

113TH CONGRESS  
1ST SESSION

# S. 1425

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 supplements with the Food and Drug Administration and to amend labeling requirements with respect to dietary supplements.

---

## IN THE SENATE OF THE UNITED STATES

AUGUST 1, 2013

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

---

## 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 supplements 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 2013”.

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

2 (a) REGISTRATION REQUIREMENTS.—

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 or processing dietary supple-  
11 ments that is required to register under this  
12 section shall comply with the requirements of  
13 this paragraph, in addition to the other require-  
14 ments of this section.

15 “(B) ADDITIONAL INFORMATION.—

16 “(i) IN GENERAL.—A facility de-  
17 scribed in subparagraph (A) shall submit a  
18 registration under paragraph (1) that in-  
19 cludes, in addition to the information re-  
20 quired under paragraph (2)—

21 “(I) a description of each dietary  
22 supplement manufactured or proc-  
23 essed by such facility;

24 “(II) a list of all ingredients in  
25 each such dietary supplement; and

1                   “(III) a copy of the label for each  
2                   such dietary supplement.

3                   “(ii) PUBLIC AVAILABILITY.—The  
4                   Secretary shall make the information pro-  
5                   vided under clause (i) publicly available, in-  
6                   cluding by posting such information on the  
7                   Internet Web site of the Food and Drug  
8                   Administration.

9                   “(C) REGISTRATION WITH RESPECT TO  
10                  NEW, REFORMULATED, AND DISCONTINUED DI-  
11                  ETARY SUPPLEMENTS.—

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

15                         “(I) manufactures or processes a  
16                         dietary supplement that the facility  
17                         previously did not manufacture or  
18                         process and for which the facility did  
19                         not submit the information required  
20                         under subclauses (I) through (III) of  
21                         subparagraph (B)(i);

22                         “(II) reformulates a dietary sup-  
23                         plement for which the facility pre-  
24                         viously submitted the information re-

1                    quired under subclauses (I) through  
2                    (III) of subparagraph (B)(i); or

3                    “(III) no longer manufactures or  
4                    processes a dietary supplement for  
5                    which the facility previously submitted  
6                    the information required under sub-  
7                    clauses (I) through (III) of subpara-  
8                    graph (B)(i),

9                    such facility shall submit to the Secretary  
10                   an updated registration describing the  
11                   change described in subclause (I), (II), or  
12                   (III) and, in the case of a facility described  
13                   in subclause (I) or (II), containing the in-  
14                   formation required under subclauses (I)  
15                   through (III) of subparagraph (B)(i).

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

18                   “(I) in the case of a facility de-  
19                   scribed in subclause (I) of clause (i),  
20                   30 days after the date on which such  
21                   facility first markets the dietary sup-  
22                   plement described in such subclause;

23                   “(II) in the case of a facility de-  
24                   scribed in subclause (II) of clause (i),  
25                   30 days after the date on which such

1 facility first markets the reformulated  
2 dietary supplement described in such  
3 subclause; or

4 “(III) in the case of a facility de-  
5 scribed in subclause (III) of clause (i),  
6 30 days after the date on which such  
7 facility removes the dietary supple-  
8 ment described in such subclause from  
9 the market.”.

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

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

18 (b) LABELING.—

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

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

24 “(a) DIETARY SUPPLEMENT INGREDIENTS.—Not  
25 later than 1 year after the date of enactment of the Die-

1 tary Supplement Labeling Act of 2013, the Secretary shall  
2 compile a list of dietary supplement ingredients and pro-  
3 prietary blends of ingredients that the Secretary deter-  
4 mines could cause potentially serious adverse events, drug  
5 interactions, or contraindications, or potential risks to  
6 subgroups such as children and pregnant or breastfeeding  
7 women.

8       “(b) IOM STUDY.—The Secretary shall seek to enter  
9 into a contract with the Institute of Medicine under which  
10 the Institute of Medicine shall evaluate dietary supplement  
11 ingredients and proprietary blends of ingredients, includ-  
12 ing those on the list compiled by the Secretary under sub-  
13 section (a), and scientific literature on dietary supplement  
14 ingredients and, not later than 18 months after the date  
15 of enactment of the Dietary Supplement Labeling Act of  
16 2013, submit to the Secretary a report evaluating the safe-  
17 ty of dietary supplement ingredients and proprietary  
18 blends of ingredients the Institute of Medicine determines  
19 could cause potentially serious adverse events, drug inter-  
20 actions, or contraindications, or potential risks to sub-  
21 groups such as children and pregnant or breastfeeding  
22 women.

23       “(c) ESTABLISHMENT OF REQUIREMENTS.—Not  
24 later than 2 years after the date on which the Institute  
25 of Medicine issues the report under subsection (b), the

1 Secretary, after providing for public notice and comment  
2 and taking into consideration such report, shall—

3 “(1) establish mandatory warning label require-  
4 ments for dietary supplement ingredients that the  
5 Secretary determines to cause potentially serious ad-  
6 verse events, drug interactions, or contraindications,  
7 or potential risks to subgroups; and

8 “(2) identify proprietary blends of ingredients  
9 for which, because of potentially serious adverse  
10 events, drug interactions, or contraindications, or  
11 potential risks to subgroups such as children and  
12 pregnant or breastfeeding women, the weight per  
13 serving of the ingredient in the proprietary blend  
14 shall be provided on the label.

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

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

18 “(2) the mandatory warning label requirements  
19 established under paragraph (1) of subsection (c);  
20 and

21 “(3) the requirements under paragraph (2) of  
22 subsection (c).”.

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

1 (A) in paragraph (q)(5)(F)(ii), by inserting  
2 “, and for each proprietary blend identified by  
3 the Secretary under section 411A(c)(2), the  
4 weight of such proprietary blend,” after “ingre-  
5 dients”); and

6 (B) in paragraph (s)(2)—

7 (i) in clause (A)(ii)(II), by inserting “,  
8 and for each proprietary blend identified  
9 by the Secretary under section 411A(c)(2),  
10 the weight of each such proprietary blend  
11 per serving” before the semicolon at the  
12 end;

13 (ii) in clause (D)(iii), by striking “or”  
14 at the end;

15 (iii) in clause (E)(ii)(II), by striking  
16 the period at the end and inserting a semi-  
17 colon; and

18 (iv) by adding at the end the fol-  
19 lowing:

20 “(F) the label does not include information  
21 with respect to potentially serious adverse  
22 events, drug interactions, or contraindications,  
23 or potential risks to subgroups such as children  
24 and pregnant or breastfeeding women, as re-  
25 quired under section 411A(c)(1); or



1                   “(G) the label does not include the batch  
2                   number.”.

3           (c) STRUCTURE AND FUNCTION CLAIMS.—Section  
4 403(r)(6)(B) of the Federal Food, Drug, and Cosmetic  
5 Act (21 U.S.C. 343(r)(6)(B)) is amended by inserting “,  
6 and provides such substantiation to the Secretary, as the  
7 Secretary may require” after “misleading”.

8           (d) CONVENTIONAL FOODS.—The Secretary of  
9 Health and Human Services, not later than 1 year after  
10 the date of enactment of this Act and after providing for  
11 public notice and comment, shall establish a definition for  
12 the term “conventional food” for purposes of the Federal  
13 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).  
14 Such definition shall take into account conventional foods  
15 marketed as dietary supplements, including products mar-  
16 keted as dietary supplements that simulate conventional  
17 foods.

○