

106TH CONGRESS
2D SESSION

S. 2692

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of imported products, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 7 (legislative day, JUNE 6), 2000

Ms. MIKULSKI (for herself, Mr. KENNEDY, and Mr. DURBIN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of imported products, 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 “Imported Products
5 Safety Improvement and Disease Prevention Act of
6 2000”.

1 **TITLE I—IMPROVEMENTS TO**
2 **THE PRODUCT SAFETY IM-**
3 **PORT SYSTEM**

4 **SEC. 101. EQUIVALENCE AUTHORITY TO PROTECT THE**
5 **PUBLIC HEALTH FROM CONTAMINATED IM-**
6 **PORTED PRODUCTS.**

7 (a) EQUIVALENCE DETERMINATIONS, AND MEAS-
8 URES, SYSTEMS, AND CONDITIONS TO ACHIEVE PUBLIC
9 HEALTH PROTECTION.—Section 801 of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 381) is amended—

11 (1) by redesignating subsections (d), (e), and
12 (f) as subsections (f), (g), and (h), respectively; and

13 (2) by inserting after subsection (c) the fol-
14 lowing:

15 “(d)(1) Subject to paragraphs (2) and (3), any cov-
16 ered product offered for import into the United States
17 shall be prepared (including produced), packed, and held
18 under a system or conditions, or subject to measures, that
19 meet the requirements of this Act or that have been deter-
20 mined by the Secretary to be equivalent to a system, con-
21 ditions, or measures for such covered product in the
22 United States and to achieve the level of public health pro-
23 tection for such covered product prepared, packed, and
24 held in the United States. Consistent with section 492 of
25 the Trade Agreements Act of 1979 (19 U.S.C. 2578a),

1 the Secretary shall make, where appropriate, equivalence
2 determinations described in that section relating to sani-
3 tary or phytosanitary measures (including systems and
4 conditions) that apply to the preparation, packing, and
5 holding of covered products offered for import into the
6 United States.

7 “(2) In carrying out this subsection, the Secretary
8 shall conduct systematic evaluations of the systems, condi-
9 tions, and measures in foreign countries that apply to the
10 preparation, packing, and holding of covered products of-
11 fered for import into the United States.

12 “(3) The Secretary shall develop a plan for the imple-
13 mentation of the authority under this subsection within
14 2 years after the date of enactment of the Imported Prod-
15 ucts Safety Improvement and Disease Prevention Act of
16 2000. In developing the plan, the Secretary shall provide
17 an opportunity for, and take into consideration, public
18 comment on a proposed plan.”.

19 (b) GENERAL AUTHORITY.—Section 801 of the Fed-
20 eral Food, Drug, and Cosmetic Act (21 U.S.C. 381), as
21 amended in subsection (a), is further amended by insert-
22 ing after subsection (d) the following:

23 “(e)(1)(A) The Secretary shall establish a system, for
24 use by the Secretary of the Treasury, to deny the entry
25 of any covered product offered for import into the United

1 States if the Secretary of Health and Human Services
2 makes and publishes—

3 “(i) a written determination that the covered
4 product—

5 “(I) has been associated with repeated and
6 separate outbreaks of disease borne in a cov-
7 ered product or has been repeatedly determined
8 by the Secretary to be adulterated within the
9 meaning of section 402;

10 “(II) presents a reasonable probability of
11 causing significant adverse health consequences
12 or death; and

13 “(III) is likely, without systemic interven-
14 tion or changes, to cause disease or be adulter-
15 ated again; or

16 “(ii) an emergency written determination that
17 the covered product has been strongly associated
18 with a single outbreak of disease borne in a covered
19 product that has caused serious adverse health con-
20 sequences or death.

21 “(B)(i) The Secretary shall make a determination de-
22 scribed in subparagraph (A) with respect to—

23 “(I) a covered product from a specific producer,
24 manufacturer, or shipper; or

1 “(II) a covered product from a specific growing
2 area or country;
3 that meets the criteria described in subparagraph (A).

4 “(ii) Only the covered product from the specific pro-
5 ducer, manufacturer, shipper, growing area, or country for
6 which the Secretary makes the determination shall be sub-
7 ject to denial of entry under this subsection.

8 “(C) The denial of entry of any covered product
9 under this paragraph shall be done in a manner consistent
10 with bilateral, regional, and multilateral trade agreements
11 and the rights and obligations of the United States under
12 the agreements.

