

.....
(Original Signature of Member)

111TH CONGRESS
1ST SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of food, drugs, devices, and cosmetics in the global market, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. DINGELL introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of food, drugs, devices, and cosmetics in the global market, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 **SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CON-**
4 **TENTS.**

5 (a) SHORT TITLE.—This Act may be cited as the
6 “Food and Drug Administration Globalization Act of
7 2009”.

1 (b) REFERENCES TO THE FEDERAL FOOD, DRUG,
2 AND COSMETIC ACT.—Except as otherwise specified,
3 whenever in this Act an amendment is expressed in terms
4 of an amendment to a section or other provision, the ref-
5 erence shall be considered to be made to a section or other
6 provision of the Federal Food, Drug, and Cosmetic Act
7 (21 U.S.C. 301 et seq.).

8 (c) TABLE OF CONTENTS.—The table of contents of
9 this Act is as follows:

- Sec. 1. Short title; references; table of contents.
- Sec. 2. Relationship to State law.

TITLE I—FOOD SAFETY

Subtitle A—Prevention

- Sec. 101. Changes in registration of food facilities.
- Sec. 102. Hazard analysis, risk-based preventive controls, and food safety plan.
- Sec. 103. Performance standards.
- Sec. 104. Safety standards for fresh produce.
- Sec. 105. Risk-based inspection.
- Sec. 106. Access to records.
- Sec. 107. Traceability of food.
- Sec. 108. Reinspection fee applicable to facilities.
- Sec. 109. Certification of food facilities.
- Sec. 110. Safe and secure food importation program.

Subtitle B—Intervention

- Sec. 111. Public health assessment system.
- Sec. 112. Public education and advisory system.
- Sec. 113. Research.
- Sec. 114. Notification, nondistribution, and recall of adulterated or misbranded articles of food.

Subtitle C—Response

- Sec. 121. Administrative detention.
- Sec. 122. Civil penalties relating to food.
- Sec. 123. Failure to consent to investigation.

Subtitle D—Miscellaneous

- Sec. 131. Labeling requirement for meat, poultry products, and seafood that contain carbon monoxide.
- Sec. 132. Food substances generally recognized as safe.
- Sec. 133. Country of origin labeling; disclosure of source of ingredients.

- Sec. 134. New food and animal feed export certification fee to improve the ability of United States firms to export their products.

TITLE II—DRUG AND DEVICE SAFETY

- Sec. 201. Registration of producers of drugs and devices; applicable fee.
Sec. 202. Inspection of producers of drugs and active pharmaceutical ingredients.
Sec. 203. Documentation for admissibility of drug imports.
Sec. 204. Drug supply quality and safety.
Sec. 205. Delay, limitation, or denial of inspection.
Sec. 206. Country of origin labeling.
Sec. 207. Nondistribution and recall of adulterated or misbranded drugs.
Sec. 208. Destruction of adulterated, misbranded or counterfeit articles offered for import.
Sec. 209. Administrative detention of drugs that appear to violate the law.
Sec. 210. Penalties regarding counterfeit drugs.
Sec. 211. Civil money penalties for violative drugs and devices and improper import entry filings.
Sec. 212. Human generic drug application and supplement fees to cover pre-approval inspection costs.

TITLE III—COSMETIC SAFETY

- Sec. 301. Registration of cosmetic establishments.
Sec. 302. Cosmetic and ingredient statements.
Sec. 303. Serious and unexpected adverse event reports for cosmetics.
Sec. 304. Good manufacturing practices for cosmetics.
Sec. 305. Authorization of appropriations.
Sec. 306. Effective date.

TITLE IV—MISCELLANEOUS

- Sec. 401. Registration for commercial importers of food, drugs, devices, and cosmetics; fee.
Sec. 402. Unique identification number for food, drug, and device facilities and establishments.
Sec. 403. Prohibition against delaying or limiting inspection.
Sec. 404. Dedicated foreign inspectorate.
Sec. 405. Continued operation of field laboratories.
Sec. 406. False or misleading reporting to FDA.
Sec. 407. Subpoena authority.
Sec. 408. Whistleblower protections.

1 **SEC. 2. RELATIONSHIP TO STATE LAW.**

2 This Act and the amendments made by this Act may
3 not be construed as modifying or otherwise affecting any
4 action or the liability of any person (as defined in section
5 201 of the Federal Food, Drug, and Cosmetic Act) under
6 the law of any State.

1 **TITLE I—FOOD SAFETY**
2 **Subtitle A—Prevention**

3 **SEC. 101. CHANGES IN REGISTRATION OF FOOD FACILI-**
4 **TIES.**

5 (a) MISBRANDING.—Section 403 (21 U.S.C. 343) is
6 amended by adding at the end the following:

7 “(z) If it was manufactured, processed, packed, or
8 held in a facility that is not duly registered under section
9 415 or is in violation of section 741 (requiring payment
10 of a fee for such registration).”.

11 (b) ANNUAL REGISTRATION AND PAYMENT OF REG-
12 ISTRATION FEE.—

13 (1) IN GENERAL.—Section 415(a) (21 U.S.C.
14 350d(a)) is amended—

15 (A) in the first sentence of paragraph (1),
16 by inserting “annually” after “be registered”;

17 (B) in paragraph (1), by inserting “and
18 pay the registration fee required under section
19 741” after “submit a registration to the Sec-
20 retary” each place it appears in subparagraphs
21 (A) and (B); and

22 (C) in paragraph (4), by inserting after the
23 first sentence the following: “The Secretary
24 shall remove from such list the name of any fa-
25 cility that fails to reregister in accordance with

1 this section and shall treat such removal as a
2 suspension of the facility’s registration.”.

3 (2) REGISTRATION FEE.—Chapter VII (21
4 U.S.C. 371 et seq.) is amended—

5 (A) by redesignating sections 741 and 742
6 as sections 744 and 745, respectively; and

7 (B) by adding at the end of subchapter C
8 the following:

9 **“PART 5—FEES RELATING TO FOOD**

10 **“SEC. 741. FACILITY REGISTRATION FEE.**

11 “(a) IN GENERAL.—The Secretary shall assess and
12 collect a fee for a facility registration under section 415
13 to defray increases (as described in subsection
14 (f)(2)(A)(ii)) in the costs of inspecting establishments reg-
15 istered under section 415 and for related activities to en-
16 sure compliance by such establishments with the require-
17 ments of this Act relating to food (including increases in
18 such costs for management of information, and the acqui-
19 sition, maintenance, and repair of information technology
20 resources).

21 “(b) FREE REVENUE AMOUNTS.—

22 “(1) IN GENERAL.—For each of fiscal years
23 2010 through 2015, fees under subsection (a) shall,
24 except as provided in subsections (c), (e), and (f), be

1 established to generate a total revenue amount
2 under subsection (a).

3 “(2) TOTAL REVENUE AMOUNT.—Not later
4 than September 1, 2009, the Secretary shall trans-
5 mit to the Congress the total revenue amount under
6 paragraph (1) and how such amount was calculated.

7 “(3) ANNUAL FEE SETTING.—The Secretary
8 shall, not later than 60 days before the start of each
9 fiscal year that begins after September 30, 2009, es-
10 tablish, for the next fiscal year, registration fees
11 under subsection (a) based on the total revenue
12 amount applicable under paragraph (1).

13 “(c) ADJUSTMENTS.—

14 “(1) INFLATION ADJUSTMENT.—For fiscal year
15 2011 and subsequent fiscal years, the revenues es-
16 tablished under subsection (b)(1) shall be adjusted
17 by the Secretary by notice, published in the Federal
18 Register, for a fiscal year to reflect the greater of—

19 “(A) the total percentage change that oc-
20 curred in the Consumer Price Index for all
21 urban consumers (all items; U.S. city average)
22 for the 12-month period ending June 30 pre-
23 ceding the fiscal year for which fees are being
24 established;

1 “(B) the total percentage change for the
2 previous fiscal year in basic pay under the Gen-
3 eral Schedule in accordance with section 5332
4 of title 5, United States Code, as adjusted by
5 any locality-based comparability payment pur-
6 suant to section 5304 of such title for Federal
7 employees stationed in the District of Columbia;
8 or

9 “(C) the average annual change in the
10 cost, per full-time equivalent position of the
11 Food and Drug Administration, of all personnel
12 compensation and benefits paid with respect to
13 such positions for the first 5 years of the pre-
14 ceding 6 fiscal years.

15 The adjustment made each fiscal year under this
16 subsection shall be added on a compounded basis to
17 the sum of all adjustments made each fiscal year
18 after fiscal year 2009 under this subsection.

19 “(2) WORKLOAD ADJUSTMENT.—For fiscal
20 year 2011 and subsequent fiscal years, after the fee
21 revenues established under subsection (b)(1) are ad-
22 justed for a fiscal year for inflation in accordance
23 with paragraph (1), the fee revenues shall be ad-
24 justed further for such fiscal year to reflect changes
25 in the workload of the Secretary for inspections and

1 related activities described in subsection (a). With
2 respect to such adjustment:

3 “(A) The adjustment shall be determined
4 by the Secretary based on a weighted average
5 of the change in the total amount of inspections
6 and related activities described in subsection
7 (a). The Secretary shall publish in the Federal
8 Register the fee revenues and fees resulting
9 from the adjustment and the supporting meth-
10 odologies.

11 “(B) Under no circumstances shall the ad-
12 justment result in fee revenues for a fiscal year
13 that are less than the fee revenues for the fiscal
14 year established under subsection (b)(1), as ad-
15 justed for inflation under paragraph (1). Any
16 adjustment for changes in inspections and re-
17 lated activities described in subsection (a) made
18 in setting fees and revenue amounts for fiscal
19 year 2011 or any subsequent year may not re-
20 sult in the total workload adjustment being
21 more than 2 percentage points higher than it
22 would have been in the absence of the adjust-
23 ment for changes in inspections and related ac-
24 tivities.

1 “(C) The Secretary shall contract with an
2 independent accounting firm to study the ad-
3 justment for changes in inspections and related
4 activities described in subsection (a) applied in
5 setting fees and revenue amounts for fiscal year
6 2011 and to make recommendations, if war-
7 ranted, for future changes in the methodology
8 for calculating the adjustment. After review of
9 the recommendations, the Secretary shall, if
10 warranted, make appropriate changes to the
11 methodology, and the changes shall be effective
12 for each of fiscal years 2012 through 2015. The
13 Secretary shall not make any adjustment for
14 changes in inspections and related activities de-
15 scribed in subsection (a) for any fiscal year
16 after 2011 unless such study has been com-
17 pleted.

18 “(3) RENT AND RENT-RELATED COST ADJUST-
19 MENT.—For fiscal year 2012 and each subsequent
20 fiscal year, the Secretary shall, before making ad-
21 justments under paragraphs (1) and (2), decrease
22 the fee revenue amount established under subsection
23 (b)(1) if actual costs paid for rent and rent-related
24 expenses for the preceding fiscal year are less than
25 estimates made for such year in fiscal year 2008.

1 Any reduction made under this paragraph shall not
2 exceed the amount by which such costs fall below the
3 estimates made in fiscal year 2008 for such fiscal
4 year, and shall not exceed \$11,721,000 for any fiscal
5 year.

6 “(4) FINAL YEAR ADJUSTMENT.—For fiscal
7 year 2015, the Secretary may, in addition to adjust-
8 ments under paragraphs (1), (2), (3), and (5), fur-
9 ther increase the fee revenues and fees established in
10 subsection (b) if such an adjustment is necessary to
11 provide for not more than 3 months of operating re-
12 serves of carryover user fees for inspections de-
13 scribed in subsection (a) for the first 3 months of
14 fiscal year 2016. If such an adjustment is necessary,
15 the rationale for the amount of the increase shall be
16 contained in the annual notice establishing fee reve-
17 nues and fees for fiscal year 2015. If the Secretary
18 has carryover balances for such inspections in excess
19 of 3 months of such operating reserves, the adjust-
20 ment under this paragraph shall not be made.

21 “(5) COST ESTIMATE ADJUSTMENT.—For fiscal
22 year 2011 and subsequent fiscal years, the Secretary
23 by notice, published in the Federal Register, shall—

1 “(A) provide an estimate of the amount of
2 the total increases described in subsection (a)
3 for such fiscal year; and

4 “(B) after making adjustments under
5 paragraphs (1), (2), and (3), adjust the reve-
6 nues established under subsection (b)(1) to be
7 equal to such amount.

8 “(6) LIMIT.—The total amount of fees charged,
9 as adjusted under this subsection, for a fiscal year
10 may not exceed the total increases described in sub-
11 section (a) for such fiscal year.

12 “(d) WAIVERS.—The Secretary shall waive the fee
13 under this section with respect to any facility that is a
14 small business, as defined by the Secretary.

15 “(e) LIMITATIONS.—

16 “(1) IN GENERAL.—Fees under subsection (a)
17 shall be refunded for a fiscal year beginning after
18 fiscal year 2010 unless appropriations for salaries
19 and expenses of the Food and Drug Administration
20 for such fiscal year (excluding the amount of fees
21 appropriated for such fiscal year) are equal to or
22 greater than the amount of appropriations for the
23 salaries and expenses of the Food and Drug Admin-
24 istration for the fiscal year 2010 (excluding the
25 amount of fees appropriated for such fiscal year)

1 multiplied by the adjustment factor applicable to the
2 fiscal year involved.

3 “(2) AUTHORITY.—If the Secretary does not
4 assess fees under subsection (a) during any portion
5 of a fiscal year because of paragraph (1) and if at
6 a later date in such fiscal year the Secretary may as-
7 sess such fees, the Secretary may assess and collect
8 such fees, without any modification in the rate, for
9 registration under section 415 at any time in such
10 fiscal year.

11 “(f) CREDITING AND AVAILABILITY OF FEES.—

12 “(1) IN GENERAL.—Fees authorized under sub-
13 section (a) shall be collected and available for obliga-
14 tion only to the extent and in the amount provided
15 in advance in appropriations Acts. Such fees are au-
16 thorized to remain available until expended. Such
17 sums as may be necessary may be transferred from
18 the Food and Drug Administration salaries and ex-
19 penses appropriation account without fiscal year lim-
20 itation to such appropriation account for salaries
21 and expenses with such fiscal year limitation.

22 “(2) COLLECTIONS AND APPROPRIATION
23 ACTS.—

24 “(A) IN GENERAL.—The fees authorized
25 by this section—

1 “(i) shall be retained in each fiscal
2 year in an amount not to exceed the
3 amount specified in appropriation Acts, or
4 otherwise made available for obligation, for
5 such fiscal year; and

6 “(ii) shall only be collected and avail-
7 able to defray increases in the costs of in-
8 specting establishments registered under
9 section 415 and related activities to ensure
10 compliance by such establishments with the
11 requirements of this Act relating to food
12 (including increases in such costs for an
13 additional number of full-time equivalent
14 positions in the Department of Health and
15 Human Services to be engaged in such in-
16 spections and for management of informa-
17 tion, and the acquisition, maintenance, and
18 repair of information technology resources)
19 over such costs, excluding costs paid from
20 fees collected under this section, for fiscal
21 year 2009 multiplied by the adjustment
22 factor.

23 “(B) COMPLIANCE.—The Secretary shall
24 be considered to have met the requirements of
25 subparagraph (A)(ii) in any fiscal year if the

1 costs funded by appropriations and allocated for
2 inspections described in subsection (a)—

3 “(i) are not more than 3 percent
4 below the level specified in subparagraph
5 (A)(ii); or

6 “(ii)(I) are more than 3 percent below
7 the level specified in subparagraph (A)(ii),
8 and fees assessed for the fiscal year fol-
9 lowing the subsequent fiscal year are de-
10 creased by the amount in excess of 3 per-
11 cent by which such costs fell below the
12 level specified in such subparagraph; and

13 “(II) such costs are not more than 5
14 percent below the level specified in such
15 subparagraph.

16 “(3) AUTHORIZATION OF APPROPRIATIONS.—
17 For each of the fiscal years 2010 through 2015,
18 there is authorized to be appropriated for fees under
19 this section an amount equal to the total revenue
20 amount determined under subsection (b)(1) for the
21 fiscal year, as adjusted or otherwise affected under
22 subsection (c) and paragraph (4) of this subsection.

23 “(4) OFFSET.—If the sum of the cumulative
24 amount of fees collected under this section for the
25 fiscal years 2010 through 2014 and the amount of

1 fees estimated to be collected under this section for
2 fiscal year 2015 exceeds the cumulative amount ap-
3 propriated under paragraph (3) for the fiscal years
4 2010 through 2014, the excess shall be credited to
5 the appropriation account of the Food and Drug Ad-
6 ministration as provided in paragraph (1), and shall
7 be subtracted from the amount of fees that would
8 otherwise be authorized to be collected under this
9 section for fiscal year 2015.

10 “(g) COLLECTION OF UNPAID FEES.—In any case
11 where the Secretary does not receive payment of a fee as-
12 sessed under subsection (a) within 30 days after it is due,
13 such fee shall be treated as a claim of the United States
14 Government subject to subchapter II of chapter 37 of title
15 31, United States Code.

16 “(h) CONSTRUCTION.—This section may not be con-
17 strued to require that the number of full-time equivalent
18 positions in the Department of Health and Human Serv-
19 ices, for officers, employers, and advisory committees not
20 engaged in inspections described in subsection (a), be re-
21 duced to offset the number of officers, employees, and ad-
22 visory committees so engaged.

23 “(i) ANNUAL FISCAL REPORTS.—Beginning with fis-
24 cal year 2011, not later than 120 days after the end of
25 each fiscal year for which fees are collected under this sec-

1 tion, the Secretary shall prepare and submit to the Com-
2 mittee on Energy and Commerce of the House of Rep-
3 resentatives and the Committee on Health, Education,
4 Labor, and Pensions of the Senate a report on the imple-
5 mentation of the authority for such fees during such fiscal
6 year and the use, by the Food and Drug Administration,
7 of the fees collected for such fiscal year.

8 “(j) DEFINITION.—In this section, the term ‘adjust-
9 ment factor’ applicable to a fiscal year is the Consumer
10 Price Index for all urban consumers (all items; United
11 States city average) for October of the preceding fiscal
12 year divided by such Index for October 2009.”.

13 (c) CONTENTS OF REGISTRATION.—Paragraph (2) of
14 section 415(a) (21 U.S.C. 350d(a)) is amended by striking
15 “containing information” and all that follows and insert-
16 ing the following: “containing information that identifies
17 the following:

18 “(A) The name, address, and emergency
19 contact information of each facility engaged in
20 manufacturing, processing, packing, or holding
21 food for consumption in the United States that
22 the registrant operates.

23 “(B) The primary purpose and business
24 activity of each such facility, including the dates
25 of operation if the facility is seasonal.

1 “(C) The general food category (as listed
2 under section 170.3(n) of title 21, Code of Fed-
3 eral Regulations, or as the Secretary may other-
4 wise designate for purposes of evaluating poten-
5 tial threats to food protection) of any food man-
6 ufactured, processed, packed, or held at each
7 such facility.

8 “(D) All trade names under which each
9 such facility conducts business related to food.

10 “(E) The name, address, and 24-hour
11 emergency contact information of the United
12 States distribution agent for each such facility,
13 which agent shall maintain information on the
14 wholesale and retail distribution of food.

