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109TH CONGRESS
2^D SESSION

S. 3546

[Report No. 109–324]

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, Mr. KENNEDY, and Mr. CORNYN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

SEPTEMBER 5, 2006

Reported by Mr. ENZI, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Dietary Supplement
3 and Nonprescription Drug Consumer Protection Act”.

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

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

9 **“Subchapter H—Serious Adverse Event**
10 **Reports**

11 **“SEC. 760. SERIOUS ADVERSE EVENT REPORTING FOR NON-**
12 **PRESCRIPTION DRUGS.**

13 “(a) DEFINITIONS.—In this section:

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

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

20 “(B) an event occurring from abuse of the
21 drug;

22 “(C) an event occurring from withdrawal
23 from the drug; and

24 “(D) any failure of expected pharma-
25 eological action of the drug.

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

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

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

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

8 “(A) results in—

9 “(i) death;

10 “(ii) a life-threatening experience;

11 “(iii) inpatient hospitalization;

12 “(iv) a persistent or significant dis-
13 ability or incapacity; or

14 “(v) a congenital anomaly or birth de-
15 fect; or

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

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

24 “(b) REPORTING REQUIREMENT.—The manufac-
25 turer, packer, or distributor whose name (pursuant to sec-

tion 502(b)(1)) appears on the label of a nonprescription drug marketed in the United States (referred to in this section as the ‘responsible person’) shall submit to the Secretary any report received of a serious adverse event associated with such drug when used in the United States, accompanied by a copy of the label on or within the retail package of such drug.

“(c) SUBMISSION OF REPORTS.—

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

“(2) NEW MEDICAL INFORMATION.—The responsible person shall submit to the Secretary any new medical information, related to a submitted serious adverse event report that is received by the responsible person within 1 year of the initial report, no later than 15 business days after the new information is received by the responsible person.

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

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

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

12 “(e) MAINTENANCE AND INSPECTION OF
 13 RECORDS.—

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

18 “(2) RECORDS INSPECTION.—

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

24 “(B) AUTHORIZED PERSON.—For pur-
 25 poses of this paragraph, the term ‘authorized

person' means an officer or employee of the Department of Health and Human Services who has—

“(i) appropriate credentials, as determined by the Secretary; and

“(ii) been duly designated by the Secretary to have access to the records required under this section.

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

“(1) a safety report under section 756 and may be accompanied by a statement, which shall be a part of any report that is released for public disclosure, that denies that the report or the records constitute an admission that the product involved caused or contributed to the adverse event; and

“(2) a record about an individual under section 552a of title 5, United States Code (commonly referred to as the ‘Privacy Act of 1974’) and a medical or similar file the disclosure of which would constitute a violation of section 552 of such title 5 (commonly referred to as the ‘Freedom of Informa-

tion Act’), and shall not be publicly disclosed unless
all personally identifiable information is redacted.

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

“(h) ~~PREEMPTION.~~—

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

“(2) ~~EFFECT OF SECTION.~~—

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

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

8 ~~“(i) be made publicly available pursu-~~
 9 ~~ant to any State or other law requiring dis-~~
 10 ~~closure of information or records; or~~

11 ~~“(ii) otherwise be disclosed or distrib-~~
 12 ~~uted to any party without the written con-~~
 13 ~~sent of the Secretary and the person sub-~~
 14 ~~mitting such information to the Secretary.~~

15 ~~“(C) USE OF SAFETY REPORTS.—~~Nothing
 16 ~~in this section shall permit a State, territory, or~~
 17 ~~political subdivision of a State or territory, to~~
 18 ~~use any safety report received from the Sec-~~
 19 ~~retary in a manner inconsistent with subsection~~
 20 ~~(g) or section 756.~~

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

24 ~~(b) MODIFICATIONS.—~~The Secretary of Health and
 25 ~~Human Services may modify requirements under the~~

1 amendments made by this section in accordance with sec-
 2 tion ~~553~~ of title 5, United States Code, to maintain con-
 3 sistency with international harmonization efforts over
 4 time.

