

111TH CONGRESS  
1ST SESSION

# H. R. 759

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.

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## IN THE HOUSE OF REPRESENTATIVES

JANUARY 28, 2009

Mr. DINGELL (for himself, Mr. STUPAK, and Mr. PALLONE) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## 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”.

8 (b) **REFERENCES TO THE FEDERAL FOOD, DRUG,**  
9 **AND COSMETIC ACT.**—Except as otherwise specified,

1 whenever in this Act an amendment is expressed in terms  
 2 of an amendment to a section or other provision, the ref-  
 3 erence shall be considered to be made to a section or other  
 4 provision of the Federal Food, Drug, and Cosmetic Act  
 5 (21 U.S.C. 301 et seq.).

6 (c) TABLE OF CONTENTS.—The table of contents of  
 7 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 abil-  
 ity 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.

# TITLE I—FOOD SAFETY

## Subtitle A—Prevention

### SEC. 101. CHANGES IN REGISTRATION OF FOOD FACILITIES.

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

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

(b) ANNUAL REGISTRATION AND PAYMENT OF REGISTRATION FEE.—

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

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

(B) in paragraph (1), by inserting “and pay the registration fee required under section 741” after “submit a registration to the Secretary” each place it appears in subparagraphs (A) and (B); and

(C) in paragraph (4), by inserting after the first sentence the following: “The Secretary shall remove from such list the name of any facility 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) FEE REVENUE AMOUNTS.—

22                   “(1) IN GENERAL.—For each of fiscal years  
23 2010 through 2014, 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 2014. 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 2014, 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 2015. 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 2014. 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 2014,  
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 2013 and the amount of

1 fees estimated to be collected under this section for  
2 fiscal year 2014 exceeds the cumulative amount ap-  
3 propriated under paragraph (3) for the fiscal years  
4 2010 through 2013, 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 2014.

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 DATES.—

8           (1) FEES.—

9           (A) EFFECTIVE DATE.—The Secretary of  
10          Health and Human Services shall first impose  
11          the fee established under section 741 of the  
12          Federal Food, Drug, and Cosmetic Act, as  
13          added by subsection (b)(2), for fiscal years be-  
14          ginning with fiscal year 2010.

15          (B) SUNSET DATE.—Section 741 of the  
16          Federal Food, Drug, and Cosmetic Act, as  
17          added by subsection (b)(2), does not authorize  
18          the assessment or collection of a fee for reg-  
19          istration under section 415 of such Act (21  
20          U.S.C. 360) occurring after fiscal year 2014.

21          (2) MODIFICATION OF REGISTRATION FORM.—

22          Not later than 30 days after the date of the enact-  
23          ment of this Act, the Secretary of Health and  
24          Human Services shall modify the registration form  
25          under section 415 of the Federal Food, Drug, and

1       Cosmetic Act (21 U.S.C. 350d) to comply with the  
2       amendments made by subsection (c).

3           (3) APPLICATION.—The amendments made by  
4       this section, other than subsections (b)(2) and (c),  
5       shall take effect on the date that is 30 days after  
6       the date on which such modified registration form  
7       takes effect, but not later than 60 days after the  
8       date of the enactment of this Act.

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

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

13           “(oo) The operation of a facility that manufactures,  
14       processes, packs, transports, or holds food for consump-  
15       tion in the United States if the owner, operator, or agent  
16       in charge of such facility is not in compliance with sections  
17       418 and 418A.”.

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

20       **“SEC. 418. HAZARD ANALYSIS AND RISK-BASED PREVEN-**  
21           **TIVE CONTROLS.**

22           “(a) IN GENERAL.—The owner, operator, or agent  
23       in charge of a facility shall, in accordance with this sec-  
24       tion, evaluate the hazards that could affect food manufac-  
25       tured, processed, packed, transported, or held by such fa-

1 cility, identify and implement preventive controls to sig-  
2 nificantly minimize, prevent, or eliminate the occurrence  
3 of such hazards, monitor the performance of such controls,  
4 and maintain records of such monitoring.

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

9 “(1) biological, chemical, physical, and radio-  
10 logical hazards, natural toxins, pesticides, drug resi-  
11 dues, decomposition, parasites, allergens, and unap-  
12 proved food and color additives;

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

16 “(3) relevant hazards identified under section  
17 419.

18 “(c) PREVENTIVE CONTROLS.—

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

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

6           “(d) MONITORING OF EFFECTIVENESS.—The owner,  
7           operator, or agent in charge of a facility shall monitor the  
8           effectiveness of the preventive controls implemented under  
9           subsection (c).

10          “(e) CORRECTIVE ACTIONS.—The owner, operator,  
11          or agent in charge of a facility shall establish procedures  
12          that the facility will implement if the preventive controls  
13          implemented under subsection (c) are found to be ineffec-  
14          tive through monitoring under subsection (d).

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

17                 “(1) the preventive controls implemented under  
18                 subsection (c) have been validated as adequate to  
19                 control the hazards identified under subsection (b);

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

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

24          “(g) RECORD KEEPING.—The owner, operator, or  
25          agent in charge of a facility shall maintain, for not less

1 than 2 years, records documenting the monitoring and  
2 verification of the effectiveness of the actions described in  
3 subsections (a) through (f).

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

6 “(1) conduct a reanalysis under subsection  
7 (b)—

8 “(A) whenever there is a reasonable poten-  
9 tial for a new hazard or a significant increase  
10 in a previously identified hazard;

11 “(B) not less frequently than once every 2  
12 years; and

13 “(C) if the Secretary determines it to be  
14 appropriate for the protection of the public  
15 health; and

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

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

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

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

4           “(3) PREVENTIVE CONTROLS.—The term ‘pre-  
5 ventive controls’ means those risk-based procedures,  
6 practices, and processes that a person knowledgeable  
7 about the safe manufacturing, processing, packing,  
8 transporting, or holding of food would have em-  
9 ployed to significantly minimize, prevent, or elimi-  
10 nate the hazards identified under the hazard anal-  
11 ysis conducted under subsection (a) and that are  
12 consistent with the current scientific understanding  
13 of safe food manufacturing, processing, packing,  
14 transporting, or holding at the time of the analysis.  
15 Those procedures, practices, and processes may in-  
16 clude the following:

17                   “(A) Sanitation procedures for food con-  
18 tact surfaces and utensils and food-contact sur-  
19 faces of equipment.

20                   “(B) Supervisor, manager, and employee  
21 hygiene training.

22                   “(C) An environmental monitoring pro-  
23 gram to verify the effectiveness of pathogen  
24 controls.

25                   “(D) An allergen control program.



1 “(E) A recall contingency plan.

2 “(F) Good manufacturing practices.

3 “(G) Supplier verification activities.

4 **“SEC. 418A. FOOD SAFETY PLAN.**

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

6 “(1) IN GENERAL.—Before a facility (as de-  
7 fined in section 418(i)) introduces or delivers for in-  
8 troduction into interstate commerce any shipment of  
9 food, the owner, operator, or agent in charge of the  
10 facility shall develop and implement a written food  
11 safety plan (in this section referred to as a ‘food  
12 safety plan’).

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

15 “(A) The hazard analysis conducted under  
16 section 418.

17 “(B) A description of the preventive con-  
18 trols being implemented under section 418(e),  
19 including any those for specific product types  
20 under section 418(e)(2).

21 “(C) Validation that such preventive con-  
22 trols are effective to reduce, control, or elimi-  
23 nate such hazard.

24 “(D) A description of monitoring of such  
25 preventive controls being implemented, includ-

1 ing sampling and testing relating to the control  
2 of hazards where appropriate to verify that the  
3 controls are effective.

4 “(E) A description of the record keeping  
5 being conducted, including evidence of correc-  
6 tive actions, sampling and testing records, mon-  
7 itoring and verification records, and validation  
8 records.

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

12 “(G) A description of established proce-  
13 dures for the trace back of articles of food,  
14 whether voluntarily or when required under sec-  
15 tion 403(g).

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

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

24 “(b) INSPECTION OF FOOD SAFETY PLAN IN COURSE  
25 OF FACILITY INSPECTION.—In the course of a facility in-

1 spection under section 704, the Secretary shall conduct  
2 a review of the food safety plan to ensure the plan meets  
3 relevant requirements of section 418, this section, and sec-  
4 tion 419 and is adequate to protect the public health.”.

5 (c) GUIDANCE OR REGULATIONS.—

6 (1) IN GENERAL.—The Secretary of Health and  
7 Human Services (referred to in this subsection as  
8 the “Secretary”) shall issue guidance or promulgate  
9 regulations to establish science-based minimum  
10 standards for conducting a hazard analysis, docu-  
11 menting hazards, implementing preventive controls,  
12 and documenting the implementation of the preven-  
13 tive controls under sections 418 and 418A of the  
14 Federal Food, Drug, and Cosmetic Act (as added by  
15 subsection (b)).

16 (2) CONSIDERATION.—In issuing guidance or  
17 promulgating regulations under this section, the Sec-  
18 retary shall consider the capacity of small busi-  
19 nesses.

20 (d) NO EFFECT ON HACCP AUTHORITIES.—Noth-  
21 ing in the amendments made by this section limits the au-  
22 thority of the Secretary under the Federal Food, Drug,  
23 and Cosmetic Act (21 U.S.C. 301 et seq.) or the Public  
24 Health Service Act (42 U.S.C. 201 et seq.) to revise, issue,  
25 or enforce product and category-specific regulations, such

1 as the Seafood Hazard Analysis Critical Controls Points  
2 Program, the Juice Hazard Analysis Critical Control Pro-  
3 gram, and the Thermally Processed Low-Acid Foods  
4 Packaged in Hermetically Sealed Containers standards.

5 (e) EFFECTIVE DATE.—

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

9 (2) EXCEPTIONS.—Notwithstanding paragraph  
10 (1)—

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

15 (B) the amendments made by this section  
16 shall apply to a very small business (as defined  
17 by the Secretary) after the date that is 3 years  
18 after the date of the enactment of this Act.