15 The registrant shall notify the Secretary of any
16 change in the products, function, or legal status of
17 each such facility (including cessation of business ac-
18 tivities) not later than 30 days after the date of such
19 change.”.

20 (d) SUSPENSION AUTHORITY.—Section 415(a) (21
21 U.S.C. 350d(a)), as amended by subsection (c), is further
22 amended by adding at the end the following:

23 “(5) SUSPENSION OF REGISTRATION.—

24 “(A) IN GENERAL.—The Secretary may
25 suspend the registration of any facility reg-

1 istered under this section, including the facility
2 of an importer—

3 “(i) for violation of this Act that could
4 result in serious adverse health con-
5 sequences or death to humans or animals;
6 or

7 “(ii) if the facility, or an employee of
8 the facility, delays or limits an inspection,
9 or refuses to permit entry or inspection, by
10 the Secretary under this Act.

11 “(B) NOTICE AND OPPORTUNITY FOR
12 HEARING.—Before suspending the registration
13 of a facility under this paragraph, the Secretary
14 shall provide notice to a registrant of an intent
15 to suspend the registration and provide the reg-
16 istrant with an opportunity for an informal
17 hearing. The Secretary may issue a written
18 order of suspension following the hearing, if the
19 Secretary finds that a violation described in
20 subparagraph (A) has occurred.

21 “(C) REINSTATEMENT.—A registration
22 that is suspended under this section may be re-
23 instated pursuant to criteria published by the
24 Secretary in the Federal Register and on a pub-

1 lic Website of the Food and Drug Administra-
2 tion.

3 “(D) APPEAL.—Any registrant whose reg-
4 istration is suspended under this section may
5 appeal that action in any appropriate district
6 court of the United States.”.

7 (e) EFFECTIVE DATE.—

8 (1) MODIFICATION OF REGISTRATION FORM.—
9 Not later than 30 days after the date of the enact-
10 ment of this Act, the Secretary of Health and
11 Human Services shall modify the registration form
12 under section 415 of the Federal Food, Drug, and
13 Cosmetic Act (21 U.S.C. 350d) to comply with the
14 amendments made by subsection (c).

15 (2) APPLICATION.—The amendments made by
16 this section, other than by subsection (c), shall take
17 effect on the date that is 30 days after the date on
18 which such modified registration form takes effect,
19 but not later than 60 days after the date of the en-
20 actment of this Act.

21 **SEC. 102. HAZARD ANALYSIS, RISK-BASED PREVENTIVE**
22 **CONTROLS, AND FOOD SAFETY PLAN.**

23 (a) PROHIBITED ACT.—Section 301 (21 U.S.C. 331)
24 is amended by adding at the end the following:

1 “(oo) The operation of a facility that manufactures,
2 processes, packs, transports, or holds food for consump-
3 tion in the United States if the owner, operator, or agent
4 in charge of such facility is not in compliance with sections
5 418 and 418A.”.

6 (b) REQUIREMENTS.—Chapter IV (21 U.S.C. 341 et
7 seq.) is amended by adding at the end the following:

8 **“SEC. 418. HAZARD ANALYSIS AND RISK-BASED PREVEN-**
9 **TIVE CONTROLS.**

10 “(a) IN GENERAL.—The owner, operator, or agent
11 in charge of a facility shall, in accordance with this sec-
12 tion, evaluate the hazards that could affect food manufac-
13 tured, processed, packed, transported, or held by such fa-
14 cility, identify and implement preventive controls to sig-
15 nificantly minimize, prevent, or eliminate the occurrence
16 of such hazards, monitor the performance of such controls,
17 and maintain records of such monitoring.

18 “(b) HAZARD ANALYSIS.—The owner, operator, or
19 agent in charge of a facility shall identify and evaluate
20 known or reasonably foreseeable hazards that may be as-
21 sociated with the facility, including—

22 “(1) biological, chemical, physical, and radio-
23 logical hazards, natural toxins, pesticides, drug resi-
24 dues, decomposition, parasites, allergens, and unap-
25 proved food and color additives;

1 “(2) hazards that occur naturally, may be unin-
2 tentionally introduced, or may be intentionally intro-
3 duced, including by acts of terrorism; and

4 “(3) relevant hazards identified under section
5 419.

6 “(c) PREVENTIVE CONTROLS.—

7 “(1) IN GENERAL.—The owner, operator, or
8 agent in charge of a facility shall identify, imple-
9 ment, and validate preventive controls, including at
10 critical control points, if any, to significantly mini-
11 mize, prevent, or eliminate hazards identified in the
12 hazard analysis conducted under subsection (b).

13 “(2) SPECIFIC PRODUCT TYPES.—The Sec-
14 retary may establish by regulation or guidance addi-
15 tional preventive controls under this section for spe-
16 cific product types to prevent intentional or uninten-
17 tional contamination throughout the supply chain.

18 “(d) MONITORING OF EFFECTIVENESS.—The owner,
19 operator, or agent in charge of a facility shall monitor the
20 effectiveness of the preventive controls implemented under
21 subsection (c).

22 “(e) CORRECTIVE ACTIONS.—The owner, operator,
23 or agent in charge of a facility shall establish procedures
24 that the facility will implement if the preventive controls

1 implemented under subsection (c) are found to be ineffec-
2 tive through monitoring under subsection (d).

3 “(f) VERIFICATION.—The owner, operator, or agent
4 in charge of a facility shall verify that—

5 “(1) the preventive controls implemented under
6 subsection (c) have been validated as adequate to
7 control the hazards identified under subsection (b);

8 “(2) the owner, operator, or agent is conducting
9 monitoring in accordance with subsection (d); and

10 “(3) the owner, operator, or agent is taking ef-
11 fective corrective actions under subsection (e).

12 “(g) RECORD KEEPING.—The owner, operator, or
13 agent in charge of a facility shall maintain, for not less
14 than 2 years, records documenting the monitoring and
15 verification of the effectiveness of the actions described in
16 subsections (a) through (f).

17 “(h) REQUIREMENT TO REANALYZE.—Each owner,
18 operator, or agent in charge of a facility shall—

19 “(1) conduct a reanalysis under subsection
20 (b)—

21 “(A) whenever there is a reasonable poten-
22 tial for a new hazard or a significant increase
23 in a previously identified hazard;

24 “(B) not less frequently than once every 2
25 years; and

1 “(C) if the Secretary determines it to be
2 appropriate for the protection of the public
3 health; and

4 “(2) revise the preventive controls under sub-
5 section (c) to significantly minimize, prevent, or
6 eliminate such hazard or document the basis for the
7 conclusion that no such revision is needed.

8 “(i) DEFINITIONS.—For purposes of this section:

9 “(1) CRITICAL CONTROL POINT.—The term
10 ‘critical control point’ means a point, step, or proce-
11 dure in a food process at which control can be ap-
12 plied and is essential to prevent or eliminate a food
13 safety hazard or reduce it to an acceptable level.

14 “(2) FACILITY.—The term ‘facility’ means a
15 domestic facility or a foreign facility that is required
16 to register under section 415.

17 “(3) PREVENTIVE CONTROLS.—The term ‘pre-
18 ventive controls’ means those risk-based procedures,
19 practices, and processes that a person knowledgeable
20 about the safe manufacturing, processing, packing,
21 transporting, or holding of food would have em-
22 ployed to significantly minimize, prevent, or elimi-
23 nate the hazards identified under the hazard anal-
24 ysis conducted under subsection (a) and that are
25 consistent with the current scientific understanding

1 of safe food manufacturing, processing, packing,
2 transporting, or holding at the time of the analysis.
3 Those procedures, practices, and processes may in-
4 clude the following:

5 “(A) Sanitation procedures for food con-
6 tact surfaces and utensils and food-contact sur-
7 faces of equipment.

8 “(B) Supervisor, manager, and employee
9 hygiene training.

10 “(C) An environmental monitoring pro-
11 gram to verify the effectiveness of pathogen
12 controls.

13 “(D) An allergen control program.

14 “(E) A recall contingency plan.

15 “(F) Good manufacturing practices.

16 “(G) Supplier verification activities.

17 **“SEC. 418A. FOOD SAFETY PLAN.**

18 “(a) IMPLEMENTATION OF FOOD SAFETY PLAN.—

19 “(1) IN GENERAL.—Before a facility (as de-
20 fined in section 418(i)) introduces or delivers for in-
21 troduction into interstate commerce any shipment of
22 food, the owner, operator, or agent in charge of the
23 facility shall develop and implement a written food
24 safety plan (in this section referred to as a ‘food
25 safety plan’).

1 “(2) CONTENTS.—The food safety plan shall in-
2 clude each of the following elements:

3 “(A) The hazard analysis conducted under
4 section 418.

5 “(B) A description of the preventive con-
6 trols being implemented under section 418(e),
7 including any those for specific product types
8 under section 418(e)(2).

9 “(C) Validation that such preventive con-
10 trols are effective to reduce, control, or elimi-
11 nate such hazard.

12 “(D) A description of monitoring of such
13 preventive controls being implemented, includ-
14 ing sampling and testing relating to the control
15 of hazards where appropriate to verify that the
16 controls are effective.

17 “(E) A description of the record keeping
18 being conducted, including evidence of correc-
19 tive actions, sampling and testing records, mon-
20 itoring and verification records, and validation
21 records.

22 “(F) A description of established proce-
23 dures for the recall of articles of food, whether
24 voluntarily or when required under section 422.

1 “(G) A description of established proce-
2 dures for the trace back of articles of food,
3 whether voluntarily or when required under sec-
4 tion 403(g).

5 “(H) A description of established proce-
6 dures to ensure a safe and secure supply chain
7 for the ingredients or components used in mak-
8 ing the food produced, processed, packed, trans-
9 ported, or held by such facility.

10 “(I) A description of established proce-
11 dures to implement the science-based perform-
12 ance standards issued under section 419.

13 “(b) INSPECTION OF FOOD SAFETY PLAN IN COURSE
14 OF FACILITY INSPECTION.—In the course of a facility in-
15 spection under section 704, the Secretary shall conduct
16 a review of the food safety plan to ensure the plan meets
17 relevant requirements of section 418, this section, and sec-
18 tion 419 and is adequate to protect the public health.”.

19 (c) GUIDANCE OR REGULATIONS.—

20 (1) IN GENERAL.—The Secretary of Health and
21 Human Services (referred to in this subsection as
22 the “Secretary”) shall issue guidance or promulgate
23 regulations to establish science-based minimum
24 standards for conducting a hazard analysis, docu-
25 menting hazards, implementing preventive controls,

1 and documenting the implementation of the preven-
2 tive controls under sections 418 and 418A of the
3 Federal Food, Drug, and Cosmetic Act (as added by
4 subsection (b)).

5 (2) CONSIDERATION.—In issuing guidance or
6 promulgating regulations under this section, the Sec-
7 retary shall consider the capacity of small busi-
8 nesses.

9 (d) NO EFFECT ON HACCP AUTHORITIES.—Noth-
10 ing in the amendments made by this section limits the au-
11 thority of the Secretary under the Federal Food, Drug,
12 and Cosmetic Act (21 U.S.C. 301 et seq.) or the Public
13 Health Service Act (42 U.S.C. 201 et seq.) to revise, issue,
14 or enforce product and category-specific regulations, such
15 as the Seafood Hazard Analysis Critical Controls Points
16 Program, the Juice Hazard Analysis Critical Control Pro-
17 gram, and the Thermally Processed Low-Acid Foods
18 Packaged in Hermetically Sealed Containers standards.

19 (e) EFFECTIVE DATE.—

20 (1) GENERAL RULE.—The amendments made
21 by this section shall take effect 18 months after the
22 date of the enactment of this Act.

23 (2) EXCEPTIONS.—Notwithstanding paragraph
24 (1)—

1 (A) the amendments made by this section
2 shall apply to a small business (as defined by
3 the Secretary) after the date that is 2 years
4 after the date of the enactment of this Act; and

5 (B) the amendments made by this section
6 shall apply to a very small business (as defined
7 by the Secretary) after the date that is 3 years
8 after the date of the enactment of this Act.

9 **SEC. 103. PERFORMANCE STANDARDS.**

10 Chapter IV (21 U.S.C. 341 et seq.), as amended by
11 section 102, is further amended by adding at the end the
12 following:

13 **“SEC. 419. PERFORMANCE STANDARDS.**

14 “The Secretary shall, not less frequently than every
15 2 years, review and evaluate epidemiological data and
16 other appropriate sources of information, including re-
17 search under section 113 of the Food and Drug Adminis-
18 tration Globalization Act of 2009, to identify the most sig-
19 nificant food-borne contaminants and the most significant
20 resulting hazards, and shall issue, through guidance or by
21 regulation, science-based performance standards (which
22 may include action levels) to significantly minimize, pre-
23 vent, or eliminate the occurrence of such hazards. Such
24 standards shall be applicable to products and product
25 classes and shall not be specific to an individual facility.”.

1 **SEC. 104. SAFETY STANDARDS FOR FRESH PRODUCE.**

2 (a) PROHIBITED ACT.—Section 301 (21 U.S.C. 331),
3 as amended by sections 102 and 103, is amended by add-
4 ing at the end the following:

5 “(pp) The production or harvesting of produce not
6 in accordance with minimum standards as provided by
7 regulation under section 419A(a) or a variance issued
8 under section 419A(e).”.

9 (b) STANDARDS.—Chapter IV (21 U.S.C. 341 et
10 seq.), as amended by sections 102 and 103, is amended
11 by adding at the end the following:

12 **“SEC. 419A. STANDARDS FOR PRODUCE SAFETY.**

13 “(a) STANDARDS.—The Secretary shall establish by
14 regulation science-based minimum standards for the safe
15 production and harvesting of those types of fruits and
16 vegetables that are raw agricultural commodities for which
17 the Secretary has determined that such standards mini-
18 mize the risk of serious adverse health consequences or
19 death.

20 “(b) CONTENTS.—The regulations under subsection
21 (a)—

22 “(1) shall set forth such procedures, processes,
23 and practices as the Secretary determines to be rea-
24 sonably necessary—

25 “(A) to prevent the introduction of known
26 or reasonably foreseeable biological, chemical,

1 and physical hazards, including hazards that
2 occur naturally, may be unintentionally intro-
3 duced, or may be intentionally introduced, in-
4 cluding by acts of terrorism, into fruits and
5 vegetables that are raw agricultural commod-
6 ities; and

7 “(B) to provide reasonable assurances that
8 the produce is not adulterated under section
9 402;

10 “(2) shall include, with respect to growing, har-
11 vesting, packing, sorting, and storage operations,
12 minimum standards for safety;

13 “(3) shall include standards addressing manure
14 use, water quality, employee hygiene, sanitation and
15 animal control, temperature controls, and nutrients;

16 “(4) may include standards for such other ele-
17 ments as the Secretary determines necessary to
18 carry out subsection (a);

19 “(5) shall provide a reasonable period of time
20 for compliance, taking into account the needs of
21 small businesses for additional time to comply; and

22 “(6) shall provide for coordination of education
23 and enforcement activities by State and local offi-
24 cials, as designated by the Governors of the respec-
25 tive States.

1 “(c) PRIORITIZATION.—The Secretary shall prioritize
2 the implementation of the regulations under subsection (a)
3 for specific fruits and vegetables that are raw agricultural
4 commodities and have been associated with food-borne ill-
5 ness outbreaks.

6 “(d) ENFORCEMENT.—The Secretary may coordinate
7 with the Secretary of Agriculture and shall contract and
8 coordinate with the agency or department designated by
9 the Governor of each State to perform activities to ensure
10 compliance with this section.”.

11 (c) GUIDANCE; RULEMAKING.—

12 (1) GUIDANCE.—Not later than 1 year after
13 the date of enactment of this Act, the Secretary
14 shall publish, after consultation with the Secretary
15 of Agriculture and representatives of State depart-
16 ments of agriculture, updated good agricultural
17 practices and guidance for the safe production and
18 harvesting of specific types of fresh produce.

19 (2) PROPOSED RULEMAKING.—

20 (A) IN GENERAL.—Not later than 1 year
21 after the date of the enactment of this Act, the
22 Secretary, in consultation with the Secretary of
23 Agriculture and representatives of State depart-
24 ments of agriculture, shall publish a notice of
25 proposed rulemaking under section 419A of the

1 Federal Food, Drug, and Cosmetic Act, as
2 added by subsection (b).

3 (B) PUBLIC INPUT.—During the comment
4 period on the notice of proposed rulemaking
5 under subparagraph (A), the Secretary shall
6 conduct not less than 3 public meetings in di-
7 verse geographical areas of the United States to
8 provide persons in different regions an oppor-
9 tunity to comment.

10 (3) FINAL REGULATION.—Not later than 1 year
11 after the close of the comment period for the pro-
12 posed rulemaking under paragraph (2), the Sec-
13 retary shall adopt a final regulation under section
14 419A of the Federal Food, Drug, and Cosmetic Act,
15 as added by subsection (b).

16 (d) NO EFFECT ON HACCP AUTHORITIES.—Noth-
17 ing in the amendments made by this section limits the au-
18 thority of the Secretary under the Federal Food, Drug,
19 and Cosmetic Act (21 U.S.C. 301 et seq.) or the Public
20 Health Service Act (42 U.S.C. 201 et seq.) to revise, issue,
21 or enforce product and category-specific regulations, such
22 as the Seafood Hazard Analysis Critical Controls Points
23 Program, the Juice Hazard Analysis Critical Control Pro-
24 gram, and the Thermally Processed Low-Acid Foods
25 Packaged in Hermetically Sealed Containers standards.

1 **SEC. 105. RISK-BASED INSPECTION.**

2 (a) RISK-BASED INSPECTION SCHEDULE.—

3 (1) IN GENERAL.—Section 704 (21 U.S.C. 374)

4 is amended by adding at the end the following:

5 “(h)(1) Each facility registered under section 415
6 shall be inspected by one or more officers duly designated
7 by the Secretary at a frequency determined pursuant to
8 a risk-based schedule.

9 “(2) The Secretary shall establish such risk-based
10 schedule not later than 18 months after the date of the
11 enactment of this subsection and may subsequently revise
12 such schedule in accordance with this section.

13 “(3) Such risk-based schedule shall provide for a fre-
14 quency of inspections commensurate with the risk pre-
15 sented by the facility, but in no case shall inspections of
16 a facility occur less than once every 4 years beginning on
17 the date of the facility’s initial registration pursuant to
18 section 415.

19 “(4) In determining the appropriate frequency of in-
20 spection, the Secretary shall consider—

21 “(A) the type of food manufactured, processed,
22 packed, or held at the facility;

23 “(B) the compliance history of the facility;

24 “(C) whether the facility is certified by a certi-
25 fying agent accredited pursuant to section 420(a);

26 and

1 “(D) such other factors as the Secretary deter-
2 mines by guidance to be relevant to assessing the
3 risk presented by the facility.”.

4 (2) FACILITIES ALREADY REGISTERED.—In
5 section 704(h)(3) of the Federal Food, Drug, and
6 Cosmetic Act, as added by paragraph (1), the term
7 “initial registration pursuant to section 415” means,
8 with respect to a facility that is registered pursuant
9 to section 415 of such Act as of the date of the en-
10 actment of this Act, the first annual registration of
11 the facility pursuant to such section 415 that occurs
12 on or after such date of enactment.

