

109TH CONGRESS
2D SESSION

S. 3546

To amend the Federal Food, Drug, and Cosmetic Act with respect to serious adverse event reporting for dietary supplements and nonprescription drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 21, 2006

Mr. HATCH (for himself, Mr. DURBIN, Mr. HARKIN, Mr. ENZI, and Mr. KENNEDY) 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 with respect to serious adverse event reporting for dietary supplements and nonprescription drugs, 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 “Dietary Supplement
5 and Nonprescription Drug Consumer Protection Act”.

1 **SEC. 2. SERIOUS ADVERSE EVENT REPORTING FOR NON-**
 2 **PRESCRIPTION DRUGS.**

3 (a) IN GENERAL.—Chapter VII of the Federal Food,
 4 Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amend-
 5 ed by adding at the end the following:

6 **“Subchapter H—Serious Adverse Event**
 7 **Reports**

8 **“SEC. 760. SERIOUS ADVERSE EVENT REPORTING FOR NON-**
 9 **PRESCRIPTION DRUGS.**

10 “(a) DEFINITIONS.—In this section:

11 “(1) ADVERSE EVENT.—The term ‘adverse
 12 event’ means any health-related event associated
 13 with the use of a nonprescription drug that is ad-
 14 verse, including—

15 “(A) an event occurring from an overdose
 16 of the drug, whether accidental or intentional;

17 “(B) an event occurring from abuse of the
 18 drug;

19 “(C) an event occurring from withdrawal
 20 from the drug; and

21 “(D) any failure of expected pharma-
 22 cological action of the drug.

23 “(2) NONPRESCRIPTION DRUG.—The term
 24 ‘nonprescription drug’ means a drug that is—

25 “(A) not subject to section 503(b); and

1 “(B) not subject to approval in an applica-
2 tion submitted under section 505.

3 “(3) SERIOUS ADVERSE EVENT.—The term ‘se-
4 rious adverse event’ is an adverse event that—

5 “(A) results in—

6 “(i) death;

7 “(ii) a life-threatening experience;

8 “(iii) inpatient hospitalization;

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

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

13 “(B) requires, based on reasonable medical
14 judgment, a medical or surgical intervention to
15 prevent an outcome described under subpara-
16 graph (A).

17 “(4) SERIOUS ADVERSE EVENT REPORT.—The
18 term ‘serious adverse event report’ means a report
19 that is required to be submitted to the Secretary
20 under subsection (b).

21 “(b) REPORTING REQUIREMENT.—The manufac-
22 turer, packer, or distributor whose name (pursuant to sec-
23 tion 502(b)(1)) appears on the label of a nonprescription
24 drug marketed in the United States (referred to in this
25 section as the ‘responsible person’) shall submit to the

1 Secretary any report received of a serious adverse event
2 associated with such drug when used in the United States,
3 accompanied by a copy of the label on or within the retail
4 package of such drug.

5 “(c) SUBMISSION OF REPORTS.—

6 “(1) TIMING OF REPORTS.—The responsible
7 person shall submit to the Secretary a serious ad-
8 verse event report no later than 15 business days
9 after the report is received through the address or
10 phone number described in section 502(x).

11 “(2) NEW MEDICAL INFORMATION.—The re-
12 sponsible person shall submit to the Secretary any
13 new medical information, related to a submitted seri-
14 ous adverse event report that is received by the re-
15 sponsible person within 1 year of the initial report,
16 no later than 15 business days after the new infor-
17 mation is received by the responsible person.

18 “(3) CONSOLIDATION OF REPORTS.—The Sec-
19 retary shall develop systems to ensure that duplicate
20 reports of, and new medical information related to,
21 a serious adverse event shall be consolidated into a
22 single report.

23 “(4) EXEMPTION.—The Secretary, after pro-
24 viding notice and an opportunity for comment from
25 interested parties, may establish an exemption to the

1 requirements under paragraphs (1) and (2) if the
2 Secretary determines that such exemption would
3 have no adverse effect on public health.

4 “(d) CONTENTS OF REPORTS.—Each serious adverse
5 event report under this section shall be submitted to the
6 Secretary using the MedWatch form, which may be modi-
7 fied by the Secretary for nonprescription drugs, and may
8 be accompanied by additional information.

9 “(e) MAINTENANCE AND INSPECTION OF
10 RECORDS.—

11 “(1) MAINTENANCE.—The responsible person
12 shall maintain records related to each report of an
13 adverse event received by the responsible person for
14 a period of 6 years.

15 “(2) RECORDS INSPECTION.—

16 “(A) IN GENERAL.—The responsible per-
17 son shall permit an authorized person to have
18 access to records required to be maintained
19 under this section, during an inspection pursu-
20 ant to section 704.

