22	Academy of Medical Colleges, and other govern-
23	mental organizations.";
24	(2) by amending subsection $(c)(2)(C)$ to read as
25	follows:

1	"(C) Consideration by secretary.—
2	The Secretary shall ensure that each determina-
3	tion made under subparagraph (B) considers
4	the type, nature, and magnitude of the financial
5	interests at issue and the public health interest
6	in having the expertise of the member with re-
7	spect to the particular matter before the advi-
8	sory committee.";
9	(3) in subsection (e), by inserting ", and shall
10	make publicly available," after "House of Represent-
11	atives"; and
12	(4) by adding at the end the following:
13	"(g) Guidance on Reported Financial Interest
14	OR INVOLVEMENT.—The Secretary shall issue guidance
15	that describes how the Secretary reviews the financial in-
16	terests and involvement of advisory committee members
17	that are reported under subsection $(c)(1)$ but that the Sec-
18	retary determines not to meet the definition of a disquali-
19	fying interest under section 208 of title 18, United States
20	Code for the purposes of participating in a particular mat-
21	ter.".
22	SEC. 1122. GUIDANCE DOCUMENT REGARDING PRODUCT
23	PROMOTION USING THE INTERNET.
24	Not later than 2 years after the date of enactment
25	this Act, the Secretary of Health and Human Services

1	shall issue guidance that describes Food and Drug Admin-
2	istration policy regarding the promotion, using the Inter-
3	net (including social media), of medical products that are
4	regulated by such Administration.
5	SEC. 1123. ELECTRONIC SUBMISSION OF APPLICATIONS.
6	Subchapter D of chapter VII (21 U.S.C. 379k et
7	seq.) is amended by inserting after section 745 the fol-
8	lowing:
9	"SEC. 745A. ELECTRONIC FORMAT FOR SUBMISSIONS.
10	"(a) Drugs and Biologics.—
11	"(1) In general.—Beginning no earlier than
12	24 months after the issuance of a final guidance
13	issued after public notice and opportunity for com-
14	ment, submissions under subsection (b), (i), or (j) of
15	section 505 of this Act or subsection (a) or (k) of
16	section 351 of the Public Health Service Act shall
17	be submitted in such electronic format as specified
18	by the Secretary in such guidance.
19	"(2) Guidance contents.—In the guidance
20	under paragraph (1), the Secretary may—
21	"(A) provide a timetable for establishment
22	by the Secretary of further standards for elec-
23	tronic submission as required by such para-
24	graph; and

1	"(B) set forth criteria for waivers of and
2	exemptions from the requirements of this sub-
3	section.
4	"(3) Exception.—This subsection shall not
5	apply to submissions described in section 561.
6	"(b) Devices.—
7	"(1) In General.—Beginning after the
8	issuance of final guidance implementing this para-
9	graph, pre-submissions and submissions for devices
10	under section $510(k)$ , $513(f)(2)(A)(ii)$ , $515(e)$ ,
11	515(d), $515(f)$ , $520(g)$ , $520(m)$ , or $564$ of this Act
12	or section 351 of the Public Health Service Act, and
13	any supplements to such pre-submissions or submis-
14	sions, shall include an electronic copy of such pre-
15	submissions or submissions.
16	"(2) Guidance contents.—In the guidance
17	under paragraph (1), the Secretary may—
18	"(A) provide standards for the electronic
19	copy required under such paragraph; and
20	"(B) set forth criteria for waivers of and
21	exemptions from the requirements of this sub-
22	section.".
23	SEC. 1124. COMBATING PRESCRIPTION DRUG ABUSE.
24	(a) In General.—To combat the significant rise in
25	prescription drug abuse and the consequences of such