13 (3) REPORTS ON RISK-BASED INSPECTIONS OF
14 FOOD FACILITIES.—

15 (A) INITIAL REPORT.—Not later than 18
16 months after the date of the enactment of this
17 Act, the Secretary of Health and Human Serv-
18 ices shall submit a report to the Committee on
19 Energy and Commerce of the House of Rep-
20 resentatives and the Committee on Health,
21 Education, Labor, and Pensions of the Senate
22 describing the risk-based inspection schedule es-
23 tablished under section 704(h)(2) of the Fed-
24 eral Food, Drug, and Cosmetic Act, as added
25 by paragraph (1). Such report shall include a

1 description of the frequency of inspections for
2 different classes of risk, the number of facilities
3 in each class, and an estimate of the projected
4 5-year costs of implementing such inspection
5 schedule.

6 (B) SUBSEQUENT REPORTS.—Annually
7 after the submission of the report required by
8 subparagraph (A), the Secretary shall submit a
9 report to the Congress on—

10 (i) the number of foreign and domes-
11 tic facilities inspected under the risk-based
12 inspection schedule established under sec-
13 tion 704(h)(2) of the Federal Food, Drug,
14 and Cosmetic Act, as added by paragraph
15 (1), in the preceding 12 months; and

16 (ii) the costs of implementing the risk-
17 based inspection schedule for the preceding
18 12 months.

19 (b) FOOD OFFERED FOR IMPORT.—The third sen-
20 tence of subsection (a) of section 801 (21 U.S.C. 381) is
21 amended by inserting “or (4) such article is food that has
22 been processed, packed, or held at a facility that is in vio-
23 lation of section 301(f) (prohibiting the delay or limitation
24 of an inspection, or the refusal to permit entry or inspec-

1 tion, under section 704),” before “then such article shall
2 be refused admission”.

3 **SEC. 106. ACCESS TO RECORDS.**

4 (a) RECORDS INSPECTION.—Section 414(a) (21
5 U.S.C. 350c) is amended—

6 (1) by striking “If the Secretary has a reason-
7 able belief that an article of food is adulterated and
8 presents a threat of serious adverse health con-
9 sequences or death to humans or animals, each” and
10 inserting “Each”;

11 (2) by striking the term “such article” the first
12 place such term appears and inserting “an article of
13 food”;

14 (3) by striking “and a written notice to such
15 person”; and

16 (4) by striking “and presents a threat of seri-
17 ous adverse health consequences or death to humans
18 or animals” and inserting “, misbranded, or other-
19 wise in violation of this Act”; and

20 (b) CONFORMING AMENDMENT.—Section 704(a)(1)
21 (21 U.S.C. 374(a)(1)) is amended by striking “when the
22 Secretary has a reasonable belief that an article of food
23 is adulterated and presents a threat of serious adverse
24 health consequences or death to humans or animals” and

1 inserting “bearing on whether such food is adulterated,
2 misbranded, or otherwise in violation of this Act”.

3 **SEC. 107. TRACEABILITY OF FOOD.**

4 (a) FARM AND RESTAURANT RECORDS.—

5 (1) INSPECTION.—Section 414(a) of the Fed-
6 eral Food, Drug, and Cosmetic Act (21 U.S.C.
7 350c(a)), as amended by section 106, is amended by
8 striking “(excluding farms and restaurants)”.

9 (2) MAINTENANCE OF RECORDS.—Section
10 414(b) of the Federal Food, Drug, and Cosmetic Act
11 (21 U.S.C. 350c(b)), as amended by section 106, is
12 amended by striking “(excluding farms and res-
13 taurants)”.

14 (b) STANDARDIZED ELECTRONIC FORMAT.—Section
15 414 of the Federal Food, Drug, and Cosmetic Act (21
16 U.S.C. 350c(a)), as amended by section 106 and sub-
17 section (a), is amended—

18 (1) in subsection (a), by striking “in any for-
19 mat (including paper and electronic formats) and”;
20 and

21 (2) in subsection (b), by adding at the end the
22 following: “The Secretary shall require such persons
23 to maintain such records in a standardized electronic
24 format.”.

1 (c) IDENTIFICATION OF SOURCE OF RAW AGRICUL-
2 TURAL PRODUCTS.—Section 403 of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 343) is amended by
4 adding at the end the following:

5 “(z) If it is a raw agricultural product, unless each
6 commercial shipment of the product contains information
7 enabling the Secretary to identify—

8 “(1) the grower of the product;

9 “(2) the lot on which the product was produced;

10 “(3) the harvesting and packing dates of the
11 product; and

12 “(4) any other information determined appro-
13 priate by the Secretary to facilitate identification of
14 the source of raw agricultural products.”.

15 (d) STUDY.—Not later than 2 years after the date
16 of the enactment of this Act, the Commissioner of Food
17 and Drugs shall—

18 (1) complete a study on the effectiveness of
19 technologies for determining the source of raw agri-
20 cultural products; and

21 (2) submit a report to the Congress on the re-
22 sults of such study.

23 **SEC. 108. REINSPECTION FEE APPLICABLE TO FACILITIES.**

24 (a) IN GENERAL.—Part 5 of subchapter C of chapter
25 VII (21 U.S.C. 371 et seq.), as added by section

1 101(b)(2), is further amended by adding at the end the
2 following:

3 **“SEC. 741A. REINSPECTION FEE APPLICABLE TO FACILI-**
4 **TIES.**

5 “(a) IN GENERAL.—The Secretary shall assess and
6 collect fees from each facility (as defined in section
7 415(b)) that—

8 “(1) during such fiscal year, commits a viola-
9 tion of any requirement of this Act relating to food,
10 including any such requirement relating to good
11 manufacturing practices; and

12 “(2) because of such violation, undergoes addi-
13 tional inspection by the Food and Drug Administra-
14 tion.

15 “(b) AMOUNT OF FEES.—The Secretary shall set the
16 amount of the fees under this section to fully defray the
17 costs of conducting the additional inspections referred to
18 in subsection (a)(2).

19 “(c) USE OF FEES.—The Secretary shall make all
20 of the fees collected pursuant to this section available sole-
21 ly to pay for the costs of additional inspections referred
22 to in subsection (a)(2).”.

23 (b) EFFECTIVE DATE.—The amendment made by
24 subsection (a) shall apply to additional inspections occur-
25 ring after the date of the enactment of this Act.

1 **SEC. 109. CERTIFICATION OF FOOD FACILITIES.**

2 (a) MISBRANDING.—

3 (1) IN GENERAL.—Section 403 (21 U.S.C.
4 343), as amended by section 101(a), is amended by
5 adding at the end the following:

6 “(aa) If it is part of a shipment offered for import
7 into the United States and such shipment is in violation
8 of section 420(b)(5) (requiring a certification to accom-
9 pany certain food shipments).”.

10 (2) EFFECTIVE DATE.—The amendment made
11 by paragraph (1) shall apply to shipments offered
12 for import on or after the date that is 3 years after
13 the date of the enactment of this Act.

14 (b) ACCREDITATION OF CERTIFYING AGENTS; CER-
15 TIFICATION OF LABORATORIES AND ACCREDITATION OF
16 LABORATORY CERTIFYING AGENTS.—Chapter IV (21
17 U.S.C. 341 et seq.), as amended by sections 102(b), 103,
18 and 104, is amended by adding at the end the following:
19 **“SEC. 420. ACCREDITATION OF CERTIFYING AGENTS.**

20 “(a) ACCREDITATION AS CERTIFYING AGENT.—

21 “(1) IN GENERAL.—Beginning not later than 2
22 years after the date of the enactment of this section,
23 the Secretary shall establish and implement an ac-
24 creditation system under which a foreign govern-
25 ment, a State or regional food authority, a foreign
26 or domestic cooperative that aggregates the products

1 of growers or processors, and any other third party
2 that the Secretary determines appropriate, may re-
3 quest to be accredited as a certifying agent to certify
4 facilities as meeting the applicable requirements of
5 this Act.

6 “(2) QUALIFICATIONS OF CERTIFYING
7 AGENTS.—Prior to accrediting an third party as a
8 certifying agent under paragraph (1), the Secretary
9 shall perform such reviews and audits of the training
10 and qualifications of auditors used by the third
11 party, and conduct such reviews of internal systems
12 and such other investigation of the third party, as
13 the Secretary deems necessary to determine whether
14 the third party—

15 “(A) meets the requirements of this sec-
16 tion; and

17 “(B) is qualified to evaluate the compli-
18 ance of a facility with the applicable require-
19 ments of this Act.

20 “(3) LIMITATION OF ACCREDITATION.—The
21 Secretary may limit the accreditation under para-
22 graph (1) of a certifying agent to the certification of
23 facilities that produce, manufacture, process, or hold
24 only specified food products (or categories of food
25 products).

1 “(4) PERFORMANCE OF AUDITS AND RENEWAL
2 OF ACCREDITATION.—The Secretary shall audit the
3 performance of certifying agents on a periodic basis,
4 but not less than every 4 years, for the purpose of
5 renewing the accreditation of such agents.

6 “(5) WITHDRAWAL OF ACCREDITATION.—The
7 Secretary—

8 “(A) may withdraw accreditation under
9 paragraph (1) from a certifying agent if—

10 “(i) a facility certified by the agent is
11 linked to an outbreak of human or animal
12 illness; or

13 “(ii) the Secretary finds that the
14 agent no longer meets the requirements for
15 accreditation; and

16 “(B) shall withdraw accreditation under
17 paragraph (1) from a certifying agent if the
18 Secretary finds that the certifying agent has re-
19 fused to allow the Secretary to conduct such
20 audits and investigations as may be necessary
21 to ensure continued compliance with the re-
22 quirements of this section.

23 “(6) PUBLICATION OF LIST OF CERTIFYING
24 AGENTS.—The Secretary shall publish and maintain
25 on the Website of the Food and Drug Administra-

1 tion a current list of certifying agents accredited
2 under this section, including—

3 “(A) each such agent’s name and location;
4 and

5 “(B) any other information deemed nec-
6 essary by the Secretary.

7 “(b) ADDITIONAL REQUIREMENTS APPLICABLE TO
8 CERTIFYING AGENTS.—As conditions of accreditation
9 under subsection (a), a certifying agent shall agree to the
10 following:

11 “(1) AUDIT REQUIREMENTS.—A certifying
12 agent shall not certify a facility unless the certifying
13 agent has—

14 “(A) conducted an on-site audit of the fa-
15 cility, which shall be unannounced for a domes-
16 tic facility;

17 “(B) reviewed the facility’s food safety
18 plan under section 418A to ensure the plan
19 meets applicable requirements of this Act and is
20 adequate to protect the public health;

21 “(C) prepared an audit report in a form
22 and manner designated by the Secretary; and

23 “(D) conducted any other review, analysis,
24 or testing determined by the Secretary to be ap-
25 propriate for determining such facility’s compli-

1 ance with the applicable requirements of this
2 Act.

3 “(2) ACCESS TO REPORTS AND RECORDS.—A
4 certifying agent shall provide to the Secretary, upon
5 request—

6 “(A) a copy of any audit report prepared
7 under paragraph (1)(C);

8 “(B) any records relating to corrective ac-
9 tions planned or taken by the audited facility;
10 and

11 “(C) any other records related to—

12 “(i) the certification or decertification
13 of a facility;

14 “(ii) compliance of a facility with the
15 requirements of this Act; or

16 “(iii) the accreditation of the certi-
17 fying agent.

18 “(3) CONFLICTS OF INTEREST.—

19 “(A) IN GENERAL.—A certifying agent
20 shall—

21 “(i) not have an ownership, manage-
22 ment, or other financial interest in any fa-
23 cility to be certified by the certifying agent
24 or in such facility’s suppliers or vendors;

1 “(ii) have procedures to ensure
2 against the use, in carrying out audits of
3 a facility under this section, of any officer
4 or employee who has a financial conflict of
5 interest regarding such facility; and

6 “(iii) have written conflict of interest
7 policies that include prompt disclosure to
8 the Secretary of all conflicts or potential
9 conflicts of interest.

10 “(B) REGULATIONS.—Not later than 18
11 months after the date of the enactment of this
12 section, the Secretary shall promulgate regula-
13 tions to implement the requirements of sub-
14 paragraph (A). Such regulations shall include a
15 structure, including timing and public disclo-
16 sure, for fees paid by facilities to certifying
17 agents.

18 “(4) DECERTIFICATION OF FACILITIES.—A cer-
19 tifying agent shall decertify a facility if the certi-
20 fying agent, after providing a reasonable opportunity
21 for corrective action, finds that the facility no longer
22 meets the applicable requirements of this Act.

23 “(5) REQUIRED CERTIFICATION OF IMPORTS.—
24 A certifying agent shall issue a written and elec-
25 tronic certification to accompany each shipment of-

1 ferred for import into the United States containing
2 food that was manufactured, processed, packed, or
3 held by a facility certified by the agent, subject to
4 requirements set forth by the Secretary.

5 “(6) RISKS TO PUBLIC HEALTH.—If, at any
6 time during an audit, an auditor of a certifying
7 agent finds a condition at a facility that could cause
8 or contribute to illness or injury to an individual
9 consuming an article of food manufactured, proc-
10 essed, packed, or held by the facility, the certifying
11 agent shall immediately notify the Secretary of the
12 identity of the facility and such condition.

13 “(c) FALSE OR MISLEADING STATEMENTS.—For
14 purposes of section 301(q)(2), any statement or represen-
15 tation made by an employee or agent of a facility to an
16 auditor of a certifying agent or a certifying agent is
17 deemed to be a report required by or under this Act.

18 “(d) DEFINITIONS.—In this section:

19 “(1) The term ‘certifying agent’ means a third
20 party accredited as a certifying agent pursuant to
21 subsection (a)(1).

22 “(2) The term ‘facility’ means a facility re-
23 quired to be registered under section 415.

1 **“SEC. 421. CERTIFICATION OF LABORATORIES; ACCREDITA-**
2 **TION OF LABORATORY CERTIFYING AGENTS.**

3 “(a) IN GENERAL.—Not later than 2 years after the
4 date of the enactment of this section, the Secretary shall
5 establish a program for the certification of laboratories for
6 the purpose of conducting sampling and testing of food
7 to ensure compliance with the requirements of this Act.

8 “(b) STANDARDS.— Not later than 18 months after
9 the date of the enactment of this section, the Secretary
10 shall develop standards to certify laboratories under this
11 section. Such standards shall include—

12 “(1) standards for sampling and analytical pro-
13 cedures;

14 “(2) training and qualification levels for indi-
15 viduals who conduct the analyses;

16 “(3) standards for internal quality systems; and

17 “(4) any other standards determined appro-
18 priate by the Secretary.

19 “(c) ACCREDITATION OF THIRD PARTIES AS LAB-
20 ORATORY CERTIFYING AGENTS.—

21 “(1) IN GENERAL.—The Secretary may estab-
22 lish an accreditation system under which third par-
23 ties, as determined appropriate by the Secretary,
24 may request to be accredited as a laboratory certi-
25 fying agent to certify laboratories as meeting the ap-
26 plicable requirements of this Act.

1 “(2) APPLICATION OF REQUIREMENTS RELAT-
2 ING TO QUALIFICATIONS OF AGENTS, PERFORMANCE
3 OF AUDITS AND RENEWAL OF ACCREDITATION, AND
4 WITHDRAWAL OF ACCREDITATION.—The provisions
5 of paragraphs (2), (4), and (5), other than para-
6 graph (5)(A)(i), of section 420(a) shall apply to the
7 accreditation of laboratory certifying agents with re-
8 spect to laboratories in the same manner as such
9 provisions apply to the accreditation of certifying
10 agents with respect to facilities.

11 “(3) APPLICATION OF ADDITIONAL REQUIRE-
12 MENTS.—The provisions of paragraphs (1) (other
13 than subparagraph (B) and other than the require-
14 ment under subparagraph (A) that an audit be un-
15 announced), (2), (3), and (4) of section 420(b) shall
16 apply to laboratory certifying agents under this sub-
17 section with respect to laboratories in the same man-
18 ner as such provisions apply to the certifying agents
19 with respect to facilities.

20 “(4) LABORATORY CERTIFYING AGENT DE-
21 FINED.—In this section, the term ‘laboratory certi-
22 fying agent’ means a third party accredited as a lab-
23 oratory certifying agent under this subsection.

24 “(d) PUBLICATION OF LIST OF CERTIFYING AGENTS
25 AND CERTIFIED LABORATORIES.—The provisions of para-

1 graph (6) of section 420(a) shall apply to third parties
2 accredited as laboratory certifying agents under sub-
3 section (c) and to laboratories certified under subsection
4 (a) in the same manner as such provisions apply to third
5 parties accredited as certifying agents under such section.

6 “(e) FOOD TESTING BY CERTIFIED LABORA-
7 TORIES.—

8 “(1) IN GENERAL.—Beginning 3 years after the
9 date of the enactment of this section, testing of food
10 described in paragraph (2) shall be conducted only
11 by Federal laboratories or by laboratories certified
12 under subsection (a).

13 “(2) TESTING OF FOOD COVERED.—The testing
14 of food described in this paragraph is testing of
15 food—

16 “(A) conducted in support of an admission
17 of an article of food under section 801;

18 “(B) conducted in support of a reoffer of
19 food previously denied admission under section
20 402(h);

21 “(C) conducted under an import alert that
22 requires successive consecutive tests;

23 “(D) conducted to show compliance with
24 an order of the Secretary;

1 “(E) conducted in support of an appeal of
2 an order of the Secretary; or

3 “(F) as otherwise required to be conducted
4 by the Secretary, as the Secretary deems appro-
5 priate.

6 “(3) ACCESS TO TESTING RESULTS.—The re-
7 sults of any testing of food described in paragraph
8 (2) by a laboratory certified under this section shall
9 be promptly transmitted by such laboratory in elec-
10 tronic format to the Secretary.

11 “(f) FALSE OR MISLEADING STATEMENTS.—For
12 purposes of section 301(q)(2), as amended by section 406,
13 any statement or representation made by an employee or
14 agent of a laboratory to a laboratory certifying agent is
15 deemed to be a report required by or under this Act.”.

16 (c) FEES.—Part 5 of subchapter C of chapter VII,
17 as added by section 101(b) and amended by section
18 108(a), is amended by adding at the end the following:

19 “**SEC. 741B. CERTIFYING AGENT FEE.**

20 “(a) IN GENERAL.—The Secretary shall assess and
21 collect a fee for the accreditation of an entity as a certi-
22 fying agent under section 420(a) for the purpose of de-
23 fraying the costs of implementing the system established
24 for such accreditation.

1 “(2) has agreed to abide by, and has been de-
2 termined by the Secretary to be in compliance with,
3 the food safety and security guidelines developed
4 under subsection (b) with respect to such food.

5 “(b) GUIDELINES.—

6 “(1) DEVELOPMENT.—For purposes of the pro-
7 gram established under subsection (a), the Secretary
8 shall develop safety and security guidelines applica-
9 ble to the importation of food.

10 “(2) FACTORS.—Such guidelines shall take into
11 account the following factors:

12 “(A) The personnel of the person import-
13 ing the food.

14 “(B) The physical and procedural safety
15 and security of such person’s food supply chain.

16 “(C) The sufficiency of access controls for
17 food and ingredients purchased by such person.

18 “(D) Vendor and supplier information.

19 “(E) Such other factors as the Secretary
20 determines necessary.”.