21 “(B) AUTHORIZED PERSON.—For pur-
22 poses of this paragraph, the term ‘authorized
23 person’ means an officer or employee of the De-
24 partment of Health and Human Services who
25 has—

1 “(i) appropriate credentials, as deter-
2 mined by the Secretary; and

3 “(ii) been duly designated by the Sec-
4 retary to have access to the records re-
5 quired under this section.

6 “(f) PROTECTED INFORMATION.—A serious adverse
7 event report submitted to the Secretary under this section,
8 including any new medical information submitted under
9 subsection (c)(2), or an adverse event report voluntarily
10 submitted to the Secretary shall be considered to be—

11 “(1) a safety report under section 756 and may
12 be accompanied by a statement, which shall be a
13 part of any report that is released for public disclo-
14 sure, that denies that the report or the records con-
15 stitute an admission that the product involved
16 caused or contributed to the adverse event; and

17 “(2) a record about an individual under section
18 552a of title 5, United States Code (commonly re-
19 ferred to as the ‘Privacy Act of 1974’) and a med-
20 ical or similar file the disclosure of which would con-
21 stitute a violation of section 552 of such title 5
22 (commonly referred to as the ‘Freedom of Informa-
23 tion Act’), and shall not be publicly disclosed unless
24 all personally identifiable information is redacted.

1 “(g) RULE OF CONSTRUCTION.—The submission of
 2 any adverse event report in compliance with this section
 3 shall not be construed as an admission that the non-
 4 prescription drug involved caused or contributed to the ad-
 5 verse event.

6 “(h) PREEMPTION.—

7 “(1) IN GENERAL.—No State or local govern-
 8 ment shall establish or continue in effect any law,
 9 regulation, order, or other requirement, related to a
 10 mandatory system for adverse event reports for non-
 11 prescription drugs, that is different from, in addition
 12 to, or otherwise not identical to, this section.

13 “(2) EFFECT OF SECTION.—

14 “(A) IN GENERAL.—Nothing in this sec-
 15 tion shall affect the authority of the Secretary
 16 to provide adverse event reports and informa-
 17 tion to any health, food, or drug officer or em-
 18 ployee of any State, territory, or political sub-
 19 division of a State or territory, under a memo-
 20 randum of understanding between the Secretary
 21 and such State, territory, or political subdivi-
 22 sion.

23 “(B) PERSONALLY-IDENTIFIABLE INFOR-
 24 MATION.—Notwithstanding any other provision
 25 of law, personally-identifiable information in ad-

verse event reports provided by the Secretary to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, shall not—

“(i) be made publicly available pursuant to any State or other law requiring disclosure of information or records; or

“(ii) otherwise be disclosed or distributed to any party without the written consent of the Secretary and the person submitting such information to the Secretary.

“(C) USE OF SAFETY REPORTS.—Nothing in this section shall permit a State, territory, or political subdivision of a State or territory, to use any safety report received from the Secretary in a manner inconsistent with subsection (g) or section 756.

“(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary.”.

(b) MODIFICATIONS.—The Secretary of Health and Human Services may modify requirements under the amendments made by this section in accordance with section 553 of title 5, United States Code, to maintain con-

1 sistency with international harmonization efforts over
2 time.

3 (c) PROHIBITED ACT.—Section 301(e) of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 331(e)) is
5 amended by—

6 (1) striking “, or 704(a);” and inserting “,
7 704(a), or 760;”; and

8 (2) striking “, or 564” and inserting “, 564, or
9 760”.

10 (d) MISBRANDING.—Section 502 of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amend-
12 ed by adding at the end the following:

13 “(x) If it is a nonprescription drug (as defined in sec-
14 tion 760) that is marketed in the United States, unless
15 the label of such drug includes an address or phone num-
16 ber through which the responsible person (as described in
17 section 760) may receive a report of a serious adverse
18 event (as defined in section 760) with such drug.”.

19 (e) EFFECTIVE DATES.—

20 (1) IN GENERAL.—Except as provided in para-
21 graph (2), the amendments made by this section
22 shall take effect 1 year after the date of enactment
23 of this Act.

24 (2) MISBRANDING.—Section 502(x) of the Fed-
25 eral Food, Drug, and Cosmetic Act (as added by

1 this section) shall apply to any nonprescription drug
 2 (as defined in such section 502(x)) labeled on or
 3 after the date that is 1 year after the date of enact-
 4 ment of this Act.

5 (3) GUIDANCE.—Not later than 270 days after
 6 the date of enactment of this Act, the Secretary of
 7 Health and Human Services shall issue guidance on
 8 the minimum data elements that should be included
 9 in a serious adverse event report described under the
 10 amendments made by this Act.