19 **SEC. 103. PERFORMANCE STANDARDS.**

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

23 **“SEC. 419. PERFORMANCE STANDARDS.**

24 “The Secretary shall, not less frequently than every  
25 2 years, review and evaluate epidemiological data and

1 other appropriate sources of information, including re-  
2 search under section 113 of the Food and Drug Adminis-  
3 tration Globalization Act of 2009, to identify the most sig-  
4 nificant food-borne contaminants and the most significant  
5 resulting hazards, and shall issue, through guidance or by  
6 regulation, science-based performance standards (which  
7 may include action levels) to significantly minimize, pre-  
8 vent, or eliminate the occurrence of such hazards. Such  
9 standards shall be applicable to products and product  
10 classes and shall not be specific to an individual facility.”.

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

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

15 “(pp) The production or harvesting of produce not  
16 in accordance with minimum standards as provided by  
17 regulation under section 419A(a) or a variance issued  
18 under section 419A(e).”.

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

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

23 “(a) STANDARDS.—The Secretary shall establish by  
24 regulation science-based minimum standards for the safe  
25 production and harvesting of those types of fruits and

1 vegetables that are raw agricultural commodities for which  
2 the Secretary has determined that such standards mini-  
3 mize the risk of serious adverse health consequences or  
4 death.

5 “(b) CONTENTS.—The regulations under subsection  
6 (a)—

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

10 “(A) to prevent the introduction of known  
11 or reasonably foreseeable biological, chemical,  
12 and physical hazards, including hazards that  
13 occur naturally, may be unintentionally intro-  
14 duced, or may be intentionally introduced, in-  
15 cluding by acts of terrorism, into fruits and  
16 vegetables that are raw agricultural commod-  
17 ities; and

18 “(B) to provide reasonable assurances that  
19 the produce is not adulterated under section  
20 402;

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

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

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

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

10           “(6) shall provide for coordination of education  
11           and enforcement activities by State and local offi-  
12           cials, as designated by the Governors of the respec-  
13           tive States.

14           “(c) PRIORITIZATION.—The Secretary shall prioritize  
15           the implementation of the regulations under subsection (a)  
16           for specific fruits and vegetables that are raw agricultural  
17           commodities and have been associated with food-borne ill-  
18           ness outbreaks.

19           “(d) ENFORCEMENT.—The Secretary may coordinate  
20           with the Secretary of Agriculture and shall contract and  
21           coordinate with the agency or department designated by  
22           the Governor of each State to perform activities to ensure  
23           compliance with this section.”.

24           (c) GUIDANCE; RULEMAKING.—

1           (1) GUIDANCE.—Not later than 1 year after  
2 the date of enactment of this Act, the Secretary  
3 shall publish, after consultation with the Secretary  
4 of Agriculture and representatives of State depart-  
5 ments of agriculture, updated good agricultural  
6 practices and guidance for the safe production and  
7 harvesting of specific types of fresh produce.

8           (2) PROPOSED RULEMAKING.—

9           (A) IN GENERAL.—Not later than 1 year  
10 after the date of the enactment of this Act, the  
11 Secretary, in consultation with the Secretary of  
12 Agriculture and representatives of State depart-  
13 ments of agriculture, shall publish a notice of  
14 proposed rulemaking under section 419A of the  
15 Federal Food, Drug, and Cosmetic Act, as  
16 added by subsection (b).

17           (B) PUBLIC INPUT.—During the comment  
18 period on the notice of proposed rulemaking  
19 under subparagraph (A), the Secretary shall  
20 conduct not less than 3 public meetings in di-  
21 verse geographical areas of the United States to  
22 provide persons in different regions an oppor-  
23 tunity to comment.

24           (3) FINAL REGULATION.—Not later than 1 year  
25 after the close of the comment period for the pro-



1 posed rulemaking under paragraph (2), the Sec-  
2 retary shall adopt a final regulation under section  
3 419A of the Federal Food, Drug, and Cosmetic Act,  
4 as added by subsection (b).

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

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

16 (a) RISK-BASED INSPECTION SCHEDULE.—

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

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

23 “(2) The Secretary shall establish such risk-based  
24 schedule not later than 18 months after the date of the

1 enactment of this subsection and may subsequently revise  
2 such schedule in accordance with this section.

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

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

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

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

14 “(C) whether the facility is certified by a certi-  
15 fying agent accredited pursuant to section 420(a);  
16 and

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

20 (2) FACILITIES ALREADY REGISTERED.—In  
21 section 704(h)(3) of the Federal Food, Drug, and  
22 Cosmetic Act, as added by paragraph (1), the term  
23 “initial registration pursuant to section 415” means,  
24 with respect to a facility that is registered pursuant  
25 to section 415 of such Act as of the date of the en-

1 actment of this Act, the first annual registration of  
2 the facility pursuant to such section 415 that occurs  
3 on or after such date of enactment.

4 (3) REPORTS ON RISK-BASED INSPECTIONS OF  
5 FOOD FACILITIES.—

6 (A) INITIAL REPORT.—Not later than 18  
7 months after the date of the enactment of this  
8 Act, the Secretary of Health and Human Serv-  
9 ices shall submit a report to the Committee on  
10 Energy and Commerce of the House of Rep-  
11 resentatives and the Committee on Health,  
12 Education, Labor, and Pensions of the Senate  
13 describing the risk-based inspection schedule es-  
14 tablished under section 704(h)(2) of the Fed-  
15 eral Food, Drug, and Cosmetic Act, as added  
16 by paragraph (1). Such report shall include a  
17 description of the frequency of inspections for  
18 different classes of risk, the number of facilities  
19 in each class, and an estimate of the projected  
20 5-year costs of implementing such inspection  
21 schedule.

22 (B) SUBSEQUENT REPORTS.—Annually  
23 after the submission of the report required by  
24 subparagraph (A), the Secretary shall submit a  
25 report to the Congress on—

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

7 (ii) the costs of implementing the risk-  
8 based inspection schedule for the preceding  
9 12 months.

10 (b) **FOOD OFFERED FOR IMPORT.**—The third sen-  
11 tence of subsection (a) of section 801 (21 U.S.C. 381) is  
12 amended by inserting “or (4) such article is food that has  
13 been processed, packed, or held at a facility that is in vio-  
14 lation of section 301(f) (prohibiting the delay or limitation  
15 of an inspection, or the refusal to permit entry or inspec-  
16 tion, under section 704),” before “then such article shall  
17 be refused admission”.

18 **SEC. 106. ACCESS TO RECORDS.**

19 (a) **RECORDS INSPECTION.**—Section 414(a) (21  
20 U.S.C. 350c) is amended—

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

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

4           (3) by striking “and a written notice to such  
5           person”; and

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

10          (b) CONFORMING AMENDMENT.—Section 704(a)(1)  
11         (21 U.S.C. 374(a)(1)) is amended by striking “when the  
12         Secretary has a reasonable belief that an article of food  
13         is adulterated and presents a threat of serious adverse  
14         health consequences or death to humans or animals” and  
15         inserting “bearing on whether such food is adulterated,  
16         misbranded, or otherwise in violation of this Act”.

17         **SEC. 107. TRACEABILITY OF FOOD.**

18           (a) FARM AND RESTAURANT RECORDS.—

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

23           (2) MAINTENANCE OF RECORDS.—Section  
24           414(b) of the Federal Food, Drug, and Cosmetic Act  
25           (21 U.S.C. 350c(b)), as amended by section 106, is

1 amended by striking “(excluding farms and res-  
2 taurants)”.

3 (b) STANDARDIZED ELECTRONIC FORMAT.—Section  
4 414 of the Federal Food, Drug, and Cosmetic Act (21  
5 U.S.C. 350c(a)), as amended by section 106 and sub-  
6 section (a), is amended—

7 (1) in subsection (a), by striking “in any for-  
8 mat (including paper and electronic formats) and”;  
9 and

10 (2) in subsection (b), by adding at the end the  
11 following: “The Secretary shall require such persons  
12 to maintain such records in a standardized electronic  
13 format.”.

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

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

21 “(1) the grower of the product;

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

23 “(3) the harvesting and packing dates of the  
24 product; and

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

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

7           (1) complete a study on the effectiveness of  
8           technologies for determining the source of raw agri-  
9           cultural products; and

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

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

13           (a) IN GENERAL.—Part 5 of subchapter C of chapter  
14 VII (21 U.S.C. 371 et seq.), as added by section  
15 101(b)(2), is further amended by adding at the end the  
16 following:

17 **“SEC. 741A. REINSPECTION FEE APPLICABLE TO FACILI-**  
18 **TIES.**

19           “(a) IN GENERAL.—The Secretary shall assess and  
20 collect fees from each facility (as defined in section  
21 415(b)) that—

22           “(1) during such fiscal year, commits a viola-  
23           tion of any requirement of this Act relating to food,  
24           including any such requirement relating to good  
25           manufacturing practices; and

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

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

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

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

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

16          (a) MISBRANDING.—

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

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

24                  (2) EFFECTIVE DATE.—The amendment made  
25                  by paragraph (1) shall apply to shipments offered



1 for import on or after the date that is 3 years after  
2 the date of the enactment of this Act.

3 (b) ACCREDITATION OF CERTIFYING AGENTS; CER-  
4 TIFICATION OF LABORATORIES AND ACCREDITATION OF  
5 LABORATORY CERTIFYING AGENTS.—Chapter IV (21  
6 U.S.C. 341 et seq.), as amended by sections 102(b), 103,  
7 and 104, is amended by adding at the end the following:

8 **“SEC. 420. ACCREDITATION OF CERTIFYING AGENTS.**

9 “(a) ACCREDITATION AS CERTIFYING AGENT.—

10 “(1) IN GENERAL.—Beginning not later than 2  
11 years after the date of the enactment of this section,  
12 the Secretary shall establish and implement an ac-  
13 creditation system under which a foreign govern-  
14 ment, a State or regional food authority, a foreign  
15 or domestic cooperative that aggregates the products  
16 of growers or processors, and any other third party  
17 that the Secretary determines appropriate, may re-  
18 quest to be accredited as a certifying agent to certify  
19 facilities as meeting the applicable requirements of  
20 this Act.