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

8 (1) striking “, or 704(a);” and inserting “,
 9 704(a), or 760;” and

10 (2) striking “, or 564” and inserting “, 564, or
 11 760”.

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

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

21 (e) ~~EFFECTIVE DATES.~~—

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

1 ~~(2) MISBRANDING.—~~Section 502(x) of the Fed-
 2 eral Food, Drug, and Cosmetic Act (as added by
 3 this section) shall apply to any nonprescription drug
 4 (as defined in such section 502(x)) labeled on or
 5 after the date that is 1 year after the date of enact-
 6 ment of this Act.

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

13 **SEC. 3. SERIOUS ADVERSE EVENT REPORTING FOR DIE-**
 14 **TARY SUPPLEMENTS.**

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

18 **“SEC. 761. SERIOUS ADVERSE EVENT REPORTING FOR DIE-**
 19 **TARY SUPPLEMENTS.**

20 ~~“(a) DEFINITIONS.—~~In this section:

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

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

1 “(A) results in—

2 “(i) death;

3 “(ii) a life-threatening experience;

4 “(iii) inpatient hospitalization;

5 “(iv) a persistent or significant dis-
6 ability or incapacity; or

7 “(v) a congenital anomaly or birth de-
8 fect; or

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

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

17 “(b) REPORTING REQUIREMENT.—

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

1 States, accompanied by a copy of the label on or
2 within the retail packaging of such dietary supple-
3 ment.

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

14 “(c) SUBMISSION OF REPORTS.—

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

20 “(2) NEW MEDICAL INFORMATION.—The re-
21 sponsible person shall submit to the Secretary any
22 new medical information, related to a submitted seri-
23 ous adverse event report that is received by the re-
24 sponsible person within 1 year of the initial report,

1 no later than 15 business days after the new infor-
2 mation is received by the responsible person.

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

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

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

19 ~~“(e) MAINTENANCE AND INSPECTION OF~~
20 ~~RECORDS.—~~

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

25 ~~“(2) RECORDS INSPECTION.—~~

1 “(A) ~~IN GENERAL.~~—The responsible per-
 2 son shall permit an authorized person to have
 3 access to records required to be maintained
 4 under this section during an inspection pursu-
 5 ant to section 704.

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

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

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

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

21 “(1) a safety report under section 756 and may
 22 be accompanied by a statement, which shall be a
 23 part of any report that is released for public disclo-
 24 sure, that denies that the report or the records con-

1 stitute an admission that the product involved
2 caused or contributed to the adverse event; and

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

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

16 ~~“(h) PREEMPTION.—~~

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

23 ~~“(2) EFFECT OF SECTION.—~~

24 ~~“(A) IN GENERAL.—Nothing in this sec-~~
25 ~~tion shall affect the authority of the Secretary~~

1 to provide adverse event reports and informa-
 2 tion to any health, food, or drug officer or em-
 3 ployee of any State, territory, or political sub-
 4 division of a State or territory, under a memo-
 5 randum of understanding between the Secretary
 6 and such State, territory, or political subdivi-
 7 sion.

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

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

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

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

1 retary in a manner inconsistent with subsection
2 (g) or section 756.

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

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

9 (1) striking “, or 760;” and inserting “, 760,
10 or 761;”; and

11 (2) striking “, or 760” and inserting “, 760, or
12 761”.

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

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

22 (d) EFFECTIVE DATE.—

23 (1) IN GENERAL.—Except as provided in para-
24 graph (2), the amendments made by this section

1 shall take effect 1 year after the date of enactment
2 of this Act.