- 1 abuse, the Secretary of Health and Human Services (re-
- 2 ferred to in this section as the "Secretary", acting
- 3 through the Commissioner of Food and Drugs (referred
- 4 to in this section as the "Commissioner") and in coordina-
- 5 tion with other Federal agencies, as appropriate, shall re-
- 6 view current Federal initiatives and identify gaps and op-
- 7 portunities with respect to ensuring the safe use of pre-
- 8 scription drugs with the potential for abuse.
- 9 (b) Report.—Not later than 1 year after the date
- 10 of enactment of this Act, the Secretary shall issue a report
- 11 to Congress on the findings of the review under subsection
- 12 (a). Such report shall include recommendations on—
- 13 (1) how best to leverage and build upon existing
- 14 Federal and federally funded data sources, such as
- prescription drug monitoring program data and the
- sentinel initiative of the Food and Drug Administra-
- tion under section 505(k)(3) of the Federal Food,
- 18 Drug, and Cosmetic Act (21 U.S.C. 351(k)(3)), as
- it relates to collection of information relevant to ad-
- verse events, patient safety, and patient outcomes, to
- create a centralized data clearinghouse and early
- warning tool;
- 23 (2) how best to develop and disseminate widely
- best practices models and suggested standard re-
- 25 quirements to States for achieving greater interoper-

- ability and effectiveness of prescription drug monitoring programs, especially with respect to producing standardized data on adverse events, patient safety, and patient outcomes; and
- 5 (3) how best to develop provider and patient 6 education tools and a strategy to widely disseminate 7 such tools and assess the efficacy of such tools.
- 8 (c) Guidance on Tamper-deterrent Prod-
- 9 UCTS.—Not later than 6 months after the date of enact-
- 10 ment of this Act, the Secretary, acting through the Com-
- 11 missioner, shall promulgate guidance on the development
- 12 of tamper-deterrent drug products.

## 13 SEC. 1125. TANNING BED LABELING.

- Not later than 18 months after the date of enactment
- 15 of this Act, the Secretary shall determine whether to
- 16 amend the warning label requirements for sunlamp prod-
- 17 ucts to include specific requirements to more clearly and
- 18 effectively convey the risks that such products pose for the
- 19 development of irreversible damage to the eyes and skin,
- 20 including skin cancer.

## 21 SEC. 1126. OPTIMIZING GLOBAL CLINICAL TRIALS.

- Subchapter E of chapter V (21 U.S.C. 360bbb et
- 23 seq.), as amended by section 903, is further amended by
- 24 adding at the end the following:

"SEC.	569A	OPTIMIZING GLOBAL CLINICAL TRIALS.	

2	"(a) In General.—The Secretary shall—
3	"(1) work with other regulatory authorities of
4	similar standing, medical research companies, and
5	international organizations to foster and encourage
6	uniform, scientifically-driven clinical trial standards
7	with respect to medical products around the world
8	and
9	"(2) enhance the commitment to provide con-
10	sistent parallel scientific advice to manufacturers
11	seeking simultaneous global development of new
12	medical products in order to—
13	"(A) enhance medical product develop-
14	ment;
15	"(B) facilitate the use of foreign data; and
16	"(C) minimize the need to conduct duplica-
17	tive clinical studies, preclinical studies, or non-
18	clinical studies.
19	"(b) Medical Product.—In this section, the term
20	'medical product' means a drug, as defined in subsection
21	(g) of section 201, a device, as defined in subsection (h)
22	of such section, or a biological product, as defined in sec-
23	tion 351(i) of the Public Health Service Act.
24	"(c) Savings Clause.—Nothing in this section shall
25	alter the criteria for evaluating the safety or effectiveness
26	of a medical product under this Act "

1	SEC. 1127. ADVANCING REGULATORY SCIENCE TO PRO-
2	MOTE PUBLIC HEALTH INNOVATION.
3	(a) In General.—Not later than 1 year after the
4	date of enactment of this Act, the Secretary of Health and
5	Human Services (referred to in this section as the "Sec-
6	retary") shall develop a strategy and implementation plan
7	for advancing regulatory science for medical products in
8	order to promote the public health and advance innovation
9	in regulatory decisionmaking.
10	(b) REQUIREMENTS.—The strategy and implementa-
11	tion plan developed under subsection (a) shall be con-
12	sistent with the user fee performance goals in the Pre-
13	scription Drug User Fee Agreement commitment letter,
14	the Generic Drug User Fee Agreement commitment letter,
15	and the Biosimilar User Fee Agreement commitment let-
16	ter transmitted by the Secretary to Congress on January
17	13, 2012, and the Medical Device User Fee Agreement
18	commitment letter transmitted by the Secretary to Con-
19	gress on April 20, 2012, and shall—
20	(1) identify a clear vision of the fundamental
21	role of efficient, consistent, and predictable, science-
22	based decisions throughout regulatory decision-
23	making of the Food and Drug Administration with
24	respect to medical products;
25	(2) identify the regulatory science priorities of
26	the Food and Drug Administration directly related