13 “(D)(i) Before making any written determination
14 under subparagraph (A)(i), the Secretary shall consider
15 written comments, on a proposed determination, made by
16 any party affected by the proposed determination and any
17 remedial actions taken to address the findings made in
18 the proposed determination. In making the written deter-
19 mination, the Secretary may modify or rescind the pro-
20 posed determination in accordance with such comments.

21 “(ii)(I) The Secretary may immediately issue an
22 emergency written determination under subparagraph
23 (A)(ii) without first considering comments on a proposed
24 determination.

1 “(II) Within 30 days after the issuance of the emer-
2 gency determination, the Secretary shall consider written
3 comments on the determination that are made by a party
4 described in clause (i) and received within the 30-day pe-
5 riod. The Secretary may affirm, modify, or rescind the
6 emergency determination in accordance with the com-
7 ments.

8 “(III) The emergency determination shall be in
9 effect—

10 “(aa) for the 30-day period; or

11 “(bb) if the Secretary affirms or modifies the
12 determination, until the Secretary rescinds the de-
13 termination.

14 “(2)(A) The covered product initially denied entry
15 under paragraph (1) may be imported into the United
16 States if the Secretary finds that—

17 “(i) the written determination made under
18 paragraph (1) no longer justifies the denial of entry
19 of the covered product; or

20 “(ii) evidence of remedial action submitted from
21 the producer, manufacturer, shipper, specific grow-
22 ing area, or country for which the Secretary made
23 the written determination under paragraph (1) ad-
24 dresses the determination.

1 “(B)(i) The Secretary shall take action on evidence
2 submitted under subparagraph (A)(ii) within 90 days after
3 the date of the submission of the evidence.

4 “(ii) The Secretary’s action may include—

5 “(I) lifting the denial of entry of the covered
6 product; or

7 “(II) continuing to deny entry of the covered
8 product while requesting additional information or
9 specific remedial action from the producer, manufac-
10 turer, shipper, specific growing area, or country.

11 “(iii) If the Secretary does not take action on evi-
12 dence submitted under subparagraph (A)(ii) within 90
13 days after the date of submission, effective on the 91st
14 day after the date of submission, the covered product ini-
15 tially denied entry under paragraph (1) may be imported
16 into the United States.

17 “(3) The Secretary shall by regulation establish cri-
18 teria and procedures for the system described in para-
19 graph (1). The Secretary may by regulation modify those
20 criteria and procedures, as the Secretary determines ap-
21 propriate.”.

22 (c) TECHNICAL AND CONFORMING AMENDMENTS.—

23 (1) Section 351(h) of the Public Health Service
24 Act (42 U.S.C. 262(h)) is amended by striking “sec-
25 tion 801(e)(1) of the Federal Food, Drug, and Cos-

1 metic Act (21 U.S.C. 381(e))” and inserting “sec-
2 tion 801(g)(1) of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 381(g)(1))”.

4 (2) Section 301 of the Federal Food, Drug, and
5 Cosmetic Act (21 U.S.C. 331) is amended—

6 (A) in paragraph (t), by striking “section
7 801(d)(1)” and inserting “section 801(f)(1)”;

8 and

9 (B) in paragraph (w)—

10 (i) by striking “sections 801(d)(3)(A)
11 and 801(d)(3)(B)” and inserting “sub-
12 paragraphs (A) and (B) of section
13 801(f)(3)”;

14 (ii) except as provided in clause (i), by
15 striking “section 801(d)(3)” each place it
16 appears and inserting “section 801(f)(3)”;

17 and

18 (iii) by striking “section 801(e)” and
19 inserting “section 801(g)”.

20 (3) Section 303(b)(1)(A) of the Federal Food,
21 Drug, and Cosmetic Act (21 U.S.C. 333(b)(1)(A)) is
22 amended by striking “section 801(d)(1)” and insert-
23 ing “section 801(f)(1)”.

1 (4) Section 304(d)(1) of the Federal Food,
2 Drug, and Cosmetic Act (21 U.S.C. 334(d)(1)) is
3 amended—

4 (A) by striking “section 801(e)(1)” and in-
5 serting “section 801(g)(1)”; and

6 (B) except as provided in subparagraph
7 (A), by striking “section 801(e)” each place it
8 appears and inserting “section 801(g)”.

