II

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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Dietary Supplement Safety Act of 2010''.

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

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

''(ss) DIETARY SUPPLEMENT FACILITY.—The term 'dietary supplement facility' means any business or operation engaged in manufacturing, packaging, holding, distributing, labeling, or licensing a dietary supplement for consumption in the United States.''.

(b) REGISTRATION OF DIETARY SUPPLEMENT FACILITIES.—

(1) ADULTERATED FOOD.—Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) is amended by inserting at the end the following:

''(j) If it is a dietary supplement that is manufactured, packaged, held, distributed, labeled, or licensed by a dietary supplement facility that is not registered with the Secretary.''.

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

(A) in the section heading, by striking ''**FACILITIES**'' and inserting ''**AND DIETARY SUPPLEMENT FACILITIES**''; and

(B) in subsection (a)—

(i) in paragraph (2)—

(I) by striking ''An entity'' and inserting the following:

''(A) FOOD FACILITIES.—An entity''; and

(II) by adding at the end the following:

''(B) DIETARY SUPPLEMENT FACILITIES.—

''(i) IN GENERAL.—A dietary supplement facility (referred to in the section as a 'dietary supplement registrant') shall submit a registration under paragraph (1) to the Secretary containing information necessary to notify the Secretary of the name and address of each facility at which, and all trade names under which, the dietary supplement registrant conducts business. At the time of registration, the dietary supplement registrant shall also file with the Secretary a list of all dietary supplements manufactured, packaged, held, distributed, labeled, or licensed by the facility. Such list shall be prepared in such form and manner as the Secretary may

prescribe, and shall be accompanied by a full list of the ingredients contained in each dietary supplement, and a copy of the labeling used by the facility for each dietary supplement.

''(ii) UPDATES.—Each dietary supplement registrant shall update the registrant's registration annually on or before the anniversary date of the registrant's initial registration. Each dietary supplement registrant shall also update the registrant's registration to include information regarding any new dietary supplement, or reformulation of an existing dietary supplement, on or before the date such dietary supplement is marketed for consumption in the United States.''; and

(ii) in paragraph (3), by inserting ''or dietary supplement registrant'' after ''notify the registrant''.

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

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

''(a) IN GENERAL.—A dietary supplement which contains a new dietary ingredient shall be deemed adulterated under section 402(f) unless there is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the Secretary with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe. The Secretary shall keep confidential any information provided under this subsection for 90 days following its receipt. After the expiration of such 90 days, the Secretary shall place such information on public display, except matters in the information which are trade secrets or otherwise confidential, commercial information.'';

(2) in subsection (c), by striking ''was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October

15, 1994'' and inserting ''is not included on the list of 'Accepted Dietary Ingredients', to be prepared, published, and maintained by the Secretary''; and

(3) by adding at the end the following:

''(d) MAINTAINING SUBSTANTIATION FILE.—Any person submitting information to the Secretary under subsection (a) shall create and maintain a scientifically reasonable substantiation file relating to the claim that the dietary ingredient or dietary supplement will reasonably be expected to be safe. The substantiation file shall be prepared and maintained in such form and manner as the Secretary may prescribe and shall be available for review and inspection by the Secretary upon request.

''(e) EVIDENCE OF COMPLIANCE.—A dietary supplement facility or retailer shall, prior to manufacturing, packaging, holding, distributing, labeling, or licensing the dietary supplement, obtain adequate written evidence from the preceding responsible entity in the chain of commerce that the product is registered as required by section 415 and that the requirements of subsection (a) have been met. Such facility or retailer shall maintain such evidence of compliance for review and inspection by the Secretary upon request.''.

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

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

''(h) CIVIL MONETARY PENALTY FOR NON-COMPLIANCE.—Notwithstanding the provisions of subsection (a), any person who manufacturers, packages, holds, distributes, labels, or licenses a dietary supplement in violation of section 301, 402, 413, 415, 501, 502, 505, or 761, may, in addition to other penalties imposed in this section, be fined not more than twice the gross profits or other proceeds derived from the manufacture, packaging, holding, distribution, labeling, or license of such dietary supplement.''.

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

(1) in the section heading, by striking ''**SERIOUS ADVERSE**'' and inserting ''**ADVERSE**'';

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

''(4) ADVERSE EVENT REPORT.—The term 'adverse event report' means a report of non-serious adverse events that is required to be submitted to the Secretary under subsection (b).'';

(3) in subsection (b)(1)—

(A) by striking ''The manufacturer'' and inserting the following:

''(A) SERIOUS ADVERSE EVENTS.—The manufacturer''; and

(B) by adding at the end the following:

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

(4) in subsection (c)(1), by adding at the end: ''The responsible person shall annually submit to the Secretary a compilation report of all non-serious adverse events received during the preceding year.'';

(5) in subsection (e)(1), by adding at the end: ''The responsible person shall maintain records related to each annually submitted adverse event report for a period of 3 years.''; and

(6) in subsection (f), by striking ''or an adverse event report voluntarily submitted'' and inserting ''or a non-serious adverse report submitted annually''.

(f) RECALL AUTHORITY FOR DIETARY SUPPLEMENTS.—

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

''SEC. 418. RECALL AUTHORITY FOR DIETARY SUPPLEMENTS.

''(a) RECALL AUTHORITY.—

''(1) CEASE DISTRIBUTION AND NOTIFICATION ORDER.—

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

''(i) cease distribution of such dietary supplement or a product marketed or sold as a dietary supplement;

"(ii) notify distributors, importers, retailers, and consumers of the order; and

"(iii) instruct those distributors, importers, retailers, and consumers to cease distributing, importing, selling, and using the dietary supplement.

"(B) INFORMAL HEARING.—An order described in subparagraph (A) shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of the dietary supplement or the product marketed or sold as a dietary supplement. The person subject to the order shall have 5 days to notify the Secretary of the person's intent to challenge the order. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

"(2) RECALL.—

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

paragraph (1), the Secretary determines that the order should be amended to include a recall of the dietary supplement or the product marketed or sold as a dietary supplement with respect to which the order was issued, the Secretary shall, except as provided in subparagraphs (B) and (C), amend the order to require a recall. The Secretary shall specify a timetable in which the dietary supplement recall will occur and shall require periodic reports to the Secretary describing the progress of the recall. The Secretary shall have the authority to initiate the action prescribed in this subparagraph regardless of whether or not the person subject to the order elects to exercise the right to challenge the initial order as permitted under paragraph (1).

''(B) CONTENT OF AMENDED ORDER.—An amended order under subparagraph (A)—

''(i) shall not include recall of the dietary supplement or the product marketed or sold as a dietary supplement from individuals; and

''(ii) shall provide for notice to individuals, at the expense of retailers and to

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

"(C) NOTIFICATION.—In providing the notice required by subparagraph (B)(ii), if a significant number of such individuals cannot be identified, the Secretary shall notify such individuals pursuant to section 705(b).".

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