21 “(2) QUALIFICATIONS OF CERTIFYING  
22 AGENTS.—Prior to accrediting an third party as a  
23 certifying agent under paragraph (1), the Secretary  
24 shall perform such reviews and audits of the training  
25 and qualifications of auditors used by the third

1 party, and conduct such reviews of internal systems  
2 and such other investigation of the third party, as  
3 the Secretary deems necessary to determine whether  
4 the third party—

5 “(A) meets the requirements of this sec-  
6 tion; and

7 “(B) is qualified to evaluate the compli-  
8 ance of a facility with the applicable require-  
9 ments of this Act.

10 “(3) LIMITATION OF ACCREDITATION.—The  
11 Secretary may limit the accreditation under para-  
12 graph (1) of a certifying agent to the certification of  
13 facilities that produce, manufacture, process, or hold  
14 only specified food products (or categories of food  
15 products).

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

21 “(5) WITHDRAWAL OF ACCREDITATION.—The  
22 Secretary—

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

1                   “(i) a facility certified by the agent is  
2                   linked to an outbreak of human or animal  
3                   illness; or

4                   “(ii) the Secretary finds that the  
5                   agent no longer meets the requirements for  
6                   accreditation; and

7                   “(B) shall withdraw accreditation under  
8                   paragraph (1) from a certifying agent if the  
9                   Secretary finds that the certifying agent has re-  
10                  fused to allow the Secretary to conduct such  
11                  audits and investigations as may be necessary  
12                  to ensure continued compliance with the re-  
13                  quirements of this section.

14                  “(6) PUBLICATION OF LIST OF CERTIFYING  
15                  AGENTS.—The Secretary shall publish and maintain  
16                  on the website of the Food and Drug Administration  
17                  a current list of certifying agents accredited under  
18                  this section, including—

19                         “(A) each such agent’s name and location;  
20                         and

21                         “(B) any other information deemed nec-  
22                         essary by the Secretary.

23                  “(b) ADDITIONAL REQUIREMENTS APPLICABLE TO  
24                  CERTIFYING AGENTS.—As conditions of accreditation

1 under subsection (a), a certifying agent shall agree to the  
2 following:

3 “(1) AUDIT REQUIREMENTS.—A certifying  
4 agent shall not certify a facility unless the certifying  
5 agent has—

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

9 “(B) reviewed the facility’s food safety  
10 plan under section 418A to ensure the plan  
11 meets applicable requirements of this Act and is  
12 adequate to protect the public health;

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

15 “(D) conducted any other review, analysis,  
16 or testing determined by the Secretary to be ap-  
17 propriate for determining such facility’s compli-  
18 ance with the applicable requirements of this  
19 Act.

20 “(2) ACCESS TO REPORTS AND RECORDS.—A  
21 certifying agent shall provide to the Secretary, upon  
22 request—

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

1           “(B) any records relating to corrective ac-  
2           tions planned or taken by the audited facility;  
3           and

4           “(C) any other records related to—

5                   “(i) the certification or decertification  
6                   of a facility;

7                   “(ii) compliance of a facility with the  
8                   requirements of this Act; or

9                   “(iii) the accreditation of the certi-  
10                  fying agent.

11           “(3) CONFLICTS OF INTEREST.—

12                   “(A) IN GENERAL.—A certifying agent  
13                   shall—

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

18                           “(ii) have procedures to ensure  
19                           against the use, in carrying out audits of  
20                           a facility under this section, of any officer  
21                           or employee who has a financial conflict of  
22                           interest regarding such facility; and

23                           “(iii) have written conflict of interest  
24                           policies that include prompt disclosure to

1           the Secretary of all conflicts or potential  
2           conflicts of interest.

3           “(B) REGULATIONS.—Not later than 18  
4           months after the date of the enactment of this  
5           section, the Secretary shall promulgate regula-  
6           tions to implement the requirements of sub-  
7           paragraph (A). Such regulations shall include a  
8           structure, including timing and public disclo-  
9           sure, for fees paid by facilities to certifying  
10          agents.

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

16          “(5) REQUIRED CERTIFICATION OF IMPORTS.—  
17          A certifying agent shall issue a written and elec-  
18          tronic certification to accompany each shipment of-  
19          fered for import into the United States containing  
20          food that was manufactured, processed, packed, or  
21          held by a facility certified by the agent, subject to  
22          requirements set forth by the Secretary.

23          “(6) RISKS TO PUBLIC HEALTH.—If, at any  
24          time during an audit, an auditor of a certifying  
25          agent finds a condition at a facility that could cause

1 or contribute to illness or injury to an individual  
2 consuming an article of food manufactured, proc-  
3 essed, packed, or held by the facility, the certifying  
4 agent shall immediately notify the Secretary of the  
5 identity of the facility and such condition.

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

11 “(d) DEFINITIONS.—In this section:

12 “(1) The term ‘certifying agent’ means a third  
13 party accredited as a certifying agent pursuant to  
14 subsection (a)(1).

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

17 **“SEC. 421. CERTIFICATION OF LABORATORIES; ACCREDITA-**  
18 **TION OF LABORATORY CERTIFYING AGENTS.**

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

24 “(b) STANDARDS.—Not later than 18 months after  
25 the date of the enactment of this section, the Secretary

1 shall develop standards to certify laboratories under this  
2 section. Such standards shall include—

3 “(1) standards for sampling and analytical pro-  
4 cedures;

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

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

8 “(4) any other standards determined appro-  
9 priate by the Secretary.

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

12 “(1) IN GENERAL.—The Secretary may estab-  
13 lish an accreditation system under which third par-  
14 ties, as determined appropriate by the Secretary,  
15 may request to be accredited as a laboratory certi-  
16 fying agent to certify laboratories as meeting the ap-  
17 plicable requirements of this Act.

18 “(2) APPLICATION OF REQUIREMENTS RELAT-  
19 ING TO QUALIFICATIONS OF AGENTS, PERFORMANCE  
20 OF AUDITS AND RENEWAL OF ACCREDITATION, AND  
21 WITHDRAWAL OF ACCREDITATION.—The provisions  
22 of paragraphs (2), (4), and (5), other than para-  
23 graph (5)(A)(i), of section 420(a) shall apply to the  
24 accreditation of laboratory certifying agents with re-  
25 spect to laboratories in the same manner as such



1 provisions apply to the accreditation of certifying  
2 agents with respect to facilities.

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

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

16 “(d) PUBLICATION OF LIST OF CERTIFYING AGENTS  
17 AND CERTIFIED LABORATORIES.—The provisions of para-  
18 graph (6) of section 420(a) shall apply to third parties  
19 accredited as laboratory certifying agents under sub-  
20 section (c) and to laboratories certified under subsection  
21 (a) in the same manner as such provisions apply to third  
22 parties accredited as certifying agents under such section.

23 “(e) FOOD TESTING BY CERTIFIED LABORA-  
24 TORIES.—

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

6           “(2) TESTING OF FOOD COVERED.—The testing  
7           of food described in this paragraph is testing of  
8           food—

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

11                  “(B) conducted in support of a reoffer of  
12                  food previously denied admission under section  
13                  402(h);

14                  “(C) conducted under an import alert that  
15                  requires successive consecutive tests;

16                  “(D) conducted to show compliance with  
17                  an order of the Secretary;

18                  “(E) conducted in support of an appeal of  
19                  an order of the Secretary; or

20                  “(F) as otherwise required to be conducted  
21                  by the Secretary, as the Secretary deems appro-  
22                  priate.

23           “(3) ACCESS TO TESTING RESULTS.—The re-  
24           sults of any testing of food described in paragraph  
25           (2) by a laboratory certified under this section shall

1 be promptly transmitted by such laboratory in elec-  
2 tronic format to the Secretary.

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

8 (c) FEES.—Part 5 of subchapter C of chapter VII,  
9 as added by section 101(b) and amended by section  
10 108(a), is amended by adding at the end the following:

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

12 “(a) IN GENERAL.—The Secretary shall assess and  
13 collect a fee for the accreditation of an entity as a certi-  
14 fying agent under section 420(a) for the purpose of de-  
15 fraying the costs of implementing the system established  
16 for such accreditation.

17 “(b) AMOUNT OF FEE.—The amount of a fee under  
18 this section shall be as determined by the Secretary.

19 **“SEC. 741C. LABORATORY CERTIFYING AGENT ACCREDITA-  
20 TION FEE.**

21 “The Secretary shall assess and collect an annual fee,  
22 specified by the Secretary, for accreditation of laboratory  
23 certifying agents under section 421 for the purpose of de-  
24 fraying the costs of the accreditation activities under such  
25 section.”.

1 **SEC. 110. SAFE AND SECURE FOOD IMPORTATION PRO-**  
2 **GRAM.**

3 Chapter VIII (21 U.S.C. 381 et seq.) is amended by  
4 adding at the end the following:

5 **“SEC. 805. SAFE AND SECURE FOOD IMPORTATION PRO-**  
6 **GRAM.**

7 “(a) IN GENERAL.—Beginning not later than 2 years  
8 after the date of the enactment of this section, the Sec-  
9 retary shall establish by regulation and carry out a pro-  
10 gram under which the Secretary expedites the movement  
11 of food through the importation process under this Act  
12 if each facility involved in the production, manufacture,  
13 processing, packaging, and holding of the food—

14 “(1) is certified by a certifying agent accredited  
15 pursuant to section 420(a)(1); and

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

20 “(b) GUIDELINES.—

21 “(1) DEVELOPMENT.—For purposes of the pro-  
22 gram established under subsection (a), the Secretary  
23 shall develop safety and security guidelines applica-  
24 ble to the importation of food.

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

1           “(A) The personnel of the person import-  
2           ing the food.

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

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

7           “(D) Vendor and supplier information.

8           “(E) Such other factors as the Secretary  
9           determines necessary.”.

