112TH CONGRESS
1ST SESSION

S. _____

To improve the safety of dietary supplements by amending the Federal Food, Drug, and Cosmetic Act to require manufacturers of dietary supplements to register dietary supplement products with the Food and Drug Administration and to amend labeling requirements with respect to dietary supplements.

IN THE SENATE OF THE UNITED STATES

Mr. DURBIN introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To improve the safety of dietary supplements by amending the Federal Food, Drug, and Cosmetic Act to require manufacturers of dietary supplements to register dietary supplement products with the Food and Drug Administration and to amend labeling requirements with respect to dietary supplements.

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 Labeling Act of 2011''.

SEC. 2. REGULATION OF DIETARY SUPPLEMENTS.

(a) REGISTRATION.—

(1) IN GENERAL.—Section 415(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d(a)) is amended by adding at the end the following:

''(6) REQUIREMENTS WITH RESPECT TO DIETARY SUPPLEMENTS.—

''(A) IN GENERAL.—A facility engaged in manufacturing dietary supplements that is required to register under this section shall comply with the requirements of this paragraph, in addition to the other requirements of this section.

''(B) ADDITIONAL INFORMATION.—A facility described in subparagraph (A) shall submit a registration under paragraph (1) that includes, in addition to the information required under paragraph (2)—

''(i) a description of each dietary supplement product manufactured by such facility;

''(ii) a list of all ingredients in each such dietary supplement product; and

''(iii) a copy of the label and labeling for each such product.

"(C) REGISTRATION WITH RESPECT TO NEW, REFORMULATED, AND DISCONTINUED DIETARY SUPPLEMENT PRODUCTS.—

"(i) IN GENERAL.—Not later than the date described in clause (ii), if a facility described in subparagraph (A)—

"(I) manufactures a dietary supplement product that the facility previously did not manufacture and for which the facility did not submit the information required under clauses (i) through (iii) of subparagraph (B);

"(II) reformulates a dietary supplement product for which the facility previously submitted the information required under clauses (i) through (iii) of subparagraph (B); or

"(III) no longer manufactures a dietary supplement for which the facility previously submitted the information required under clauses (i) through (iii) of subparagraph (B),

such facility shall submit to the Secretary an updated registration describing the change described in subclause (I), (II), or

(III) and, in the case of a facility described in subclause (I) or (II), containing the information required under clauses (i) through (iii) of subparagraph (B).

''(ii) DATE DESCRIBED.—The date described in this clause is—

''(I) in the case of a facility described in subclause (I) of clause (i), 30 days after the date on which such facility first markets the dietary supplement product described in such subclause;

''(II) in the case of a facility described in subclause (II) of clause (i), 30 days after the date on which such facility first markets the reformulated dietary supplement product described in such subclause; or

''(III) in the case of a facility described in subclause (III) of clause (i), 30 days after the date on which such facility removes the dietary supplement product described in such subclause from the market.''.

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

''(z) If it is a dietary supplement for which a facility is required to submit the registration information required under section 415(a)(6) and such facility has not complied with the requirements of such section 415(a)(6) with respect to such dietary supplement.''.

(b) LABELING.—

(1) ESTABLISHMENT OF LABELING REQUIREMENTS.—Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by inserting after section 411 the following:

''SEC. 411A. DIETARY SUPPLEMENTS.

''(a) DIETARY SUPPLEMENT INGREDIENTS.—Not later than 1 year after the date of enactment of the Dietary Supplement Labeling Act of 2011, the Secretary shall compile a list of dietary supplement ingredients and proprietary blends of ingredients that the Secretary determines could cause potentially serious adverse events, drug interactions, contraindications, or potential risks to subgroups such as children and pregnant or breastfeeding women.

''(b) IOM STUDY.—The Secretary shall seek to enter into a contract with the Institute of Medicine under which

the Institute of Medicine shall evaluate dietary supplement ingredients and proprietary blends of ingredients, including those on the list compiled by the Secretary under subsection (a), and scientific literature on dietary supplement ingredients and, not later than 18 months after the date of enactment of the Dietary Supplement Labeling Act of 2011, submit to the Secretary a report evaluating the safety of dietary supplement ingredients and proprietary blends of ingredients the Institute of Medicine determines could cause potentially serious adverse events, drug interactions, contraindications, or potential risks to subgroups such as children and pregnant or breastfeeding women.

''(c) ESTABLISHMENT OF REQUIREMENTS.—Not later than 2 years after the date on which the Institute of Medicine issues the report under subsection (b), the Secretary, after providing for public notice and comment and taking into consideration such report, shall—

''(1) establish mandatory warning label requirements for dietary supplement ingredients that the Secretary determines to cause potentially serious adverse events, drug interactions, contraindications, or potential risks to subgroups; and

''(2) identify proprietary blends of ingredients for which, because of potentially serious adverse events, drug interactions, contraindications, or po-

tential risks to subgroups such as children and pregnant or breastfeeding women, the weight per serving of the ingredient in the proprietary blend shall be provided on the label.

''(d) UPDATES.—As appropriate, the Secretary, after providing for public notice and comment, shall update—

''(1) the list compiled under subsection (a);

''(2) the mandatory warning label requirements established under paragraph (1) of subsection (c); and

''(3) the requirements under paragraph (2) of subsection (c).''.

(2) ENFORCEMENT.—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended—

(A) in subsection (q)(5)(F)(ii), by inserting '', and for each proprietary blend identified by the Secretary under section 411A(c)(1)(B), the weight of such proprietary blend,'' after ''ingredients)''; and

(B) in subsection (s)(2)—

(i) in subparagraph (A)(ii)(II), by inserting '', and for each proprietary blend identified by the Secretary under section 411A(c)(1)(B), the weight of each such

proprietary blend per serving'' before the semicolon at the end;

(ii) in subparagraph (D)(iii), by striking ''or'' at the end;

(iii) in subparagraph (E)(ii)(II), by striking the period at the end and inserting a semicolon; and

(iv) by adding at the end the following:

''(F) the label or labeling does not include information with respect to potentially serious adverse events, drug interactions, contraindications, or potential risks to subgroups such as children and pregnant or breastfeeding women, as required under section 411A(c); or

''(G) the label does not include the batch number.''.

(c) CONVENTIONAL FOODS.—The Secretary of Health and Human Services, not later than 1 year after the date of enactment of this Act and after providing for public notice and comment, shall establish a definition for the term ''conventional food'' for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.). Such definition shall take into account conventional foods marketed as dietary supplements, including products mar-

keted as dietary supplements that simulate conventional foods.