

109TH CONGRESS  
2D SESSION

# S. 3546

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## AN ACT

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.—

22          ``(1) IN GENERAL.—The manufacturer, packer,  
23          or distributor whose name (pursuant to section  
24          502(b)(1)) appears on the label of a nonprescription  
25          drug marketed in the United States (referred to in

1 this section as the 'responsible person') shall submit  
2 to the Secretary any report received of a serious ad-  
3 verse event associated with such drug when used in  
4 the United States, accompanied by a copy of the  
5 label on or within the retail package of such drug.

6 '(2) RETAILER.—A retailer whose name ap-  
7 pears on the label described in paragraph (1) as a  
8 distributor may, by agreement, authorize the manu-  
9 facturer or packer of the nonprescription drug to  
10 submit the required reports for such drugs to the  
11 Secretary so long as the retailer directs to the manu-  
12 facturer or packer all adverse events associated with  
13 such drug that are reported to the retailer through  
14 the address or telephone number described in section  
15 502(x).

16 '(c) SUBMISSION OF REPORTS.—

17 '(1) TIMING OF REPORTS.—The responsible  
18 person shall submit to the Secretary a serious ad-  
19 verse event report no later than 15 business days  
20 after the report is received through the address or  
21 phone number described in section 502(x).

22 '(2) NEW MEDICAL INFORMATION.—The re-  
23 sponsible person shall submit to the Secretary any  
24 new medical information, related to a submitted seri-  
25 ous adverse event report that is received by the re-

1 responsible person within 1 year of the initial report,  
2 no later than 15 business days after the new infor-  
3 mation is received by the responsible person.

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

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

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

20       ``(e) MAINTENANCE AND INSPECTION OF  
21 RECORDS.—

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

1       ``(2) RECORDS INSPECTION.—

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

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

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

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

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

22           ``(1) a safety report under section 756 and may  
23      be accompanied by a statement, which shall be a  
24      part of any report that is released for public disclo-  
25      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 non-  
14     prescription drug involved caused or contributed to the ad-  
15     verse 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 non-  
21       prescription drugs, 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) MODIFICATIONS.—The Secretary of Health and  
7 Human Services may modify requirements under the  
8 amendments made by this section in accordance with sec-  
9 tion 553 of title 5, United States Code, to maintain con-  
10 sistency with international harmonization efforts over  
11 time.

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

15           (1) striking “, or 704(a);” and inserting “,  
16 704(a), or 760;”; and

17           (2) striking “, or 564” and inserting “, 564, or  
18 760”.

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

22       “(x) If it is a nonprescription drug (as defined in sec-  
23 tion 760) that is marketed in the United States, unless  
24 the label of such drug includes a domestic address or do-  
25 mestic phone number through which the responsible per-

1 son (as described in section 760) may receive a report of  
2 a serious adverse event (as defined in section 760) with  
3 such drug.''. .

4 (e) EFFECTIVE DATES.—

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

9 (2) MISBRANDING.—Section 502(x) of the Fed-  
10 eral Food, Drug, and Cosmetic Act (as added by  
11 this section) shall apply to any nonprescription drug  
12 (as defined in such section 502(x)) labeled on or  
13 after the date that is 1 year after the date of enact-  
14 ment 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 described under the  
20 amendments made by this Act.

21 **SEC. 3. SERIOUS ADVERSE EVENT REPORTING FOR DIE-**

22 **TARY SUPPLEMENTS.**

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

1 **“SEC. 761. SERIOUS ADVERSE EVENT REPORTING FOR DIE-**  
2 **TARY SUPPLEMENTS.**

3 ‘‘(a) DEFINITIONS.—In this section:

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

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

9 ‘‘(A) results in—

10 ‘‘(i) death;

11 ‘‘(ii) a life-threatening experience;

12 ‘‘(iii) inpatient hospitalization;

13 ‘‘(iv) a persistent or significant dis-  
14 ability or incapacity; or

15 ‘‘(v) a congenital anomaly or birth de-  
16 fect; or

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

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

25 ‘‘(b) REPORTING REQUIREMENT.—

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

12       ``(2) RETAILER.—A retailer whose name ap-  
13 pears on the label described in paragraph (1) as a  
14 distributor may, by agreement, authorize the manu-  
15 facturer or packer of the dietary supplement to sub-  
16 mit the required reports for such dietary supple-  
17 ments to the Secretary so long as the retailer directs  
18 to the manufacturer or packer all adverse events as-  
19 sociated with such dietary supplement that are re-  
20 ported to the retailer through the address or tele-  
21 phone number described in section 403(y).

22       ``(c) SUBMISSION OF REPORTS.—

23       ``(1) TIMING OF REPORTS.—The responsible  
24 person shall submit to the Secretary a serious ad-  
25 verse event report no later than 15 business days

1 after the report is received through the address or  
2 phone number described in section 403(y).

3 `` (2) NEW MEDICAL INFORMATION.—The re-  
4 sponsible person shall submit to the Secretary any  
5 new medical information, related to a submitted seri-  
6 ous adverse event report that is received by the re-  
7 sponsible person within 1 year of the initial report,  
8 no later than 15 business days after the new infor-  
9 mation is received by the responsible person.