## 10           **Subtitle B—Intervention**

### 11   **SEC. 111. PUBLIC HEALTH ASSESSMENT SYSTEM.**

12           (a) ACTIVE SURVEILLANCE SYSTEM.—The Secretary  
13   of Health and Human Services (in this subtitle referred  
14   to as the “Secretary”), acting through the Centers for  
15   Disease Control and Prevention, shall establish and imple-  
16   ment an active surveillance system for food, based on a  
17   representative proportion of the population of the United  
18   States, to assess more accurately the frequency and  
19   sources of human illness in the United States associated  
20   with the consumption of food.

21           (b) SAMPLING SYSTEM.—

22           (1) IN GENERAL.—The Secretary shall establish  
23   and implement a sampling system under which the  
24   Secretary takes and analyzes samples of food prod-  
25   ucts—

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

4 (B) to more accurately assess the nature,  
5 frequency of occurrence, and amounts of con-  
6 taminants in food products.

7 (2) REQUIREMENTS.—Such sampling system  
8 shall provide—

9 (A) statistically valid monitoring, including  
10 market-basket studies, on the nature, frequency  
11 of occurrence, and amounts of contaminants in  
12 food products available to consumers; and

13 (B) at the request of the Secretary, such  
14 other information, including analysis of moni-  
15 toring and verification samples, as the Sec-  
16 retary determines may be useful in assessing  
17 the occurrence of contaminants in food prod-  
18 ucts.

19 (3) GUIDELINES.—Within 12 months after the  
20 date of the enactment of this Act, the Secretary  
21 shall establish guidelines for the sampling system  
22 under this subsection.

23 (c) ASSESSMENT OF HEALTH HAZARDS.—Through  
24 the surveillance system under subsection (a) and the sam-  
25 pling system under subsection (b), the Secretary shall

1 rank food categories based on their hazard to human  
2 health and identify appropriate industry and regulatory  
3 approaches to minimize hazards in the food supply. Such  
4 analysis may include—

5           (1) the safety of commercial harvesting and  
6           processing, as compared with the health hazards as-  
7           sociated with food products that are harvested for  
8           recreational or subsistence purposes and prepared  
9           noncommercially;

10           (2) the safety of food products that are domes-  
11           tically harvested and processed, as compared with  
12           the health hazards associated with food products  
13           that are harvested or processed outside the United  
14           States;

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

18           (4) use of comparative risk assessments.

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

20           (a) PUBLIC EDUCATION.—The Secretary, in coopera-  
21           tion with private and public organizations, including the  
22           appropriate State entities, shall design and implement a  
23           national public education program on food safety. The  
24           program shall provide—

1           (1) information to the public regarding Federal  
2 standards and good practice requirements and pro-  
3 motion of public awareness, understanding, and ac-  
4 ceptance of such standards and requirements;

5           (2) information to health professionals so that  
6 they may improve diagnosis and treatment of food-  
7 related illness and advise individuals whose health  
8 conditions place them in particular risk; and

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

12       (b) HEALTH ADVISORIES.—The Secretary shall work  
13 with the States and other appropriate entities to—

14           (1) develop and distribute regional and national  
15 advisories concerning food safety;

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

18           (3) incorporate State and local advisories into  
19 the national public education program required  
20 under subsection (a).

21 **SEC. 113. RESEARCH.**

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



- 1           (1) improve sanitation and food safety practices  
2           in the processing of food products;
- 3           (2) develop improved techniques for the moni-  
4           toring of food and inspection of food products;
- 5           (3) develop efficient, rapid, and sensitive meth-  
6           ods for determining and detecting the presence of  
7           contaminants in food products;
- 8           (4) determine the sources of contamination of  
9           food and food products with contaminants;
- 10          (5) develop consumption data with respect to  
11          food products;
- 12          (6) draw upon research and educational pro-  
13          grams that exist at the State and local level;
- 14          (7) utilize the DNA matching system and other  
15          processes to identify and control pathogens;
- 16          (8) address common and emerging zoonotic dis-  
17          eases;
- 18          (9) develop methods to reduce or destroy patho-  
19          gens before, during, and after processing;
- 20          (10) analyze the incidence of antibiotic resist-  
21          ance as it pertains to the food supply and develop  
22          new methods to reduce the transfer of antibiotic re-  
23          sistance to humans; and
- 24          (11) conduct other research that supports the  
25          purposes of this Act.

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

5 **SEC. 114. NOTIFICATION, NONDISTRIBUTION, AND RECALL**  
6 **OF ADULTERATED OR MISBRANDED ARTI-**  
7 **CLES OF FOOD.**

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

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

13 “(2) The failure to comply with—

14 “(A) an order issued under section 422(b) fol-  
15 lowing any hearing requested under section 422(e);  
16 or

17 “(B) an amended order issued under section  
18 422(d)(1).”.

19 (b) NOTIFICATION, NONDISTRIBUTION, AND RECALL  
20 OF ADULTERATED OR MISBRANDED ARTICLES OF  
21 FOOD.—Chapter IV (21 U.S.C. 341 et seq.), as amended  
22 by sections 102(b), 104, and 108(e), is amended by adding  
23 at the end the following:

1 **“SEC. 422. NOTIFICATION, NONDISTRIBUTION, AND RECALL**  
2 **OF ADULTERATED OR MISBRANDED ARTI-**  
3 **CLES OF FOOD.**

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

5 “(1) IN GENERAL.—A person (other than a  
6 household consumer or other individual who is the  
7 intended consumer of an article of food) that has  
8 reason to believe that an article of food when intro-  
9 duced into or while in interstate commerce, or while  
10 held for sale (regardless of whether the first sale)  
11 after shipment in interstate commerce, is adulter-  
12 ated or misbranded in a manner that, if consumed,  
13 may result in illness or injury shall, as soon as prac-  
14 ticable, notify the Secretary of the identity and loca-  
15 tion of the article.

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

20 “(b) RECALL AND CONSUMER NOTIFICATION.—

21 “(1) VOLUNTARY ACTIONS.—On receiving noti-  
22 fication under subsection (a) or by other means of  
23 a suspected adulteration or misbranding of food, if  
24 the Secretary finds that an article of food when in-  
25 troduced into or while in interstate commerce, or  
26 while held for sale (regardless of whether the first

1 sale) after shipment in interstate commerce, is adul-  
2 terated or misbranded in a manner that, if con-  
3 sumed, may result in illness or injury (as determined  
4 by the Secretary), the Secretary shall provide all ap-  
5 propriate persons (including the manufacturer, im-  
6 porter, distributor, or retailer of the article) with an  
7 opportunity (as determined by the Secretary)—

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

9 “(B) to notify all persons—

10 “(i) that produce, manufacture, pack,  
11 process, prepare, treat, package, distribute,  
12 or hold the article, to cease immediately  
13 those activities with respect to the article;

14 or

15 “(ii) to which the article has been dis-  
16 tributed, transported, or sold, to cease im-  
17 mediately distribution of the article;

18 “(C) to recall the article;

19 “(D) in consultation with the Secretary, to  
20 provide notice of the finding of the Secretary to  
21 all consumers to which the article was, or may  
22 have been, distributed and to appropriate State  
23 and local health officials; and

24 “(E) to notify State and local public health  
25 officials.

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

6                   “(A) shall issue an order requiring the per-  
7 son—

8                           “(i) to immediately cease distribution  
9 of the article; and

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

12                   “(B) may take control or possession of the  
13 article.

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

21           “(c) HEARINGS ON ORDERS.—

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

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

1           “(B) any reasons why the article of food  
2           that is the subject of the order should not be  
3           recalled.

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

9           “(d) POST-HEARING RECALL ORDERS.—

10           “(1) AMENDMENT OF ORDERS.—If, after pro-  
11           viding an opportunity for a hearing (and a hearing  
12           if requested) under subsection (c), the Secretary de-  
13           termines that an article of food when introduced into  
14           or while in interstate commerce, or while held for  
15           sale (regardless of whether the first sale) after ship-  
16           ment in interstate commerce, is adulterated or mis-  
17           branded in a manner that, if consumed, may result  
18           in illness or injury, the Secretary may, as the Sec-  
19           retary determines to be necessary—

20           “(A) amend the order under subsection  
21           (b)(2)—

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

24           “(ii) to specify a timetable during  
25           which the recall shall occur;



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

3           (2) striking “presents a threat of serious ad-  
4           verse health consequences or death to humans or  
5           animals” and inserting “is adulterated or mis-  
6           branded”.

7           (b) REGULATIONS.—Not later than 120 days after  
8           the date of enactment of this Act, the Secretary shall issue  
9           an interim final rule amending subpart K of part 1 of title  
10          21, Code of Federal Regulations, to implement the amend-  
11          ment made by this section.

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

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

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

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

19                 “(a) IN GENERAL.—

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

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



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

3           “(2) SEPARATE OFFENSES.—Each prohibited  
4           act described in paragraph (1) and each day during  
5           which the act continues shall be considered to be a  
6           separate offense.

7           “(3) NOTICE AND OPPORTUNITY FOR HEAR-  
8           ING.—The Secretary shall not assess a civil penalty  
9           under this section against a person unless the person  
10          is given notice and opportunity for a hearing on the  
11          record before the Secretary in accordance with sec-  
12          tions 554 and 556 of title 5, United States Code.

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

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

18                         “(i) the gravity of the violation;

19                         “(ii) the degree of culpability of the  
20                         person;

21                         “(iii) the size and type of the business  
22                         of the person; and

23                         “(iv) any history of prior offenses by  
24                         the person; and

1           “(B) shall be reviewed only in accordance  
2           with subsection (b).

3           “(b) JUDICIAL REVIEW.—

4           “(1) IN GENERAL.—An order assessing a civil  
5           penalty against a person under subsection (a) shall  
6           be final unless the person—

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

10           “(i) the United States court of ap-  
11           peals for the circuit in which the person re-  
12           sides or has its principal place of business;  
13           or

14           “(ii) the United States Court of Ap-  
15           peals for the District of Columbia Circuit;  
16           and

17           “(B) simultaneously sends a copy of the  
18           petition by certified mail to the Secretary.