11 **SEC. 3. SERIOUS ADVERSE EVENT REPORTING FOR DIE-**
 12 **TARY SUPPLEMENTS.**

13 (a) IN GENERAL.—Chapter VII of the Federal Food,
 14 Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amend-
 15 ed by adding at the end the following:

16 **“SEC. 761. SERIOUS ADVERSE EVENT REPORTING FOR DIE-**
 17 **TARY SUPPLEMENTS.**

18 “(a) DEFINITIONS.—In this section:

19 “(1) ADVERSE EVENT.—The term ‘adverse
 20 event’ means any health-related event associated
 21 with the use of a dietary supplement that is adverse.

22 “(2) SERIOUS ADVERSE EVENT.—The term ‘se-
 23 rious adverse event’ is an adverse event that—

24 “(A) results in—

25 “(i) death;

- 1 “(ii) a life-threatening experience;
2 “(iii) inpatient hospitalization;
3 “(iv) a persistent or significant dis-
4 ability or incapacity; or
5 “(v) a congenital anomaly or birth de-
6 fect; or

7 “(B) requires, based on reasonable medical
8 judgment, a medical or surgical intervention to
9 prevent an outcome described under subpara-
10 graph (A).

11 “(3) SERIOUS ADVERSE EVENT REPORT.—The
12 term ‘serious adverse event report’ means a report
13 that is required to be submitted to the Secretary
14 under subsection (b).

15 “(b) REPORTING REQUIREMENT.—

16 “(1) IN GENERAL.—The manufacturer, packer,
17 or distributor of a dietary supplement whose name
18 (pursuant to section 403(e)(1)) appears on the label
19 of a dietary supplement marketed in the United
20 States (referred to in this section as the ‘responsible
21 person’) shall submit to the Secretary any report re-
22 ceived of a serious adverse event associated with
23 such dietary supplement when used in the United
24 States, accompanied by a copy of the label on or

1 within the retail packaging of such dietary supple-
2 ment.

3 “(2) RETAILER.—A retailer whose name ap-
4 pears on the label described in paragraph (1) as a
5 distributor may, by agreement, authorize the manu-
6 facturer or packer of the dietary supplement to sub-
7 mit the required reports for such dietary supple-
8 ments to the Secretary so long as the retailer directs
9 to the manufacturer or packer all adverse events as-
10 sociated with such dietary supplement that are re-
11 ported to the retailer through the address or tele-
12 phone number described in section 403(y).

13 “(c) SUBMISSION OF REPORTS.—

14 “(1) TIMING OF REPORTS.—The responsible
15 person shall submit to the Secretary a serious ad-
16 verse event report no later than 15 business days
17 after the report is received through the address or
18 phone number described in section 403(y).

19 “(2) NEW MEDICAL INFORMATION.—The re-
20 sponsible person shall submit to the Secretary any
21 new medical information, related to a submitted seri-
22 ous adverse event report that is received by the re-
23 sponsible person within 1 year of the initial report,
24 no later than 15 business days after the new infor-
25 mation is received by the responsible person.

1 “(3) CONSOLIDATION OF REPORTS.—The Sec-
2 retary shall develop systems to ensure that duplicate
3 reports of, and new medical information related to,
4 a serious adverse event shall be consolidated into a
5 single report.

6 “(4) EXEMPTION.—The Secretary, after pro-
7 viding notice and an opportunity for comment from
8 interested parties, may establish an exemption to the
9 requirements under paragraphs (1) and (2) if the
10 Secretary determines that such exemption would
11 have no adverse effect on public health.

12 “(d) CONTENTS OF REPORTS.—Each serious adverse
13 event report under this section shall be submitted to the
14 Secretary using the MedWatch form, which may be modi-
15 fied by the Secretary for dietary supplements, and may
16 be accompanied by additional information.

17 “(e) MAINTENANCE AND INSPECTION OF
18 RECORDS.—

19 “(1) MAINTENANCE.—The responsible person
20 shall maintain records related to each report of an
21 adverse event received by the responsible person for
22 a period of 6 years.

23 “(2) RECORDS INSPECTION.—

24 “(A) IN GENERAL.—The responsible per-
25 son shall permit an authorized person to have

1 access to records required to be maintained
2 under this section during an inspection pursu-
3 ant to section 704.

4 “(B) AUTHORIZED PERSON.—For pur-
5 poses of this paragraph, the term ‘authorized
6 person’ means an officer or employee of the De-
7 partment of Health and Human Services, who
8 has—

9 “(i) appropriate credentials, as deter-
10 mined by the Secretary; and

11 “(ii) been duly designated by the Sec-
12 retary to have access to the records re-
13 quired under this section.