9 (5) Section 801 of the Federal Food, Drug, and
10 Cosmetic Act (21 U.S.C. 381) is amended—

11 (A) in subsection (a), in the third sentence,
12 by striking “subsection (b) of this section” and
13 inserting “subsection (b) or subsection
14 (e)(2)(A) (in the case of a covered product de-
15 scribed in that subsection)”;

16 (B) in paragraph (3)(A) of subsection (f),
17 as redesignated in subsection (a), by striking
18 “section 801(e) or 802” and inserting “sub-
19 section (g), section 802,”; and

20 (C) in paragraph (1) of subsection (h), as
21 redesignated in subsection (a), by striking “sub-
22 section (e)” and inserting “subsection (g)”.

23 (6) Section 802 of the Federal Food, Drug, and
24 Cosmetic Act (21 U.S.C. 382) is amended—

1 (A) in subsection (a)(2)(C), by striking
2 “section 801(e)(2)” and inserting “section
3 801(g)(2)”;

4 (B) in subsection (f)(3), by striking “sec-
5 tion 801(e)(1)” and inserting “section
6 801(g)(1)”; and

7 (C) in subsection (i), by striking “section
8 801(e)(1)” and inserting “section 801(g)(1)”.

9 **SEC. 102. PROHIBITION AGAINST THE DISTRIBUTION OF**
10 **CERTAIN PRODUCTS.**

11 (a) **ADULTERATED PRODUCTS.**—Section 402 of the
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342)
13 is amended by adding at the end the following:

14 “(h)(1) If—

15 “(A) it is a covered product being imported or
16 offered for import into the United States;

17 “(B) the covered product has been designated
18 by the Secretary for sampling, examination, or re-
19 view for the purpose of determining whether the cov-
20 ered product is in compliance with this Act;

21 “(C) the Secretary requires, under section
22 801(a)(2)(B), that the covered product not be dis-
23 tributed until the Secretary authorizes the distribu-
24 tion of the covered product; and

1 “(D) the covered product is distributed before
2 the Secretary authorizes the distribution.

3 “(2) In this paragraph, the term ‘distributed’, used
4 with respect to a covered product, means—

5 “(A) moved for the purpose of selling the cov-
6 ered product, offering the covered product for sale,
7 or delivering the covered product for the purpose of
8 selling the covered product or offering the covered
9 product for sale; or

10 “(B) delivered contrary to any bond require-
11 ment.”.

12 (b) PROHIBITION.—Section 801(a) of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is
14 amended—

15 (1) in the third sentence, by redesignating para-
16 graphs (1) through (3) as subparagraphs (A)
17 through (C), respectively;

18 (2) by striking “(a) The” and inserting “(a)(1)
19 The”;

20 (3) in the last sentence, by striking “Clause
21 (2)” and inserting “Subparagraph (B)”;

22 (4) by moving the fourth sentence to the end;

23 (5) in the sentence so moved, by striking “The
24 Secretary” and inserting the following:

25 “(2)(A) The Secretary”; and

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

2 “(B) The Secretary of Health and Human Services
3 may require that a covered product being imported or of-
4 fered for import into the United States not be distributed
5 until the Secretary authorizes distribution of the covered
6 product.”.

7 **SEC. 103. REQUIREMENT OF SECURE STORAGE OF CERTAIN**
8 **IMPORTED PRODUCTS.**

9 (a) **ADULTERATED PRODUCTS.**—Section 402 of the
10 Federal Food, Drug, and Cosmetic Act, as amended in
11 section 102(a), is further amended by adding at the end
12 the following:

13 “(i) If—

14 “(1) it is a covered product being imported or
15 offered for import into the United States;

16 “(2) the Secretary requires, under section
17 801(a)(2)(C), that the covered product be held in a
18 secure storage facility until the Secretary authorizes
19 distribution of the covered product; and

20 “(3) the covered product is not held in a secure
21 storage facility as described in section 801(a)(2)(C)
22 until the Secretary authorizes the distribution.”.

23 (b) **REQUIREMENT.**—Section 801(a)(2) of the Fed-
24 eral Food, Drug, and Cosmetic Act, as amended in section

1 102(b), is further amended by adding at the end the fol-
 2 lowing:

3 “(C)(i) The Secretary of Health and Human Services
 4 may require that a covered product that is being imported
 5 or offered for import into the United States be held, at
 6 the expense of the owner or consignee of the covered prod-
 7 uct, in a secure storage facility until the Secretary author-
 8 izes distribution of the covered product, if the Secretary
 9 makes the determination that the covered product is—

10 “(I) being imported or offered for import into
 11 the United States by a person described in clause
 12 (ii); or

13 “(II) owned by or consigned to a person de-
 14 scribed in clause (ii).