19           “(2) FILING OF COPY OF RECORD.—The Sec-  
20           retary shall promptly file in the court a certified  
21           copy of the record on which the order was issued.

22           “(3) STANDARD OF REVIEW.—The findings of  
23           the Secretary relating to the order shall be set aside  
24           only if the findings are found to be unsupported by  
25           substantial evidence on the record as a whole.

1       “(c) COLLECTION ACTIONS FOR FAILURE TO PAY  
2 ASSESSMENT.—

3               “(1) REFERRAL TO ATTORNEY GENERAL.—If a  
4 person fails to pay a civil penalty assessed under  
5 subsection (a) after the order assessing the civil pen-  
6 alty has become a final order, or after the court of  
7 appeals has entered final judgment in favor of the  
8 Secretary, the Secretary may refer the matter to the  
9 Attorney General.

10              “(2) ACTION BY ATTORNEY GENERAL.—The  
11 Attorney General shall bring a civil action to recover  
12 the amount of the civil penalty in United States dis-  
13 trict court.

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

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

23              “(e) PENALTIES IN LIEU OF OTHER ACTIONS.—  
24 Nothing in this Act requires the Secretary to report for  
25 prosecution, or for the commencement of any libel or in-

1 junction proceeding, any violation of this Act in any case  
2 in which the Secretary believes that the public interest will  
3 be adequately served by the assessment of a civil penalty  
4 under this section.

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

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

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

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

14 “(p) The Secretary may deny importation of food,  
15 other than only for personal use, from any foreign country,  
16 or which is manufactured, processed, packed, or held by  
17 a facility (as defined in section 415), if the government  
18 of such country, or such facility, respectively, does not  
19 timely consent to an investigation by the Administration  
20 when food from that country or facility is linked to a food-  
21 borne illness outbreak or is otherwise found to be adulter-  
22 ated or mislabeled.”.

## 1                   **Subtitle D—Miscellaneous**

### 2   **SEC. 131. LABELING REQUIREMENT FOR MEAT, POULTRY** 3                   **PRODUCTS, AND SEAFOOD THAT CONTAIN** 4                   **CARBON MONOXIDE.**

5           (a) LABELING REQUIREMENT.—

6                   (1) IN GENERAL.—Paragraph (t) of section 201  
7           (21 U.S.C. 321) is amended by adding at the end  
8           the following:

9           “(4) In the case of food that is meat within the mean-  
10   ing of the Federal Meat Inspection Act, a poultry product  
11   within the meaning of the Poultry Products Inspection  
12   Act, or seafood (including all fresh or saltwater fish,  
13   molluscan shellfish, crustaceans, and other forms of  
14   aquatic animal life) intended for human consumption as  
15   food within the meaning of section 201(f) (referred to col-  
16   lectively in this paragraph as ‘seafood’), the term ‘color  
17   additive’ shall include carbon monoxide under conditions  
18   of use that may impart, maintain, preserve, stabilize, fix,  
19   or otherwise affect the color of fresh meat, poultry prod-  
20   ucts, or seafood, unless the label of such food bears,  
21   prominently and conspicuously in such place and in such  
22   manner as to render it likely to be read and understood  
23   by the ordinary person, the following statement to prevent  
24   consumer deception and serious risks to the public health:  
25   ‘CONSUMER NOTICE: Carbon monoxide has been used

1 to preserve the color of this product. Do not rely on color  
2 or the “use or freeze by” date alone to judge the freshness  
3 of the product.’”.

4 (2) EFFECTIVE DATE.—The amendment made  
5 by this subsection shall apply to food labeled on or  
6 after the date that is 30 days after the date of the  
7 enactment of this Act.

8 (b) DISCRETIONARY AUTHORITY.—If, not earlier  
9 than 5 years after the effective date described in sub-  
10 section (a)(2), the Secretary of Health and Human Serv-  
11 ices finds, based on competent and reliable scientific evi-  
12 dence, that the statement prescribed in section 201(t)(4)  
13 of the Federal Food, Drug, and Cosmetic Act is no longer  
14 required to prevent consumer deception and other harms,  
15 then the Secretary is authorized to issue regulations estab-  
16 lishing alternative labeling requirements that are shown  
17 to be adequate and effective in preventing consumer de-  
18 ception and other harms related to the conditions of use  
19 of carbon monoxide, including with respect to preventing  
20 any consumer deception or other harm that may result  
21 from the actual conditions of carbon monoxide use and  
22 its potential to impart a persistent color to meat, poultry  
23 products, or seafood described in such section through a  
24 reaction with natural pigment.

1 **SEC. 132. FOOD SUBSTANCES GENERALLY RECOGNIZED AS**  
2 **SAFE.**

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

5 “Substances Generally Recognized as Safe

6 “(k)(1) Not later than 60 days after the date of re-  
7 ceipt by the Secretary, after the date of the enactment  
8 of this subsection, of a request for a substance to be deter-  
9 mined by the Secretary to be a GRAS food substance, the  
10 Secretary shall publish notice of such request in the Fed-  
11 eral Register.

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

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

19 “(4) In this subsection, the term ‘GRAS food sub-  
20 stance’ means a substance excluded from the definition of  
21 the term ‘food additive’ in section 201(s) because such  
22 substance is generally recognized, among experts qualified  
23 by scientific training and experience to evaluate its safety,  
24 as having been adequately shown through scientific proce-  
25 dures (or, in the case of a substances used in food prior  
26 to January 1, 1958, through either scientific procedures

1 or experience based on common use in food) to be safe  
2 under the conditions of its intended use.”.

3 **SEC. 133. COUNTRY OF ORIGIN LABELING; DISCLOSURE OF**  
4 **SOURCE OF INGREDIENTS.**

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

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

9 “(1) the labeling of the food fails to identify the  
10 country in which the final processing of the food oc-  
11 curs; and

12 “(2) the website for the manufacturer of the  
13 food fails to identify the country (or countries) of or-  
14 igin for each ingredient in the food.

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

16 “(1) the labeling of the food fails to identify the  
17 country of origin of the food; and

18 “(2) the website for the original packer of the  
19 food fails to identify the country of origin for the  
20 food.”.

21 (b) REGULATIONS.—Not later than 180 days after  
22 the date of the enactment of this Act, the Secretary of  
23 Health and Human Services shall promulgate final regula-  
24 tions to carry out paragraphs (bb) and (cc) of section 403



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

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

8 **SEC. 134. NEW FOOD AND ANIMAL FEED EXPORT CERTIFI-**  
9 **CATION FEE TO IMPROVE THE ABILITY OF**  
10 **UNITED STATES FIRMS TO EXPORT THEIR**  
11 **PRODUCTS.**

12 Part 5 of subchapter C of chapter VII (21 U.S.C.  
13 371 et seq.), as added by section 101(b) and amended by  
14 sections 108 and 109, is further amended by adding at  
15 the end the following:

16 **“SEC. 741D. NEW FOOD AND ANIMAL FEED EXPORT CER-**  
17 **TIFICATION FEE TO IMPROVE THE ABILITY**  
18 **OF UNITED STATES FIRMS TO EXPORT THEIR**  
19 **PRODUCTS.**

20 “(a) IN GENERAL.—If the Secretary provides for the  
21 issuance of export certificates for foods and animal feeds  
22 in cases where exportation is restricted without such a cer-  
23 tificate, the Secretary may impose a fee for the issuance  
24 of such a certificate.



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

4   **“SEC. 736C. REGISTRATION FEE.**

5           “(a) IN GENERAL.—Except as provided in subsection  
6 (b) of this section, the Secretary shall assess and collect  
7 an annual fee for registration under subsection (b), (c),  
8 (d), or (i) of section 510 to defray increases (as described  
9 in subsection (g)(2)(A)(ii)) in the costs of inspecting es-  
10 tablishments registered under subsection (b), (c), (d), or  
11 (i) of section 510 to ensure compliance by such establish-  
12 ments with the requirements of this Act relating to drugs  
13 or devices.

14           “(b) EXCEPTION.—The Secretary shall not assess or  
15 collect a fee under this section for registration of an estab-  
16 lishment under section 510 on the basis of such establish-  
17 ment’s manufacture, preparation, propagation, or proc-  
18 essing of an excipient of a drug.

19           “(c) FEE REVENUE AMOUNTS.—

20           “(1) IN GENERAL.—For each of fiscal years  
21 2010 through 2014, fees under subsection (a) shall,  
22 except as provided in subsections (d), (f), and (g),  
23 be established to generate a total revenue amount  
24 under subsection (a).

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

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

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

12                   “(B) taking into consideration the dif-  
13 ference in costs of inspections between foreign  
14 and domestic establishments.

15           “(d) ADJUSTMENTS.—

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

21                   “(A) the total percentage change that oc-  
22 curred in the Consumer Price Index for all  
23 urban consumers (all items; U.S. city average)  
24 for the 12-month period ending June 30 pre-

1 ceding the fiscal year for which fees are being  
2 established;

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

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

17 The adjustment made each fiscal year by this sub-  
18 section will be added on a compounded basis to the  
19 sum of all adjustments made each fiscal year after  
20 fiscal year 2009 under this subsection.

21 “(2) WORKLOAD ADJUSTMENT.—For fiscal  
22 year 2011 and subsequent fiscal years, after the fee  
23 revenues established in subsection (c)(1) are ad-  
24 justed for a fiscal year for inflation in accordance  
25 with paragraph (1), the fee revenues shall be ad-

1       justed further for such fiscal year to reflect changes  
2       in the workload of the Secretary for inspections de-  
3       scribed in subsection (a). With respect to such ad-  
4       justment:

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

12             “(B) Under no circumstances shall the ad-  
13             justment result in fee revenues for a fiscal year  
14             that are less than the fee revenues for the fiscal  
15             year established in subsection (c)(1), as ad-  
16             justed for inflation under paragraph (1). Any  
17             adjustment for changes in inspection activities  
18             made in setting fees and revenue amounts for  
19             fiscal year 2011 may not result in the total  
20             workload adjustment being more than 2 per-  
21             centage points higher than it would have been  
22             in the absence of the adjustment for changes in  
23             inspection activities.