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

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

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

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

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

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

1 **SECTION 1. SHORT TITLE.**

2 *This Act may be cited as the “Dietary Supplement and*
 3 *Nonprescription Drug Consumer Protection Act”.*

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

6 *(a) IN GENERAL.—Chapter VII of the Federal Food,*
 7 *Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended*
 8 *by adding at the end the following:*

9 **“Subchapter H—Serious Adverse Event**
 10 **Reports**

11 **“SEC. 760. SERIOUS ADVERSE EVENT REPORTING FOR NON-**
 12 **PRESCRIPTION DRUGS.**

13 *“(a) DEFINITIONS.—In this section:*

14 *“(1) ADVERSE EVENT.—The term ‘adverse event’*
 15 *means any health-related event associated with the*
 16 *use of a nonprescription drug that is adverse, includ-*
 17 *ing—*

18 *“(A) an event occurring from an overdose of*
 19 *the drug, whether accidental or intentional;*

20 *“(B) an event occurring from abuse of the*
 21 *drug;*

22 *“(C) an event occurring from withdrawal*
 23 *from the drug; and*

24 *“(D) any failure of expected pharma-*
 25 *cological action of the drug.*

1 “(2) *NONPRESCRIPTION DRUG.*—*The term ‘non-*
 2 *prescription drug’ means a drug that is—*

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

4 “(B) *not subject to approval in an applica-*
 5 *tion submitted under section 505.*

6 “(3) *SERIOUS ADVERSE EVENT.*—*The term ‘seri-*
 7 *ous adverse event’ is an adverse event that—*

8 “(A) *results in—*

9 “(i) *death;*

10 “(ii) *a life-threatening experience;*

11 “(iii) *inpatient hospitalization;*

12 “(iv) *a persistent or significant dis-*
 13 *ability or incapacity; or*

14 “(v) *a congenital anomaly or birth de-*
 15 *fect; or*

16 “(B) *requires, based on reasonable medical*
 17 *judgment, a medical or surgical intervention to*
 18 *prevent an outcome described under subpara-*
 19 *graph (A).*

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

24 “(b) *REPORTING REQUIREMENT.*—

1 “(1) *IN GENERAL.*—*The manufacturer, packer,*
 2 *or distributor whose name (pursuant to section*
 3 *502(b)(1)) appears on the label of a nonprescription*
 4 *drug marketed in the United States (referred to in*
 5 *this section as the ‘responsible person’)* shall submit
 6 *to the Secretary any report received of a serious ad-*
 7 *verse event associated with such drug when used in*
 8 *the United States, accompanied by a copy of the label*
 9 *on or within the retail package of such drug.*

10 “(2) *RETAILER.*—*A retailer whose name appears*
 11 *on the label described in paragraph (1) as a dis-*
 12 *tributor may, by agreement, authorize the manufac-*
 13 *turer or packer of the nonprescription drug to submit*
 14 *the required reports for such drugs to the Secretary so*
 15 *long as the retailer directs to the manufacturer or*
 16 *packer all adverse events associated with such drug*
 17 *that are reported to the retailer through the address*
 18 *or telephone number described in section 502(x).*

19 “(c) *SUBMISSION OF REPORTS.*—

20 “(1) *TIMING OF REPORTS.*—*The responsible per-*
 21 *son shall submit to the Secretary a serious adverse*
 22 *event report no later than 15 business days after the*
 23 *report is received through the address or phone num-*
 24 *ber described in section 502(x).*

1 “(2) *NEW MEDICAL INFORMATION.*—*The respon-*
 2 *sible person shall submit to the Secretary any new*
 3 *medical information, related to a submitted serious*
 4 *adverse event report that is received by the responsible*
 5 *person within 1 year of the initial report, no later*
 6 *than 15 business days after the new information is*
 7 *received by the responsible person.*

8 “(3) *CONSOLIDATION OF REPORTS.*—*The Sec-*
 9 *retary shall develop systems to ensure that duplicate*
 10 *reports of, and new medical information related to, a*
 11 *serious adverse event shall be consolidated into a sin-*
 12 *gle report.*

13 “(4) *EXEMPTION.*—*The Secretary, after pro-*
 14 *viding notice and an opportunity for comment from*
 15 *interested parties, may establish an exemption to the*
 16 *requirements under paragraphs (1) and (2) if the*
 17 *Secretary determines that such exemption would have*
 18 *no adverse effect on public health.*