to fulfilling the mission of the agency with respect to decisionmaking concerning medical products and allocation of resources towards such regulatory science priorities; (3) identify regulatory and scientific gaps that impede the timely development and review of, and regulatory certainty with respect to, the approval, li-

9 with respect to companion products and new tech-

censure, or clearance of medical products, including

10 nologies, and facilitating the timely introduction and

11 adoption of new technologies and methodologies in a

12 safe and effective manner;

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- (4) identify clear, measurable metrics by which progress on the priorities identified under paragraph (2) and gaps identified under paragraph (3) will be measured by the Food and Drug Administration, including metrics specific to the integration and adoption of advances in regulatory science described in paragraph (5) and improving medical product decisionmaking, in a predictable and science-based manner; and
- (5) set forth how the Food and Drug Administration will ensure that advances in regulatory science for medical products are adopted, as appropriate, on an ongoing basis and in an manner inte-

1	grated across centers, divisions, and branches of the
2	Food and Drug Administration, including by senior
3	managers and reviewers, including through the—
4	(A) development, updating, and consistent
5	application of guidance documents that support
6	medical product decisionmaking; and
7	(B) the adoption of the tools, methods, and
8	processes under section 566 of the Federal
9	Food, Drug, and Cosmetic Act (21 U.S.C.
10	360bbb-5).
11	(c) Annual Performance Reports.—As part of
12	the annual performance reports submitted to Congress
13	under sections 736B(a) (as amended by section 104),
14	738A(a) (as amended by section 204), 744C(a) (as added
15	by section 303), and 744I(a) (as added by section 403)
16	of the Federal Food, Drug, and Cosmetic Act for each
17	of fiscal years 2013 through 2017, the Secretary shall an-
18	nually report on the progress made with respect to—
19	(1) advancing the regulatory science priorities
20	and resolving the gaps identified under paragraph
21	(3) of subsection (b), including reporting on specific
22	metrics identified under paragraph (4) of such sub-
23	section;

1	(2) the integration and adoption of advances in
2	regulatory science as set forth in paragraph (5) of
3	such subsection; and
4	(3) the progress made in advancing the regu-
5	latory science goals outlined in the Prescription
6	Drug User Fee Agreement commitment letter, the
7	Generic Drug User Fee Agreement commitment let-
8	ter, and the Biosimilar User Fee Agreement commit-
9	ment letter transmitted by the Secretary to Congress
10	on January 13, 2012, and the Medical Device User
11	Fee Agreement transmitted by the Secretary to Con-
12	gress on April 20, 2012.
13	(d) Independent Assessment.—Not later than
14	January 1, 2016, the Comptroller General of the United
15	States shall submit to Congress a report—
16	(1) detailing the progress made by the Food
17	and Drug Administration in meeting the priorities
18	and addressing the gaps identified in subsection (b),
19	including any outstanding gaps; and
20	(2) containing recommendations, as appro-
21	priate, on how regulatory science initiatives for med-
22	ical products can be strengthened and improved to
23	promote the public health and advance innovation in
24	regulatory decisionmaking.

1	(e) Medical Product.—In this section, the term
2	"medical product" means a drug, as defined in subsection
3	(g) of section 201 of the Federal Food, Drug, and Cos-
4	metic Act (21 U.S.C. 321), a device, as defined in sub-
5	section (h) of such section, or a biological product, as de-
6	fined in section 351(i) of the Public Health Service Act.
7	SEC. 1128. INFORMATION TECHNOLOGY.
8	(a) HHS REPORT.—Not later than 1 year after the
9	date of enactment of this Act, the Secretary of Health and
10	Human Services shall—
11	(1) report to Congress on—
12	(A) the milestones and a completion date
13	for developing and implementing a comprehen-
14	sive information technology strategic plan to
15	align the information technology systems mod-
16	ernization projects with the strategic goals of
17	the Food and Drug Administration, including
18	results-oriented goals, strategies, milestones,
19	performance measures;
20	(B) efforts to finalize and approve a com-
21	prehensive inventory of the information tech-
22	nology systems of the Food and Drug Adminis-
23	tration that includes information describing
24	each system, such as costs, system function or
25	purpose, and status information, and incor-

