

108TH CONGRESS
1ST SESSION

H. R. 3547

To amend the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Federal Food, Drug, and Cosmetic Act to provide for improved public health and food safety through enhanced enforcement, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 20, 2003

Ms. DEGETTE (for herself, Ms. DELAURO, Mr. HINCHEY, Mr. STARK, and Mr. WAXMAN) introduced the following bill; which was referred to the Committee on Agriculture, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Federal Food, Drug, and Cosmetic Act to provide for improved public health and food safety through enhanced enforcement, 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Safe And Fair En-
3 forcement and Recall for Meat, Poultry, and Food Act”
4 or “SAFER Meat, Poultry, and Food Act”.

5 **SEC. 2. FOOD SAFETY ENFORCEMENT FOR MEAT AND MEAT**
6 **FOOD PRODUCTS.**

7 (a) IN GENERAL.—The Federal Meat Inspection Act
8 (21 U.S.C. 601 et seq.) is amended—

9 (1) by redesignating section 411 (21 U.S.C.
10 680) as section 414; and

11 (2) by inserting after section 410 (21 U.S.C.
12 679a) the following:

13 **“SEC. 411. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
14 **OF ADULTERATED OR MISBRANDED ARTI-**
15 **CLES.**

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

17 “(1) IN GENERAL.—A person (other than a
18 household consumer) that has reason to believe that
19 any carcass, part of a carcass, meat, or meat food
20 product of cattle, sheep, swine, goats, horses, mules,
21 or other equines (referred to in this section as an
22 ‘article’) transported, stored, distributed, or other-
23 wise handled by the person is adulterated or mis-
24 branded shall, as soon as practicable, notify the Sec-
25 retary of the identity and location of the article.

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

5 “(b) RECALL AND CONSUMER NOTIFICATION.—

6 “(1) VOLUNTARY ACTIONS.—On receiving noti-
7 fication under subsection (a) or by other means, if
8 the Secretary finds that an article is adulterated or
9 misbranded and that there is a reasonable prob-
10 ability that human consumption of the article would
11 present a threat to public health (as determined by
12 the Secretary), the Secretary shall provide all appro-
13 priate persons (as determined by the Secretary),
14 that transported, stored, distributed, or otherwise
15 handled the article with an opportunity—

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

17 “(B) to notify all persons that transport,
18 store, distribute, or otherwise handle the article,
19 or to which the article has been transported,
20 sold, distributed, or otherwise handled, to cease
21 immediately distribution of the article;

22 “(C) to recall the article; or

23 “(D) in consultation with the Secretary, to
24 provide notice of the finding of the Secretary to

1 all consumers to which the article was, or may
2 have been, distributed.

3 “(2) MANDATORY ACTIONS.—If the appropriate
4 person referred to in paragraph (1) does not carry
5 out the actions described in that paragraph with re-
6 spect to an article within the time period and in the
7 manner prescribed by the Secretary, the Secretary
8 shall, by order, require, as the Secretary determines
9 to be necessary, the person—

10 “(A) to cease immediately distribution of
11 the article; and

12 “(B) to make immediately the notification
13 described in paragraph (1)(B).

14 “(3) NOTICE TO CONSUMERS.—The Secretary
15 shall, as the Secretary determines to be necessary,
16 provide notice of the finding of the Secretary under
17 paragraph (1) to consumers to which the article was,
18 or may have been, distributed.

19 “(4) NONDISTRIBUTION BY NOTIFIED PER-
20 SONS.—A person that transports, stores, distributes,
21 or otherwise handles the article, or to which the arti-
22 cle has been transported, sold, distributed, or other-
23 wise handled, and that is notified under paragraph
24 (1)(B) or (2)(B) shall cease immediately distribution
25 of the article.

1 “(5) AVAILABILITY OF RECORDS TO SEC-
2 RETARY.—Each appropriate person referred to in
3 paragraph (1) that transported, stored, distributed,
4 or otherwise handled an article shall make available
5 to the Secretary information necessary to carry out
6 this subsection, as determined by the Secretary, re-
7 garding—

8 “(A) persons that transport, store, dis-
9 tribute, or otherwise handle the article; and

10 “(B) persons to which the article has been
11 transported, sold, distributed, or otherwise han-
12 dled.