19 “(d) *CONTENTS OF REPORTS.*—*Each serious adverse*
 20 *event report under this section shall be submitted to the Sec-*
 21 *retary using the MedWatch form, which may be modified*
 22 *by the Secretary for nonprescription drugs, and may be ac-*
 23 *companied by additional information.*

24 “(e) *MAINTENANCE AND INSPECTION OF RECORDS.*—

1 “(1) *MAINTENANCE.*—*The responsible person*
 2 *shall maintain records related to each report of an*
 3 *adverse event received by the responsible person for a*
 4 *period of 6 years.*

5 “(2) *RECORDS INSPECTION.*—

6 “(A) *IN GENERAL.*—*The responsible person*
 7 *shall permit an authorized person to have access*
 8 *to records required to be maintained under this*
 9 *section, during an inspection pursuant to section*
 10 *704.*

11 “(B) *AUTHORIZED PERSON.*—*For purposes*
 12 *of this paragraph, the term ‘authorized person’*
 13 *means an officer or employee of the Department*
 14 *of Health and Human Services who has—*

15 “(i) *appropriate credentials, as deter-*
 16 *mined by the Secretary; and*

17 “(ii) *been duly designated by the Sec-*
 18 *retary to have access to the records required*
 19 *under this section.*

20 “(f) *PROTECTED INFORMATION.*—*A serious adverse*
 21 *event report submitted to the Secretary under this section,*
 22 *including any new medical information submitted under*
 23 *subsection (c)(2), or an adverse event report voluntarily*
 24 *submitted to the Secretary shall be considered to be—*

1 “(1) a safety report under section 756 and may
 2 be accompanied by a statement, which shall be a part
 3 of any report that is released for public disclosure,
 4 that denies that the report or the records constitute an
 5 admission that the product involved caused or con-
 6 tributed to the adverse event; and

7 “(2) a record about an individual under section
 8 552a of title 5, United States Code (commonly re-
 9 ferred to as the ‘Privacy Act of 1974’) and a medical
 10 or similar file the disclosure of which would constitute
 11 a violation of section 552 of such title 5 (commonly
 12 referred to as the ‘Freedom of Information Act’), and
 13 shall not be publicly disclosed unless all personally
 14 identifiable information is redacted.

15 “(g) *RULE OF CONSTRUCTION.*—The submission of
 16 any adverse event report in compliance with this section
 17 shall not be construed as an admission that the non-
 18 prescription drug involved caused or contributed to the ad-
 19 verse event.

20 “(h) *PREEMPTION.*—

21 “(1) *IN GENERAL.*—No State or local government
 22 shall establish or continue in effect any law, regula-
 23 tion, order, or other requirement, related to a manda-
 24 tory system for adverse event reports for nonprescrip-

tion drugs, that is different from, in addition to, or otherwise not identical to, this section.

“(2) *EFFECT OF SECTION.*—

“(A) *IN GENERAL.*—Nothing in this section shall affect the authority of the Secretary to provide adverse event reports and information to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, under a memorandum of understanding between the Secretary and such State, territory, or political subdivision.

“(B) *PERSONALLY-IDENTIFIABLE INFORMATION.*—Notwithstanding any other provision of law, personally-identifiable information in adverse 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.

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

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

10 (b) *MODIFICATIONS.*—*The Secretary of Health and*
 11 *Human Services may modify requirements under the*
 12 *amendments made by this section in accordance with sec-*
 13 *tion 553 of title 5, United States Code, to maintain consist-*
 14 *ency with international harmonization efforts over time.*

15 (c) *PROHIBITED ACT.*—*Section 301(e) of the Federal*
 16 *Food, Drug, and Cosmetic Act (21 U.S.C. 331(e)) is amend-*
 17 *ed by—*

18 (1) *striking “, or 704(a);” and inserting “,*
 19 *704(a), or 760;”; and*

20 (2) *striking “, or 564” and inserting “, 564, or*
 21 *760”.*

22 (d) *MISBRANDING.*—*Section 502 of the Federal Food,*
 23 *Drug, and Cosmetic Act (21 U.S.C. 352) is amended by*
 24 *adding at the end the following:*

1 “(x) If it is a nonprescription drug (as defined in sec-
 2 tion 760) that is marketed in the United States, unless the
 3 label of such drug includes a domestic address or domestic
 4 phone number through which the responsible person (as de-
 5 scribed in section 760) may receive a report of a serious
 6 adverse event (as defined in section 760) with such drug.”.