21 **Subtitle B—Intervention**

22 **SEC. 111. PUBLIC HEALTH ASSESSMENT SYSTEM.**

23 (a) ACTIVE SURVEILLANCE SYSTEM.—The Secretary
24 of Health and Human Services (in this subtitle referred
25 to as the “Secretary”), acting through the Centers for

1 Disease Control and Prevention, shall establish and imple-
2 ment an active surveillance system for food, based on a
3 representative proportion of the population of the United
4 States, to assess more accurately the frequency and
5 sources of human illness in the United States associated
6 with the consumption of food.

7 (b) SAMPLING SYSTEM.—

8 (1) IN GENERAL.—The Secretary shall establish
9 and implement a sampling system under which the
10 Secretary takes and analyzes samples of food prod-
11 ucts—

12 (A) to assist the Secretary in carrying out
13 this Act and the Federal Food, Drug, and Cos-
14 metic Act (21 U.S.C. 301 et seq.); and

15 (B) to more accurately assess the nature,
16 frequency of occurrence, and amounts of con-
17 taminants in food products.

18 (2) REQUIREMENTS.—Such sampling system
19 shall provide—

20 (A) statistically valid monitoring, including
21 market-basket studies, on the nature, frequency
22 of occurrence, and amounts of contaminants in
23 food products available to consumers; and

24 (B) at the request of the Secretary, such
25 other information, including analysis of moni-

1 toring and verification samples, as the Sec-
2 retary determines may be useful in assessing
3 the occurrence of contaminants in food prod-
4 ucts.

5 (3) GUIDELINES.—Within 12 months after the
6 date of the enactment of this Act, the Secretary
7 shall establish guidelines for the sampling system
8 under this subsection.

9 (c) ASSESSMENT OF HEALTH HAZARDS.—Through
10 the surveillance system under subsection (a) and the sam-
11 pling system under subsection (b), the Secretary shall
12 rank food categories based on their hazard to human
13 health and identify appropriate industry and regulatory
14 approaches to minimize hazards in the food supply. Such
15 analysis may include—

16 (1) the safety of commercial harvesting and
17 processing, as compared with the health hazards as-
18 sociated with food products that are harvested for
19 recreational or subsistence purposes and prepared
20 noncommercially;

21 (2) the safety of food products that are domes-
22 tically harvested and processed, as compared with
23 the health hazards associated with food products
24 that are harvested or processed outside the United
25 States;

1 (3) contamination originating from handling
2 practices that occur prior to or after sale of food
3 products to consumers; and

4 (4) use of comparative risk assessments.

5 **SEC. 112. PUBLIC EDUCATION AND ADVISORY SYSTEM.**

6 (a) **PUBLIC EDUCATION.**—The Secretary, in coopera-
7 tion with private and public organizations, including the
8 appropriate State entities, shall design and implement a
9 national public education program on food safety. The
10 program shall provide—

11 (1) information to the public regarding Federal
12 standards and good practice requirements and pro-
13 motion of public awareness, understanding, and ac-
14 ceptance of such standards and requirements;

15 (2) information to health professionals so that
16 they may improve diagnosis and treatment of food-
17 related illness and advise individuals whose health
18 conditions place them in particular risk; and

19 (3) such other information or advice to con-
20 sumers and other persons as the Secretary deter-
21 mines will promote the purposes of this Act.

22 (b) **HEALTH ADVISORIES.**—The Secretary shall work
23 with the States and other appropriate entities to—

24 (1) develop and distribute regional and national
25 advisories concerning food safety;

1 (2) develop standardized formats for written
2 and broadcast advisories; and

3 (3) incorporate State and local advisories into
4 the national public education program required
5 under subsection (a).

6 **SEC. 113. RESEARCH.**

7 (a) IN GENERAL.—The Secretary shall conduct re-
8 search to assist in the implementation of this Act, includ-
9 ing studies to—

10 (1) improve sanitation and food safety practices
11 in the processing of food products;

12 (2) develop improved techniques for the moni-
13 toring of food and inspection of food products;

14 (3) develop efficient, rapid, and sensitive meth-
15 ods for determining and detecting the presence of
16 contaminants in food products;

17 (4) determine the sources of contamination of
18 food and food products with contaminants;

19 (5) develop consumption data with respect to
20 food products;

21 (6) draw upon research and educational pro-
22 grams that exist at the State and local level;

23 (7) utilize the DNA matching system and other
24 processes to identify and control pathogens;

1 (8) address common and emerging zoonotic dis-
2 eases;

3 (9) develop methods to reduce or destroy patho-
4 gens before, during, and after processing;

5 (10) analyze the incidence of antibiotic resist-
6 ance as it pertains to the food supply and develop
7 new methods to reduce the transfer of antibiotic re-
8 sistance to humans; and

9 (11) conduct other research that supports the
10 purposes of this Act.

11 (b) CONTRACT AUTHORITY.—The Secretary is au-
12 thorized to enter into contracts and agreements with any
13 State, university, government agency, or other person to
14 carry out this section.

15 **SEC. 114. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
16 **OF ADULTERATED OR MISBRANDED ARTI-**
17 **CLES OF FOOD.**

18 (a) PROHIBITED ACTS.—Section 301 (21 U.S.C.
19 331), as amended by sections 102 and 104, is amended
20 by adding at the end the following:

21 “(qq)(1) The failure to notify the Secretary in viola-
22 tion of section 422(a).

23 “(2) The failure to comply with—

1 “(A) an order issued under section 422(b) fol-
2 lowing any hearing requested under section 422(c);
3 or

4 “(B) an amended order issued under section
5 422(d)(1).”.

6 (b) NOTIFICATION, NONDISTRIBUTION, AND RECALL
7 OF ADULTERATED OR MISBRANDED ARTICLES OF
8 FOOD.—Chapter IV (21 U.S.C. 341 et seq.), as amended
9 by sections 102(b), 104, and 108(c), is amended by adding
10 at the end the following:

11 **“SEC. 422. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
12 **OF ADULTERATED OR MISBRANDED ARTI-**
13 **CLES OF FOOD.**

14 “(a) NOTIFICATION TO SECRETARY OF VIOLATION.—

15 “(1) IN GENERAL.—A person (other than a
16 household consumer or other individual who is the
17 intended consumer of an article of food) that has
18 reason to believe that an article of food when intro-
19 duced into or while in interstate commerce, or while
20 held for sale (regardless of whether the first sale)
21 after shipment in interstate commerce, is adulter-
22 ated or misbranded in a manner that, if consumed,
23 may result in illness or injury shall, as soon as prac-
24 ticable, notify the Secretary of the identity and loca-
25 tion of the article.

1 “(2) MANNER OF NOTIFICATION.—Notification
2 under paragraph (1) shall be made in such manner
3 and by such means as the Secretary may require by
4 regulation.

5 “(b) RECALL AND CONSUMER NOTIFICATION.—

6 “(1) VOLUNTARY ACTIONS.—On receiving noti-
7 fication under subsection (a) or by other means of
8 a suspected adulteration or misbranding of food, if
9 the Secretary finds that an article of food when in-
10 troduced into or while in interstate commerce, or
11 while held for sale (regardless of whether the first
12 sale) after shipment in interstate commerce, is adul-
13 terated or misbranded in a manner that, if con-
14 sumed, may result in illness or injury (as determined
15 by the Secretary), the Secretary shall provide all ap-
16 propriate persons (including the manufacturer, im-
17 porter, distributor, or retailer of the article) with an
18 opportunity (as determined by the Secretary)—

19 “(A) to cease distribution of the article;

20 “(B) to notify all persons—

21 “(i) that produce, manufacture, pack,
22 process, prepare, treat, package, distribute,
23 or hold the article, to cease immediately
24 those activities with respect to the article;

25 or

1 “(ii) to which the article has been dis-
2 tributed, transported, or sold, to cease im-
3 mediately distribution of the article;

4 “(C) to recall the article;

5 “(D) in consultation with the Secretary, to
6 provide notice of the finding of the Secretary to
7 all consumers to which the article was, or may
8 have been, distributed and to appropriate State
9 and local health officials; and

10 “(E) to notify State and local public health
11 officials.

12 “(2) MANDATORY ACTIONS.—If the appropriate
13 person referred to in paragraph (1) does not carry
14 out the actions described in that paragraph with re-
15 spect to an article within the time period and in the
16 manner prescribed by the Secretary, the Secretary—

17 “(A) shall issue an order requiring the per-
18 son—

19 “(i) to immediately cease distribution
20 of the article; and

21 “(ii) to immediately make the notifica-
22 tion described in paragraph (1)(B); and

23 “(B) may take control or possession of the
24 article.

1 “(3) NOTICE TO CONSUMERS AND HEALTH OF-
2 FICIALS.—The Secretary shall, as the Secretary de-
3 termines to be necessary, provide notice of the find-
4 ing of the Secretary under paragraph (1) to con-
5 sumers to which the article was, or may have been,
6 distributed and to appropriate State and local health
7 officials.

8 “(c) HEARINGS ON ORDERS.—

9 “(1) IN GENERAL.—The Secretary shall provide
10 a person subject to an order under subsection (b)(2)
11 with an opportunity for a hearing on—

12 “(A) the actions required by the order; and

13 “(B) any reasons why the article of food
14 that is the subject of the order should not be
15 recalled.

16 “(2) TIMING OF HEARINGS.—If a hearing is re-
17 quested under paragraph (1) with respect to an
18 order, the Secretary shall hold the hearing as soon
19 as practicable, but not later than 2 business days,
20 after the date of issuance of the order.

21 “(d) POST-HEARING RECALL ORDERS.—

22 “(1) AMENDMENT OF ORDERS.—If, after pro-
23 viding an opportunity for a hearing (and a hearing
24 if requested) under subsection (c), the Secretary de-
25 termines that an article of food when introduced into

1 or while in interstate commerce, or while held for
2 sale (regardless of whether the first sale) after ship-
3 ment in interstate commerce, is adulterated or mis-
4 branded in a manner that, if consumed, may result
5 in illness or injury, the Secretary may, as the Sec-
6 retary determines to be necessary—

7 “(A) amend the order under subsection
8 (b)(2)—

9 “(i) to require recall of the article or
10 other appropriate action; and

11 “(ii) to specify a timetable during
12 which the recall shall occur;

13 “(B) require periodic reports to the Sec-
14 retary describing the progress of any such re-
15 call; and

16 “(C) provide notice of such a recall to con-
17 sumers to which the article was, or may have
18 been, distributed.

19 “(2) VACATION OF ORDERS.—If, after providing
20 an opportunity for a hearing (and a hearing if re-
21 quested) under subsection (c), the Secretary deter-
22 mines that adequate grounds do not exist to con-
23 tinue the actions required by the order, the Sec-
24 retary shall vacate the order.

1 “(e) REMEDIES NOT EXCLUSIVE.—The remedies au-
2 thorized by this section shall be in addition to any other
3 remedies that may be available.”.

4 (c) EFFECTIVE DATE.—Sections 301(qq)(1) and 422
5 of the Federal Food, Drug, and Cosmetic Act, as added
6 by subsections (a) and (b), shall apply with respect to arti-
7 cles of food as of such date, not later than 1 year after
8 the date of the enactment of this Act, as the Secretary
9 of Health and Human Services shall specify.

10 **Subtitle C—Response**

11 **SEC. 121. ADMINISTRATIVE DETENTION.**

12 (a) IN GENERAL.—Section 304(h)(1)(A) (21 U.S.C.
13 334(h)(1)(A)) is amended by—

14 (1) striking “credible evidence or information
15 indicating” and inserting “reason to believe”; and

16 (2) striking “presents a threat of serious ad-
17 verse health consequences or death to humans or
18 animals” and inserting “is adulterated or mis-
19 branded”.

20 (b) REGULATIONS.—Not later than 120 days after
21 the date of enactment of this Act, the Secretary shall issue
22 an interim final rule amending subpart K of part 1 of title
23 21, Code of Federal Regulations, to implement the amend-
24 ment made by this section.

1 (c) EFFECTIVE DATE.—The amendments made by
2 this section shall take effect 180 days after the date of
3 enactment of this Act.

4 **SEC. 122. CIVIL PENALTIES RELATING TO FOOD.**

5 (a) IN GENERAL.—Chapter III (21 U.S.C. 331 et
6 seq.) is amended by adding after section 303 the following:

7 **“SEC. 303A. CIVIL PENALTIES RELATING TO FOODS.**

8 “(a) IN GENERAL.—

9 “(1) ASSESSMENT.—The Secretary may assess
10 against a person that commits an act prohibited by
11 section 301 with respect to an article of food a civil
12 penalty for each such act of not more than—

13 “(A) \$100,000, in the case of an indi-
14 vidual; and

15 “(B) \$500,000, in the case of any other
16 person.

17 “(2) SEPARATE OFFENSES.—Each prohibited
18 act described in paragraph (1) and each day during
19 which the act continues shall be considered to be a
20 separate offense.

21 “(3) NOTICE AND OPPORTUNITY FOR HEAR-
22 ING.—The Secretary shall not assess a civil penalty
23 under this section against a person unless the person
24 is given notice and opportunity for a hearing on the

1 record before the Secretary in accordance with sec-
2 tions 554 and 556 of title 5, United States Code.

3 “(4) DETERMINATION OF CIVIL PENALTY
4 AMOUNT.—The amount of a civil penalty under this
5 section—

6 “(A) shall be assessed by the Secretary by
7 written order, taking into account—

8 “(i) the gravity of the violation;

9 “(ii) the degree of culpability of the
10 person;

11 “(iii) the size and type of the business
12 of the person; and

13 “(iv) any history of prior offenses by
14 the person; and

15 “(B) shall be reviewed only in accordance
16 with subsection (b).

17 “(b) JUDICIAL REVIEW.—

18 “(1) IN GENERAL.—An order assessing a civil
19 penalty against a person under subsection (a) shall
20 be final unless the person—

21 “(A) not later than 30 days after the effec-
22 tive date of the order, files a petition for judi-
23 cial review of the order in—

24 “(i) the United States court of ap-
25 peals for the circuit in which the person re-

1 sides or has its principal place of business;

2 or

3 “(ii) the United States Court of Ap-

4 peals for the District of Columbia Circuit;

5 and

6 “(B) simultaneously sends a copy of the

7 petition by certified mail to the Secretary.

8 “(2) FILING OF COPY OF RECORD.—The Sec-

9 retary shall promptly file in the court a certified

10 copy of the record on which the order was issued.

11 “(3) STANDARD OF REVIEW.—The findings of

12 the Secretary relating to the order shall be set aside

13 only if the findings are found to be unsupported by

14 substantial evidence on the record as a whole.

15 “(c) COLLECTION ACTIONS FOR FAILURE TO PAY

16 ASSESSMENT.—

17 “(1) REFERRAL TO ATTORNEY GENERAL.—If a

18 person fails to pay a civil penalty assessed under

19 subsection (a) after the order assessing the civil pen-

20 alty has become a final order, or after the court of

21 appeals has entered final judgment in favor of the

22 Secretary, the Secretary may refer the matter to the

23 Attorney General.

24 “(2) ACTION BY ATTORNEY GENERAL.—The

25 Attorney General shall bring a civil action to recover

1 the amount of the civil penalty in United States dis-
2 trict court.

3 “(3) SCOPE OF REVIEW.—In a civil action
4 under paragraph (2), the validity and appropriate-
5 ness of the order of the Secretary assessing the civil
6 penalty shall not be subject to review.

7 “(d) PENALTIES DEPOSITED IN TREASURY.—All
8 amounts collected as civil penalties under this section shall
9 be deposited in the Treasury of the United States and
10 shall be available to cover costs of the Administration in
11 carrying out food safety activities under this Act.

12 “(e) PENALTIES IN LIEU OF OTHER ACTIONS.—
13 Nothing in this Act requires the Secretary to report for
14 prosecution, or for the commencement of any libel or in-
15 junction proceeding, any violation of this Act in any case
16 in which the Secretary believes that the public interest will
17 be adequately served by the assessment of a civil penalty
18 under this section.

19 “(f) REMEDIES NOT EXCLUSIVE.—The remedies au-
20 thorized by this section shall be in addition to any other
21 remedies that may be available.”.

22 (b) EFFECTIVE DATE.—The amendment made by
23 subsection (a) shall apply to prohibited acts committed on
24 or after the date of the enactment of this Act .

1 **SEC. 123. FAILURE TO CONSENT TO INVESTIGATION.**

2 Section 801 (21 U.S.C. 381) is amended by adding
3 at the end the following:

4 “(p) The Secretary may deny importation of food,
5 other than only for personal use, from any foreign country,
6 or which is manufactured, processed, packed, or held by
7 a facility (as defined in section 415), if the government
8 of such country, or such facility, respectively, does not
9 timely consent to an investigation by the Administration
10 when food from that country or facility is linked to a food-
11 borne illness outbreak or is otherwise found to be adulter-
12 ated or mislabeled.”.

13 **Subtitle D—Miscellaneous**

14 **SEC. 131. LABELING REQUIREMENT FOR MEAT, POULTRY**
15 **PRODUCTS, AND SEAFOOD THAT CONTAIN**
16 **CARBON MONOXIDE.**

17 (a) LABELING REQUIREMENT.—

18 (1) IN GENERAL.—Paragraph (t) of section 201
19 (21 U.S.C. 321) is amended by adding at the end
20 the following:

21 “(4) In the case of food that is meat within the mean-
22 ing of the Federal Meat Inspection Act, a poultry product
23 within the meaning of the Poultry Products Inspection
24 Act, or seafood (including all fresh or saltwater fish,
25 molluscan shellfish, crustaceans, and other forms of
26 aquatic animal life) intended for human consumption as

1 food within the meaning of section 201(f) (referred to col-
2 lectively in this paragraph as ‘seafood’), the term ‘color
3 additive’ shall include carbon monoxide under conditions
4 of use that may impart, maintain, preserve, stabilize, fix,
5 or otherwise affect the color of fresh meat, poultry prod-
6 ucts, or seafood, unless the label of such food bears,
7 prominently and conspicuously in such place and in such
8 manner as to render it likely to be read and understood
9 by the ordinary person, the following statement to prevent
10 consumer deception and serious risks to the public health:
11 ‘CONSUMER NOTICE: Carbon monoxide has been used
12 to preserve the color of this product. Do not rely on color
13 or the “use or freeze by” date alone to judge the freshness
14 of the product.’”.

15 (2) EFFECTIVE DATE.—The amendment made
16 by this subsection shall apply to food labeled on or
17 after the date that is 30 days after the date of the
18 enactment of this Act.

19 (b) DISCRETIONARY AUTHORITY.—If, not earlier
20 than 5 years after the effective date described in sub-
21 section (a)(2), the Secretary of Health and Human Serv-
22 ices finds, based on competent and reliable scientific evi-
23 dence, that the statement prescribed in section 201(t)(4)
24 of the Federal Food, Drug, and Cosmetic Act is no longer
25 required to prevent consumer deception and other harms,

1 then the Secretary is authorized to issue regulations estab-
2 lishing alternative labeling requirements that are shown
3 to be adequate and effective in preventing consumer de-
4 ception and other harms related to the conditions of use
5 of carbon monoxide, including with respect to preventing
6 any consumer deception or other harm that may result
7 from the actual conditions of carbon monoxide use and
8 its potential to impart a persistent color to meat, poultry
9 products, or seafood described in such section through a
10 reaction with natural pigment.