15 “(ii) An importer, owner, or consignee referred to in
 16 subclause (I) or (II) of clause (i) is a person against whom
 17 the Secretary of the Treasury has assessed liquidated
 18 damages not less than twice under subsection (b) for fail-
 19 ure to redeliver, at the request of the Secretary of the
 20 Treasury, a covered product subject to a bond under sub-
 21 section (b).”.

22 **SEC. 104. REQUIREMENT OF ADMINISTRATIVE DESTRUC-**
 23 **TION OF CERTAIN IMPORTED PRODUCTS.**

24 (a) **ADULTERATED PRODUCTS.**—Section 402 of the
 25 Federal Food, Drug, and Cosmetic Act, as amended in

1 section 103(a), is further amended by adding at the end
2 the following:

3 “(j) Notwithstanding subsections (a)(2)(A) and (b) of
4 section 801, if—

5 “(1) it is a covered product being imported or
6 offered for import into the United States;

7 “(2) the covered product presents a reasonable
8 probability of causing significant adverse health con-
9 sequences or death;

10 “(3) the Secretary, after the covered product
11 has been refused admission under section 801(a), re-
12 quires under section 801(a)(2)(D) that the covered
13 product be destroyed; and

14 “(4) the owner or consignee of the covered
15 product fails to comply with that destruction re-
16 quirement.”.

17 (b) REQUIREMENT.—Section 801(a)(2) of the Fed-
18 eral Food, Drug, and Cosmetic Act, as amended in section
19 103(b), is further amended by adding at the end the fol-
20 lowing:

21 “(D) The Secretary of Health and Human Services
22 may require destruction, at the expense of the owner or
23 consignee, of a covered product imported or offered for
24 import into the United States that presents a reasonable

1 probability of causing significant adverse health con-
2 sequences or death.”.

3 **SEC. 105. PROHIBITION AGAINST PORT SHOPPING.**

4 Section 402 of the Federal Food, Drug, and Cosmetic
5 Act, as amended in section 104(a), is further amended by
6 adding at the end the following:

7 “(k) If it is a covered product being imported or of-
8 fered for import into the United States, and the covered
9 product previously has been refused admission under sec-
10 tion 801(a), unless the person reoffering the article affirm-
11 atively establishes, at the expense of the owner or con-
12 signee of the article, that the article complies with the ap-
13 plicable requirements of this Act, as determined by the
14 Secretary.”.

15 **SEC. 106. PROHIBITION OF IMPORTS BY DEBARRED PER-**
16 **SONS.**

17 Section 402 of the Federal Food, Drug, and Cosmetic
18 Act, as amended in section 105, is further amended by
19 adding at the end the following:

20 “(l) If it is a covered product being imported or of-
21 fered for import into the United States by a person
22 debarred under section 306(b)(4).”.

1 **SEC. 107. AUTHORITY TO MARK REFUSED ARTICLES.**

2 (a) MISBRANDED PRODUCTS.—Section 403 of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343)
4 is amended by adding at the end the following:

5 “(t) If—

6 “(1) it has been refused admission under sec-
7 tion 801(a);

8 “(2) the covered product has not been required
9 to be destroyed under subparagraph (A) or (B) of
10 section 801(a)(2); and

11 “(3) the packaging of the covered product does
12 not bear a label or labeling described in section
13 801(a)(2)(E).”.

14 (b) REQUIREMENT.—Section 801(a)(2) of the Fed-
15 eral Food, Drug, and Cosmetic Act, as amended in section
16 104(b), is further amended by adding at the end the fol-
17 lowing:

18 “(E) The Secretary of Health and Human Services
19 may require the owner or consignee of a covered product
20 that has been refused admission under paragraph (1), and
21 has not been required to be destroyed under subparagraph
22 (A) or (B), to affix to the packaging of the covered prod-
23 uct a label or labeling that—

24 “(i) clearly and conspicuously bears the fol-
25 lowing statement: ‘United States: Refused Entry.’;

1 “(ii) is affixed to the packaging until the cov-
2 ered product is brought into compliance with this
3 Act; and

4 “(iii) has been provided at the expense of the
5 owner or consignee of the covered product.”.

