

107<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 5230

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.

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## IN THE HOUSE OF REPRESENTATIVES

JULY 25, 2002

Ms. RIVERS (for herself and Ms. DEGETTE) 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

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## 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Safe And Fair En-  
5 forcement and Recall for Meat, Poultry, and Food Act”  
6 (SAFER Meat, Poultry, and Food Act).

1 **SEC. 2. FOOD SAFETY ENFORCEMENT FOR MEAT AND MEAT**  
2 **FOOD PRODUCTS.**

3 (a) IN GENERAL.—The Federal Meat Inspection Act  
4 (21 U.S.C. 601 et seq.) is amended—

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

7 (2) by inserting after section 410 (21 U.S.C.  
8 679a) the following:

9 **“SEC. 411. NOTIFICATION, NONDISTRIBUTION, AND RECALL**  
10 **OF ADULTERATED OR MISBRANDED ARTI-**  
11 **CLES.**

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

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

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

26 “(b) RECALL AND CONSUMER NOTIFICATION.—

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

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

12                   “(B) to notify all persons that transport,  
13                   store, distribute, or otherwise handle the article,  
14                   or to which the article has been transported,  
15                   sold, distributed, or otherwise handled, to cease  
16                   immediately 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 “(4) NONDISTRIBUTION BY NOTIFIED PER-  
14 SONS.—A person that transports, stores, distributes,  
15 or otherwise handles the article, or to which the arti-  
16 cle has been transported, sold, distributed, or other-  
17 wise handled, and that is notified under paragraph  
18 (1)(B) or (2)(B) shall cease immediately distribution  
19 of the article.

20 “(5) AVAILABILITY OF RECORDS TO SEC-  
21 RETARY.—Each appropriate person referred to in  
22 paragraph (1) that transported, stored, distributed,  
23 or otherwise handled an article shall make available  
24 to the Secretary information necessary to carry out

1 this subsection, as determined by the Secretary,  
2 regarding—

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

5 “(B) persons to which the article has been  
6 transported, sold, distributed, or otherwise han-  
7 dled.

8 “(c) INFORMAL HEARINGS ON ORDERS.—

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

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

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

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

21 “(d) POST-HEARING RECALL ORDERS.—

22 “(1) AMENDMENT OF ORDERS.—If, after pro-  
23 viding an opportunity for an informal hearing under  
24 subsection (c), the Secretary determines that there is  
25 a reasonable probability that human consumption of

1 the article that is the subject of an order under sub-  
2 section (b) presents a threat to public health, the  
3 Secretary may, as the Secretary determines to be  
4 necessary—

5 “(A) amend the order under subsection  
6 (b)—

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

9 “(ii) to specify a timetable during  
10 which the recall shall occur;

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

13 “(C) provide notice of the recall to con-  
14 sumers to which the article was, or may have  
15 been, distributed.

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

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

1 **“SEC. 412. REFUSAL OR WITHDRAWAL OF INSPECTION OF**  
2 **ESTABLISHMENTS.**

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

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

22 “(c) JUDICIAL REVIEW.—

23 “(1) IN GENERAL.—A determination and order  
24 of the Secretary with respect to the refusal or with-  
25 drawal of inspection under this section shall be final  
26 unless, not later than 30 days after the effective

1 date of the order, the affected applicant for, or re-  
2 cipient of, inspection—

3 “(A) files a petition for judicial review of  
4 the order; and

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

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

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

14 “(A) in—

15 “(i) the United States court of ap-  
16 peals for the circuit in which the applicant  
17 for, or recipient of, inspection resides or  
18 has its principal place of business; or

19 “(ii) the United States Court of Ap-  
20 peals for the District of Columbia Circuit;  
21 and

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

1       “(d) 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. 413. CIVIL PENALTIES.**

5       “(a) IN GENERAL.—

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

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

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

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

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

25                           “(i) the gravity of the violation;

1                   “(ii) the degree of culpability of the  
2                   person;

3                   “(iii) the size and type of the business  
4                   of the person; and

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

7                   “(B) shall be reviewed only in accordance  
8                   with subsection (b).

9                   “(b) JUDICIAL REVIEW.—

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

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

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

20                   “(ii) the United States Court of Ap-  
21                   peals for the District of Columbia Circuit;  
22                   and

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

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

4           “(c) COLLECTION ACTIONS FOR FAILURE TO PAY  
5 ASSESSMENT.—

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

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

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

21          “(d) REFUSAL OR WITHDRAWAL OF INSPECTION  
22 PENDING PAYMENT.—If a person fails to pay the amount  
23 of a civil penalty after the order assessing the civil penalty  
24 has become a final order, the Secretary may refuse to pro-  
25 vide or withdraw inspection under title I of the person

1 until the civil penalty is paid or until the Secretary directs  
2 otherwise.

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

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

12 (b) CONFORMING AMENDMENTS.—

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

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

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

21 (A) by striking “person, firm, or corpora-  
22 tion” each place it appears and inserting “per-  
23 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,  
16 regarding—

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;



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       “(gg)(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  
10          necessary—

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                   “(4) 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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