11 **SEC. 132. FOOD SUBSTANCES GENERALLY RECOGNIZED AS**
12 **SAFE.**

13 Section 409 (21 U.S.C. 348) is amended by adding
14 at the end the following:

15 “Substances Generally Recognized as Safe

16 “(k)(1) Not later than 60 days after the date of re-
17 ceipt by the Secretary, after the date of the enactment
18 of this subsection, of a request for a substance to be deter-
19 mined by the Secretary to be a GRAS food substance, the
20 Secretary shall publish notice of such request in the Fed-
21 eral Register.

22 “(2) Not later than 90 days after the date of publica-
23 tion of a notice under paragraph (1), the Secretary shall
24 determine whether the substance is a GRAS food sub-
25 stance.

1 “(3) A determination by the Secretary of whether a
2 substance is a GRAS food substance shall be published
3 in the Federal Register.

4 “(4) In this subsection, the term ‘GRAS food sub-
5 stance’ means a substance excluded from the definition of
6 the term ‘food additive’ in section 201(s) because such
7 substance is generally recognized, among experts qualified
8 by scientific training and experience to evaluate its safety,
9 as having been adequately shown through scientific proce-
10 dures (or, in the case of a substances used in food prior
11 to January 1, 1958, through either scientific procedures
12 or experience based on common use in food) to be safe
13 under the conditions of its intended use.”.

14 **SEC. 133. COUNTRY OF ORIGIN LABELING; DISCLOSURE OF**
15 **SOURCE OF INGREDIENTS.**

16 (a) FOOD.—Section 403 (21 U.S.C. 343), as amend-
17 ed by sections 101(a) and 108(b), is amended by adding
18 at the end the following:

19 “(bb) In the case of a processed food if—

20 “(1) the labeling of the food fails to identify the
21 country in which the final processing of the food oc-
22 curs; and

23 “(2) the Website for the manufacturer of the
24 food fails to identify the country (or countries) of or-
25 igin for each ingredient in the food.

1 “(cc) In the case of non-processed food if—

2 “(1) the labeling of the food fails to identify the
3 country of origin of the food; and

4 “(2) the Website for the original packer of the
5 food fails to identify the country of origin for the
6 food.”.

7 (b) REGULATIONS.—Not later than 180 days after
8 the date of the enactment of this Act, the Secretary of
9 Health and Human Services shall promulgate final regula-
10 tions to carry out paragraphs (bb) and (cc) of section 403
11 of the Federal Food, Drug, and Cosmetic Act, as added
12 by subsection (a).

13 (c) EFFECTIVE DATE.—The requirements of para-
14 graphs (bb) and (cc) of section 403 of the Federal Food,
15 Drug, and Cosmetic Act, as added by subsection (a), take
16 effect on the date that is 2 years after the date of the
17 enactment of this Act.

18 **SEC. 134. NEW FOOD AND ANIMAL FEED EXPORT CERTIFI-**
19 **CATION FEE TO IMPROVE THE ABILITY OF**
20 **UNITED STATES FIRMS TO EXPORT THEIR**
21 **PRODUCTS.**

22 Part 5 of subchapter C of chapter VII (21 U.S.C.
23 371 et seq.), as added by section 101(b) and amended by
24 sections 108 and 109, is further amended by adding at
25 the end the following:

1 **“SEC. 741D. NEW FOOD AND ANIMAL FEED EXPORT CER-**
2 **TIFICATION FEE TO IMPROVE THE ABILITY**
3 **OF UNITED STATES FIRMS TO EXPORT THEIR**
4 **PRODUCTS.**

5 “(a) IN GENERAL.—If the Secretary provides for the
6 issuance of export certificates for foods and animal feeds
7 in cases where exportation is restricted without such a cer-
8 tificate, the Secretary may impose a fee for the issuance
9 of such a certificate.

10 “(b) AMOUNT.—The amount of the fee under this
11 section shall be an amount that is reasonably related to
12 the cost of issuing such certificates.

13 “(c) USE OF FEES.—The Secretary shall make all
14 of the fees collected pursuant to this section available sole-
15 ly to pay for the costs of issuance of such certificates.”.

16 **TITLE II—DRUG AND DEVICE**
17 **SAFETY**

18 **SEC. 201. REGISTRATION OF PRODUCERS OF DRUGS AND**
19 **DEVICES; APPLICABLE FEE.**

20 (a) REGISTRATION.—

21 (1) MISBRANDING.—Paragraph (o) of section
22 502 (21 U.S.C. 352) is amended by striking “in any
23 State”.

24 (2) EFFECTIVE DATE.—The amendment made
25 by paragraph (1) applies only with respect to reg-
26 istration under section 510 of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 360) occurring
2 on or after the date of the enactment of this Act.

3 (b) REGISTRATION FEE.—

4 (1) MISBRANDING.—Paragraph (o) of section
5 502 (21 U.S.C. 352), as amended by subsection
6 (a)(2), is further amended by inserting after “not
7 duly registered under section 510” the following: “or
8 in violation of section 736C for failure to pay a fee”.

9 (2) ESTABLISHMENT.—Part 2 of subchapter C
10 of chapter VII (21 U.S.C. 379g et seq.) is amended
11 by adding at the end the following:

12 **“SEC. 736C. REGISTRATION FEE.**

13 “(a) IN GENERAL.—Except as provided in subsection
14 (b) of this section, the Secretary shall assess and collect
15 an annual fee for registration under subsection (b), (c),
16 (d), or (i) of section 510 to defray increases (as described
17 in subsection (g)(2)(A)(ii)) in the costs of inspecting es-
18 tablishments registered under subsection (b), (c), (d), or
19 (i) of section 510 to ensure compliance by such establish-
20 ments with the requirements of this Act relating to drugs
21 or devices.

22 “(b) EXCEPTION.—The Secretary shall not assess or
23 collect a fee under this section for registration of an estab-
24 lishment under section 510 on the basis of such establish-

1 ment's manufacture, preparation, propagation, or proc-
2 essing of an excipient of a drug.

3 “(c) FEE REVENUE AMOUNTS.—

4 “(1) IN GENERAL.—For each of fiscal years
5 2010 through 2018, fees under subsection (a) shall,
6 except as provided in subsections (d), (f), and (g),
7 be established to generate a total revenue amount
8 under subsection (a).

9 “(2) TOTAL REVENUE AMOUNT.—Not later
10 than September 1, 2010, the Secretary shall trans-
11 mit to the Congress the total revenue amount under
12 paragraph (1) and how such amount was calculated.

13 “(3) ANNUAL FEE SETTING.—The Secretary
14 shall, not later than 60 days before the start of each
15 fiscal year that begins after September 30, 2009, es-
16 tablish, for the next fiscal year, registration fees
17 under subsection (a)—

18 “(A) based on the total revenue amount
19 applicable under paragraph (1); and

20 “(B) taking into consideration the dif-
21 ference in costs of inspections between foreign
22 and domestic establishments.

23 “(d) ADJUSTMENTS.—

24 “(1) INFLATION ADJUSTMENT.—For fiscal year
25 2011 and subsequent fiscal years, the revenues es-

1 tablished in subsection (c)(1) shall be adjusted by
2 the Secretary by notice, published in the Federal
3 Register, for a fiscal year to reflect the greater of—

4 “(A) the total percentage change that oc-
5 curred in the Consumer Price Index for all
6 urban consumers (all items; U.S. city average)
7 for the 12 month period ending June 30 pre-
8 ceding the fiscal year for which fees are being
9 established;

10 “(B) the total percentage change for the
11 previous fiscal year in basic pay under the Gen-
12 eral Schedule in accordance with section 5332
13 of title 5, United States Code, as adjusted by
14 any locality-based comparability payment pur-
15 suant to section 5304 of such title for Federal
16 employees stationed in the District of Columbia;
17 or

18 “(C) the average annual change in the
19 cost, per full-time equivalent position of the
20 Food and Drug Administration, of all personnel
21 compensation and benefits paid with respect to
22 such positions for the first 5 years of the pre-
23 ceding 6 fiscal years.

24 The adjustment made each fiscal year by this sub-
25 section will be added on a compounded basis to the

1 sum of all adjustments made each fiscal year after
2 fiscal year 2009 under this subsection.

3 “(2) WORKLOAD ADJUSTMENT.—For fiscal
4 year 2011 and subsequent fiscal years, after the fee
5 revenues established in subsection (c)(1) are ad-
6 justed for a fiscal year for inflation in accordance
7 with paragraph (1), the fee revenues shall be ad-
8 justed further for such fiscal year to reflect changes
9 in the workload of the Secretary for inspections de-
10 scribed in subsection (a). With respect to such ad-
11 justment:

12 “(A) The adjustment shall be determined
13 by the Secretary based on a weighted average
14 of the change in the total amount of inspections
15 described in subsection (a). The Secretary shall
16 publish in the Federal Register the fee revenues
17 and fees resulting from the adjustment and the
18 supporting methodologies.

19 “(B) Under no circumstances shall the ad-
20 justment result in fee revenues for a fiscal year
21 that are less than the fee revenues for the fiscal
22 year established in subsection (c)(1), as ad-
23 justed for inflation under paragraph (1). Any
24 adjustment for changes in inspection activities
25 made in setting fees and revenue amounts for

1 fiscal year 2011 may not result in the total
2 workload adjustment being more than 2 per-
3 centage points higher than it would have been
4 in the absence of the adjustment for changes in
5 inspection activities.

6 “(C) The Secretary shall contract with an
7 independent accounting firm to study the ad-
8 justment for changes in inspection activities ap-
9 plied in setting fees and revenue amounts for
10 fiscal year 2011 and to make recommendations,
11 if warranted, for future changes in the method-
12 ology for calculating the adjustment. After re-
13 view of the recommendations, the Secretary
14 shall, if warranted, make appropriate changes
15 to the methodology, and the changes shall be ef-
16 fective for each of the fiscal years 2012 through
17 2018. The Secretary shall not make any adjust-
18 ment for changes in inspection activities for any
19 fiscal year after 2011 unless such study has
20 been completed.

21 “(3) RENT AND RENT-RELATED COST ADJUST-
22 MENT.—For fiscal year 2012 and each subsequent
23 fiscal year, the Secretary shall, before making ad-
24 justments under paragraphs (1) and (2), decrease
25 the fee revenue amount established in subsection

1 (c)(1) if actual costs paid for rent and rent-related
2 expenses for the preceding fiscal year are less than
3 estimates made for such year in fiscal year 2008.
4 Any reduction made under this paragraph shall not
5 exceed the amount by which such costs fall below the
6 estimates made in fiscal year 2008 for such fiscal
7 year, and shall not exceed \$11,721,000 for any fiscal
8 year.

9 “(4) FINAL YEAR ADJUSTMENT.—For fiscal
10 year 2018, the Secretary may, in addition to adjust-
11 ments under paragraphs (1), (2), (3), and (5), fur-
12 ther increase the fee revenues and fees established in
13 subsection (c) if such an adjustment is necessary to
14 provide for not more than 3 months of operating re-
15 serves of carryover user fees for inspections de-
16 scribed in subsection (a) for the first 3 months of
17 fiscal year 2019. If such an adjustment is necessary,
18 the rationale for the amount of the increase shall be
19 contained in the annual notice establishing fee reve-
20 nues and fees for fiscal year 2018. If the Secretary
21 has carryover balances for such inspections in excess
22 of 3 months of such operating reserves, the adjust-
23 ment under this paragraph shall not be made.

1 “(5) COST ESTIMATE ADJUSTMENT.—For fiscal
2 year 2011 and subsequent fiscal years, the Secretary
3 by notice, published in the Federal Register, shall—

4 “(A) provide an estimate of the amount of
5 the total increases described in subsection (a)
6 for such fiscal year; and

7 “(B) after making adjustments under
8 paragraphs (1), (2), and (3), adjust the reve-
9 nues established in subsection (c)(1) to be equal
10 to such amount.

11 “(6) LIMIT.—The total amount of fees charged,
12 as adjusted under this subsection, for a fiscal year
13 may not exceed the total increases described in sub-
14 section (a) for such fiscal year.

15 “(e) FEE WAIVER OR REDUCTION.—

16 “(1) IN GENERAL.—The Secretary may grant
17 to a person a waiver from, or a reduction of, one or
18 more fees under this section if the Secretary finds
19 that—

20 “(A) such waiver or reduction is necessary
21 to protect the public health; or

22 “(B) the assessment of the fee would im-
23 pose significant financial hardship because of
24 limited resources available to such person or
25 other circumstances.

1 “(2) SPECIAL RULES FOR POSITRON EMISSION
2 TOMOGRAPHY DRUGS.—

3 “(A) IN GENERAL.—Except as provided in
4 subparagraph (B), each person who is named
5 as the applicant in an approved human drug
6 application for a positron emission tomography
7 drug shall be subject under paragraph (a) to
8 one-sixth of an annual registration fee with re-
9 spect to each establishment identified in the ap-
10 plication as producing positron emission tomog-
11 raphy drugs under the approved application.

12 “(B) EXCEPTION FROM ANNUAL REG-
13 ISTRATION FEE.—Each person who is named as
14 the applicant in an application described in sub-
15 paragraph (A) shall be granted a waiver under
16 paragraph (1) from an annual registration fee
17 under subsection (a) for a fiscal year if the per-
18 son certifies to the Secretary, at a time speci-
19 fied by the Secretary and using procedures
20 specified by the Secretary, that—

21 “(i) the person is a not-for-profit
22 medical center that has only 1 establish-
23 ment for the production of positron emis-
24 sion tomography drugs; and

1 “(ii) at least 95 percent of the total
2 number of doses of each positron emission
3 tomography drug produced by such estab-
4 lishment during such fiscal year will be
5 used within the medical center.

6 “(3) DESIGNATED ORPHAN DRUG.—An estab-
7 lishment registered under section 510 shall, with re-
8 spect to the manufacture, preparation, propagation,
9 compounding, or processing of drugs, be granted a
10 waiver under paragraph (1) from a fee under sub-
11 section (a) if all drugs manufactured, prepared,
12 propagated, compounded, or processed by the estab-
13 lishment are designated as a drug for a rare disease
14 or condition pursuant to section 526. The preceding
15 sentence shall not apply if the application approved
16 under section 505 for any such drug includes an in-
17 dication for a disease or condition other than such
18 a rare disease or condition.

19 “(f) LIMITATIONS.—

20 “(1) IN GENERAL.—Fees under subsection (a)
21 shall be refunded for a fiscal year beginning after
22 fiscal year 2010 unless appropriations for salaries
23 and expenses of the Food and Drug Administration
24 for such fiscal year (excluding the amount of fees
25 appropriated for such fiscal year) are equal to or

1 greater than the amount of appropriations for the
2 salaries and expenses of the Food and Drug Admin-
3 istration for the fiscal year 2010 (excluding the
4 amount of fees appropriated for such fiscal year)
5 multiplied by the adjustment factor applicable to the
6 fiscal year involved.

7 “(2) AUTHORITY.—If the Secretary does not
8 assess fees under subsection (a) during any portion
9 of a fiscal year because of paragraph (1) and if at
10 a later date in such fiscal year the Secretary may as-
11 sess such fees, the Secretary may assess and collect
12 such fees, without any modification in the rate, for
13 registration under subsection (b), (c), (d), or (i) of
14 section 510 at any time in such fiscal year.

15 “(g) CREDITING AND AVAILABILITY OF FEES.—

16 “(1) IN GENERAL.—Fees authorized under sub-
17 section (a) shall be collected and available for obliga-
18 tion only to the extent and in the amount provided
19 in advance in appropriations Acts. Such fees are au-
20 thorized to remain available until expended. Such
21 sums as may be necessary may be transferred from
22 the Food and Drug Administration salaries and ex-
23 penses appropriation account without fiscal year lim-
24 itation to such appropriation account for salaries
25 and expenses with such fiscal year limitation.

1 “(2) COLLECTIONS AND APPROPRIATION
2 ACTS.—

3 “(A) IN GENERAL.—The fees authorized
4 by this section—

5 “(i) shall be retained in each fiscal
6 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

10 “(ii) shall only be collected and avail-
11 able to defray increases in the costs of in-
12 specting establishments registered under
13 subsection (b), (c), (d), or (i) of section
14 510 to ensure compliance by such estab-
15 lishments with the requirements of this Act
16 relating to drugs and devices (including in-
17 creases in such costs for an additional
18 number of full-time equivalent positions in
19 the Department of Health and Human
20 Services to be engaged in such inspections)
21 over such costs, excluding costs paid from
22 fees collected under this section, for fiscal
23 year 2009 multiplied by the adjustment
24 factor.

1 “(B) COMPLIANCE.—The Secretary shall
2 be considered to have met the requirements of
3 subparagraph (A)(ii) in any fiscal year if the
4 costs funded by appropriations and allocated for
5 inspections described in subsection (a)—

6 “(i) are not more than 3 percent
7 below the level specified in subparagraph
8 (A)(ii); or

9 “(ii)(I) are more than 3 percent below
10 the level specified in subparagraph (A)(ii),
11 and fees assessed for the fiscal year fol-
12 lowing the subsequent fiscal year are de-
13 creased by the amount in excess of 3 per-
14 cent by which such costs fell below the
15 level specified in such subparagraph; and

16 “(II) such costs are not more than 5
17 percent below the level specified in such
18 subparagraph.

19 “(3) AUTHORIZATION OF APPROPRIATIONS.—
20 For each of the fiscal years 2010 through 2018,
21 there is authorized to be appropriated for fees under
22 this section an amount equal to the total revenue
23 amount determined under subsection (c)(1) for the
24 fiscal year, as adjusted or otherwise affected under
25 subsection (d) and paragraph (4) of this subsection.

1 “(4) OFFSET.—If the sum of the cumulative
2 amount of fees collected under this section for the
3 fiscal years 2010 through 2017 and the amount of
4 fees estimated to be collected under this section for
5 fiscal year 2018 exceeds the cumulative amount ap-
6 propriated under paragraph (3) for the fiscal years
7 2010 through 2017, the excess shall be credited to
8 the appropriation account of the Food and Drug Ad-
9 ministration as provided in paragraph (1), and shall
10 be subtracted from the amount of fees that would
11 otherwise be authorized to be collected under this
12 section for fiscal year 2018.

13 “(h) COLLECTION OF UNPAID FEES.—In any case
14 where the Secretary does not receive payment of a fee as-
15 sessed under subsection (a) within 30 days after it is due,
16 such fee shall be treated as a claim of the United States
17 Government subject to subchapter II of chapter 37 of title
18 31, United States Code.

19 “(i) WRITTEN REQUESTS FOR WAIVERS, REDUC-
20 TIONS, AND REFUNDS.—To qualify for consideration for
21 a waiver or reduction under subsection (e), or for a refund
22 of any fee collected in accordance with subsection (a), a
23 person shall submit to the Secretary a written request for
24 such waiver, reduction, or refund not later than 180 days
25 after such fee is due.

1 “(j) CONSTRUCTION.—This section may not be con-
2 strued to require that the number of full-time equivalent
3 positions in the Department of Health and Human Serv-
4 ices, for officers, employers, and advisory committees not
5 engaged in inspections described in subsection (a), be re-
6 duced to offset the number of officers, employees, and ad-
7 visory committees so engaged.