13 “(c) INFORMAL HEARINGS ON ORDERS.—

14 “(1) IN GENERAL.—The Secretary shall provide
15 a person subject to an order under subsection (b)
16 with an opportunity for an informal hearing (in ac-
17 cordance with such rules or regulations as the Sec-
18 retary shall prescribe) on—

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

20 “(B) any reasons why the article that is
21 the subject of the order should not be recalled.

22 “(2) TIMING OF HEARINGS.—The Secretary
23 shall hold a hearing under paragraph (1) as soon as
24 practicable, but not later than 2 business days, after
25 the date of issuance of the order.

1 “(d) POST-HEARING RECALL ORDERS.—

2 “(1) AMENDMENT OF ORDERS.—If, after pro-
3 viding an opportunity for an informal hearing under
4 subsection (c), the Secretary determines that there is
5 a reasonable probability that human consumption of
6 the article that is the subject of an order under sub-
7 section (b) presents a threat to public health, the
8 Secretary may, as the Secretary determines to be
9 necessary—

10 “(A) amend the order under subsection
11 (b)—

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

14 “(ii) to specify a timetable during
15 which the recall shall occur;

16 “(B) require periodic reports to the Sec-
17 retary describing the progress of the recall; or

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

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

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

4 **“SEC. 412. REFUSAL OR WITHDRAWAL OF INSPECTION OF**
5 **ESTABLISHMENTS.**

6 “(a) IN GENERAL.—The Secretary may, for such pe-
7 riod, or indefinitely, as the Secretary considers necessary
8 to carry out this Act, refuse to provide or withdraw inspec-
9 tion under title I with respect to an establishment if the
10 Secretary determines, after opportunity for a hearing on
11 the record is provided to the applicant for, or recipient
12 of, inspection, that the applicant or recipient, or any per-
13 son responsibly connected with the applicant or recipient
14 (within the meaning of section 401), has committed a will-
15 ful violation or repeated violations of this Act (including
16 a regulation promulgated under this Act).

17 “(b) DENIAL OR SUSPENSION OF INSPECTION PEND-
18 ING HEARING.—The Secretary may deny or suspend in-
19 spection under title I, pending opportunity for an expe-
20 dited hearing, with respect to an action under subsection
21 (a), if the Secretary determines that the denial or suspen-
22 sion is in the public interest to protect the health or wel-
23 fare of consumers or to ensure the effective performance
24 of an official duty under this Act.

25 “(c) JUDICIAL REVIEW.—

1 “(1) IN GENERAL.—A determination and order
2 of the Secretary with respect to the refusal or with-
3 drawal of inspection under this section shall be final
4 unless, not later than 30 days after the effective
5 date of the order, the affected applicant for, or re-
6 cipient of, inspection—

7 “(A) files a petition for judicial review of
8 the order; and

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

11 “(2) REFUSAL OR WITHDRAWAL OF INSPEC-
12 TION PENDING REVIEW.—Inspection shall be refused
13 or withdrawn as of the effective date of the order
14 pending any judicial review of the order unless the
15 Secretary directs otherwise.

16 “(3) VENUE; RECORD.—Judicial review of the
17 order shall be—

18 “(A) in—

19 “(i) the United States court of ap-
20 peals for the circuit in which the applicant
21 for, or recipient of, inspection resides or
22 has its principal place of business; or

23 “(ii) the United States Court of Ap-
24 peals for the District of Columbia Circuit;
25 and

1 “(B) on the record on which the deter-
2 mination and order are based.

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

6 **“SEC. 413. CIVIL PENALTIES.**

7 “(a) IN GENERAL.—

8 “(1) ASSESSMENT.—The Secretary may assess
9 against a person that violates this Act (including a
10 regulation promulgated or order issued under this
11 Act) a civil penalty for each violation of not more
12 than \$100,000.

13 “(2) SEPARATE OFFENSES.—Each violation
14 and each day during which the violation continues
15 shall be considered to be a separate offense.

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

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

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

3 “(i) the gravity of the violation;

4 “(ii) the degree of culpability of the
5 person;

6 “(iii) the size and type of the business
7 of the person; and

8 “(iv) any history of prior offenses by
9 the person under this Act; and

10 “(B) shall be reviewed only in accordance
11 with subsection (b).