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1	porate use of the system portfolio into the in-
2	formation investment management process of
3	the Food and Drug Administration;
4	(C) the ways in which the Food and Drug
5	Administration uses the plan described in sub-
6	paragraph (A) to guide and coordinate the
7	modernization projects and activities of the
8	Food and Drug Administration, including the
9	interdependencies among projects and activities;
10	and
11	(D) the extent to which the Food and
12	Drug Administration has fulfilled or is imple-
13	menting recommendations of the Government
14	Accountability Office with respect to the Food
15	and Drug Administration and information tech-
16	nology; and
17	(2) develop—
18	(A) a documented enterprise architecture
19	program management plan that includes the
20	tasks, activities, and timeframes associated with
21	developing and using the architecture and ad-
22	dresses how the enterprise architecture program
23	management will be performed in coordination
24	with other management disciplines, such as or-

ganizational strategic planning, capital planning

1	and investment control, and performance man-
2	agement; and
3	(B) a skills inventory, needs assessment
4	gap analysis, and initiatives to address skills
5	gaps as part of a strategic approach to informa-
6	tion technology human capital planning.
7	(b) GAO REPORT.—Not later than January 1, 2016
8	the Comptroller General of the United States shall issue
9	a report regarding the strategic plan described in sub-
10	section (a) and related actions carried out by the Food
11	and Drug Administration. Such report shall assess the
12	progress the Food and Drug Administration has made
13	on—
14	(1) the development and implementation of a
15	comprehensive information technology strategic plan
16	including the results-oriented goals, strategies, mile-
17	stones, and performance measures identified in sub-
18	paragraph (a);
	paragraph (a); (2) the effectiveness of the comprehensive infor-
19	
19 20	(2) the effectiveness of the comprehensive infor-
19 20 21	(2) the effectiveness of the comprehensive information technology strategic plan in subparagraph
18 19 20 21 22 23	(2) the effectiveness of the comprehensive information technology strategic plan in subparagraph (a), including the results-oriented goals and performance.

1 Government Accountability Office with respect to

- 2 such agency and information technology.
- 3 SEC. 1129. REPORTING REQUIREMENTS.
- 4 Subchapter A of chapter VII (21 U.S.C. 371 et seq.),
- 5 as amended by section 208, is further amended by adding
- 6 at the end the following:
- 7 "SEC. 715. REPORTING REQUIREMENTS.
- 8 "(a) New Drugs.—Beginning with fiscal year 2013
- 9 and ending after fiscal year 2017, not later than 120 days
- 10 after the end of each fiscal year for which fees are col-
- 11 lected under part 2 of subchapter C, the Secretary shall
- 12 prepare and submit to the Committee on Health Edu-
- 13 cation, Labor, and Pensions of the Senate and the Com-
- 14 mittee on Energy and Commerce of the House of Rep-
- 15 resentatives a report concerning, for all applications for
- 16 approval of a new drug under section 505(b) of this Act
- 17 or a new biological product under section 351(a) of the
- 18 Public Health Service Act filed in the previous fiscal year
- 19 —
- 20 "(1) the number of such applications that met
- 21 the goals identified for purposes of part 3 of sub-
- chapter C in the letters from the Secretary of
- Health and Human Services to the Chairman of the
- Committee on Health, Education, Labor, and Pen-
- sions of the Senate and the Chairman of the Com-