24             “(C) The Secretary shall contract with an  
25             independent accounting firm to study the ad-

1           justment for changes in inspection activities ap-  
2           plied in setting fees and revenue amounts for  
3           fiscal year 2011 and to make recommendations,  
4           if warranted, for future changes in the method-  
5           ology for calculating the adjustment. After re-  
6           view of the recommendations, the Secretary  
7           shall, if warranted, make appropriate changes  
8           to the methodology, and the changes shall be ef-  
9           fective for each of the fiscal years 2012 through  
10          2014. The Secretary shall not make any adjust-  
11          ment for changes in inspection activities for any  
12          fiscal year after 2011 unless such study has  
13          been completed.

14           “(3) RENT AND RENT-RELATED COST ADJUST-  
15          MENT.—For fiscal year 2012 and each subsequent  
16          fiscal year, the Secretary shall, before making ad-  
17          justments under paragraphs (1) and (2), decrease  
18          the fee revenue amount established in subsection  
19          (c)(1) if actual costs paid for rent and rent-related  
20          expenses for the preceding fiscal year are less than  
21          estimates made for such year in fiscal year 2008.  
22          Any reduction made under this paragraph shall not  
23          exceed the amount by which such costs fall below the  
24          estimates made in fiscal year 2008 for such fiscal

1 year, and shall not exceed \$11,721,000 for any fiscal  
2 year.

3 “(4) FINAL YEAR ADJUSTMENT.—For fiscal  
4 year 2014, the Secretary may, in addition to adjust-  
5 ments under paragraphs (1), (2), (3), and (5), fur-  
6 ther increase the fee revenues and fees established in  
7 subsection (c) if such an adjustment is necessary to  
8 provide for not more than 3 months of operating re-  
9 serves of carryover user fees for inspections de-  
10 scribed in subsection (a) for the first 3 months of  
11 fiscal year 2015. If such an adjustment is necessary,  
12 the rationale for the amount of the increase shall be  
13 contained in the annual notice establishing fee reve-  
14 nues and fees for fiscal year 2014. If the Secretary  
15 has carryover balances for such inspections in excess  
16 of 3 months of such operating reserves, the adjust-  
17 ment under this paragraph shall not be made.

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

21 “(A) provide an estimate of the amount of  
22 the total increases described in subsection (a)  
23 for such fiscal year; and

24 “(B) after making adjustments under  
25 paragraphs (1), (2), and (3), adjust the reve-



1           nues established in subsection (c)(1) to be equal  
2           to such amount.

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

7           “(e) FEE WAIVER OR REDUCTION.—

8           “(1) IN GENERAL.—The Secretary may grant  
9           to a person a waiver from, or a reduction of, one or  
10          more fees under this section if the Secretary finds  
11          that—

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

14                 “(B) the assessment of the fee would im-  
15                 pose significant financial hardship because of  
16                 limited resources available to such person or  
17                 other circumstances.

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

20                 “(A) IN GENERAL.—Except as provided in  
21                 subparagraph (B), each person who is named  
22                 as the applicant in an approved human drug  
23                 application for a positron emission tomography  
24                 drug shall be subject under paragraph (a) to  
25                 one-sixth of an annual registration fee with re-

1           spect to each establishment identified in the ap-  
2           plication as producing positron emission tomog-  
3           raphy drugs under the approved application.

4           “(B) EXCEPTION FROM ANNUAL REG-  
5           ISTRATION FEE.—Each person who is named as  
6           the applicant in an application described in sub-  
7           paragraph (A) shall be granted a waiver under  
8           paragraph (1) from an annual registration fee  
9           under subsection (a) for a fiscal year if the per-  
10          son certifies to the Secretary, at a time speci-  
11          fied by the Secretary and using procedures  
12          specified by the Secretary, that—

13                 “(i) the person is a not-for-profit  
14                 medical center that has only 1 establish-  
15                 ment for the production of positron emis-  
16                 sion tomography drugs; and

17                 “(ii) at least 95 percent of the total  
18                 number of doses of each positron emission  
19                 tomography drug produced by such estab-  
20                 lishment during such fiscal year will be  
21                 used within the medical center.

22          “(3) DESIGNATED ORPHAN DRUG.—An estab-  
23          lishment registered under section 510 shall, with re-  
24          spect to the manufacture, preparation, propagation,  
25          compounding, or processing of drugs, be granted a

1 waiver under paragraph (1) from a fee under sub-  
2 section (a) if all drugs manufactured, prepared,  
3 propagated, compounded, or processed by the estab-  
4 lishment are designated as a drug for a rare disease  
5 or condition pursuant to section 526. The preceding  
6 sentence shall not apply if the application approved  
7 under section 505 for any such drug includes an in-  
8 dication for a disease or condition other than such  
9 a rare disease or condition.

10 “(f) LIMITATIONS.—

11 “(1) IN GENERAL.—Fees under subsection (a)  
12 shall be refunded for a fiscal year beginning after  
13 fiscal year 2010 unless appropriations for salaries  
14 and expenses of the Food and Drug Administration  
15 for such fiscal year (excluding the amount of fees  
16 appropriated for such fiscal year) are equal to or  
17 greater than the amount of appropriations for the  
18 salaries and expenses of the Food and Drug Admin-  
19 istration for the fiscal year 2010 (excluding the  
20 amount of fees appropriated for such fiscal year)  
21 multiplied by the adjustment factor applicable to the  
22 fiscal year involved.

23 “(2) AUTHORITY.—If the Secretary does not  
24 assess fees under subsection (a) during any portion  
25 of a fiscal year because of paragraph (1) and if at

1 a later date in such fiscal year the Secretary may as-  
2 sess such fees, the Secretary may assess and collect  
3 such fees, without any modification in the rate, for  
4 registration under subsection (b), (c), (d), or (i) of  
5 section 510 at any time in such fiscal year.

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

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

17 “(2) COLLECTIONS AND APPROPRIATION  
18 ACTS.—

19 “(A) IN GENERAL.—The fees authorized  
20 by this section—

21 “(i) shall be retained in each fiscal  
22 year in an amount not to exceed the  
23 amount specified in appropriation Acts, or  
24 otherwise made available for obligation, for  
25 such fiscal year; and

1           “(ii) shall only be collected and avail-  
2           able to defray increases in the costs of in-  
3           specting establishments registered under  
4           subsection (b), (c), (d), or (i) of section  
5           510 to ensure compliance by such estab-  
6           lishments with the requirements of this Act  
7           relating to drugs and devices (including in-  
8           creases in such costs for an additional  
9           number of full-time equivalent positions in  
10          the Department of Health and Human  
11          Services to be engaged in such inspections)  
12          over such costs, excluding costs paid from  
13          fees collected under this section, for fiscal  
14          year 2009 multiplied by the adjustment  
15          factor.

16          “(B) COMPLIANCE.—The Secretary shall  
17          be considered to have met the requirements of  
18          subparagraph (A)(ii) in any fiscal year if the  
19          costs funded by appropriations and allocated for  
20          inspections described in subsection (a)—

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

24                 “(ii)(I) are more than 3 percent below  
25                 the level specified in subparagraph (A)(ii),

1 and fees assessed for the fiscal year fol-  
2 lowing the subsequent fiscal year are de-  
3 creased by the amount in excess of 3 per-  
4 cent by which such costs fell below the  
5 level specified in such subparagraph; and

6 “(II) such costs are not more than 5  
7 percent below the level specified in such  
8 subparagraph.

9 “(3) AUTHORIZATION OF APPROPRIATIONS.—  
10 For each of the fiscal years 2010 through 2014,  
11 there is authorized to be appropriated for fees under  
12 this section an amount equal to the total revenue  
13 amount determined under subsection (c)(1) for the  
14 fiscal year, as adjusted or otherwise affected under  
15 subsection (d) and paragraph (4) of this subsection.

16 “(4) OFFSET.—If the sum of the cumulative  
17 amount of fees collected under this section for the  
18 fiscal years 2010 through 2013 and the amount of  
19 fees estimated to be collected under this section for  
20 fiscal year 2014 exceeds the cumulative amount ap-  
21 propriated under paragraph (3) for the fiscal years  
22 2010 through 2014, the excess shall be credited to  
23 the appropriation account of the Food and Drug Ad-  
24 ministration as provided in paragraph (1), and shall  
25 be subtracted from the amount of fees that would

1 otherwise be authorized to be collected under this  
2 section for fiscal year 2014.

3 “(h) COLLECTION OF UNPAID FEES.—In any case  
4 where the Secretary does not receive payment of a fee as-  
5 sessed under subsection (a) within 30 days after it is due,  
6 such fee shall be treated as a claim of the United States  
7 Government subject to subchapter II of chapter 37 of title  
8 31, United States Code.

9 “(i) WRITTEN REQUESTS FOR WAIVERS, REDUC-  
10 TIONS, AND REFUNDS.—To qualify for consideration for  
11 a waiver or reduction under subsection (e), or for a refund  
12 of any fee collected in accordance with subsection (a), a  
13 person shall submit to the Secretary a written request for  
14 such waiver, reduction, or refund not later than 180 days  
15 after such fee is due.

16 “(j) 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 “(k) 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       “(1) DEFINITION.—The term ‘costs of inspecting es-  
9 tablishments registered under subsection (b), (c), (d), or  
10 (i) of section 510 to ensure compliance by such establish-  
11 ments with the requirements of this Act relating to drugs  
12 and devices’ means the expenses incurred, in connection  
13 with inspecting establishments registered under subsection  
14 (b), (c), (d), or (i) of section 510 to ensure compliance  
15 by such establishments with the requirements of this Act  
16 relating to drugs and devices, for—

17               “(1) officers and employees of the Food and  
18 Drug Administration, contractors of the Food and  
19 Drug Administration, and costs related to such offi-  
20 cers and employees and to contracts with such con-  
21 tractors;

22               “(2) management of information, and the ac-  
23 quisition, maintenance, and repair of information  
24 technology resources;



1           “(3) leasing, maintenance, renovation, and re-  
2           pair of facilities and acquisition, maintenance, and  
3           repair of fixtures, furniture, scientific equipment,  
4           and other necessary materials and supplies; and

5           “(4) collecting fees under this section and ac-  
6           counting for resources allocated for such inspec-  
7           tions.”.