10 `` (3) CONSOLIDATION OF REPORTS.—The Sec-  
11 retary shall develop systems to ensure that duplicate  
12 reports of, and new medical information related to,  
13 a serious adverse event shall be consolidated into a  
14 single report.

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

21 `` (d) CONTENTS OF REPORTS.—Each serious adverse  
22 event report under this section shall be submitted to the  
23 Secretary using the MedWatch form, which may be modi-  
24 fied by the Secretary for dietary supplements, and may  
25 be accompanied by additional information.

1       ``(e)       MAINTENANCE       AND       INSPECTION       OF  
2 RECORDS.—

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

7           ``(2) RECORDS INSPECTION.—

8           ``(A) IN GENERAL.—The responsible per-  
9 son shall permit an authorized person to have  
10 access to records required to be maintained  
11 under this section during an inspection pursu-  
12 ant to section 704.

13           ``(B) AUTHORIZED PERSON.—For pur-  
14 poses of this paragraph, the term 'authorized  
15 person' means an officer or employee of the De-  
16 partment of Health and Human Services, who  
17 has—

18           ``(i) appropriate credentials, as deter-  
19 mined by the Secretary; and

20           ``(ii) been duly designated by the Sec-  
21 retary to have access to the records re-  
22 quired under this section.

23       ``(f) PROTECTED INFORMATION.—A serious adverse  
24 event report submitted to the Secretary under this section,  
25 including any new medical information submitted under

1 subsection (c)(2), or an adverse event report voluntarily  
2 submitted to the Secretary shall be considered to be—

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

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

17       “(g) RULE OF CONSTRUCTION.—The submission of  
18 any adverse event report in compliance with this section  
19 shall not be construed as an admission that the dietary  
20 supplement involved caused or contributed to the adverse  
21 event.

22       “(h) PREEMPTION.—

23       “(1) IN GENERAL.—No State or local govern-  
24 ment shall establish or continue in effect any law,  
25 regulation, order, or other requirement, related to a

1 mandatory system for adverse event reports for die-  
2 tary supplements, that is different from, in addition  
3 to, or otherwise not identical to, this section.

4 `` (2) EFFECT OF SECTION.—

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

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

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

24 `` (ii) otherwise be disclosed or distrib-  
25 uted to any party without the written con-



1 sent of the Secretary and the person sub-  
 2 mitting such information to the Secretary.

3 `` (C) USE OF SAFETY REPORTS.—Nothing  
 4 in this section shall permit a State, territory, or  
 5 political subdivision of a State or territory, to  
 6 use any safety report received from the Sec-  
 7 retary in a manner inconsistent with subsection  
 8 (g) or section 756.

9 `` (i) AUTHORIZATION OF APPROPRIATIONS.—There  
 10 are authorized to be appropriated to carry out this section  
 11 such sums as may be necessary.''.  
 12

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

16 (1) striking `` , or 760;'' and inserting `` , 760,  
 17 or 761;''; and

18 (2) striking `` , or 760'' and inserting `` , 760, or  
 19 761''.

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

23 `` (y) If it is a dietary supplement that is marketed  
 24 in the United States, unless the label of such dietary sup-  
 25 plement includes a domestic address or domestic phone  
 number through which the responsible person (as de-

1 scribed in section 761) may receive a report of a serious  
2 adverse event with such dietary supplement.''.

3 (d) EFFECTIVE DATE.—

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

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

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

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

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

23 `` (ii) The falsification of a report of a serious adver  
24 event submitted to a responsible person (as defined under  
25 section 760 or 761) or the falsification of a serious adver

1 event report (as defined under section 760 or 761) sub-  
2 mitted to the Secretary.''.

3 (b) EFFECTIVE DATE.—The amendment made by  
4 this section shall take effect 1 year after the date of ena  
5 ment of this Act.

6 **SEC. 5. IMPORTATION OF CERTAIN NONPRESCRIPTION**

7 **DRUGS AND DIETARY SUPPLEMENTS.**

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

10 (1) in subsection (a), by inserting after the  
11 third sentence the following: ‘‘If such article is sub  
12 ject to a requirement under section 760 or 761 and  
13 if the Secretary has credible evidence or information  
14 indicating that the responsible person (as defined in  
15 such section 760 or 761) has not complied with a re-  
16 quirement of such section 760 or 761 with respect  
17 to any such article, or has not allowed access to  
18 records described in such section 760 or 761, then  
19 such article shall be refused admission, except as  
20 provided in subsection (b) of this section.’’; and

21 (2) in the second sentence of subsection (b)—

22 (A) by inserting ‘‘(1)’’ before ‘‘an article  
23 included’’;

24 (B) by inserting before ‘‘final determina-  
25 tion’’ the following: ‘‘or (2) with respect to an

1 article included within the provision of the  
2 fourth sentence of subsection (a), the respon-  
3 sible person (as defined in section 760 or 761)  
4 can take action that would assure that the re-  
5 sponsible person is in compliance with section  
6 760 or 761, as the case may be,''; and

7 (C) by inserting `` , or, with respect to  
8 clause (2), the responsible person, '' before ``to  
9 perform''.

10 (b) EFFECTIVE DATE.—The amendments made by  
11 this section shall take effect 1 year after the date of ena-  
12 ment of this Act.

Passed the Senate December 6, 2006.

Attest:

Secretary.

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

**S. 3546**

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**AN ACT**

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.