7 (e) *EFFECTIVE DATES.*—

8 (1) *IN GENERAL.*—Except as provided in para-
 9 graph (2), the amendments made by this section shall
 10 take effect 1 year after the date of enactment of this
 11 Act.

12 (2) *MISBRANDING.*—Section 502(x) of the Fed-
 13 eral Food, Drug, and Cosmetic Act (as added by this
 14 section) shall apply to any nonprescription drug (as
 15 defined in such section 502(x)) labeled on or after the
 16 date that is 1 year after the date of enactment of this
 17 Act.

18 (3) *GUIDANCE.*—Not later than 270 days after
 19 the date of enactment of this Act, the Secretary of
 20 Health and Human Services shall issue guidance on
 21 the minimum data elements that should be included
 22 in a serious adverse event report described under the
 23 amendments made by this Act.

1 **SEC. 3. SERIOUS ADVERSE EVENT REPORTING FOR DIE-**
 2 **TARY SUPPLEMENTS.**

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

6 **“SEC. 761. SERIOUS ADVERSE EVENT REPORTING FOR DIE-**
 7 **TARY SUPPLEMENTS.**

8 “(a) *DEFINITIONS.*—In this section:

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

12 “(2) *SERIOUS ADVERSE EVENT.*—The term ‘seri-
 13 ous adverse event’ is an adverse event that—

14 “(A) results in—

15 “(i) death;

16 “(ii) a life-threatening experience;

17 “(iii) inpatient hospitalization;

18 “(iv) a persistent or significant dis-
 19 ability or incapacity; or

20 “(v) a congenital anomaly or birth de-
 21 fect; or

22 “(B) requires, based on reasonable medical
 23 judgment, a medical or surgical intervention to
 24 prevent an outcome described under subpara-
 25 graph (A).

1 “(3) *SERIOUS ADVERSE EVENT REPORT.*—The
 2 term ‘serious adverse event report’ means a report
 3 that is required to be submitted to the Secretary
 4 under subsection (b).

5 “(b) *REPORTING REQUIREMENT.*—

6 “(1) *IN GENERAL.*—The manufacturer, packer,
 7 or distributor of a dietary supplement whose name
 8 (pursuant to section 403(e)(1)) appears on the label
 9 of a dietary supplement marketed in the United
 10 States (referred to in this section as the ‘responsible
 11 person’) shall submit to the Secretary any report re-
 12 ceived of a serious adverse event associated with such
 13 dietary supplement when used in the United States,
 14 accompanied by a copy of the label on or within the
 15 retail packaging of such dietary supplement.

16 “(2) *RETAILER.*—A retailer whose name appears
 17 on the label described in paragraph (1) as a dis-
 18 tributor may, by agreement, authorize the manufac-
 19 turer or packer of the dietary supplement to submit
 20 the required reports for such dietary supplements to
 21 the Secretary so long as the retailer directs to the
 22 manufacturer or packer all adverse events associated
 23 with such dietary supplement that are reported to the
 24 retailer through the address or telephone number de-
 25 scribed in section 403(y).