12 “(b) JUDICIAL REVIEW.—

13 “(1) IN GENERAL.—An order assessing a civil
14 penalty against a person under subsection (a) shall
15 be final unless the person—

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

19 “(i) the United States court of ap-
20 peals for the circuit in which the person re-
21 sides or has its principal place of business;
22 or

23 “(ii) the United States Court of Ap-
24 peals for the District of Columbia Circuit;
25 and

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

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

6 “(c) COLLECTION ACTIONS FOR FAILURE TO PAY
7 ASSESSMENT.—

8 “(1) REFERRAL TO ATTORNEY GENERAL.—If a
9 person fails to pay a civil penalty assessed under
10 subsection (a) after the order assessing the civil pen-
11 alty has become a final order, or after the court of
12 appeals has entered final judgment in favor of the
13 Secretary, the Secretary shall refer the matter to the
14 Attorney General.

15 “(2) ACTION BY ATTORNEY GENERAL.—The
16 Attorney General shall bring a civil action to recover
17 the amount of the civil penalty in United States dis-
18 trict court.

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

23 “(d) REFUSAL OR WITHDRAWAL OF INSPECTION
24 PENDING PAYMENT.—If a person fails to pay the amount
25 of a civil penalty after the order assessing the civil penalty

1 has become a final order, the Secretary may refuse to pro-
2 vide or withdraw inspection under title I of the person
3 until the civil penalty is paid or until the Secretary directs
4 otherwise.

5 “(e) PENALTIES IN LIEU OF OTHER ACTIONS.—
6 Nothing in this Act requires the Secretary to report for
7 prosecution, or for the commencement of an action, any
8 violation of this Act in any case in which the Secretary
9 believes that the public interest will be adequately served
10 by the assessment of a civil penalty under this section.

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

14 (b) CONFORMING AMENDMENTS.—

15 (1) Section 1 of the Federal Meat Inspection
16 Act (21 U.S.C. 601) is amended by adding at the
17 end the following:

18 “(w) PERSON.—The term ‘person’ means any indi-
19 vidual, partnership, corporation, association, or other busi-
20 ness unit.”.

21 (2) The Federal Meat Inspection Act (21
22 U.S.C. 601 et seq.) is amended—

23 (A) by striking “person, firm, or corpora-
24 tion” each place it appears and inserting “per-
25 son”;

1 (B) by striking “persons, firms, and cor-
 2 porations” each place it appears and inserting
 3 “persons”; and

4 (C) by striking “persons, firms, or corpora-
 5 tions” each place it appears and inserting “per-
 6 sons”.

7 **SEC. 3. FOOD SAFETY ENFORCEMENT FOR POULTRY AND**
 8 **POULTRY FOOD PRODUCTS.**

9 The Poultry Products Inspection Act (21 U.S.C. 451
 10 et seq.) is amended—

11 (1) in the first sentence of section 5(c)(1) (21
 12 U.S.C. 454(c)(1))—

13 (A) by striking “, by thirty days prior to
 14 the expiration of two years after enactment of
 15 the Wholesome Poultry Products Act,”; and

16 (B) by striking “sections 1–4, 6–10, and
 17 12–22 of this Act” and inserting “sections 1
 18 through 4, 6 through 10, 12 through 22, and
 19 31 through 33”; and

20 (2) by adding at the end the following:

21 **“SEC. 31. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
 22 **OF ADULTERATED OR MISBRANDED ARTI-**
 23 **CLES.**

24 **“(a) NOTIFICATION TO SECRETARY OF VIOLATION.—**

1 “(1) IN GENERAL.—A person (other than a
2 household consumer) that has reason to believe that
3 any poultry or poultry product (referred to in this
4 section as an ‘article’) transported, stored, distrib-
5 uted, or otherwise handled by the person is adulter-
6 ated or misbranded shall, as soon as practicable, no-
7 tify the Secretary of the identity and location of the
8 article.