8 “(k) ANNUAL FISCAL REPORTS.—Beginning with fis-
9 cal year 2011, not later than 120 days after the end of
10 each fiscal year for which fees are collected under this sec-
11 tion, the Secretary shall prepare and submit to the Com-
12 mittee on Energy and Commerce of the House of Rep-
13 resentatives and the Committee on Health, Education,
14 Labor, and Pensions of the Senate a report on the imple-
15 mentation of the authority for such fees during such fiscal
16 year and the use, by the Food and Drug Administration,
17 of the fees collected for such fiscal year.

18 “(l) DEFINITION.—The term ‘costs of inspecting es-
19 tablishments registered under subsection (b), (c), (d), or
20 (i) of section 510 to ensure compliance by such establish-
21 ments with the requirements of this Act relating to drugs
22 and devices’ means the expenses incurred, in connection
23 with inspecting establishments registered under subsection
24 (b), (c), (d), or (i) of section 510 to ensure compliance

1 by such establishments with the requirements of this Act
2 relating to drugs and devices, for—

3 “(1) officers and employees of the Food and
4 Drug Administration, contractors of the Food and
5 Drug Administration, and costs related to such offi-
6 cers and employees and to contracts with such con-
7 tractors;

8 “(2) management of information, and the ac-
9 quisition, maintenance, and repair of information
10 technology resources;

11 “(3) leasing, maintenance, renovation, and re-
12 pair of facilities and acquisition, maintenance, and
13 repair of fixtures, furniture, scientific equipment,
14 and other necessary materials and supplies; and

15 “(4) collecting fees under this section and ac-
16 counting for resources allocated for such inspec-
17 tions.”.

18 (3) EFFECTIVE DATE.—The Secretary of
19 Health and Human Services shall first impose the
20 fee established under section 736C of the Federal
21 Food, Drug, and Cosmetic Act, as added by para-
22 graph (2), for fiscal years beginning with fiscal year
23 2010.

24 (4) SUNSET DATE.—Section 736C of the Fed-
25 eral Food, Drug, and Cosmetic Act, as added by

1 paragraph (2), does not authorize the assessment or
2 collection of a fee for registration under section 510
3 of such Act (21 U.S.C. 360) occurring after fiscal
4 year 2018.

5 **SEC. 202. INSPECTION OF PRODUCERS OF DRUGS AND AC-**
6 **TIVE PHARMACEUTICAL INGREDIENTS.**

7 (a) INSPECTION.—Subsection (h) of section 510 (21
8 U.S.C. 351) is amended—

9 (1) by striking “(h)” and inserting “(h)(1)”;

10 (2) by striking “Every establishment in any
11 State registered with the Secretary pursuant to this
12 section” and inserting “Every establishment reg-
13 istered with the Secretary pursuant to subsection
14 (b), (c), (d), or (i)”;

15 (3) by striking “704(g), at least once” and all
16 that follows and inserting the following: “704(g)—
17 “(A) at least once in the 2-year period begin-
18 ning with the date of registration of such establish-
19 ment pursuant to this section and at least once in
20 every successive 2-year period thereafter; or

21 “(B) at least once in the 4-year period begin-
22 ning with the date of registration of such establish-
23 ment pursuant to this section and at least once in
24 every successive 4-year period thereafter, if the Sec-
25 retary determines that sufficient information about

1 the type of product produced in the establishment,
2 inspection history, compliance history, and such ad-
3 ditional factors as the Secretary determines, by
4 guidance, exists to assess risk and to establish a
5 risk-based inspection schedule.”; and

6 (4) by adding at the end the following:

7 “(2)(A) The Secretary shall conduct an inspection of
8 a drug establishment when the establishment begins to
9 manufacture, prepare, propagate, compound, or process a
10 drug or active pharmaceutical ingredient of a drug before
11 its introduction into interstate commerce if the drug or
12 ingredient is new or has undergone a major change requir-
13 ing prior approval by the Secretary of a supplement to
14 an application submitted under section 505. Notwith-
15 standing the preceding sentence, the Secretary may opt
16 against conducting such an inspection if the Secretary de-
17 termines, based on the inspection history of the establish-
18 ment, that such an inspection is not necessary to verify
19 the data contained in the application (or supplement to
20 the application) submitted under section 505, ensure com-
21 pliance with current good manufacturing practice, or oth-
22 erwise ensure the safety of the drug or ingredient.

23 “(B) The Secretary shall annually submit a report
24 to the Congress on each instance during the preceding

1 year in which the Secretary determined under subpara-
2 graph (A) that an inspection was not necessary.

3 “(3) The Secretary may, by regulation, provide for
4 a risk-based inspection schedule for establishments en-
5 gaged in the manufacture, propagation, compounding, or
6 processing of an excipient of a drug at a frequency dif-
7 ferent than the inspection schedule for an establishment
8 under paragraph (1).

9 “(4) Nothing in this subsection shall be construed as
10 limiting the authority of the Secretary to conduct inspec-
11 tions under any other provision of the Act.

12 “(5) With respect to fiscal year 2010 and each subse-
13 quent fiscal year, the Secretary shall submit an annual
14 report to the Congress on—

15 “(A) funding dedicated to inspections under
16 this subsection; and

17 “(B) the number of establishments for which
18 the frequency of such inspections has been modified
19 pursuant to paragraph (1)(B).

20 “(6) For purposes of determining inspection fre-
21 quency under subparagraphs (A) and (B) of paragraph
22 (1), the Secretary shall establish information systems ca-
23 pacity sufficient to assess risk and shall develop and main-
24 tain a risk-based system for conducting surveillance of
25 current good manufacturing practices by establishments

1 registered with the Secretary pursuant to subsection (b),
2 (c), (d), or (i). The Secretary shall have such capacity in
3 place and begin implementation of such risk-based system
4 not later than 3 years after the date of the enactment of
5 the Food and Drug Administration Globalization Act of
6 2009. Such risk-based system shall include consideration
7 of the class of the establishment's products and associated
8 risks, the date the establishment was last inspected, the
9 establishment's compliance and safety history, the estab-
10 lishment's shipping volume and history, and such other
11 factors as the Secretary determines relevant to assessing
12 the risk presented by the establishment.”.

13 (b) GAO REPORT.—Not later than 3 years after the
14 date of the enactment of this Act, the Comptroller General
15 of the United States shall submit a report to the Congress
16 on the risk-based process for conducting surveillance of
17 current good manufacturing practices developed and im-
18 plemented under section 510(h)(6) of the Federal Food,
19 Drug, and Cosmetic Act, as added by subsection (a)(4)
20 of this section.

21 (c) EFFECTIVE DATE.—The amendments made by
22 this section shall apply to drugs introduced or delivered
23 for introduction into interstate commerce on or after the
24 date of the enactment of this Act.

1 **SEC. 203. DOCUMENTATION FOR ADMISSIBILITY OF DRUG**
2 **IMPORTS.**

3 Section 801 (21 U.S.C. 381), as amended by section
4 123, is further amended by adding at the end the fol-
5 lowing:

6 “(q) Beginning 3 years after the date of the enact-
7 ment of this subsection, a drug shall not enter the United
8 States unless the party offering the drug for import pro-
9 vides the Secretary, at the time of offering the drug for
10 import, information demonstrating compliance with appli-
11 cable requirements pertaining to identity, strength, qual-
12 ity, purity, approval, listing, labeling, registration, and
13 such additional categories as the Secretary, by guidance,
14 determines are necessary for protection of the public
15 health. The Secretary may allow that such compliance be
16 demonstrated through verification by an accredited third
17 party or through such other means as determined, by
18 guidance, by the Secretary.”.

19 **SEC. 204. DRUG SUPPLY QUALITY AND SAFETY.**

20 (a) ADULTERATION.—Section 501 (21 U.S.C. 351)
21 is amended by adding at the end the following:

22 “(j) If it is drug that was manufactured, prepared,
23 propagated, compounded, or processed by an establish-
24 ment that is or was at the time of such manufacture, prep-
25 aration, propagation, compounding, or processing in viola-
26 tion of section 505–2 because of—

1 “(1) the failure to have in effect and implement
2 a quality risk management plan in accordance with
3 section 505–2; or

4 “(2) the failure to transmit information in elec-
5 tronic form as requested by the Secretary under sec-
6 tion 505–2(f).”.

7 (b) **QUALITY RISK MANAGEMENT PLANS.**—Chapter
8 V (21 U.S.C. 351 et seq.) is amended by inserting after
9 section 505–1 the following:

10 **“SEC. 505–2. DRUG SUPPLY QUALITY AND SAFETY.**

11 “(a) **IMPLEMENTATION OF QUALITY RISK MANAGE-**
12 **MENT PLAN.**—An establishment required to be registered
13 with the Secretary pursuant to subsection (b), (c), (d), or
14 (i) of section 510 for the manufacture, preparation, propa-
15 gation, compounding, or processing of a drug shall have
16 in effect and implement an adequate quality risk manage-
17 ment plan that ensures the safety and quality of each such
18 drug, including any ingredients produced, manufactured,
19 processed, packed, or held by another person.

20 “(b) **PLAN PROVISIONS.**—A quality risk management
21 plan required by subsection (a) shall address risk assess-
22 ment, risk control, risk communication, and risk review
23 and shall—

24 “(1) provide for an assessment, prior to con-
25 tracting with a person to supply raw materials or in-

1 ingredients or to undertake any aspect of the manu-
2 facturing of the drug, of the suitability and com-
3 petence of such person to carry out such activity,
4 using audits, material evaluations, or qualification,
5 as appropriate;

6 “(2) define responsibilities and communication
7 processes for manufacturing, quality control, and
8 quality assurance activities of any person referred to
9 in paragraph (1);

10 “(3) provide for the monitoring and review
11 through periodic on-site audits of the facility condi-
12 tions, controls, and practices of any person referred
13 to in paragraph (1) and ensure the implementation
14 of appropriate measures to improve such conditions,
15 controls, and practices;

16 “(4) provide for the monitoring of incoming
17 materials to ensure they are from a person that
18 meets the requirements in paragraphs (1) through
19 (3);

20 “(5) provide for implementation of effective sys-
21 tems, including appropriate specifications and test
22 methods and verification of the drug ingredients’
23 identity, quality, strength, and purity, to detect any
24 hazard that has been, or is reasonably likely to be,
25 present in or on the drug during production, manu-

1 facturing, processing, packing, holding, or trans-
2 porting; and

3 “(6) be periodically reviewed and, as needed,
4 updated.

5 “(c) ADDITIONAL PROVISIONS.—If the Secretary de-
6 termines that provisions in addition to those described in
7 subsections (a) and (b) would be appropriate to include
8 in a quality risk management plan for protection of the
9 public health, including provisions for the prevention of
10 intentional adulteration of a drug or class of drugs, the
11 Secretary may by regulation require the inclusion of such
12 provisions in a quality risk management plan.

13 “(d) APPLICATION OF SPECIFICATIONS OR TEST
14 METHODS BY ORDER OF THE SECRETARY.—Upon a find-
15 ing that there is a significant threat to public health, the
16 Secretary may order an establishment—

17 “(1) to promptly revise its quality risk manage-
18 ment plan to include new or modified specifications
19 or test methods for a drug; and

20 “(2) to promptly implement such specifications
21 or test methods.

22 “(e) INSPECTION OF QUALITY RISK MANAGEMENT
23 PLAN.—The Secretary shall, in the course of an inspection
24 of an establishment subject to this section or upon request

1 by the Secretary, conduct a review of the establishment's
2 quality risk management plan.

3 “(f) DOCUMENTATION OF SUPPLY CHAIN.—

4 “(1) IN GENERAL.—Each establishment re-
5 quired to be registered with the Secretary pursuant
6 to subsection (b), (c), (d), or (i) of Section 510 for
7 the manufacture, preparation, propagation,
8 compounding, or processing of a drug, shall provide
9 to the Secretary, upon request, adequate information
10 transmitted in electronic form, establishing—

11 “(A) where the drug, including its raw ma-
12 terials, were produced, including all preceding
13 producers, manufacturers, distributors, and
14 shippers; and

15 “(B) that the drug, its ingredients and raw
16 materials were manufactured, prepared, propa-
17 gated, compounded, processed, distributed,
18 shipped, warehoused, brokered, imported, and
19 conveyed under conditions that ensure the iden-
20 tity, strength, quality, and purity of the drug.

21 “(2) REPACKAGERS.—For those establishments
22 that are repackagers, paragraph (1)(A) requires only
23 information regarding the immediately preceding es-
24 tablishment.”.

25 (c) EFFECTIVE DATE.—

1 (1) IN GENERAL.—The requirements of sections
2 501(j) and 505–2 of the Federal Food, Drug, and
3 Cosmetic Act, as added by subsections (a) and (b),
4 take effect 2 years after the date of the enactment
5 of this Act.

6 (2) EXCEPTION.—Notwithstanding the effective
7 date specified in paragraph (1)—

8 (A) the authority of the Secretary to order
9 an establishment to promptly implement new or
10 modified specifications or test methods for a
11 drug, as described in section 505–2(d)(2) of the
12 Federal Food, Drug, and Cosmetic Act, as
13 amended by subsection (b), shall take effect on
14 the date of the enactment of this Act;

15 (B) such authority shall apply irrespective
16 of whether the establishment has in effect a
17 quality risk management plan; and

18 (C) a civil penalty under section 303(f)(5)
19 of the Federal Food, Drug, and Cosmetic Act,
20 as added by section 211 of this Act, shall apply
21 to a violation of an order under this paragraph
22 to the same extent and in the same manner as
23 such a penalty applies to a violation of an order
24 under such section 505–2(d)(2).

1 **SEC. 205. DELAY, LIMITATION, OR DENIAL OF INSPECTION.**

2 (a) REQUIREMENT.—Subsection (h) of section 510
3 (21 U.S.C. 351), as amended by section 202(a), is further
4 amended by adding at the end the following:

5 “(7) The person who owns or operates an establish-
6 ment registered with the Secretary pursuant to subsection
7 (b), (c), (d), or (i), any agent or employee of such person,
8 and any agent of a governmental authority in the foreign
9 country within which such establishment is located shall
10 not delay or limit an inspection, or refuse to permit entry
11 or inspection, authorized by this subsection.”.

12 (b) REFERENCE TO PROHIBITED ACT.—For provi-
13 sion making delay, limiting, or denying an inspection
14 under section 510(h) of the Federal Food, Drug, and Cos-
15 metic Act a prohibited act under section 301(f) of such
16 Act, see the amendment made by section 403.

17 (c) DRUGS OFFERED FOR IMPORT.—The third sen-
18 tence of subsection (a) of section 801 (21 U.S.C. 381),
19 as amended by section 105(b), is amended by inserting
20 “or (5) such article has been manufactured, prepared,
21 propagated, compounded, or processed by an establish-
22 ment required to be registered with the Secretary pursu-
23 ant to subsection (b), (c), (d), or (i) of section 510 and
24 such establishment is in violation of section 510(h)(7)
25 (prohibiting the delay, limitation, or denial of an inspec-

1 tion under section 510(h)),” before “then such article
2 shall be refused admission”.

3 **SEC. 206. COUNTRY OF ORIGIN LABELING.**

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

6 “(aa) If it is a drug and the Website of the manufac-
7 turer of the drug does not list the country of origin for
8 each active pharmaceutical ingredient and finished dosage
9 form of such drug.”.

10 (b) REGULATIONS.—Not later than 1 year after the
11 date of the enactment of this Act, the Secretary shall pro-
12 mulgate final regulations to carry out section 502(aa) of
13 the Federal Food, Drug, and Cosmetic Act, as added by
14 subsection (a).

15 (c) EFFECTIVE DATE.—The requirement of section
16 502(aa) of the Federal Food, Drug, and Cosmetic Act,
17 as added by subsection (a), takes effect 2 years after the
18 date of the enactment of this Act.

19 **SEC. 207. NONDISTRIBUTION AND RECALL OF ADULTER-
20 ATED OR MISBRANDED DRUGS.**

21 (a) PROHIBITED ACTS.—Section 301 (21 U.S.C.
22 331), as amended by sections 102, 104, and 112 of this
23 Act, is amended by adding at the end the following:

24 “(rr) The failure to comply with—

1 “(1) an order issued under section 568(a) fol-
2 lowing any hearing requested under section 568(b);
3 or

4 “(2) an amended order issued under section
5 568(c)(1).”.

6 (b) NONDISTRIBUTION AND RECALL OF ADULTER-
7 ATED OR MISBRANDED DRUGS.—Subchapter E of chapter
8 V (21 U.S.C. 360bb et seq.) is amended by adding at the
9 end the following:

10 **“SEC. 568. NONDISTRIBUTION AND RECALL OF ADULTER-**
11 **ATED OR MISBRANDED DRUGS.**

12 “(a) RECALL AND CONSUMER NOTIFICATION.—

13 “(1) VOLUNTARY ACTIONS.—On receiving infor-
14 mation of a suspected adulteration or misbranding
15 of a drug, if the Secretary finds that there is a rea-
16 sonable probability that a drug intended for human
17 use would cause serious, adverse health con-
18 sequences or death, the Secretary shall provide all
19 persons (including the manufacturer, importer, dis-
20 tributor, or retailer of the drug) with an opportunity
21 (as determined by the Secretary)—

22 “(A) to cease distribution of the drug;

23 “(B) to notify all entities—

24 “(i) that produce, manufacture, pack,
25 process, prepare, treat, package, distribute,

1 or hold the drug, to cease immediately
2 those activities with respect to the drug; or

3 “(ii) to which the drug has been dis-
4 tributed, transported, or sold, to cease im-
5 mediately distribution of the drug;

6 “(C) to recall the drug;

7 “(D) in consultation with the Secretary, to
8 provide notice of the finding of the Secretary to
9 all consumers to which the drug was, or may
10 have been, distributed and to appropriate State
11 and local health officials; and

12 “(E) to notify State and local public health
13 officials.

14 “(2) MANDATORY ACTIONS.—If a person re-
15 ferred to in paragraph (1) does not carry out the ac-
16 tions described in that paragraph with respect to a
17 drug within the time period and in the manner pre-
18 scribed by the Secretary, the Secretary shall issue an
19 order requiring such person—

20 “(A) to immediately cease distribution of
21 the drug; and

22 “(B) to immediately notify health profes-
23 sionals and drug user facilities of the order and
24 to instruct such professionals and facilities to
25 cease use of such drug.

1 “(b) HEARINGS ON ORDERS.—The Secretary shall
2 provide a person subject to an order under subsection
3 (a)(2) with an opportunity for an informal hearing, to be
4 held not later than 10 days after the date of the issuance
5 of the order, on—

6 “(1) the actions required by the order; and

7 “(2) any reasons why the drug that is the sub-
8 ject of the order should not be recalled.

9 “(c) POST-HEARING RECALL ORDERS.—

10 “(1) AMENDMENT OF ORDERS.—If, after pro-
11 viding an opportunity for an informal hearing under
12 subsection (b), the Secretary determines that an
13 order under subsection (a)(2) with respect to a drug
14 should be amended to include a recall or other ap-
15 propriate action, the Secretary shall, except as pro-
16 vided in paragraph (2)—

17 “(A) amend the order—

18 “(i) to require recall of the drug or
19 other appropriate action; and

20 “(ii) to specify a timetable during
21 which any such recall shall occur; and

22 “(B) require periodic reports to the Sec-
23 retary describing the progress of any such re-
24 call.