1 “(c) *SUBMISSION OF REPORTS.*—

2 “(1) *TIMING OF REPORTS.*—*The responsible per-*
 3 *son shall submit to the Secretary a serious adverse*
 4 *event report no later than 15 business days after the*
 5 *report is received through the address or phone num-*
 6 *ber described in section 403(y).*

7 “(2) *NEW MEDICAL INFORMATION.*—*The respon-*
 8 *sible person shall submit to the Secretary any new*
 9 *medical information, related to a submitted serious*
 10 *adverse event report that is received by the responsible*
 11 *person within 1 year of the initial report, no later*
 12 *than 15 business days after the new information is*
 13 *received by the responsible person.*

14 “(3) *CONSOLIDATION OF REPORTS.*—*The Sec-*
 15 *retary shall develop systems to ensure that duplicate*
 16 *reports of, and new medical information related to, a*
 17 *serious adverse event shall be consolidated into a sin-*
 18 *gle report.*

19 “(4) *EXEMPTION.*—*The Secretary, after pro-*
 20 *viding notice and an opportunity for comment from*
 21 *interested parties, may establish an exemption to the*
 22 *requirements under paragraphs (1) and (2) if the*
 23 *Secretary determines that such exemption would have*
 24 *no adverse effect on public health.*

1 “(d) *CONTENTS OF REPORTS.*—Each serious adverse
 2 event report under this section shall be submitted to the Sec-
 3 retary using the MedWatch form, which may be modified
 4 by the Secretary for dietary supplements, and may be ac-
 5 companied by additional information.

6 “(e) *MAINTENANCE AND INSPECTION OF RECORDS.*—

7 “(1) *MAINTENANCE.*—The responsible person
 8 shall maintain records related to each report of an
 9 adverse event received by the responsible person for a
 10 period of 6 years.

11 “(2) *RECORDS INSPECTION.*—

12 “(A) *IN GENERAL.*—The responsible person
 13 shall permit an authorized person to have access
 14 to records required to be maintained under this
 15 section during an inspection pursuant to section
 16 704.

17 “(B) *AUTHORIZED PERSON.*—For purposes
 18 of this paragraph, the term ‘authorized person’
 19 means an officer or employee of the Department
 20 of Health and Human Services, who has—

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

23 “(ii) been duly designated by the Sec-
 24 retary to have access to the records required
 25 under this section.

1 “(f) *PROTECTED INFORMATION.*—A serious adverse
 2 event report submitted to the Secretary under this section,
 3 including any new medical information submitted under
 4 subsection (c)(2), or an adverse event report voluntarily
 5 submitted to the Secretary shall be considered to be—

6 “(1) a safety report under section 756 and may
 7 be accompanied by a statement, which shall be a part
 8 of any report that is released for public disclosure,
 9 that denies that the report or the records constitute an
 10 admission that the product involved caused or con-
 11 tributed to the adverse event; and

12 “(2) a record about an individual under section
 13 552a of title 5, United States Code (commonly re-
 14 ferred to as the ‘Privacy Act of 1974’) and a medical
 15 or similar file the disclosure of which would constitute
 16 a violation of section 552 of such title 5 (commonly
 17 referred to as the ‘Freedom of Information Act’), and
 18 shall not be publicly disclosed unless all personally
 19 identifiable information is redacted.

20 “(g) *RULE OF CONSTRUCTION.*—The submission of
 21 any adverse event report in compliance with this section
 22 shall not be construed as an admission that the dietary sup-
 23 plement involved caused or contributed to the adverse event.

24 “(h) *PREEMPTION.*—

1 “(1) *IN GENERAL.*—No State or local government
 2 shall establish or continue in effect any law, regula-
 3 tion, order, or other requirement, related to a manda-
 4 tory system for adverse event reports for dietary sup-
 5 plements, that is different from, in addition to, or
 6 otherwise not identical to, this section.

7 “(2) *EFFECT OF SECTION.*—

8 “(A) *IN GENERAL.*—Nothing in this section
 9 shall affect the authority of the Secretary to pro-
 10 vide adverse event reports and information to
 11 any health, food, or drug officer or employee of
 12 any State, territory, or political subdivision of a
 13 State or territory, under a memorandum of un-
 14 derstanding between the Secretary and such
 15 State, territory, or political subdivision.