1	mittee on Energy and Commerce of the House of
2	Representatives, as set forth in the Congressional
3	Record;
4	"(2) the percentage of such applications that
5	were approved;
6	"(3) the percentage of such applications that
7	were issued complete response letters;
8	"(4) the percentage of such applications that
9	were subject to a refuse-to-file action;
10	"(5) the percentage of such applications that
11	were withdrawn; and
12	"(6) the average total time to decision by the
13	Secretary for all applications for approval of a new
14	drug under section 505(b) of this Act or a new bio-
15	logical product under section 351(a) of the Public
16	Health Service Act filed in the previous fiscal year,
17	including the number of calendar days spent during
18	the review by the Food and Drug Administration
19	and the number of calendar days spent by the spon-
20	sor responding to a complete response letter or rel-
21	evant legal, scientific, or medical questions raised by
22	the Secretary.".
23	"(b) Generic Drugs.—Beginning with fiscal year
24	2013 and ending after fiscal year 2017, not later than
25	120 days after the end of each fiscal year for which fees

are collected under part 7 of subchapter C, the Secretary 2 shall prepare and submit to the Committee on Health 3 Education, Labor, and Pensions of the Senate and the 4 Committee on Energy and Commerce of the House of Representatives a report concerning, for all applications 6 for approval of a generic drug under section 505(j), 7 amendments to such applications, and prior approval sup-8 plements with respect to such applications filed in the pre-9 vious fiscal year— 10 "(1) the number of such applications that met 11 the goals identified for purposes of part 7 of sub-12 chapter C, in the letters from the Secretary of 13 Health and Human Services to the Chairman of the 14 Committee on Health, Education, Labor, and Pen-15 sions of the Senate and the Chairman of the Com-16 mittee on Energy and Commerce of the House of 17 Representatives, as set forth in the Congressional 18 Record; 19 "(2) the average total time to decision by the 20 Secretary for applications for approval of a generic 21 drug under section 505(j), amendments to such ap-22 plications, and prior approval supplements with re-23 spect to such applications filed in the previous fiscal 24 year, including the number of calendar days spent

during the review by the Food and Drug Adminis-

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I	tration and days spent by the sponsor responding to
2	a complete response letter or relevant legal, sci-
3	entific, or medical questions raised by the Secretary
4	"(3) the total number of applications under sec-
5	tion 505(j), amendments to such applications, and
6	prior approval supplements with respect to such ap-
7	plications that were pending with the Secretary for
8	more than 10 months on the date of enactment of
9	the Food and Drug Administration Safety and Inno-
10	vation Act; and
11	"(4) the number of applications described in
12	paragraph (3) on which the Food and Drug Admin-
13	istration took final regulatory action in the previous
14	fiscal year.
15	"(c) Biosimilar Biological Products.—
16	"(1) In general.—Beginning with fiscal year
17	2014, not later than 120 days after the end of each
18	fiscal year for which fees are collected under part 8
19	of subchapter C, the Secretary shall prepare and
20	submit to the Committee on Health Education
21	Labor, and Pensions of the Senate and the Com-
22	mittee on Energy and Commerce of the House of
23	Representatives a report concerning—

1	"(A) the number of applications for ap-
2	proval filed under section 351(k) of the Public
3	Health Service Act; and
4	"(B) the percentage of applications de-
5	scribed in subparagraph (A) that were approved
6	by the Secretary.
7	"(2) Additional information.—As part of
8	the performance report described in paragraph (1),
9	the Secretary shall include an explanation of how the
10	Food and Drug Administration is managing the bio-
11	logical product review program to ensure that the
12	user fees collected under part 2 are not used to re-
13	view an application under section 351(k) of the Pub-
14	lic Health Service Act.".
15	SEC. 1130. STRATEGIC INTEGRATED MANAGEMENT PLAN.
16	(a) Strategic Integrated Management Plan.—
17	Not later than 1 year after the date of enactment of this
18	Act, the Secretary of Health and Human Services (re-
19	ferred to in this section as the "Secretary") shall submit
20	to Congress a strategic integrated management plan for
21	the Center for Drug Evaluation and Research, the Center
22	for Biologics Evaluation and Research, and the Center for
23	Devices and Radiological Health. Such strategic manage-
24	ment plan shall—