25 “(2) CONTENTS OF ORDER.—

1 “(A) INDIVIDUALS AND DRUG USER FA-
2 CILITIES.—An amended order under paragraph
3 (1) shall not include—

4 “(i) a recall of a drug from individ-
5 uals; or

6 “(ii) a recall of a drug from drug user
7 facilities if the Secretary determines that
8 the risk of recalling such drug from the fa-
9 cilities presents a greater health risk than
10 the health risk of not recalling the drug
11 from use.

12 “(B) NOTICE TO INDIVIDUALS SUBJECT TO
13 RISKS.—An amended order under paragraph
14 (1) shall provide for notice to individuals sub-
15 ject to the risks associated with the use of such
16 drug. In providing the notice required by this
17 paragraph, the Secretary may use the assist-
18 ance of health professionals who prescribed or
19 dispensed such a drug for individuals. If a sig-
20 nificant number of such individuals cannot be
21 identified, the Secretary shall notify such indi-
22 viduals pursuant to section 705(b).

23 “(3) VACATION OF ORDERS.—If, after providing
24 an opportunity for an informal hearing under sub-
25 section (b), the Secretary determines that adequate

1 grounds do not exist to continue the actions required
2 by the order, the Secretary shall vacate the order.

3 “(d) REMEDIES NOT EXCLUSIVE.—The remedies au-
4 thorized by this section shall be in addition to any other
5 remedies that may be available.”.

6 **SEC. 208. DESTRUCTION OF ADULTERATED, MISBRANDED**
7 **OR COUNTERFEIT ARTICLES OFFERED FOR**
8 **IMPORT.**

9 (a) IN GENERAL.—The fifth sentence of subsection
10 (a) of section 801 (21 U.S.C. 381), as amended by sec-
11 tions 105(b) and 205(c), is further amended by inserting
12 before the period at the end of the following: “, except
13 that any article that is refused admission may, at the dis-
14 cretion of the Secretary, be promptly (subject to the next
15 sentence) destroyed and not exported if it appears to pose
16 a risk of injury or death”.

17 (b) NOTICE.—Subsection (a) of section 801 (21
18 U.S.C. 381), as amended by sections 105(b) and 205(c)
19 and subsection (a) of this section, is amended by inserting
20 after the fifth sentence the following: “Before causing the
21 destruction of an article with a value greater than \$2,000
22 under the preceding sentence, the Secretary shall provide
23 notice and an opportunity for an informal hearing to the
24 owner or consignee.”.

1 (c) IMPROPER DESTRUCTION.—Section 801 (21
2 U.S.C. 381), as amended by sections 123 and 203, is
3 amended by adding at the end the following:

4 “(r) Any person claiming any article which has been
5 destroyed under subsection (a) may, at any time within
6 3 months after the date of destruction, apply to the Sec-
7 retary for reimbursement of the value of the article as de-
8 termined by the Secretary. Upon the production of satis-
9 factory proof that the destruction of the article was not
10 within the authority of the Secretary as provided in this
11 section, the Secretary shall order the value of the article
12 restored to the applicant.”.

13 (d) SAMPLES OF DESTROYED ARTICLES.—Section
14 801 (21 U.S.C. 381), as amended by sections 123 and
15 203 and subsection (c) of this section, is amended by add-
16 ing at the end the following:

17 “(s) Where an article is caused to be destroyed under
18 subsection (a) the Secretary shall, upon request, provide
19 a sample of the article to the owner of the article, the
20 owner’s attorney or agent, or if applicable any person
21 named on the label of the article, except that the Secretary
22 is authorized, by regulations, to make such reasonable ex-
23 ceptions from, and impose such reasonable terms and con-
24 ditions relating to, the operation of this subsection as the

1 Secretary finds necessary for the proper administration of
2 the provisions of this Act.”.

3 (e) EFFECTIVE DATE.—The amendments made by
4 subsections (a), (b), (c), and (d) shall take effect 90 days
5 after the date of the enactment of this Act.

6 **SEC. 209. ADMINISTRATIVE DETENTION OF DRUGS THAT**
7 **APPEAR TO VIOLATE THE LAW.**

8 (a) IN GENERAL.—Section 304(g) (21 U.S.C.
9 334(g)) is amended—

10 (1) by inserting “drug or” before “device” each
11 place it appears; and

12 (2) in paragraph (1), by inserting after “adul-
13 terated or misbranded” the following: “or, in the
14 case of a drug, which in the determination of the of-
15 ficer or employee making the inspection appears to
16 be in violation of section 505,”.

17 (b) EFFECTIVE DATE.—The amendments made by
18 subsection (a) shall take effect on a date, specified by the
19 Secretary of Health and Human Services, not later than
20 1 year after the date of the enactment of this Act.

21 **SEC. 210. PENALTIES REGARDING COUNTERFEIT DRUGS.**

22 Section 303(a) (21 U.S.C. 333(a)) is amended by
23 adding at the end the following paragraph:

24 “(3) Notwithstanding paragraph (1) or (2), any per-
25 son who engages in any conduct described in section

1 301(i)(2) knowing that the conduct concerns the rendering
2 of a drug as a counterfeit drug, or who engages in conduct
3 described in section 301(i)(3) knowing that the conduct
4 will cause a drug to be a counterfeit drug or knowing that
5 a drug held, sold, or dispensed is a counterfeit drug, shall
6 be fined in accordance with title 18, United States Code,
7 or imprisoned not more than 20 years, or both, except that
8 if the use of the counterfeit drug by a consumer is the
9 proximate cause of the death of the consumer, the term
10 of imprisonment shall be any term of years or for life.”.

11 **SEC. 211. CIVIL MONEY PENALTIES FOR VIOLATIVE DRUGS**
12 **AND DEVICES AND IMPROPER IMPORT**
13 **ENTRY FILINGS.**

14 (a) IN GENERAL.—Section 303(f) (21 U.S.C. 333)
15 is amended—

16 (1) by redesignating paragraphs (5), (6), and
17 (7) as paragraphs (6), (7), and (8), respectively;

18 (2) by inserting after paragraph (4) the fol-
19 lowing:

20 “(5)(A)(i) Any person that violates a require-
21 ment of this Act that relates to drugs for human use
22 (except a requirement referred to in paragraph (4)
23 or subsection (g)) shall be liable to the United
24 States for a civil penalty not to exceed—

1 “(I) \$100,000 for an initial violation
2 of such a requirement; or

3 “(II) \$200,000 for a subsequent viola-
4 tion of the same requirement.

5 “(ii) In clause (i)(I), the term ‘initial violation’
6 means the first violation by a person of a require-
7 ment described in clause (i) that occurs on or after
8 the date of the enactment of the Food and Drug Ad-
9 ministration Globalization Act of 2009.

10 “(iii) Each day during which a violation con-
11 tinues shall be considered a separate violation under
12 clause (i), except that a continuing initial violation
13 shall not be treated as a subsequent violation for
14 purposes of clause (i)(II).

15 “(B)(i) Any person that knowingly reports or
16 enters false or misleading data on documents related
17 to the importation of a drug shall be liable to the
18 United States for a civil penalty not to exceed
19 \$200,000.

20 “(ii) Each act of reporting or entering false
21 data shall be considered a separate violation under
22 clause (i).

23 “(C) Any manufacturer, importer, distributor,
24 or retailer who fails to comply with an order or an
25 amended order issued under section 568(a) or

1 568(c)(1), respectively, shall be liable to the United
2 States for a civil penalty not to exceed \$250,000 per
3 day.”.

4 (3) in paragraph (6), as so redesignated, by
5 striking “, or (4)” each place it appears and insert-
6 ing “(4), or (5)”;

7 (4) in paragraph (7), as so redesignated, by
8 striking “(5)(A)” and inserting “(6)(A)”;

9 (5) in paragraph (8), as so redesignated, by
10 striking “paragraph (6)” each place it appears and
11 inserting “paragraph (7)”.

12 (b) **APPLICABILITY.**—Section 303(f)(5) (as amended
13 by subsection (a)), shall apply to violations described in
14 such section that occur after the date of the enactment
15 of this Act.

16 **SEC. 212. HUMAN GENERIC DRUG APPLICATION AND SUP-**
17 **PLEMENT FEES TO COVER PRE-APPROVAL**
18 **INSPECTION COSTS.**

19 (a) **SENSE OF CONGRESS.**—It is the sense of the Con-
20 gress that the amount of additional revenues generated
21 from fees under this section should be used to support pre-
22 approval inspections of generic drug establishments, in ac-
23 cordance with performance goals to be developed by the
24 Secretary of Health and Human Services in consultation
25 with the entities listed in subparagraphs (A) through (F)

1 of section 736B(d)(1) of the Federal Food, Drug, and
2 Cosmetic Act (21 U.S.C. 379h-2(d)(1)).

3 (b) FEE.—

4 (1) MISBRANDING.—Paragraph (o) of section
5 502 (21 U.S.C. 352), as amended by subsections (a)
6 and (b) of section 501, is further amended by strik-
7 ing “736C” and inserting “736C or 736D”.

8 (2) ESTABLISHMENT.—Part 2 of subchapter C
9 of chapter VII (21 U.S.C. 379g et seq.), as amended
10 by section 201(b), is amended by adding at the end
11 the following:

12 **“SEC. 736D. HUMAN GENERIC DRUG APPLICATION AND**
13 **SUPPLEMENT FEES TO COVER PRE-AP-**
14 **PROVAL INSPECTION COSTS.**

15 “(a) IN GENERAL.—The Secretary shall assess and
16 collect a fee upon submission of any human generic drug
17 application or supplement to defray increases (as de-
18 scribed in subsection (c)(2)(B)) in the costs of resources
19 allocated for conducting inspections in connection with the
20 review of human generic drug applications and supple-
21 ments.

22 “(b) FEE REVENUE AMOUNTS.—For each of fiscal
23 years 2010 through 2013, fees under subsection (a) shall
24 be established, subject to the provisions referred to in sub-
25 section (d), to generate a total revenue amount.

1 “(c) CREDITING AND AVAILABILITY OF FEES.—

2 “(1) IN GENERAL.—Fees authorized under sub-
3 section (a) shall be collected and available for obliga-
4 tion only to the extent and in the amount provided
5 in advance in appropriations Acts. Such fees are au-
6 thorized to remain available until expended. Such
7 sums as may be necessary may be transferred from
8 the Food and Drug Administration salaries and ex-
9 penses appropriation account without fiscal year lim-
10 itation to such appropriation account for salaries
11 and expenses with such fiscal year limitation.

12 “(2) COLLECTIONS AND APPROPRIATION
13 ACTS.—The fees authorized by this section—

14 “(A) shall be retained in each fiscal year in
15 an amount not to exceed the amount specified
16 in appropriation Acts, or otherwise made avail-
17 able for obligation, for such fiscal year; and

18 “(B) shall only be collected and available
19 to defray increases in the costs of resources al-
20 located for conducting inspections in connection
21 with the review of human generic drug applica-
22 tions and supplements (including increases in
23 such costs for an additional number of full-time
24 equivalent positions in the Department of
25 Health and Human Services to be engaged in

1 such review) over such costs, excluding costs
2 paid from fees collected under this section, for
3 fiscal year 2009 multiplied by the adjustment
4 factor.

5 “(d) APPLICABILITY OF CERTAIN PROVISIONS.—To
6 the extent determined by the Secretary to be consistent
7 with this section, the provisions of section 736 apply with
8 respect to human generic drug application fees and sup-
9 plement fees under this section to the same extent and
10 in the same manner as such provisions apply with respect
11 to human drug application fees and supplement fees under
12 section 736.

13 “(e) DEFINITIONS.—In this section:

14 “(1) The term ‘costs of resources allocated for
15 conducting inspections in connection with the review
16 of human generic drug applications and supple-
17 ments’ means the expenses that are—

18 “(A) incurred in connection with inspec-
19 tions undertaken as part of the Secretary’s re-
20 view of pending human generic drug applica-
21 tions and supplements; and

22 “(B) described in subparagraphs (A)
23 through (D) of section 735(7), except that the
24 reference in section 735(7)(D) to section 736 is
25 deemed to be a reference to this section, and

1 the reference is section 735(7)(D) to human
2 drug applications and supplements (as defined
3 in section 735(2)) is deemed to be a reference
4 to human generic drug applications and supple-
5 ments (as defined in this section).

6 “(2) The term ‘human generic drug application’
7 means an application for approval of a new drug
8 submitted under section 505(j). Such term does not
9 include an application or a supplement to an appli-
10 cation described in section 735(1).

11 “(3) Notwithstanding section 735(2), the term
12 ‘supplement’ means a request to the Secretary to ap-
13 prove a change in a human generic drug application
14 which has been approved.”.

15 (3) EFFECTIVE DATE.—The Secretary of
16 Health and Human Services shall first impose the
17 fee established under section 736D of the Federal
18 Food, Drug, and Cosmetic Act, as added by para-
19 graph (2), for fiscal years beginning with fiscal year
20 2010.

21 (4) SUNSET DATE.—Section 736D, as added by
22 paragraph (2), does not authorize the assessment or
23 collection of a fee for submission of an application
24 or supplement under section 505(j) of such Act (21
25 U.S.C. 355(j)) occurring after fiscal year 2013.

1 **TITLE III—COSMETIC SAFETY**

2 **SEC. 301. REGISTRATION OF COSMETIC ESTABLISHMENTS.**

3 (a) MISBRANDING.—Section 602 is amended by add-
4 ing at the end the following:

5 “(g) If it was manufactured or packaged in an estab-
6 lishment that is not duly registered under section 604.”.

7 (b) ANNUAL REGISTRATION.—Chapter VI is amend-
8 ed by adding at the end the following:

9 **“SEC. 604. REGISTRATION OF COSMETIC ESTABLISHMENTS.**

10 “(a) REGISTRATION.—

11 “(1) IN GENERAL.—The Secretary shall by reg-
12 ulation require that any establishment engaged in
13 manufacturing or packaging cosmetics for use in the
14 United States be registered annually with the Sec-
15 retary. To be registered—

16 “(A) for a domestic establishment, the
17 owner, operator, or agent in charge of the es-
18 tablishment shall submit a registration to the
19 Secretary; and

20 “(B) for a foreign establishment, the
21 owner, operator, or agent in charge of the es-
22 tablishment shall submit a registration to the
23 Secretary and shall include with the registration
24 the name of the United States agent for the es-
25 tablishment.

1 “(2) REGISTRATION.—An entity (referred to in
2 this section as the ‘registrant’) shall submit a reg-
3 istration under paragraph (1) to the Secretary con-
4 taining information necessary to notify the Secretary
5 of the name and address of each establishment at
6 which, and all trade names under which, the reg-
7 istrant manufactures or packages cosmetics. The
8 registrant shall notify the Secretary in a timely man-
9 ner of changes to such information. The registrant
10 shall notify the Secretary of any change in the prod-
11 ucts, function, or legal status of each such establish-
12 ment (including cessation of business activities) not
13 later than 30 days after the date of such change.

14 “(3) PROCEDURE.—Upon receipt of a com-
15 pleted registration described in paragraph (1), the
16 Secretary shall notify the registrant of the receipt of
17 such registration and assign a registration number
18 to each registered establishment.

19 “(4) LIST.—The Secretary shall compile and
20 maintain an up-to-date list of establishments that
21 are registered under this section. The Secretary shall
22 remove from such list the name of any establishment
23 that fails to reregister in accordance with this sec-
24 tion and shall treat such removal as a suspension of
25 the establishment’s registration. Such list and any

1 registration documents submitted pursuant to this
2 subsection shall not be subject to disclosure under
3 section 552 of title 5, United States Code. Informa-
4 tion derived from such list or registration documents
5 shall not be subject to disclosure under section 552
6 of title 5, United States Code, to the extent that
7 such information discloses the identity or location of
8 a specific registered person.

9 “(b) ESTABLISHMENT.—For purposes of this section:

10 “(1) The term ‘domestic establishment’ means
11 an establishment located in any State (as defined in
12 section 201).

13 “(2)(A) The term ‘foreign establishment’ means
14 an establishment that manufactures or packages cos-
15 metics that are exported to the United States with-
16 out further processing or packaging outside the
17 United States.

18 “(B) A cosmetic may not be considered to have
19 undergone further processing or packaging for pur-
20 poses of subparagraph (A) solely on the basis that
21 labeling was added or that any similar activity of a
22 de minimis nature was carried out with respect to
23 the cosmetic.”.

1 **SEC. 302. COSMETIC AND INGREDIENT STATEMENTS.**

2 (a) MISBRANDING.—Section 602, as amended by sec-
3 tion 301 of this Act, is amended by adding at the end
4 the following:

5 “(h) If its manufacturer is in violation of section 605
6 for failure to submit a cosmetic and ingredient statement
7 with respect to the cosmetic.”.

8 (a) STATEMENTS.— Chapter VI, as amended by sec-
9 tion 301 of this Act, is amended by adding at the end
10 the following:

11 **“SEC. 605. COSMETIC AND INGREDIENT STATEMENTS.**

12 “(a) IN GENERAL.—The Secretary shall require by
13 regulation that every establishment engaged in the manu-
14 facture of a cosmetic intended to be marketed in the
15 United States submit to the Secretary for each cosmetic
16 manufactured in the establishment, within 60 days after
17 beginning manufacture of the product, a cosmetic and in-
18 gredient statement containing—

19 “(1) the registration number of the manufac-
20 turing establishment where the cosmetic is manufac-
21 tured or, if the same cosmetic is manufactured in
22 more than one establishment, the registration num-
23 ber of each establishment where it is manufactured;

24 “(2) the brand name or names for the cosmetic;

25 “(3) the applicable cosmetic category or cat-
26 egories for the cosmetic;

1 “(4) the ingredients in the cosmetic in descend-
2 ing order of predominance by weight, except that—

3 “(A) flavors and fragrances may be des-
4 ignated as such; and

5 “(B) all variations in color, flavor, or fra-
6 grance may be included in one statement; and

7 “(5) the title and full contact information for
8 the individual or individuals responsible for submit-
9 ting and maintaining the statement.

10 The registrant shall notify the Secretary in a timely man-
11 ner of any change to the information required to be in
12 such statement.

13 “(b) PROCEDURE.—Upon receipt of a completed cos-
14 metic and ingredient statement described in paragraph
15 (a), the Secretary shall notify the registrant of the receipt
16 of such statement and assign a cosmetic and ingredient
17 statement number.

18 “(c) LIST.—The Secretary shall compile and main-
19 tain an up-to-date list of cosmetics and ingredients for
20 which statements are submitted under this section.”.

21 **SEC. 303. SERIOUS AND UNEXPECTED ADVERSE EVENT RE-**
22 **PORTS FOR COSMETICS.**

23 (a) PROHIBITED ACTS.—Section 301 is amended—

24 (1) in paragraph (e), by striking “or 761” each
25 place it appears and inserting “761, or 762”; and

1 (2) in paragraph (ii)—

2 (A) by striking “or the” and inserting “,
3 the”; and

4 (B) by striking the period at the end and
5 inserting “, or the falsification of a report sub-
6 mitted under section 762 to the Secretary.”.

7 (b) ADVERSE EVENT REPORTING.—Subchapter H of
8 chapter VII is amended by adding at the end the following:

9 **“SEC. 762. SERIOUS AND UNEXPECTED ADVERSE EVENT RE-**
10 **PORTS FOR COSMETICS.**

11 “(a) IN GENERAL.—The Secretary shall require by
12 regulation that the manufacturer, packager, or distributor
13 whose name appears on the label of a cosmetic marketed
14 in the United States pursuant to section 602(b)(1) submit
15 to the Secretary under subsection (b) a report containing
16 information received concerning any serious and unex-
17 pected adverse event in the United States associated with
18 the use of the cosmetic.