8           (3) EFFECTIVE DATE.—The Secretary of  
9           Health and Human Services shall first impose the  
10          fee established under section 736C of the Federal  
11          Food, Drug, and Cosmetic Act, as added by para-  
12          graph (2), for fiscal years beginning with fiscal year  
13          2010.

14          (4) SUNSET DATE.—Section 736C of the Fed-  
15          eral Food, Drug, and Cosmetic Act, as added by  
16          paragraph (2), does not authorize the assessment or  
17          collection of a fee for registration under section 510  
18          of such Act (21 U.S.C. 360) occurring after fiscal  
19          year 2014.

20 **SEC. 202. INSPECTION OF PRODUCERS OF DRUGS AND AC-**  
21 **TIVE PHARMACEUTICAL INGREDIENTS.**

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

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

1           (2) by striking “Every establishment in any  
2 State registered with the Secretary pursuant to this  
3 section” and inserting “Every establishment reg-  
4 istered with the Secretary pursuant to subsection  
5 (b), (c), (d), or (i)”;

6           (3) by striking “704(g), at least once” and all  
7 that follows and inserting the following: “704(g)—

8           “(A) at least once in the 2-year period begin-  
9 ning with the date of registration of such establish-  
10 ment pursuant to this section and at least once in  
11 every successive 2-year period thereafter; or

12           “(B) at least once in the 4-year period begin-  
13 ning with the date of registration of such establish-  
14 ment pursuant to this section and at least once in  
15 every successive 4-year period thereafter, if the Sec-  
16 retary determines that sufficient information about  
17 the type of product produced in the establishment,  
18 inspection history, compliance history, and such ad-  
19 ditional factors as the Secretary determines, by  
20 guidance, exists to assess risk and to establish a  
21 risk-based inspection schedule.”; and

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

23           “(2)(A) The Secretary shall conduct an inspection of  
24 a drug establishment when the establishment begins to  
25 manufacture, prepare, propagate, compound, or process a

1 drug or active pharmaceutical ingredient of a drug before  
2 its introduction into interstate commerce if the drug or  
3 ingredient is new or has undergone a major change requir-  
4 ing prior approval by the Secretary of a supplement to  
5 an application submitted under section 505. Notwith-  
6 standing the preceding sentence, the Secretary may opt  
7 against conducting such an inspection if the Secretary de-  
8 termines, based on the inspection history of the establish-  
9 ment, that such an inspection is not necessary to verify  
10 the data contained in the application (or supplement to  
11 the application) submitted under section 505, ensure com-  
12 pliance with current good manufacturing practice, or oth-  
13 erwise ensure the safety of the drug or ingredient.

14       “(B) The Secretary shall annually submit a report  
15 to the Congress on each instance during the preceding  
16 year in which the Secretary determined under subpara-  
17 graph (A) that an inspection was not necessary.

18       “(3) The Secretary may, by regulation, provide for  
19 a risk-based inspection schedule for establishments en-  
20 gaged in the manufacture, propagation, compounding, or  
21 processing of an excipient of a drug at a frequency dif-  
22 ferent than the inspection schedule for an establishment  
23 under paragraph (1).

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

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

7           “(A) funding dedicated to inspections under  
8 this subsection; and

9           “(B) the number of establishments for which  
10 the frequency of such inspections has been modified  
11 pursuant to paragraph (1)(B).

12       “(6) For purposes of determining inspection fre-  
13 quency under subparagraphs (A) and (B) of paragraph  
14 (1), the Secretary shall establish information systems ca-  
15 pacity sufficient to assess risk and shall develop and main-  
16 tain a risk-based system for conducting surveillance of  
17 current good manufacturing practices by establishments  
18 registered with the Secretary pursuant to subsection (b),  
19 (c), (d), or (i). The Secretary shall have such capacity in  
20 place and begin implementation of such risk-based system  
21 not later than 3 years after the date of the enactment of  
22 the Food and Drug Administration Globalization Act of  
23 2009. Such risk-based system shall include consideration  
24 of the class of the establishment’s products and associated  
25 risks, the date the establishment was last inspected, the

1 establishment’s compliance and safety history, the estab-  
2 lishment’s shipping volume and history, and such other  
3 factors as the Secretary determines relevant to assessing  
4 the risk presented by the establishment.”.

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

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

17 **SEC. 203. DOCUMENTATION FOR ADMISSIBILITY OF DRUG**  
18 **IMPORTS.**

19 Section 801 (21 U.S.C. 381), as amended by section  
20 123, is further amended by adding at the end the fol-  
21 lowing:

22 “(q) Beginning 3 years after the date of the enact-  
23 ment of this subsection, a drug shall not enter the United  
24 States unless the party offering the drug for import pro-  
25 vides the Secretary, at the time of offering the drug for

1 import, information demonstrating compliance with appli-  
2 cable requirements pertaining to identity, strength, qual-  
3 ity, purity, approval, listing, labeling, registration, and  
4 such additional categories as the Secretary, by guidance,  
5 determines are necessary for protection of the public  
6 health. The Secretary may allow that such compliance be  
7 demonstrated through verification by an accredited third  
8 party or through such other means as determined, by  
9 guidance, by the Secretary.”.

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

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

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

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

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

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

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

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

14 “(b) PLAN PROVISIONS.—A quality risk management  
15 plan required by subsection (a) shall address risk assess-  
16 ment, risk control, risk communication, and risk review  
17 and shall—

18 “(1) provide for an assessment, prior to con-  
19 tracting with a person to supply raw materials or in-  
20 gredients or to undertake any aspect of the manu-  
21 facturing of the drug, of the suitability and com-  
22 petence of such person to carry out such activity,  
23 using audits, material evaluations, or qualification,  
24 as appropriate;

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

5           “(3) provide for the monitoring and review  
6 through periodic on-site audits of the facility condi-  
7 tions, controls, and practices of any person referred  
8 to in paragraph (1) and ensure the implementation  
9 of appropriate measures to improve such conditions,  
10 controls, and practices;

11           “(4) provide for the monitoring of incoming  
12 materials to ensure they are from a person that  
13 meets the requirements in paragraphs (1) through  
14 (3);

15           “(5) provide for implementation of effective sys-  
16 tems, including appropriate specifications and test  
17 methods and verification of the drug ingredients’  
18 identity, quality, strength, and purity, to detect any  
19 hazard that has been, or is reasonably likely to be,  
20 present in or on the drug during production, manu-  
21 facturing, processing, packing, holding, or trans-  
22 porting; and

23           “(6) be periodically reviewed and, as needed,  
24 updated.



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

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

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

16                 “(2) to promptly implement such specifications  
17 or test methods.

18           “(e) INSPECTION OF QUALITY RISK MANAGEMENT  
19 PLAN.—The Secretary shall, in the course of an inspection  
20 of an establishment subject to this section or upon request  
21 by the Secretary, conduct a review of the establishment’s  
22 quality risk management plan.

23           “(f) DOCUMENTATION OF SUPPLY CHAIN.—

24                 “(1) IN GENERAL.—Each establishment re-  
25 quired to be registered with the Secretary pursuant

1 to subsection (b), (c), (d), or (i) of Section 510 for  
2 the manufacture, preparation, propagation,  
3 compounding, or processing of a drug, shall provide  
4 to the Secretary, upon request, adequate information  
5 transmitted in electronic form, establishing—

6 “(A) where the drug, including its raw ma-  
7 terials, were produced, including all preceding  
8 producers, manufacturers, distributors, and  
9 shippers; and

10 “(B) that the drug, its ingredients and raw  
11 materials were manufactured, prepared, propa-  
12 gated, compounded, processed, distributed,  
13 shipped, warehoused, brokered, imported, and  
14 conveyed under conditions that ensure the iden-  
15 tity, strength, quality, and purity of the drug.

16 “(2) REPACKAGERS.—For those establishments  
17 that are repackagers, paragraph (1)(A) requires only  
18 information regarding the immediately preceding es-  
19 tablishment.”.

20 (c) EFFECTIVE DATE.—

21 (1) IN GENERAL.—The requirements of sections  
22 501(j) and 505–2 of the Federal Food, Drug, and  
23 Cosmetic Act, as added by subsections (a) and (b),  
24 take effect 2 years after the date of the enactment  
25 of this Act.

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

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

10                   (B) such authority shall apply irrespective  
11                   of whether the establishment has in effect a  
12                   quality risk management plan; and

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

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

21           (a) REQUIREMENT.—Subsection (h) of section 510  
22           (21 U.S.C. 351), as amended by section 202(a), is further  
23           amended by adding at the end the following:

24                   “(7) The person who owns or operates an establish-  
25                   ment registered with the Secretary pursuant to subsection

1 (b), (c), (d), or (i), any agent or employee of such person,  
2 and any agent of a governmental authority in the foreign  
3 country within which such establishment is located shall  
4 not delay or limit an inspection, or refuse to permit entry  
5 or inspection, authorized by this subsection.”.

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

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

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

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

1       “(aa) If it is a drug and the website of the manufac-  
2 turer of the drug does not list the country of origin for  
3 each active pharmaceutical ingredient and finished dosage  
4 form of such drug.”.

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

10       (c) EFFECTIVE DATE.—The requirement of section  
11 502(aa) of the Federal Food, Drug, and Cosmetic Act,  
12 as added by subsection (a), takes effect 2 years after the  
13 date of the enactment of this Act.

14 **SEC. 207. NONDISTRIBUTION AND RECALL OF ADULTER-**  
15 **ATED OR MISBRANDED DRUGS.**

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

19       “(rr) The failure to comply with—

20               “(1) an order issued under section 568(a) fol-  
21 lowing any hearing requested under section 568(b);

22               or

23               “(2) an amended order issued under section  
24 568(c)(1).”.

