

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.

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

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 (6) in subsection (f), by striking “or an adverse
2 event report voluntarily submitted” and inserting
3 “or a non-serious adverse report submitted annu-
4 ally”.

5 (f) RECALL AUTHORITY FOR DIETARY SUPPLE-
6 MENTS.—

7 (1) IN GENERAL.—Chapter IV of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 341 et
9 seq.) is amended by adding at the end the following:

10 **“SEC. 418. RECALL AUTHORITY FOR DIETARY SUPPLE-
11 MENTS.**

12 “(a) RECALL AUTHORITY.—

13 “(1) CEASE DISTRIBUTION AND NOTIFICATION
14 ORDER.—

15 “(A) IN GENERAL.—If the Secretary finds
16 there is a reasonable probability that a dietary
17 supplement or a product marketed or sold as a
18 dietary supplement would cause serious, adverse
19 health consequences or death, or is adulterated
20 or misbranded, the Secretary shall issue a cease
21 distribution and notification order requiring the
22 person named in the order to immediately—

23 “(i) cease distribution of such dietary
24 supplement or a product marketed or sold
25 as a dietary supplement;

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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