

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.

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 Labeling Act of 2011”.

1 **SEC. 2. REGULATION OF DIETARY SUPPLEMENTS.**

2 (a) REGISTRATION.—

3 (1) IN GENERAL.—Section 415(a) of the Fed-
4 eral Food, Drug, and Cosmetic Act (21 U.S.C.
5 350d(a)) is amended by adding at the end the fol-
6 lowing:

7 “(6) REQUIREMENTS WITH RESPECT TO DIE-
8 TARY SUPPLEMENTS.—

9 “(A) IN GENERAL.—A facility engaged in
10 manufacturing dietary supplements that is re-
11 quired to register under this section shall com-
12 ply with the requirements of this paragraph, in
13 addition to the other requirements of this sec-
14 tion.

15 “(B) ADDITIONAL INFORMATION.—A facil-
16 ity described in subparagraph (A) shall submit
17 a registration under paragraph (1) that in-
18 cludes, in addition to the information required
19 under paragraph (2)—

20 “(i) a description of each dietary sup-
21 plement product manufactured by such fa-
22 cility;

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

25 “(iii) a copy of the label and labeling
26 for each such product.

1 “(C) REGISTRATION WITH RESPECT TO
2 NEW, REFORMULATED, AND DISCONTINUED DI-
3 ETARY SUPPLEMENT PRODUCTS.—

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

7 “(I) manufactures a dietary sup-
8 plement product that the facility pre-
9 viously did not manufacture and for
10 which the facility did not submit the
11 information required under clauses (i)
12 through (iii) of subparagraph (B);

13 “(II) reformulates a dietary sup-
14 plement product for which the facility
15 previously submitted the information
16 required under clauses (i) through
17 (iii) of subparagraph (B); or

18 “(III) no longer manufactures a
19 dietary supplement for which the fa-
20 cility previously submitted the infor-
21 mation required under clauses (i)
22 through (iii) of subparagraph (B),

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

1 (III) and, in the case of a facility described
2 in subclause (I) or (II), containing the in-
3 formation required under clauses (i)
4 through (iii) of subparagraph (B).

5 “(ii) DATE DESCRIBED.—The date de-
6 scribed in this clause is—

7 “(I) in the case of a facility de-
8 scribed in subclause (I) of clause (i),
9 30 days after the date on which such
10 facility first markets the dietary sup-
11 plement product described in such
12 subclause;

13 “(II) in the case of a facility de-
14 scribed in subclause (II) of clause (i),
15 30 days after the date on which such
16 facility first markets the reformulated
17 dietary supplement product described
18 in such subclause; or

19 “(III) in the case of a facility de-
20 scribed in subclause (III) of clause (i),
21 30 days after the date on which such
22 facility removes the dietary supple-
23 ment product described in such sub-
24 clause from the market.”.

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

4 “(z) If it is a dietary supplement for which a facility
5 is required to submit the registration information required
6 under section 415(a)(6) and such facility has not complied
7 with the requirements of such section 415(a)(6) with re-
8 spect to such dietary supplement.”.

9 (b) LABELING.—

10 (1) ESTABLISHMENT OF LABELING REQUIRE-
11 MENTS.—Chapter IV of the Federal Food, Drug,
12 and Cosmetic Act (21 U.S.C. 341 et seq.) is amend-
13 ed by inserting after section 411 the following:

14 **“SEC. 411A. DIETARY SUPPLEMENTS.**

15 “(a) DIETARY SUPPLEMENT INGREDIENTS.—Not
16 later than 1 year after the date of enactment of the Die-
17 tary Supplement Labeling Act of 2011, the Secretary shall
18 compile a list of dietary supplement ingredients and pro-
19 prietary blends of ingredients that the Secretary deter-
20 mines could cause potentially serious adverse events, drug
21 interactions, contraindications, or potential risks to sub-
22 groups such as children and pregnant or breastfeeding
23 women.

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

1 the Institute of Medicine shall evaluate dietary supplement
2 ingredients and proprietary blends of ingredients, includ-
3 ing those on the list compiled by the Secretary under sub-
4 section (a), and scientific literature on dietary supplement
5 ingredients and, not later than 18 months after the date
6 of enactment of the Dietary Supplement Labeling Act of
7 2011, submit to the Secretary a report evaluating the safe-
8 ty of dietary supplement ingredients and proprietary
9 blends of ingredients the Institute of Medicine determines
10 could cause potentially serious adverse events, drug inter-
11 actions, contraindications, or potential risks to subgroups
12 such as children and pregnant or breastfeeding women.

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

18 “(1) establish mandatory warning label require-
19 ments for dietary supplement ingredients that the
20 Secretary determines to cause potentially serious ad-
21 verse events, drug interactions, contraindications, or
22 potential risks to subgroups; and

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

1 potential risks to subgroups such as children and preg-
2 nant or breastfeeding women, the weight per serving
3 of the ingredient in the proprietary blend shall be
4 provided on the label.

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

7 “(1) the list compiled under subsection (a);

8 “(2) the mandatory warning label requirements
9 established under paragraph (1) of subsection (c);
10 and

11 “(3) the requirements under paragraph (2) of
12 subsection (c).”.

13 (2) ENFORCEMENT.—Section 403 of the Fed-
14 eral Food, Drug, and Cosmetic Act (21 U.S.C. 343)
15 is amended—

16 (A) in subsection (q)(5)(F)(ii), by inserting
17 “, and for each proprietary blend identified by
18 the Secretary under section 411A(c)(1)(B), the
19 weight of such proprietary blend,” after “ingre-
20 dients”); and

21 (B) in subsection (s)(2)—

22 (i) in subparagraph (A)(ii)(II), by in-
23 sserting “, and for each proprietary blend
24 identified by the Secretary under section
25 411A(c)(1)(B), the weight of each such

1 proprietary blend per serving” before the
2 semicolon at the end;

3 (ii) in subparagraph (D)(iii), by strik-
4 ing “or” at the end;

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

8 (iv) by adding at the end the fol-
9 lowing:

10 “(F) the label or labeling does not include
11 information with respect to potentially serious
12 adverse events, drug interactions, contraindica-
13 tions, or potential risks to subgroups such as
14 children and pregnant or breastfeeding women,
15 as required under section 411A(e); or

16 “(G) the label does not include the batch
17 number.”.

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

- 1 keted as dietary supplements that simulate conventional
- 2 foods.