19 “(b) SUBMISSION OF REPORTS.—

20 “(1) IN GENERAL.—A report under subsection
21 (a) shall be submitted to the Secretary no later than
22 15 business days after information concerning the
23 adverse event is received at the place of business la-
24 beled on the cosmetic under section 602(b)(1); and

1 “(2) CONTENTS.—A report under subsection
2 (a) shall include the following information, to the ex-
3 tent to which the person submitting the report has
4 been able to verify the information—

5 “(A) an identifiable patient;

6 “(B) an identifiable reporter;

7 “(C) a suspect cosmetic; and

8 “(D) a serious and unexpected adverse
9 event.

10 “(3) ADDITIONAL INFORMATION.—The person
11 submitting a report under subsection (a) may in-
12 clude in the submission any additional pertinent in-
13 formation and may supplement the report with addi-
14 tional information at a later time

15 “(c) RELATION TO OTHER PROVISIONS.—A report
16 under subsection (a) (including all information submitted
17 in the initial report or added later) shall be considered
18 to be—

19 “(1) a safety report under section 756;

20 “(2) a record about an individual under section
21 552a of title 5, United States Code; and

22 “(3) a medical or similar file the disclosure of
23 which would constitute a violation of section
24 552(b)(6) of such title 5, United States Codes, and
25 shall not be disclosed under section 552 of such title.

1 “(d) DEFINITIONS.—In this section:

2 “(1) The term ‘serious’, with respect to an ad-
3 verse event, means—

4 “(A) resulting in—

5 “(i) death;

6 “(ii) a life-threatening experience;

7 “(iii) inpatient hospitalization;

8 “(iv) a persistent and significant dis-
9 ability or incapacity; or

10 “(v) a congenital anomaly or birth de-
11 fect; or

12 “(B) requiring, based on reasonable med-
13 ical judgment, a medical or surgical interven-
14 tion to prevent an outcome described in sub-
15 paragraph (A).

16 “(2) The term ‘unexpected’, with respect to an
17 adverse event, means not identified in the current la-
18 beling for the cosmetic.”.

19 **SEC. 304. GOOD MANUFACTURING PRACTICES FOR COS-**
20 **METICS.**

21 Section 601 is amended by adding at the end the fol-
22 lowing:

23 “(f) If the methods used in, or the facilities or con-
24 trols used for, its manufacture, processing, packaging,
25 storage, or holding do not conform to current good manu-

1 facturing practice, as prescribed by the Secretary in regu-
2 lations, to ensure that the cosmetic is safe and otherwise
3 in compliance with this Act.”.

4 **SEC. 305. AUTHORIZATION OF APPROPRIATIONS.**

5 Chapter VI, as amended by sections 301 and 302,
6 is amended by adding at the end the following:

7 **“SEC. 606. AUTHORIZATION OF APPROPRIATIONS.**

8 “To carry out this chapter and section 762, there is
9 authorized to be appropriated \$10,000,000 for each of fis-
10 cal years 2010 through 2014.”.

11 **SEC. 306. EFFECTIVE DATE.**

12 The amendments made by sections 301, 302, 303,
13 and 304 shall take effect 18 months after the date of the
14 enactment of this Act.

15 **TITLE IV—MISCELLANEOUS**

16 **SEC. 401. REGISTRATION FOR COMMERCIAL IMPORTERS**
17 **OF FOOD, DRUGS, DEVICES, AND COSMETICS;**
18 **FEE.**

19 (a) PROHIBITIONS.—Section 301 (21 U.S.C. 331), as
20 amended by sections 102, 104, 112, and 207, is amended
21 by adding at the end the following:

22 “(ss) The importation of food, drugs, devices, or cos-
23 metics other than only for personal use by an importer
24 that is not registered with respect to such food, drugs,
25 devices, or cosmetics under section 415, 510, or 604, re-

1 spectively, unless the importer is registered under section
2 801(t).”.

3 (b) REGISTRATION.—Section 801, as amended by
4 sections 123, 203, and 208, is amended by adding at the
5 end the following:

6 “(t) The Secretary shall by regulation require that
7 an importer of food, drugs, devices, or cosmetics, other
8 than only for personal use, that is not required to be reg-
9 istered with respect to such food, drugs, devices, or cos-
10 metics under section 415, 510, or 604, respectively, shall
11 be registered with the Secretary in a form and manner
12 specified by the Secretary. The Secretary shall assign a
13 unique identification number to each importer so reg-
14 istered.”.

15 (c) FEE.—Subchapter C of chapter VII (21 U.S.C.
16 379f et seq.) is amended by adding at the end the fol-
17 lowing:

18 **“PART 6—IMPORTERS OF FOOD, DRUGS, AND**

19 **DEVICES**

20 **“SEC. 742. IMPORTERS OF FOOD, DRUGS, AND DEVICES.**

21 “(a) IN GENERAL.—The Secretary shall assess and
22 collect an annual fee for the registration of an importer
23 of food, drugs, or devices under section 801(t).

24 “(b) AMOUNT OF FEE.—The amount of the fee under
25 this section shall be \$10,000.

1 “(c) **RULE OF CONSTRUCTION.**—This section shall
2 not be construed to authorize the assessment or collection
3 of any fee from an importer of food, drugs, or devices if,
4 with respect to such food, drugs, or devices, the importer
5 is registered under section 415 or 510 and required to
6 pay a fee under section 736C or 741.”.

7 (d) **EFFECTIVE DATE.**—

8 (1) **REGISTRATION.**—Not later than 1 year
9 after the date of the enactment of this Act, the Sec-
10 retary of Health and Human Services shall establish
11 procedures for the registration of importers under
12 section 801(t) of the Federal Food, Drug, and Cos-
13 metic Act, as added by subsection (a).

14 (2) **REGISTRATION.**—The amendments made by
15 this section shall first apply not later than 1 year
16 after the date of the enactment of this Act.

17 **SEC. 402. UNIQUE IDENTIFICATION NUMBER FOR FOOD,**
18 **DRUG, AND DEVICE FACILITIES AND ESTAB-**
19 **LISHMENTS.**

20 (a) **FOOD AND COSMETICS.**—Section 415(a)(3) (21
21 U.S.C. 350d(a)(3)) is amended by inserting “unique” be-
22 fore “registration number”.

23 (b) **DRUGS AND DEVICES.**—Section 510(e) (21
24 U.S.C. 360(e)) is amended by adding after the first sen-
25 tence the following: “The registration number shall be the

1 unique identification number for each such establish-
2 ment.”.

3 (c) **EFFECTIVE DATE.**—The Secretary of Health and
4 Human Services shall implement the amendments made
5 by this section not later than 1 year after the date of the
6 enactment of this Act.

7 **SEC. 403. PROHIBITION AGAINST DELAYING OR LIMITING**
8 **INSPECTION.**

9 Section 301(f) (21 U.S.C. 331(e)) is amended to read
10 as follows:

11 “(f) The delay or limitation of an inspection, or the
12 refusal to permit entry or inspection, as authorized by sec-
13 tion 510(h) or 704, including any such delay, limitation,
14 or refusal by an agent of a governmental authority in a
15 foreign country.”.

16 **SEC. 404. DEDICATED FOREIGN INSPECTORATE.**

17 Section 704 (21 U.S.C. 374) is amended by adding
18 at the end the following:

19 “(i) The Secretary shall establish and maintain a
20 corps of inspectors dedicated to inspections of foreign
21 food, drug, device, and cosmetics facilities and establish-
22 ments. This corps shall be staffed and funded by the Sec-
23 retary at a level sufficient to allow it to conduct inspec-
24 tions of foreign food, drug, device, and cosmetic facilities
25 and establishments at a frequency at least equivalent to

1 the inspection rate of domestic food, drug, device, and cos-
2 metic facilities and establishments.”.

3 **SEC. 405. CONTINUED OPERATION OF FIELD LABORA-**
4 **TORIES.**

5 (a) IN GENERAL.—Subject to subsections (b) and
6 (d), the Secretary of Health and Human Services (in this
7 section referred to as the “Secretary”) shall not—

8 (1) terminate any of the 13 field laboratories
9 that were operated by the Office of Regulatory Af-
10 fairs of the Food and Drug Administration as of
11 January 1, 2007;

12 (2) consolidate any such laboratory with any
13 other laboratory;

14 (3) terminate any of the 20 district offices or
15 any of the inspection or compliance functions of any
16 of the 20 district offices of the Food and Drug Ad-
17 ministration functioning as of January 1, 2007; or

18 (4) consolidate—

19 (A) any such district office with an office
20 in any other district; or

21 (B) transfer any of the compliance or in-
22 spection functions of any such district office to
23 any other district.

24 (b) REPORT BY SECRETARY.—

1 (1) SUBMISSION.—The Secretary shall submit a
2 reorganization plan involving the termination or con-
3 solidation of the laboratories, the district offices, or
4 the functions of such district offices specified in sub-
5 section (a) to the Comptroller General of the United
6 States, the Committee on Energy and Commerce of
7 the House of Representatives, and the Committee on
8 Health, Education, Labor, and Pensions of the Sen-
9 ate.

10 (2) CONSULTATION.—In preparing the reorga-
11 nization plan described in paragraph (1), the Sec-
12 retary shall consult with personnel and unions to be
13 affected by the plan.

14 (c) REPORT BY GAO.—The Comptroller General
15 shall study the cost effectiveness of the reorganization
16 plan described in subsection (b) and its impact on the
17 safety of food, drug, and other products regulated under
18 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301
19 et seq.) and the Public Health Service Act (42 U.S.C. 201
20 et seq.) and report to the Committee on Energy and Com-
21 merce of the House of Representatives and the Committee
22 on Health, Education, Labor, and Pensions of the Senate.

23 (d) REORGANIZATION.—

24 (1) CONGRESSIONAL REVIEW.—The reorganiza-
25 tion plan described in subsection (b) is deemed to be

1 a major rule (as defined in section 804(2) of title 5,
2 United States Code) for purposes of chapter 8 of
3 such title.

4 (2) **EFFECTIVE DATE.**—Notwithstanding sec-
5 tion 801(a)(3) of title 5, United States Code, the re-
6 organization plan described in subsection (b) shall
7 take effect (unless disapproved under section 802 of
8 such title) on the date that is specified in such plan,
9 but not earlier than 180 days after the date on
10 which the Comptroller General submits the report
11 required by subsection (c).

12 **SEC. 406. FALSE OR MISLEADING REPORTING TO FDA.**

13 (a) **IN GENERAL.**—Section 301(q)(2) (21 U.S.C.
14 331(q)(2)) is amended by inserting after “device” the fol-
15 lowing: “food, drug, or biological product”.

16 (b) **EFFECTIVE DATE.**— The amendment made by
17 subsection (a) shall apply to submissions made on or after
18 the date of the enactment of this Act.

19 **SEC. 407. SUBPOENA AUTHORITY.**

20 Chapter III (21 U.S.C. 331 et seq.) is amended by
21 adding at the end the following:

22 **“SEC. 311. EXERCISE OF SUBPOENA AUTHORITY.**

23 “(a) **IN GENERAL.**—For the purpose of—

24 “(1) any hearing, investigation, or other pro-
25 ceeding respecting a violation of the Act, or

1 “(2) any hearing, investigation, or other pro-
2 ceeding to determine if a person is in violation of a
3 specific provision of the Act,
4 the Commissioner may issue subpoenas requiring the at-
5 tendance and testimony of witnesses and the production
6 of documentary evidence. Such attendance of witnesses
7 and production of evidence at the designated place of such
8 hearing, investigation, or other proceeding may be re-
9 quired from any place in the United States or in any terri-
10 tory or possession of the United States. Subpoenas of the
11 Commissioner shall be served by a person authorized by
12 the Commissioner by delivering a copy thereof to the per-
13 son named therein or by certified mail addressed to such
14 person at such person’s last known dwelling place or prin-
15 cipal place of business. A verified return by the person
16 so serving the subpoena setting forth the manner of serv-
17 ice, or, in the case of service by certified mail, the return
18 post office receipt therefor signed by the person so served,
19 shall be proof of service. Witnesses so subpoenaed shall
20 be paid the same fees and mileage as are paid witnesses
21 in the district courts of the United States.

22 “(b) ENFORCEMENT.—In the case of a refusal to
23 obey a subpoena duly served upon any person under sub-
24 section (a), any district court of the United States for the
25 judicial district in which such person charged with refusal

1 to obey is found, resides, or transacts business, upon ap-
2 plication by the Commissioner, shall have jurisdiction to
3 issue an order requiring such person to appear and give
4 testimony or to appear and produce evidence, or both. The
5 failure to obey such order of the court may be punished
6 by the court as contempt thereof. Furthermore, the failure
7 or refusal to obey such a subpoena shall be treated as a
8 prohibited act under section 301(a).

9 “(c) **RELATION TO OTHER PROVISIONS.**—The sub-
10 poena authority vested in the Commissioner and the dis-
11 trict courts of the United States by this section is in addi-
12 tion to any such authority vested in the Commissioner or
13 such courts by other provisions of law.”.

14 **SEC. 408. WHISTLEBLOWER PROTECTIONS.**

15 Chapter IX (21 U.S.C. 391 et seq.) is amended by
16 adding at the end the following:

17 **“SEC. 911. PROTECTIONS FOR EMPLOYEES WHO REFUSE TO**
18 **VIOLATE, OR WHO DISCLOSE VIOLATIONS OF,**
19 **THIS ACT OR SECTION 351 OF THE PUBLIC**
20 **HEALTH SERVICE ACT.**

21 “(a) **IN GENERAL.**—No person that submits or is re-
22 quired to submit to the Secretary, a registration under
23 section 415, 510, or 604, a new drug application under
24 section 505(b), an abbreviated new drug application under
25 section 505(j), a biologics license application under section

1 351 of the Public Health Service Act, an application for
2 an investigational new drug exemption under section
3 505(i), a new animal drug application under section
4 512(b), an abbreviated new animal drug application under
5 section 512(b), an application under section 571, a request
6 under section 572, an application or report for premarket
7 approval under section 515, an application for an inves-
8 tigational device exemption under section 520(g), a report
9 under section 510(k), an application for a humanitarian
10 device exemption under section 520(m), an amendment,
11 supplement, or other submission with respect to any such
12 registration, application, or report, or a record or report
13 related to an adverse event, a postapproval study, a post-
14 approval clinical trial, a report, or postmarket surveillance
15 under section 505(k), 505(o), 519, 522, or 760, or any
16 officer, employee, contractor, subcontractor, or agent of
17 such a person, may discharge, demote, suspend, threaten,
18 harass, or in any other manner discriminate against an
19 employee in the terms and conditions of employment be-
20 cause of any lawful act done by the employee, including
21 within the ordinary course of the job duties of such em-
22 ployee—

23 “(1) to provide information, cause information
24 to be provided, or otherwise assist in any investiga-
25 tion regarding any conduct which the employee rea-

1 sonably believes constitutes a violation of this Act or
2 section 351 of the Public Health Service Act, any
3 other provision of Federal law relating to the safety
4 or effectiveness of a drug, biological product, or de-
5 vice or to the safety of a food or cosmetic, or any
6 provision of Federal law prohibiting fraud against
7 the Food and Drug Administration, if the informa-
8 tion or assistance is provided to, or an investigation
9 stemming from the provided information is con-
10 ducted by—

11 “(A) a Federal regulatory or law enforce-
12 ment agency;

13 “(B) any Member of Congress or any com-
14 mittee of Congress; or

15 “(C) a person with supervisory authority
16 over the employee (or such other person work-
17 ing for the employer who has the authority to
18 investigate, discover, or terminate the mis-
19 conduct);

20 “(2) to file, cause to be filed, testify, participate
21 in, or otherwise assist in a proceeding filed or about
22 to be filed (with any knowledge of the employer) re-
23 lating to any such alleged violation; or

24 “(3) to refuse to commit or assist in any such
25 violation.

1 “(b) ENFORCEMENT ACTION.—

2 “(1) IN GENERAL.—An employee who alleges
3 discharge, or other discrimination in violation of
4 subsection (a), may seek relief in accordance with
5 the provisions of subsection (c), by—

6 “(A) filing a complaint with the Secretary
7 of Labor; or

8 “(B) if the Secretary of Labor has not
9 issued a final decision within 210 days of the
10 filing of the complaint, or within 90 days after
11 receiving a final decision or order from the Sec-
12 retary, and there is no showing that such delay
13 is due to the bad faith of the claimant, bringing
14 an action at law or equity for de novo review in
15 the appropriate district court of the United
16 States, which court shall have jurisdiction over
17 such action without regard to the amount in
18 controversy, and which action shall, at the re-
19 quest of either party to such action, be tried by
20 the court with a jury.

21 “(2) PROCEDURE.—

22 “(A) IN GENERAL.—Any action under
23 paragraph (1) shall be governed under the rules
24 and procedures set forth in section 42121(b) of
25 title 49, United States Code.

1 “(B) EXCEPTION.—Notification in an ac-
2 tion under paragraph (1) shall be made in ac-
3 cordance with section 42121(b)(1) of title 49,
4 United States Code, except that such notifica-
5 tion shall be made to the person named in the
6 complaint and to the employer.

7 “(C) BURDENS OF PROOF.—An action
8 brought under paragraph (1)(B) shall be gov-
9 erned by the legal burdens of proof set forth in
10 section 42121(b) of title 49, United States
11 Code.

12 “(D) STATUTE OF LIMITATIONS.—An ac-
13 tion under paragraph (1) shall be commenced
14 not later than 180 days after the date on which
15 the violation occurs.

16 “(c) REMEDIES.—

17 “(1) IN GENERAL.—An employee prevailing in
18 any action under subsection (b)(1) shall be entitled
19 to all relief necessary to make the employee whole.

20 “(2) ISSUANCE OF ORDER.—If, in response to
21 a complaint filed under paragraph (b)(1), the Sec-
22 retary of Labor or the district court, as applicable,
23 determines that a violation of subsection (a) has oc-
24 curred, the Secretary or the court shall order the
25 person who committed such violation—

1 “(A) to take affirmative action to abate
2 the violation;

3 “(B) to reinstate the complainant to his or
4 her former position together with compensation
5 (including back pay) and restore the terms,
6 conditions, and privileges associated with his or
7 her employment; and

8 “(C) to provide compensatory damages to
9 the complainant.

10 If such an order is issued under this paragraph, the
11 Secretary or the court, at the request of the com-
12 plainant, shall assess against the person against
13 whom the order is issued a sum equal to the aggre-
14 gate amount of all costs and expenses (including at-
15 torney and expert witness fees) reasonably incurred,
16 as determined by the Secretary, by the complainant
17 for, or in connection with, the bringing of the com-
18 plaint upon which the order was issued.

19 “(d) RIGHTS RETAINED BY EMPLOYEE.—Nothing in
20 this section shall be deemed to diminish the rights, privi-
21 leges, or remedies of any employee under any Federal or
22 State law or under any collective bargaining agreement.
23 The rights and remedies in this section may not be waived
24 by any agreement, policy, form, or condition of employ-
25 ment.”.