

111TH CONGRESS  
2D SESSION

# S. 3002

To amend the Federal Food, Drug, and Cosmetic Act to more effectively regulate dietary supplements that may pose safety risks unknown to consumers.

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## IN THE SENATE OF THE UNITED STATES

FEBRUARY 4, 2010

Mr. McCAIN (for himself and Mr. DORGAN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to more effectively regulate dietary supplements that may pose safety risks unknown to consumers.

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 Safety Act of 2010”.

1 **SEC. 2. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND**  
2 **COSMETIC ACT.**

3 (a) DEFINITIONS.—Section 201 of the Federal Food,  
4 Drug, and Cosmetic Act (21 U.S.C. 321) is amended by  
5 adding at the end the following:

6 “(ss) DIETARY SUPPLEMENT FACILITY.—The term  
7 ‘dietary supplement facility’ means any business or oper-  
8 ation engaged in manufacturing, packaging, holding, dis-  
9 tributing, labeling, or licensing a dietary supplement for  
10 consumption in the United States.”.

11 (b) REGISTRATION OF DIETARY SUPPLEMENT FA-  
12 CILITIES.—

13 (1) ADULTERATED FOOD.—Section 402 of the  
14 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
15 342) is amended by inserting at the end the fol-  
16 lowing:

17 “(j) If it is a dietary supplement that is manufac-  
18 tured, packaged, held, distributed, labeled, or licensed by  
19 a dietary supplement facility that is not registered with  
20 the Secretary.”.

21 (2) REGISTRATION OF FOOD FACILITIES.—Sec-  
22 tion 415 of the Federal Food, Drug, and Cosmetic  
23 Act (21 U.S.C. 350d) is amended—

24 (A) in the section heading, by striking  
25 “**FACILITIES**” and inserting “**AND DIETARY**  
26 **SUPPLEMENT FACILITIES**”; and

1 (B) in subsection (a)—

2 (i) in paragraph (2)—

3 (I) by striking “An entity” and  
4 inserting the following:

5 “(A) FOOD FACILITIES.—An entity”; and

6 (II) by adding at the end the fol-  
7 lowing:

8 “(B) DIETARY SUPPLEMENT FACILI-  
9 TIES.—

10 “(i) IN GENERAL.—A dietary supple-  
11 ment facility (referred to in the section as  
12 a ‘dietary supplement registrant’) shall  
13 submit a registration under paragraph (1)  
14 to the Secretary containing information  
15 necessary to notify the Secretary of the  
16 name and address of each facility at which,  
17 and all trade names under which, the die-  
18 tary supplement registrant conducts busi-  
19 ness. At the time of registration, the die-  
20 tary supplement registrant shall also file  
21 with the Secretary a list of all dietary sup-  
22 plements manufactured, packaged, held,  
23 distributed, labeled, or licensed by the fa-  
24 cility. Such list shall be prepared in such  
25 form and manner as the Secretary may

1           prescribe, and shall be accompanied by a  
2           full list of the ingredients contained in  
3           each dietary supplement, and a copy of the  
4           labeling used by the facility for each die-  
5           tary supplement.

6           “(ii) UPDATES.—Each dietary supple-  
7           ment registrant shall update the reg-  
8           istrant’s registration annually on or before  
9           the anniversary date of the registrant’s ini-  
10          tial registration. Each dietary supplement  
11          registrant shall also update the registrant’s  
12          registration to include information regard-  
13          ing any new dietary supplement, or refor-  
14          mulation of an existing dietary supplement,  
15          on or before the date such dietary supple-  
16          ment is marketed for consumption in the  
17          United States.”; and

18          (ii) in paragraph (3), by inserting “or  
19          dietary supplement registrant” after “no-  
20          tify the registrant”.