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

5 **“SEC. 568. NONDISTRIBUTION AND RECALL OF ADULTER-**  
 6 **ATED OR MISBRANDED DRUGS.**

7 “(a) RECALL AND CONSUMER NOTIFICATION.—

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

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

18 “(B) to notify all entities—

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

23 “(ii) to which the drug has been dis-  
 24 tributed, transported, or sold, to cease im-  
 25 mediately distribution of the drug;

1 “(C) to recall the drug;

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

7 “(E) to notify State and local public health  
8 officials.

9 “(2) MANDATORY ACTIONS.—If a person re-  
10ferred to in paragraph (1) does not carry out the ac-  
11tions described in that paragraph with respect to a  
12drug within the time period and in the manner pre-  
13scribed by the Secretary, the Secretary shall issue an  
14order requiring such person—

15 “(A) to immediately cease distribution of  
16the drug; and

17 “(B) to immediately notify health profes-  
18sionals and drug user facilities of the order and  
19to instruct such professionals and facilities to  
20cease use of such drug.

21 “(b) HEARINGS ON ORDERS.—The Secretary shall  
22provide a person subject to an order under subsection  
23(a)(2) with an opportunity for an informal hearing, to be  
24held not later than 10 days after the date of the issuance  
25of the order, on—

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

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

4       “(c) POST-HEARING RECALL ORDERS.—

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

12           “(A) amend the order—

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

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

17           “(B) require periodic reports to the Sec-  
18       retary describing the progress of any such re-  
19       call.

20       “(2) CONTENTS OF ORDER.—

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

24           “(i) a recall of a drug from individ-  
25           uals; or



1           “(ii) a recall of a drug from drug user  
2           facilities if the Secretary determines that  
3           the risk of recalling such drug from the fa-  
4           cilities presents a greater health risk than  
5           the health risk of not recalling the drug  
6           from use.

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

18          “(3) VACATION OF ORDERS.—If, after providing  
19          an opportunity for an informal hearing under sub-  
20          section (b), the Secretary determines that adequate  
21          grounds do not exist to continue the actions required  
22          by the order, the Secretary shall vacate the order.

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

1 **SEC. 208. DESTRUCTION OF ADULTERATED, MISBRANDED**  
2 **OR COUNTERFEIT ARTICLES OFFERED FOR**  
3 **IMPORT.**

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

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

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

23 “(r) Any person claiming any article which has been  
24 destroyed under subsection (a) may, at any time within  
25 3 months after the date of destruction, apply to the Sec-  
26 retary for reimbursement of the value of the article as de-

1 terminated by the Secretary. Upon the production of satis-  
2 factory proof that the destruction of the article was not  
3 within the authority of the Secretary as provided in this  
4 section, the Secretary shall order the value of the article  
5 restored to the applicant.”.

6 (d) SAMPLES OF DESTROYED ARTICLES.—Section  
7 801 (21 U.S.C. 381), as amended by sections 123 and  
8 203 and subsection (c) of this section, is amended by add-  
9 ing at the end the following:

10 “(s) Where an article is caused to be destroyed under  
11 subsection (a) the Secretary shall, upon request, provide  
12 a sample of the article to the owner of the article, the  
13 owner’s attorney or agent, or if applicable any person  
14 named on the label of the article, except that the Secretary  
15 is authorized, by regulations, to make such reasonable ex-  
16 ceptions from, and impose such reasonable terms and con-  
17 ditions relating to, the operation of this subsection as the  
18 Secretary finds necessary for the proper administration of  
19 the provisions of this Act.”.

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

1 **SEC. 209. ADMINISTRATIVE DETENTION OF DRUGS THAT**  
2 **APPEAR TO VIOLATE THE LAW.**

3 (a) IN GENERAL.—Section 304(g) (21 U.S.C.  
4 334(g)) is amended—

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

7 (2) in paragraph (1), by inserting after “adul-  
8 terated or misbranded” the following: “or, in the  
9 case of a drug, which in the determination of the of-  
10 ficer or employee making the inspection appears to  
11 be in violation of section 505,”.

12 (b) EFFECTIVE DATE.—The amendments made by  
13 subsection (a) shall take effect on a date, specified by the  
14 Secretary of Health and Human Services, not later than  
15 1 year after the date of the enactment of this Act.

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

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

19 “(3) Notwithstanding paragraph (1) or (2), any per-  
20 son who engages in any conduct described in section  
21 301(i)(2) knowing that the conduct concerns the rendering  
22 of a drug as a counterfeit drug, or who engages in conduct  
23 described in section 301(i)(3) knowing that the conduct  
24 will cause a drug to be a counterfeit drug or knowing that  
25 a drug held, sold, or dispensed is a counterfeit drug, shall  
26 be fined in accordance with title 18, United States Code,

1 or imprisoned not more than 20 years, or both, except that  
2 if the use of the counterfeit drug by a consumer is the  
3 proximate cause of the death of the consumer, the term  
4 of imprisonment shall be any term of years or for life.”.

5 **SEC. 211. CIVIL MONEY PENALTIES FOR VIOLATIVE DRUGS**  
6 **AND DEVICES AND IMPROPER IMPORT**  
7 **ENTRY FILINGS.**

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

10 (1) by redesignating paragraphs (5), (6), and  
11 (7) as paragraphs (6), (7), and (8), respectively;

12 (2) by inserting after paragraph (4) the fol-  
13 lowing:

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

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

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

23 “(ii) In clause (i)(I), the term ‘initial violation’  
24 means the first violation by a person of a require-  
25 ment described in clause (i) that occurs on or after

1 the date of the enactment of the Food and Drug Ad-  
2 ministration Globalization Act of 2009.

3 “(iii) Each day during which a violation con-  
4 tinues shall be considered a separate violation under  
5 clause (i), except that a continuing initial violation  
6 shall not be treated as a subsequent violation for  
7 purposes of clause (i)(II).

8 “(B)(i) Any person that knowingly reports or  
9 enters false or misleading data on documents related  
10 to the importation of a drug shall be liable to the  
11 United States for a civil penalty not to exceed  
12 \$200,000.

13 “(ii) Each act of reporting or entering false  
14 data shall be considered a separate violation under  
15 clause (i).

16 “(C) Any manufacturer, importer, distributor,  
17 or retailer who fails to comply with an order or an  
18 amended order issued under section 568(a) or  
19 568(c)(1), respectively, shall be liable to the United  
20 States for a civil penalty not to exceed \$250,000 per  
21 day.”.

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

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

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

6 (b) APPLICABILITY.—Section 303(f)(5) (as amended  
7 by subsection (a)), shall apply to violations described in  
8 such section that occur after the date of the enactment  
9 of this Act.

10 **SEC. 212. HUMAN GENERIC DRUG APPLICATION AND SUP-**  
11 **PLEMENT FEES TO COVER PRE-APPROVAL**  
12 **INSPECTION COSTS.**

13 (a) SENSE OF CONGRESS.—It is the sense of the Con-  
14 gress that the amount of additional revenues generated  
15 from fees under this section should be used to support pre-  
16 approval inspections of generic drug establishments, in ac-  
17 cordance with performance goals to be developed by the  
18 Secretary of Health and Human Services in consultation  
19 with the entities listed in subparagraphs (A) through (F)  
20 of section 736B(d)(1) of the Federal Food, Drug, and  
21 Cosmetic Act (21 U.S.C. 379h–2(d)(1)).

22 (b) FEE.—

23 (1) MISBRANDING.—Paragraph (o) of section  
24 502 (21 U.S.C. 352), as amended by subsections (a)

1 and (b) of section 501, is further amended by strik-  
2 ing “736C” and inserting “736C or 736D”.

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

7 **“SEC. 736D. HUMAN GENERIC DRUG APPLICATION AND**  
8 **SUPPLEMENT FEES TO COVER PRE-AP-**  
9 **PROVAL INSPECTION COSTS.**

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

17 “(b) FEE REVENUE AMOUNTS.—For each of fiscal  
18 years 2010 through 2014, fees under subsection (a) shall  
19 be established, subject to the provisions referred to in sub-  
20 section (d), to generate a total revenue amount.

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

22 “(1) IN GENERAL.—Fees authorized under sub-  
23 section (a) shall be collected and available for obliga-  
24 tion only to the extent and in the amount provided  
25 in advance in appropriations Acts. Such fees are au-



1       thorized to remain available until expended. Such  
2       sums as may be necessary may be transferred from  
3       the Food and Drug Administration salaries and ex-  
4       penses appropriation account without fiscal year lim-  
5       itation to such appropriation account for salaries  
6       and expenses with such fiscal year limitation.

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

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

13              “(B) shall only be collected and available  
14              to defray increases in the costs of resources al-  
15              located for conducting inspections in connection  
16              with the review of human generic drug applica-  
17              tions and supplements (including increases in  
18              such costs for an additional number of full-time  
19              equivalent positions in the Department of  
20              Health and Human Services to be engaged in  
21              such review) over such costs, excluding costs  
22              paid from fees collected under this section, for  
23              fiscal year 2009 multiplied by the adjustment  
24              factor.

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

9       “(e) DEFINITIONS.—In this section:

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

14                   “(A) incurred in connection with inspec-  
15 tions undertaken as part of the Secretary’s re-  
16 view of pending human generic drug applica-  
17 tions and supplements; and

18                   “(B) described in subparagraphs (A)  
19 through (D) of section 735(7), except that the  
20 reference in section 735(7)(D) to section 736 is  
21 deemed to be a reference to this section, and  
22 the reference is section 735(7)(D) to human  
23 drug applications and supplements (as defined  
24 in section 735(2)) is deemed to be a reference

1 to human generic drug applications and supple-  
2 ments (as defined in this section).

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

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

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

18 (4) SUNSET DATE.—Section 736D, as added by  
19 paragraph (2), does not authorize the assessment or  
20 collection of a fee for submission of an application  
21 or supplement under section 505(j) of such Act (21  
22 U.S.C. 355(j)) occurring after fiscal year 2014.

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 (b) 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).

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

1 by any agreement, policy, form, or condition of employ-  
2 ment.”.

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