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

13 “(b) RECALL AND CONSUMER NOTIFICATION.—

14 “(1) VOLUNTARY ACTIONS.—On receiving noti-
15 fication under subsection (a) or by other means, if
16 the Secretary finds that an article is adulterated or
17 misbranded and that there is a reasonable prob-
18 ability that human consumption of the article would
19 present a threat to public health (as determined by
20 the Secretary), the Secretary shall provide all appro-
21 priate persons (as determined by the Secretary),
22 that transported, stored, distributed, or otherwise
23 handled the article with an opportunity—

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

1 “(B) to notify all persons that transport,
2 store, distribute, or otherwise handle the article,
3 or to which the article has been transported,
4 sold, distributed, or otherwise handled, to cease
5 immediately distribution of the article;

6 “(C) to recall the article; or

7 “(D) in consultation with the Secretary, to
8 provide notice of the finding of the Secretary to
9 all consumers to which the article was, or may
10 have been, distributed.

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

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

20 “(B) to make immediately the notification
21 described in paragraph (1)(B).

22 “(3) NOTICE TO CONSUMERS.—The Secretary
23 shall, as the Secretary determines to be necessary,
24 provide notice of the finding of the Secretary under

1 paragraph (1) to consumers to which the article was,
2 or may have been, distributed.

3 “(4) NONDISTRIBUTION BY NOTIFIED PER-
4 SONS.—A person that transports, stores, distributes,
5 or otherwise handles the article, or to which the arti-
6 cle has been transported, sold, distributed, or other-
7 wise handled, and that is notified under paragraph
8 (1)(B) or (2)(B) shall cease immediately distribution
9 of the article.

10 “(5) AVAILABILITY OF RECORDS TO SEC-
11 RETARY.—Each appropriate person referred to in
12 paragraph (1) that transported, stored, distributed,
13 or otherwise handled an article shall make available
14 to the Secretary information necessary to carry out
15 this subsection, as determined by the Secretary, re-
16 garding—

17 “(A) persons that transport, store, dis-
18 tribute, or otherwise handle the article; and

19 “(B) persons to which the article has been
20 transported, sold, distributed, or otherwise han-
21 dled.

22 “(c) INFORMAL HEARINGS ON ORDERS.—

23 “(1) IN GENERAL.—The Secretary shall provide
24 a person subject to an order under subsection (b)
25 with an opportunity for an informal hearing (in ac-

1 cordance with such rules or regulations as the Sec-
2 retary shall prescribe) on—

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

4 “(B) any reasons why the article that is
5 the subject of the order should not be recalled.

6 “(2) TIMING OF HEARINGS.—The Secretary
7 shall hold a hearing under paragraph (1) as soon as
8 practicable, but not later than 2 business days, after
9 the date of issuance of the order.

10 “(d) POST-HEARING RECALL ORDERS.—

11 “(1) AMENDMENT OF ORDERS.—If, after pro-
12 viding an opportunity for an informal hearing under
13 subsection (c), the Secretary determines that there is
14 a reasonable probability that human consumption of
15 the article that is the subject of an order under sub-
16 section (b) presents a threat to public health, the
17 Secretary may, as the Secretary determines to be
18 necessary—

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

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

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

6 “(2) VACATION OF ORDERS.—If, after providing
7 an opportunity for an informal hearing under sub-
8 section (c), the Secretary determines that adequate
9 grounds do not exist to continue the actions required
10 by the order, the Secretary shall vacate the order.

14 "SEC. 32. REFUSAL OR WITHDRAWAL OF INSPECTION OF
15 ESTABLISHMENTS.

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1 willful violation or repeated violations of this Act (includ-
2 ing a regulation promulgated under this Act).

3 “(b) DENIAL OR SUSPENSION OF INSPECTION PEND-
4 ING HEARING.—The Secretary may deny or suspend in-
5 spection under this Act, pending opportunity for an expe-
6 dited hearing, with respect to an action under subsection
7 (a), if the Secretary determines that the denial or suspen-
8 sion is in the public interest to protect the health or wel-
9 fare of consumers or to ensure the effective performance
10 of an official duty under this Act.

11 “(c) JUDICIAL REVIEW.—

12 “(1) IN GENERAL.—A determination and order
13 of the Secretary with respect to the refusal or with-
14 drawal of inspection under this section shall be final
15 unless, not later than 30 days after the effective
16 date of the order, the affected applicant for, or re-
17 cipient of, inspection—

18 “(A) files a petition for judicial review of
19 the order; and

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

22 “(2) REFUSAL OR WITHDRAWAL OF INSPEC-
23 TION PENDING REVIEW.—Inspection shall be refused
24 or withdrawn as of the effective date of the order

1 pending any judicial review of the order unless the
2 Secretary directs otherwise.