21          (c) NEW DIETARY INGREDIENTS.—Section 413 of  
22          the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
23          350b) is amended—

24                  (1) by striking subsection (a) and inserting the  
25          following:

1           “(a) IN GENERAL.—A dietary supplement which con-  
2 tains a new dietary ingredient shall be deemed adulterated  
3 under section 402(f) unless there is a history of use or  
4 other evidence of safety establishing that the dietary ingre-  
5 dient when used under the conditions recommended or  
6 suggested in the labeling of the dietary supplement will  
7 reasonably be expected to be safe and, at least 75 days  
8 before being introduced or delivered for introduction into  
9 interstate commerce, the manufacturer or distributor of  
10 the dietary ingredient or dietary supplement provides the  
11 Secretary with information, including any citation to pub-  
12 lished articles, which is the basis on which the manufac-  
13 turer or distributor has concluded that a dietary supple-  
14 ment containing such dietary ingredient will reasonably be  
15 expected to be safe. The Secretary shall keep confidential  
16 any information provided under this subsection for 90  
17 days following its receipt. After the expiration of such 90  
18 days, the Secretary shall place such information on public  
19 display, except matters in the information which are trade  
20 secrets or otherwise confidential, commercial informa-  
21 tion.”;

22           (2) in subsection (c), by striking “was not mar-  
23 keted in the United States before October 15, 1994  
24 and does not include any dietary ingredient which  
25 was marketed in the United States before October

1 15, 1994” and inserting “is not included on the list  
2 of ‘Accepted Dietary Ingredients’, to be prepared,  
3 published, and maintained by the Secretary”; and

4 (3) by adding at the end the following:

5 “(d) MAINTAINING SUBSTANTIATION FILE.—Any  
6 person submitting information to the Secretary under sub-  
7 section (a) shall create and maintain a scientifically rea-  
8 sonable substantiation file relating to the claim that the  
9 dietary ingredient or dietary supplement will reasonably  
10 be expected to be safe. The substantiation file shall be pre-  
11 pared and maintained in such form and manner as the  
12 Secretary may prescribe and shall be available for review  
13 and inspection by the Secretary upon request.

14 “(e) EVIDENCE OF COMPLIANCE.—A dietary supple-  
15 ment facility or retailer shall, prior to manufacturing,  
16 packaging, holding, distributing, labeling, or licensing the  
17 dietary supplement, obtain adequate written evidence from  
18 the preceding responsible entity in the chain of commerce  
19 that the product is registered as required by section 415  
20 and that the requirements of subsection (a) have been  
21 met. Such facility or retailer shall maintain such evidence  
22 of compliance for review and inspection by the Secretary  
23 upon request.”.

24 (d) CIVIL MONETARY PENALTY FOR NON-COMPLI-  
25 ANCE.—Section 303 of the Federal Food, Drug, and Cos-

1    etic Act (21 U.S.C. 333) is amended by adding at the  
2    end the following:

3           “(h) CIVIL MONETARY PENALTY FOR NON-COMPLI-  
4    ANCE.—Notwithstanding the provisions of subsection (a),  
5    any person who manufacturers, packages, holds, distrib-  
6    utes, labels, or licenses a dietary supplement in violation  
7    of section 301, 402, 413, 415, 501, 502, 505, or 761, may,  
8    in addition to other penalties imposed in this section, be  
9    fined not more than twice the gross profits or other pro-  
10   ceeds derived from the manufacture, packaging, holding,  
11   distribution, labeling, or license of such dietary supple-  
12   ment.”.