6 **SEC. 108. EXPORT OF REFUSED ARTICLES.**

7 Paragraph (2)(A) of section 801(a) of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)), as des-
9 ignated in section 102(b), is amended by striking “ninety
10 days” and inserting “30 days”.

11 **SEC. 109. COLLECTION AND ANALYSIS OF SAMPLES OF**
12 **PRODUCT IMPORTS.**

13 Section 801 of the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 381), as amended in section 101(a), is fur-
15 ther amended by adding at the end the following:

16 “(i) The Secretary may issue regulations or guidance
17 as necessary to govern the collection and analysis by enti-
18 ties other than the Food and Drug Administration of sam-
19 ples of a covered product imported or offered for import
20 into the United States to ensure the integrity of the sam-
21 ples collected and the validity of the analytical results.”.

22 **SEC. 110. DEFINITION.**

23 Section 201 of the Federal Food, Drug, and Cosmetic
24 Act (21 U.S.C. 321) is amended by adding at the end the
25 following:

1 “(kk) The term ‘covered product’ means an article
 2 that is described in subparagraph (1), (2), or (3) of para-
 3 graph (f) and that is not a dietary supplement. The term
 4 shall not include an article to the extent that the Secretary
 5 of Agriculture exercises inspection authority over the arti-
 6 cle at the time of import into the United States.”.

7 **TITLE II—ENFORCEMENT AND**
 8 **PENALTIES FOR IMPORTING**
 9 **CONTAMINATED PRODUCTS**

10 **SEC. 201. ENHANCED BONDING REQUIREMENTS FOR PRIOR**
 11 **INVOLVEMENT IN IMPORTING ADULTERATED**
 12 **OR MISBRANDED PRODUCTS.**

13 Section 801(b) of the Federal Food, Drug, and Cos-
 14 metic Act (21 U.S.C. 381(b)) is amended—

15 (1) by inserting “(1)” after “(b)”; and

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

17 “(2)(A) The Secretary of the Treasury, acting
 18 through the Commissioner of Customs, shall issue regula-
 19 tions that establish a rate for a bond required to be exe-
 20 cuted under paragraph (1) for a covered product if an
 21 owner, consignee, or importer of the covered product has
 22 committed a covered violation.

23 “(B) The regulations shall require the owner or con-
 24 signee to execute such a bond—

25 “(i) at twice the usual rate; or

1 “(ii) if the owner, consignee, or importer has
2 committed more than 1 covered violation, at a rate
3 that increases with the number of covered violations
4 committed, as determined in accordance with a slid-
5 ing scale established in the regulations.

6 “(C) In this paragraph:

7 “(i) The term ‘committed’ means been con-
8 victed of, or found liable for, a violation by an ap-
9 propriate court or administrative officer.

10 “(ii) The term ‘covered violation’ means a viola-
11 tion relating to—

12 “(I) importing or offering for import into
13 the United States—

14 “(aa) a covered product during a pe-
15 riod of debarment under section 306(b)(4);

16 “(bb) a covered product that is adul-
17 terated within the meaning of paragraph
18 (h), (i), (j), (k), or (l) of section 402; or

19 “(cc) a covered product that is mis-
20 branded within the meaning of section
21 403(t); or

22 “(II) making a false or misleading state-
23 ment in conduct relating to the import or offer-
24 ing for import of a covered product into the
25 United States.

1 “(A) IN GENERAL.—The Secretary may
2 debar a person from importing a covered prod-
3 uct or offering a covered product for import
4 into the United States, if—

5 “(i) the Secretary finds that the per-
6 son has been convicted for conduct that is
7 a felony under Federal law and relates to
8 the importation or offering for importation
9 of any covered product into the United
10 States; or

11 “(ii) the Secretary makes a written
12 determination that the person has repeat-
13 edly or deliberately imported or offered for
14 import into the United States a covered
15 product adulterated within the meaning of
16 paragraph (h), (i), (j), or (k) of section
17 402, or misbranded within the meaning of
18 section 403(t).

19 “(B) IMPACT.—On debarring a person
20 under subparagraph (A), the Secretary shall
21 provide notice of the debarment to the Sec-
22 retary of the Treasury, who shall deny entry of
23 a covered product offered for import by the per-
24 son.”.