1 (1) identify strategic institutional goals and pri-2 orities for the Center for Drug Evaluation and Re-3 search, the Center for Biologics Evaluation and Re-4 search, and the Center for Devices and Radiological 5 Health; 6 (2) describe the actions the Secretary will take 7 to recruit, retain, train, and continue to develop the 8 workforce at the Center for Drug Evaluation and 9 Research, the Center for Biologics Evaluation and 10 Research, and the Center for Devices and Radio-11 logical Health to fulfill the public health mission of 12 the Food and Drug Administration; and 13 (3)identify results-oriented, outcome-based 14 measures that the Secretary will use to measure the 15 progress of achieving the strategic goals and prior-16 ities identified under paragraph (1) and the effec-17 tiveness of the actions identified under paragraph 18 (2), including metrics to ensure that managers and 19 reviewers of the Center for Drug Evaluation and Re-20 search, the Center for Biologics Evaluation and Re-21 search, and the Center for Devices and Radiological 22 Health are familiar with and appropriately and con-23 sistently apply the requirements under the Federal 24 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et 25 seq.), including new requirements under parts 2, 3,

1	7, and 8 of subchapter C of title VII of the Federal
2	Food, Drug, and Cosmetic Act (21 U.S.C. 379f et
3	seq.).
4	(b) Report.—Not later than January 1, 2016, the
5	Comptroller General of the United States shall issue a re-
6	port regarding the strategic management plan described
7	in subsection (a) and related actions carried out by the
8	Food and Drug Administration. Such report shall—
9	(1) assess the effectiveness of the actions de-
10	scribed in subsection (a)(2) in recruiting, retaining,
11	training, and developing the workforce at the Center
12	for Drug Evaluation and Research, the Center for
13	Biologics Evaluation and Research, and the Center
14	for Devices and Radiological Health in fulfilling the
15	public health mission of the Food and Drug Admin-
16	istration;
17	(2) assess the effectiveness of the measures
18	identified under subsection (a)(3) in gauging
19	progress against the strategic goals and priorities
20	identified under subsection(a)(1);
21	(3) assess the extent to which the Center for
22	Drug Evaluation and Research, the Center for Bio-
23	logics Evaluation and Research, and the Center for
24	Devices and Radiological Health are using the iden-
25	tified results-oriented set of performance measures

1	in tracking their workload by strategic goals and the
2	effectiveness of such measures;
3	(4) assess the extent to which performance in-
4	formation is collected, analyzed, and acted on by
5	managers; and
6	(5) make recommendations, as appropriate, re-
7	garding how the strategic management plan and re-
8	lated actions of the Center for Drug Evaluation and
9	Research, the Center for Biologics Evaluation and
10	Research, and the Center for Devices and Radio-
11	logical Health could be improved to fulfill the public
12	health mission of the Food and Drug Administration
10	·
13	in as efficient and effective manner as possible.
13 14	SEC. 1131. DRUG DEVELOPMENT AND BIOEQUIVALENCE
14	SEC. 1131. DRUG DEVELOPMENT AND BIOEQUIVALENCE
14 15	SEC. 1131. DRUG DEVELOPMENT AND BIOEQUIVALENCE TESTING.
<ul><li>14</li><li>15</li><li>16</li></ul>	SEC. 1131. DRUG DEVELOPMENT AND BIOEQUIVALENCE TESTING.  (a) IN GENERAL.—Section 505–1 (21 U.S.C. 355–
<ul><li>14</li><li>15</li><li>16</li><li>17</li></ul>	SEC. 1131. DRUG DEVELOPMENT AND BIOEQUIVALENCE TESTING.  (a) IN GENERAL.—Section 505–1 (21 U.S.C. 355– 1) is amended by adding at the end the following:
<ul><li>14</li><li>15</li><li>16</li><li>17</li><li>18</li></ul>	SEC. 1131. DRUG DEVELOPMENT AND BIOEQUIVALENCE TESTING.  (a) IN GENERAL.—Section 505–1 (21 U.S.C. 355– 1) is amended by adding at the end the following:  "(k) Drug Development and Bioequivalence
<ul><li>14</li><li>15</li><li>16</li><li>17</li><li>18</li><li>19</li></ul>	SEC. 1131. DRUG DEVELOPMENT AND BIOEQUIVALENCE TESTING.  (a) IN GENERAL.—Section 505–1 (21 U.S.C. 355– 1) is amended by adding at the end the following:  "(k) Drug Development and Bioequivalence Testing.—
14 15 16 17 18 19 20	SEC. 1131. DRUG DEVELOPMENT AND BIOEQUIVALENCE TESTING.  (a) IN GENERAL.—Section 505–1 (21 U.S.C. 355– 1) is amended by adding at the end the following:  "(k) Drug Development and Bioequivalence Testing.—  "(1) In General.—Notwithstanding any other
14 15 16 17 18 19 20 21	SEC. 1131. DRUG DEVELOPMENT AND BIOEQUIVALENCE TESTING.  (a) IN GENERAL.—Section 505–1 (21 U.S.C. 355– 1) is amended by adding at the end the following:  "(k) Drug Development and Bioequivalence Testing.—  "(1) In general.—Notwithstanding any other provision of law, if a drug is a covered drug, no ele-
14 15 16 17 18 19 20 21 22	TESTING.  (a) In General.—Section 505–1 (21 U.S.C. 355–1) is amended by adding at the end the following:  "(k) Drug Development and Bioequivalence Testing.—  "(1) In General.—Notwithstanding any other provision of law, if a drug is a covered drug, no elements to assure safe use shall prohibit, or be con-