3 “(3) VENUE; RECORD.—Judicial review of the
4 order shall be—

5 “(A) in—

6 “(i) the United States court of ap-
7 peals for the circuit in which the applicant
8 for, or recipient of, inspection resides or
9 has its principal place of business; or

10 “(ii) the United States Court of Ap-
11 peals for the District of Columbia Circuit;
12 and

13 “(B) on the record on which the deter-
14 mination and order are based.

15 “(d) REMEDIES NOT EXCLUSIVE.—The remedies au-
16 thorized by this section shall be in addition to any other
17 remedies that may be available.

18 **“SEC. 33. CIVIL PENALTIES.**

19 “(a) IN GENERAL.—

20 “(1) ASSESSMENT.—The Secretary may assess
21 against a person that violates this Act (including a
22 regulation promulgated or order issued under this
23 Act) a civil penalty for each violation of not more
24 than \$100,000.

1 “(2) SEPARATE OFFENSES.—Each violation
2 and each day during which the violation continues
3 shall be considered to be a separate offense.

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

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

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

15 “(i) the gravity of the violation;

16 “(ii) the degree of culpability of the
17 person;

18 “(iii) the size and type of the business
19 of the person; and

20 “(iv) any history of prior offenses by
21 the person under this Act; and

22 “(B) shall be reviewed only in accordance
23 with subsection (b).

24 “(b) JUDICIAL REVIEW.—

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

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

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

11 “(ii) the United States Court of Ap-
12 peals for the District of Columbia Circuit;
13 and

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

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

19 “(c) COLLECTION ACTIONS FOR FAILURE TO PAY
20 ASSESSMENT.—

21 “(1) REFERRAL TO ATTORNEY GENERAL.—If a
22 person fails to pay a civil penalty assessed under
23 subsection (a) after the order assessing the civil pen-
24 alty has become a final order, or after the court of
25 appeals has entered final judgment in favor of the

1 Secretary, the Secretary shall refer the matter to the
2 Attorney General.

3 “(2) ACTION BY ATTORNEY GENERAL.—The
4 Attorney General shall bring a civil action to recover
5 the amount of the civil penalty in United States dis-
6 trict court.

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

11 “(d) REFUSAL OR WITHDRAWAL OF INSPECTION
12 PENDING PAYMENT.—If a person fails to pay the amount
13 of a civil penalty after the order assessing the civil penalty
14 has become a final order, the Secretary may refuse to pro-
15 vide or withdraw inspection under this Act of the person
16 until the civil penalty is paid or until the Secretary directs
17 otherwise.

18 “(e) PENALTIES IN LIEU OF OTHER ACTIONS.—
19 Nothing in this Act requires the Secretary to report for
20 prosecution, or for the commencement of an action, any
21 violation of this Act in any case in which the Secretary
22 believes that the public interest will be adequately served
23 by the assessment of a civil penalty under this section.

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

4 **SEC. 4. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
 5 **OF ADULTERATED OR MISBRANDED ARTI-**
 6 **CLES OF FOOD.**

7 (a) PROHIBITED ACTS.—Section 301 of the Federal
 8 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
 9 ed by adding at the end the following:

10 “(hh)(1) The failure to notify the Secretary in viola-
 11 tion of section 311(a).

12 “(2) The failure to comply with—

13 “(A) an order issued under section 311(b) fol-
 14 lowing any hearing requested under section 311(c);
 15 or

16 “(B) an amended order issued under section
 17 311(d)(1).”.

18 (b) NOTIFICATION, NONDISTRIBUTION, AND RECALL
 19 OF ADULTERATED OR MISBRANDED ARTICLES OF FOOD;
 20 CIVIL PENALTIES RELATING TO FOODS.—Chapter III of
 21 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331
 22 et seq.) is amended by adding at the end the following:

1 **“SEC. 311. 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, if
23 the Secretary finds that an article of food when in-
24 troduced into or while in interstate commerce, or
25 while held for sale (regardless of whether the first
26 sale) after shipment in interstate commerce, is adul-

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

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

8 “(B) to notify all persons—

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

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

17 “(C) to recall the article; or

18 “(D) in consultation with the Secretary, to
19 provide notice of the finding of the Secretary to
20 all consumers to which the article was, or may
21 have been, distributed.