25 (b) TECHNICAL AND CONFORMING AMENDMENTS.—

1 (1) IN GENERAL.—Section 306 of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C. 335a) is
3 amended—

4 (A) in subsection (c)—

5 (i) in paragraph (1)—

6 (I) in subparagraph (B), by
7 striking “, and” at the end and in-
8 serting a comma;

9 (II) by redesignating subpara-
10 graph (C) as subparagraph (D); and

11 (III) by inserting after subpara-
12 graph (B) the following:

13 “(C) shall, during the period of a debar-
14 ment under subsection (b)(4), prohibit the
15 debarred person from importing a covered prod-
16 uct or offering a covered product for import
17 into the United States, and”;

18 (ii) in paragraph (2)(A), by inserting
19 after clause (iii) the following:

20 “(iv) The period of debarment of any
21 person under subsection (b)(4) shall be not
22 less than 1 year.”; and

23 (iii) in paragraph (3)—

24 (I) in subparagraph (C)—

- 1 (aa) by striking “suspect
2 drugs” and inserting “suspect
3 drugs or covered products”; and
- 4 (bb) by striking “fraudu-
5 lently obtained” and inserting
6 “fraudulently obtained or on a
7 covered product wrongfully im-
8 ported into the United States”;
9 and
- 10 (II) in subparagraph (E), by in-
11 sserting “in the case of a debarment
12 relating to a drug,” after “(E)”;
- 13 (B) in subsection (d)—
- 14 (i) in paragraph (3)—
- 15 (I) in subparagraph (A)—
- 16 (aa) in clause (i), by striking
17 “or (b)(2)(A)” and inserting “or
18 paragraph (2)(A) or (4) of sub-
19 section (b)”;
- 20 (bb) in clause (ii)(II), by in-
21 sserting “in the case of a debar-
22 ment relating to a drug,” after
23 “(II)”;
- 24 (II) in subparagraph (B)—

1 (aa) in clause (i), by striking
2 “or clause (i), (ii), (iii) or (iv) of
3 subsection (b)(2)(B)” and insert-
4 ing “, clause (i), (ii), (iii), or (iv)
5 of subsection (b)(2)(B), or sub-
6 section (b)(4)”; and

7 (bb) in clause (ii), by strik-
8 ing “subsection (b)(2)(B)” and
9 inserting “paragraph (2)(B) or
10 (4) of subsection (b)”; and

11 (ii) in paragraph (4)—

12 (I) in subparagraph (A), by strik-
13 ing “(a)(2)” and inserting “(a)(2) or
14 (b)(4)”; and

15 (II) in subparagraph (B)—

16 (aa) in clause (ii), by strik-
17 ing “involving the development or
18 approval of any drug subject to
19 section 505” and inserting “in-
20 volving, as appropriate, the devel-
21 opment or approval of any drug
22 subject to section 505 or the im-
23 portation of any covered prod-
24 uct”; and

1 (bb) in clause (iv), by strik-
2 ing “drug” each place it appears
3 and inserting “drug or covered
4 product”; and

5 (III) in subparagraph (D), in the
6 matter following clause (ii), by insert-
7 ing “, in the case of a debarment re-
8 lating to a drug,” before “protects”;
9 and

10 (C) in subsection (l)(2), in the second sen-
11 tence, by striking “(b)(2)(B)” and inserting
12 “(b)(2)(B), subsection (b)(4),”.

13 (2) CIVIL PENALTIES.—Paragraphs (6) and (7)
14 of section 307(a) of the Federal Food, Drug, and
15 Cosmetic Act (21 U.S.C. 335b(a)) are amended by
16 striking “306” and inserting “306 (except section
17 306(b)(4))”.

18 **SEC. 203. INCREASED ENFORCEMENT TO IMPROVE THE**
19 **SAFETY OF IMPORTED PRODUCTS.**

20 Subchapter A of chapter VII of the Federal Food,
21 Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amend-
22 ed by adding at the end the following:

1 **“SEC. 712. POSITIONS TO IMPROVE THE SAFETY OF IM-**
 2 **PORTED PRODUCTS.**

3 “There is authorized to be appropriated such sums
 4 as may be necessary for each of fiscal years 2001 through
 5 2003 to enable the Commissioner, in carrying out chapters
 6 IV and VIII, to decrease the health risks associated with
 7 imported covered products through the creation of addi-
 8 tional employment positions for laboratory, inspection,
 9 and compliance personnel.”.