14 “(f) PROTECTED INFORMATION.—A serious adverse
15 event report submitted to the Secretary under this section,
16 including any new medical information submitted under
17 subsection (c)(2), or an adverse event report voluntarily
18 submitted to the Secretary shall be considered to be—

19 “(1) a safety report under section 756 and may
20 be accompanied by a statement, which shall be a
21 part of any report that is released for public dislo-
22 sure, that denies that the report or the records con-
23 stitute an admission that the product involved
24 caused or contributed to the adverse event; and

1 “(2) a record about an individual under section
 2 552a of title 5, United States Code (commonly re-
 3 ferred to as the ‘Privacy Act of 1974’) and a med-
 4 ical or similar file the disclosure of which would con-
 5 stitute a violation of section 552 of such title 5
 6 (commonly referred to as the ‘Freedom of Informa-
 7 tion Act’), and shall not be publicly disclosed unless
 8 all personally identifiable information is redacted.

9 “(g) RULE OF CONSTRUCTION.—The submission of
 10 any adverse event report in compliance with this section
 11 shall not be construed as an admission that the dietary
 12 supplement involved caused or contributed to the adverse
 13 event.

14 “(h) PREEMPTION.—

15 “(1) IN GENERAL.—No State or local govern-
 16 ment shall establish or continue in effect any law,
 17 regulation, order, or other requirement, related to a
 18 mandatory system for adverse event reports for die-
 19 tary supplements, that is different from, in addition
 20 to, or otherwise not identical to, this section.

21 “(2) EFFECT OF SECTION.—

22 “(A) IN GENERAL.—Nothing in this sec-
 23 tion shall affect the authority of the Secretary
 24 to provide adverse event reports and informa-
 25 tion to any health, food, or drug officer or em-

1 ployee of any State, territory, or political sub-
2 division of a State or territory, under a memo-
3 randum of understanding between the Secretary
4 and such State, territory, or political subdivi-
5 sion.

6 “(B) PERSONALLY-IDENTIFIABLE INFOR-
7 MATION.—Notwithstanding any other provision
8 of law, personally-identifiable information in ad-
9 verse event reports provided by the Secretary to
10 any health, food, or drug officer or employee of
11 any State, territory, or political subdivision of a
12 State or territory, shall not—

13 “(i) be made publicly available pursu-
14 ant to any State or other law requiring dis-
15 closure of information or records; or

16 “(ii) otherwise be disclosed or distrib-
17 uted to any party without the written con-
18 sent of the Secretary and the person sub-
19 mitting such information to the Secretary.

20 “(C) USE OF SAFETY REPORTS.—Nothing
21 in this section shall permit a State, territory, or
22 political subdivision of a State or territory, to
23 use any safety report received from the Sec-
24 retary in a manner inconsistent with subsection
25 (g) or section 756.

1 “(i) AUTHORIZATION OF APPROPRIATIONS.—There
2 are authorized to be appropriated to carry out this section
3 such sums as may be necessary.”.

4 (b) PROHIBITED ACT.—Section 301(e) of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 331(e)) is
6 amended by—

7 (1) striking “, or 760;” and inserting “, 760,
8 or 761;”; and

9 (2) striking “, or 760” and inserting “, 760, or
10 761”.

11 (c) MISBRANDING.—Section 403 of the Federal
12 Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amend-
13 ed by adding at the end the following:

14 “(y) If it is a dietary supplement that is marketed
15 in the United States, unless the label of such dietary sup-
16 plement includes an address or phone number through
17 which the responsible person (as described in section 761)
18 may receive a report of a serious adverse event with such
19 dietary supplement.”.

20 (d) EFFECTIVE DATE.—

21 (1) IN GENERAL.—Except as provided in para-
22 graph (2), the amendments made by this section
23 shall take effect 1 year after the date of enactment
24 of this Act.

1 (2) MISBRANDING.—Section 403(y) of the Fed-
 2 eral Food, Drug, and Cosmetic Act (as added by
 3 this section) shall apply to any dietary supplement
 4 labeled on or after the date that is 1 year after the
 5 date of enactment of this Act.

6 (3) GUIDANCE.—Not later than 270 days after
 7 the date of enactment of this Act, the Secretary of
 8 Health and Human Services shall issue guidance on
 9 the minimum data elements that should be included
 10 in a serious adverse event report as described under
 11 the amendments made by this Act.

12 **SEC. 4. PROHIBITION OF FALSIFICATION OF REPORTS.**

13 (a) IN GENERAL.—Section 301 of the Federal Food,
 14 Drug, and Cosmetic Act (21 U.S.C. 331) is amended by
 15 adding at the end the following:

16 “(ii) The falsification of a report of a serious adverse
 17 event submitted to a responsible person (as defined under
 18 section 760 or 761) or the falsification of a serious adverse
 19 event report (as defined under section 760 or 761) sub-
 20 mitted to the Secretary.”.

21 (b) EFFECTIVE DATE.—The amendment made by
 22 this section shall take effect 1 year after the date of enact-
 23 ment of this Act.