22 “(2) MANDATORY ACTIONS.—If the appropriate
23 person referred to in paragraph (1) does not carry
24 out the actions described in that paragraph with re-
25 spect to an article within the time period and in the

1 manner prescribed by the Secretary, the Secretary
2 shall, by order, require, as the Secretary determines
3 to be necessary, the person—

4 “(A) to cease immediately distribution of
5 the article; and

6 “(B) to make immediately the notification
7 described in paragraph (1)(B).

8 “(3) NOTICE TO CONSUMERS.—The Secretary
9 shall, as the Secretary determines to be necessary,
10 provide notice of the finding of the Secretary under
11 paragraph (1) to consumers to which the article was,
12 or may have been, distributed.

13 “(c) HEARINGS ON ORDERS.—

14 “(1) IN GENERAL.—The Secretary shall provide
15 a person subject to an order under subsection (b)
16 with an opportunity for a hearing on—

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

18 “(B) any reasons why the article of food
19 that is the subject of the order should not be
20 recalled.

21 “(2) TIMING OF HEARINGS.—The Secretary
22 shall hold a hearing under paragraph (1) as soon as
23 practicable, but not later than 2 business days, after
24 the date of issuance of the order.

25 “(d) POST-HEARING RECALL ORDERS.—

1 “(1) AMENDMENT OF ORDERS.—If, after pro-
2 viding an opportunity for a hearing under subsection
3 (c), the Secretary determines that an article of food
4 when introduced into or while in interstate com-
5 merce, or while held for sale (regardless of whether
6 the first sale) after shipment in interstate commerce,
7 is adulterated or misbranded in a manner that, if
8 consumed, may result in illness or injury, the Sec-
9 retary may, as the Secretary determines to be nec-
10 essary—

11 “(A) amend the order under subsection
12 (b)—

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

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

17 “(B) require periodic reports to the Sec-
18 retary describing the progress of the recall; or

19 “(C) provide notice of the recall to con-
20 sumers to which the article was, or may have
21 been, distributed.

22 “(2) VACATION OF ORDERS.—If, after providing
23 an opportunity for a hearing under subsection (c),
24 the Secretary determines that adequate grounds do

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

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

6 **“SEC. 312. CIVIL PENALTIES RELATING TO FOODS.**

7 “(a) IN GENERAL.—

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

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

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

16 “(2) SEPARATE OFFENSES.—Each prohibited
17 act and each day during which the act continues
18 shall be considered to be a separate offense.

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

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

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

6 “(i) the gravity of the violation;

7 “(ii) the degree of culpability of the
8 person;

9 “(iii) the size and type of the business
10 of the person; and

11 “(iv) any history of prior offenses by
12 the person; and

13 “(B) shall be reviewed only in accordance
14 with subsection (b).

15 “(b) JUDICIAL REVIEW.—

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

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

22 “(i) the United States court of ap-
23 peals for the circuit in which the person re-
24 sides or has its principal place of business;
25 or

1 “(ii) the United States Court of Ap-
2 peals for the District of Columbia Circuit;
3 and

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

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

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

13 “(c) COLLECTION ACTIONS FOR FAILURE TO PAY
14 ASSESSMENT.—

15 “(1) REFERRAL TO ATTORNEY GENERAL.—If a
16 person fails to pay a civil penalty assessed under
17 subsection (a) after the order assessing the civil pen-
18 alty has become a final order, or after the court of
19 appeals has entered final judgment in favor of the
20 Secretary, the Secretary may refer the matter to the
21 Attorney General.

22 “(2) ACTION BY ATTORNEY GENERAL.—The
23 Attorney General shall bring a civil action to recover
24 the amount of the civil penalty in United States dis-
25 trict court.

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

5 “(d) PENALTIES DEPOSITED IN TREASURY.—All
6 amounts collected as civil penalties under this section shall
7 be deposited in the Treasury of the United States.

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

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

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