10 **TITLE III—IMPROVEMENTS TO**
 11 **PUBLIC HEALTH INFRA-**
 12 **STRUCTURE AND AWARENESS**

13 **SEC. 301. IMPROVEMENTS.**

14 Title II of the Public Health Service Act (42 U.S.C.
 15 202 et seq.) is amended by adding at the end the fol-
 16 lowing:

17 **“PART C—PUBLIC HEALTH INFRASTRUCTURE**
 18 **AND AWARENESS**

19 **“SEC. 251. DEFINITIONS.**

20 “In this part:

21 “(1) COVERED PRODUCT.—The term ‘covered
 22 product’ has the meaning given the term in section
 23 201 of the Federal Food, Drug, and Cosmetic Act
 24 (21 U.S.C. 321).

25 “(2) INSTITUTION OF HIGHER EDUCATION.—

26 The term ‘institution of higher education’ has the

1 meaning given the term in section 101(a) of the
2 Higher Education Act of 1965 (20 U.S.C. 1001(a)).

3 “(3) SECRETARY.—The term ‘Secretary’ means
4 the Secretary of Health and Human Services, acting
5 through the Director of the Centers for Disease
6 Control and Prevention.

7 **“SEC. 252. PUBLIC HEALTH SURVEILLANCE ENHANCE-**
8 **MENT.**

9 “(a) IN GENERAL.—The Secretary may—

10 “(1) make grants to, enter into cooperative
11 agreements with, and provide technical assistance to
12 eligible agencies to enable the agencies to enhance
13 their capacity to carry out activities relating to sur-
14 veillance and prevention of pathogen-related disease
15 borne in a covered product, particularly pathogen-re-
16 lated disease associated with imported covered prod-
17 ucts, as described in subsection (b)(1); and

18 “(2) carry out the activities described in sub-
19 section (b)(2).

20 “(b) USE OF ASSISTANCE.—

21 “(1) AGENCIES.—An eligible agency that re-
22 ceives assistance under subsection (a) shall use the
23 assistance to enhance the capacity of the agency—

24 “(A) to identify, investigate, and contain
25 threats of pathogen-related disease borne in a

1 covered product, particularly pathogen-related
2 disease associated with imported covered prod-
3 ucts; and

4 “(B) to conduct additional surveillance and
5 studies to address prevention and control of the
6 disease.

7 “(2) CENTERS FOR DISEASE CONTROL AND
8 PREVENTION.—The Secretary may use not more
9 than 30 percent of the funds appropriated to carry
10 out this section—

11 “(A) to assist an agency described in para-
12 graph (1) in enhancing the capacity described
13 in paragraph (1) by providing standards, tech-
14 nologies, information, materials, and other re-
15 sources; and

16 “(B) to enhance national surveillance sys-
17 tems, including the ability of domestic and
18 international agencies and entities to respond to
19 product safety issues associated with imported
20 covered products that are identified through
21 such systems.

22 “(c) ELIGIBLE AGENCIES.—To be eligible to receive
23 assistance under subsection (a)(1), an agency shall be a
24 State or local health department.

1 application to the Secretary at such time, in such manner,
2 and containing such information as the Secretary may re-
3 quire.

4 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
5 are authorized to be appropriated to carry out this section
6 such sums as may be necessary for fiscal years 2001
7 through 2003.

8 **“SEC. 256. SUPPLIES AND SERVICES IN LIEU OF GRANT**
9 **FUNDS.**

10 “(a) IN GENERAL.—On the request of a recipient of
11 assistance under section 252, 253, 254, or 255, the Sec-
12 retary may, subject to subsection (b), provide supplies,
13 equipment, and services for the purpose of aiding the re-
14 cipient in carrying out the section involved and, for such
15 purpose, may detail to the grant recipient any officer or
16 employee of the Department of Health and Human Serv-
17 ices. Such detail shall be without interruption or loss of
18 civil service status or privilege.

19 “(b) CORRESPONDING REDUCTION IN PAYMENTS.—
20 With respect to a request described in subsection (a), the
21 Secretary shall reduce the amount of payments under the
22 section involved by an amount equal to the cost of detail-
23 ing the officer or employee and the fair market value of
24 the supplies, equipment, or services provided by the Sec-
25 retary. The Secretary shall, for the payment of expenses

1 incurred in complying with such a request, expend the
2 amounts withheld.”.

○