13           (e) ADVERSE EVENT REPORTING FOR DIETARY SUP-  
14   PLEMENTS.—Section 761 of the Federal Food, Drug, and  
15   Cosmetic Act (21 U.S.C. 379aa–1) is amended—

16           (1) in the section heading, by striking “**SERI-**  
17           **IOUS ADVERSE**” and inserting “**ADVERSE**”;

18           (2) in subsection (a), by adding at the end the  
19   following:

20           “(4) ADVERSE EVENT REPORT.—The term ‘ad-  
21   verse event report’ means a report of non-serious ad-  
22   verse events that is required to be submitted to the  
23   Secretary under subsection (b).”;

24           (3) in subsection (b)(1)—

1 (A) by striking “The manufacturer” and  
2 inserting the following:

3 “(A) SERIOUS ADVERSE EVENTS.—The  
4 manufacturer”; and

5 (B) by adding at the end the following:

6 “(B) NON-SERIOUS ADVERSE EVENTS.—  
7 The manufacturer, packer, holder, distributor,  
8 labeler, or licensee of a dietary supplement,  
9 whose name appears on the label of a dietary  
10 supplement marketed in the United States,  
11 shall submit to the Secretary, in such form and  
12 manner as the Secretary shall determine, a  
13 compilation report of all non-serious adverse  
14 events associated with such dietary supplement  
15 when used in the United States, accompanied  
16 by a copy of the label on or within the retail  
17 packaging of such dietary supplement.”;

18 (4) in subsection (c)(1), by adding at the end:  
19 “The responsible person shall annually submit to the  
20 Secretary a compilation report of all non-serious ad-  
21 verse events received during the preceding year.”;

22 (5) in subsection (e)(1), by adding at the end:  
23 “The responsible person shall maintain records re-  
24 lated to each annually submitted adverse event re-  
25 port for a period of 3 years.”; and



1           “(ii) notify distributors, importers, re-  
2           tailers, and consumers of the order; and

3           “(iii) instruct those distributors, im-  
4           porters, retailers, and consumers to cease  
5           distributing, importing, selling, and using  
6           the dietary supplement.

7           “(B) INFORMAL HEARING.—An order de-  
8           scribed in subparagraph (A) shall provide the  
9           person subject to the order with an opportunity  
10          for an informal hearing, to be held not later  
11          than 10 days after the date of the issuance of  
12          the order, on the actions required by the order  
13          and on whether the order should be amended to  
14          require a recall of the dietary supplement or the  
15          product marketed or sold as a dietary supple-  
16          ment. The person subject to the order shall  
17          have 5 days to notify the Secretary of the per-  
18          son’s intent to challenge the order. If, after pro-  
19          viding an opportunity for such a hearing, the  
20          Secretary determines that inadequate grounds  
21          exist to support the actions required by the  
22          order, the Secretary shall vacate the order.

23          “(2) RECALL.—

24                 “(A) IN GENERAL.—If, after providing an  
25                 opportunity for an informal hearing under

1 paragraph (1), the Secretary determines that  
2 the order should be amended to include a recall  
3 of the dietary supplement or the product mar-  
4 keted or sold as a dietary supplement with re-  
5 spect to which the order was issued, the Sec-  
6 retary shall, except as provided in subpara-  
7 graphs (B) and (C), amend the order to require  
8 a recall. The Secretary shall specify a timetable  
9 in which the dietary supplement recall will  
10 occur and shall require periodic reports to the  
11 Secretary describing the progress of the recall.  
12 The Secretary shall have the authority to ini-  
13 tiate the action prescribed in this subparagraph  
14 regardless of whether or not the person subject  
15 to the order elects to exercise the right to chal-  
16 lenge the initial order as permitted under para-  
17 graph (1).

18 “(B) CONTENT OF AMENDED ORDER.—An  
19 amended order under subparagraph (A)—

20 “(i) shall not include recall of the die-  
21 tary supplement or the product marketed  
22 or sold as a dietary supplement from indi-  
23 viduals; and

24 “(ii) shall provide for notice to indi-  
25 viduals, at the expense of retailers and to

1           the satisfaction of the Secretary, subject to  
2           the risks associated with the use of such  
3           dietary supplement.

4           “(C) NOTIFICATION.—In providing the no-  
5           tice required by subparagraph (B)(ii), if a sig-  
6           nificant number of such individuals cannot be  
7           identified, the Secretary shall notify such indi-  
8           viduals pursuant to section 705(b).”.

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