16 “(B) *PERSONALLY-IDENTIFIABLE INFORMA-*
 17 *TION.*—Notwithstanding any other provision of
 18 law, personally-identifiable information in ad-
 19 verse event reports provided by the Secretary to
 20 any health, food, or drug officer or employee of
 21 any State, territory, or political subdivision of a
 22 State or territory, shall not—

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

1 “(ii) otherwise be disclosed or distrib-
 2 uted to any party without the written con-
 3 sent of the Secretary and the person submit-
 4 ting such information to the Secretary.

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

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

14 (b) *PROHIBITED ACT.*—Section 301(e) of the Federal
 15 Food, Drug, and Cosmetic Act (21 U.S.C. 331(e)) is amend-
 16 ed by—

17 (1) striking “, or 760;” and inserting “, 760, or
 18 761;”; and

19 (2) striking “, or 760” and inserting “, 760, or
 20 761”.

21 (c) *MISBRANDING.*—Section 403 of the Federal Food,
 22 Drug, and Cosmetic Act (21 U.S.C. 343) is amended by
 23 adding at the end the following:

24 “(y) If it is a dietary supplement that is marketed in
 25 the United States, unless the label of such dietary supple-

1 *ment includes a domestic address or domestic phone number*
 2 *through which the responsible person (as described in sec-*
 3 *tion 761) may receive a report of a serious adverse event*
 4 *with such dietary supplement.”.*

5 *(d) EFFECTIVE DATE.—*

6 *(1) IN GENERAL.—Except as provided in para-*
 7 *graph (2), the amendments made by this section shall*
 8 *take effect 1 year after the date of enactment of this*
 9 *Act.*

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

15 *(3) GUIDANCE.—Not later than 270 days after*
 16 *the date of enactment of this Act, the Secretary of*
 17 *Health and Human Services shall issue guidance on*
 18 *the minimum data elements that should be included*
 19 *in a serious adverse event report as described under*
 20 *the amendments made by this Act.*

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

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

1 “(ii) *The falsification of a report of a serious adverse*
 2 *event submitted to a responsible person (as defined under*
 3 *section 760 or 761) or the falsification of a serious adverse*
 4 *event report (as defined under section 760 or 761) submitted*
 5 *to the Secretary.*”.

6 (b) *EFFECTIVE DATE.*—*The amendment made by this*
 7 *section shall take effect 1 year after the date of enactment*
 8 *of this Act.*

9 **SEC. 5. IMPORTATION OF CERTAIN NONPRESCRIPTION**
 10 **DRUGS AND DIETARY SUPPLEMENTS.**

11 (a) *IN GENERAL.*—*Section 801 of the Federal Food,*
 12 *Drug, and Cosmetic Act (21 U.S.C. 381) is amended—*

13 (1) *in subsection (a), by inserting after the third*
 14 *sentence the following: “If such article is subject to a*
 15 *requirement under section 760 or 761 and if the Sec-*
 16 *retary has credible evidence or information indicating*
 17 *that the responsible person (as defined in such section*
 18 *760 or 761) has not complied with a requirement of*
 19 *such section 760 or 761 with respect to any such arti-*
 20 *cle, or has not allowed access to records described in*
 21 *such section 760 or 761, then such article shall be re-*
 22 *fused admission, except as provided in subsection (b)*
 23 *of this section.”; and*

24 (2) *in the second sentence of subsection (b)—*

1 (A) by inserting “(1)” before “an article in-
2 cluded”;

3 (B) by inserting before “final determina-
4 tion” the following: “or (2) with respect to an
5 article included within the provision of the
6 fourth sentence of subsection (a), the responsible
7 person (as defined in section 760 or 761) can
8 take action that would assure that the respon-
9 sible person is in compliance with section 760 or
10 761, as the case may be,”; and

11 (C) by inserting “, or, with respect to clause
12 (2), the responsible person,” before “to perform”.

13 (b) *EFFECTIVE DATE.*—The amendments made by this
14 section shall take effect 1 year after the date of enactment
15 of this Act.

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109TH CONGRESS
2^D Session

S. 3546

[Report No. 109-324]

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.

SEPTEMBER 5, 2006

Reported with an amendment