1	to support, an application under subsection (b)(2) or
2	(j) of section 505, if the Secretary has issued a no-
3	tice described in paragraph (2), and the eligible drug
4	developer has agreed to comply with the terms of the
5	notice.
6	"(2) Written notice.—For purposes of this
7	subsection, the Secretary shall issue a written notice
8	to an eligible drug developer and the holder of an
9	application for a covered drug authorizing the supply
10	of a drug to such eligible drug developer for pur-
11	poses of bioequivalence testing if—
12	"(A) the eligible drug developer has agreed
13	to comply with any conditions the Secretary
14	considers necessary; and
15	"(B) the eligible drug developer has sub-
16	mitted and the Secretary has approved a pro-
17	tocol for bioequivalence testing that includes
18	protections that the Secretary finds will provide
19	assurance of safety comparable to the assurance
20	of safety provided by the elements to assure
21	safe use in the risk evaluation and mitigation
22	strategy for the covered drug.
23	"(3) Additional required element.—The
24	Secretary shall require as an element of each risk
25	evaluation and mitigation strategy approved by the

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Secretary that the holder of an application for a covered drug shall not restrict the resale of the covered drug to an eligible drug developer that receives a written notice from the Secretary under paragraph (2).

"(4) Penalties.—For purposes of subsection (f)(8) and sections 301, 303(f)(4), 502(y), and 505(p), it shall be a violation of the risk evaluation and mitigation strategy for the holder of the covered application to restrict the sale of the drug to an eligible drug developer. The Secretary shall provide written notice to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives of any penalty assessed under this subsection within 7 days of such assessment.

"(5) LIABILITY.—The holder of an application for a covered drug shall not be liable for any claim arising out of the eligible drug developer's provision or testing of a drug under this subsection, including a claim arising out of failure of the eligible drug developer to follow adequate safeguards to assure safe use of the drug.

24 "(6) Definitions.—

1	"(A) COVERED DRUG.—Notwithstanding
2	subsection (b)(2), for purposes of this sub-
3	section, the term 'covered drug' means a drug
4	subject to a risk evaluation and mitigation
5	strategy with elements to assure safe use under
6	subsection (f), or that is deemed under section
7	909(b) of the Food and Drug Administration
8	Amendments Act of 2007 to be a drug subject
9	to a risk evaluation and mitigation strategy
10	with elements to assure safe use.
11	"(B) Eligible drug developer.—For
12	purposes of this subsection, the term 'eligible
13	drug developer' means a sponsor seeking to de-
14	velop an application for submission under sub-
15	section (b)(2) or (j) of section 505.".
16	(b) Technical and Conforming Amendment.—
17	Section 505–1(c)(2) (21 U.S.C. 355–1(c)(2)) is amended
18	by striking "(e) and (f)" and inserting "(e), (f), and
19	(k)(3)".