

109TH CONGRESS  
1ST SESSION

# H. R. 3156

To amend the Federal Food, Drug, and Cosmetic Act with respect to dietary supplements.

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IN THE HOUSE OF REPRESENTATIVES

JUNE 30, 2005

Mrs. DAVIS of California (for herself, Mr. WAXMAN, and Mr. DINGELL) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act 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 Access and Awareness Act”.

1 **SEC. 2. DIETARY SUPPLEMENTS; PRODUCT LISTING; RE-**  
2 **PORTING, POSTMARKET SURVEILLANCE, AND**  
3 **OTHER PROVISIONS REGARDING SAFETY.**

4 (a) IN GENERAL.—Chapter IV of the Federal Food,  
5 Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amend-  
6 ed by adding at the end the following section:

7 **“SEC. 416. DIETARY SUPPLEMENTS; PRODUCT LISTING; RE-**  
8 **PORTING, POSTMARKET SURVEILLANCE, AND**  
9 **OTHER PROVISIONS REGARDING SAFETY.**

10 “(a) LIMITATION ON APPLICABILITY.—Notwith-  
11 standing the other subsections of this section, this section  
12 does not apply to any dietary supplement that meets the  
13 conditions described in paragraphs (1) and (2), as follows:

14 “(1) The supplement bears or contains one or  
15 more of the following dietary ingredients:

16 “(A) A vitamin.

17 “(B) A mineral.

18 “(C) A concentrate, metabolite, con-  
19 stituent, extract, or combination of any vitamin  
20 or mineral.

21 “(2) The supplement does not bear or con-  
22 tain—

23 “(A) an herb or other botanical, an amino  
24 acid, or a dietary substance for use by man to  
25 supplement the diet by increasing the total die-  
26 tary intake; or

1           “(B) a concentrate, metabolite, con-  
2           stituent, extract, or combination of any ingre-  
3           dient specified in subparagraph (A).

4           “(b) PRODUCT LISTING.—Every person who is re-  
5           quired under section 415 to register with the Secretary  
6           with respect to manufacturing or processing a dietary sup-  
7           plement shall, in the form and manner prescribed by the  
8           Secretary, report to the Secretary twice each year, once  
9           during the month of June and once during the month of  
10          December, the following information:

11           “(1) A list of each dietary supplement manufac-  
12          tured or processed by the person for commercial dis-  
13          tribution in the United States, other than dietary  
14          supplements previously included on a list reported  
15          under this subsection by the person.

16           “(2) The labeling for each of the dietary supple-  
17          ments on the list.

18           “(3) A listing of the major ingredients of each  
19          dietary supplement on the list (including active in-  
20          gredients, as applicable), except that the Secretary  
21          may require the submission of a quantitative listing  
22          of all ingredients in such a supplement if the Sec-  
23          retary finds that such submission is necessary to  
24          carry out the purposes of this Act.

1           “(4) If, since the date the person last made a  
2 report under this subsection (or if the person has  
3 not previously made such a report, since the effective  
4 date of this section), the person has discontinued the  
5 manufacture or processing of a dietary supplement  
6 included on a list reported under this subsection by  
7 the person—

8                   “(A) notice of such discontinuance;

9                   “(B) the date of such discontinuance; and

10                   “(C) the identity of such supplement.

11           “(5) Such other information describing the die-  
12 tary supplements as the Secretary may by regulation  
13 require.

14           “(c) REPORTING OF INFORMATION ON ADVERSE EX-  
15 PERIENCES.—

16                   “(1) SERIOUS EXPERIENCES.—Each person  
17 who is a manufacturer or distributor of a dietary  
18 supplement shall report to the Secretary any infor-  
19 mation received by such person on serious adverse  
20 experiences regarding the supplement. Such a report  
21 shall be submitted to the Secretary not later than 15  
22 days after the date on which the person receives  
23 such information.

24                   “(2) INVESTIGATION AND FOLLOW-UP.—A per-  
25 son submitting a report under paragraph (1) on a

1 serious adverse experience shall promptly investigate  
2 the experience, and if additional information is ob-  
3 tained, shall report the information to the Secretary  
4 not later than 15 days after obtaining the informa-  
5 tion. If no additional information is obtained,  
6 records of the steps taken to seek additional infor-  
7 mation shall be maintained by the person.

8 “(3) AUTHORITY OF SECRETARY.—In addition  
9 to requirements established in this subsection, the  
10 Secretary may establish such requirements regarding  
11 the reporting of information on adverse experiences  
12 as the Secretary determines to be appropriate to  
13 protect the public health. The Secretary may estab-  
14 lish waivers from requirements under this subsection  
15 regarding such information if the Secretary deter-  
16 mines that compliance with the requirement involved  
17 is not necessary to protect the public health regard-  
18 ing such supplements.

19 “(4) DEFINITIONS.—For purposes of this sub-  
20 section:

21 “(A) The term ‘adverse experience regard-  
22 ing a dietary supplement’ means any adverse  
23 event associated with the use of such supple-  
24 ment in humans, whether or not such event is  
25 considered to be related to the supplement by a

1 person referred to in paragraph (1) who obtains  
2 the information.

3 “(B) The term ‘serious’, with respect to an  
4 adverse experience regarding a dietary supple-  
5 ment, means an adverse experience that—

6 “(i) results in death; a life-threatening  
7 condition; inpatient hospitalization or pro-  
8 longation of hospitalization; a persistent or  
9 significant disability or incapacity; or a  
10 congenital anomaly, birth defect, or other  
11 effect regarding pregnancy, including pre-  
12 mature labor or low birth weight; or

13 “(ii) requires medical or surgical  
14 intervention to prevent one of the outcomes  
15 described in clause (i).

16 “(d) POSTMARKET SURVEILLANCE.—The Secretary  
17 may by order require a manufacturer of a dietary supple-  
18 ment to conduct postmarket surveillance for the supple-  
19 ment if the Secretary determines that there is a reasonable  
20 possibility that a use or expected use of the supplement  
21 may have serious adverse health consequences.

22 “(e) AUTHORITY TO ORDER DEMONSTRATION OF  
23 SAFETY.—

24 “(1) IN GENERAL.—If the Secretary has rea-  
25 sonable grounds for believing that a dietary supple-

1       ment may be adulterated under section 402(f)(1),  
2       the Secretary may by order require the manufac-  
3       turer to demonstrate to the Secretary that the sup-  
4       plement is not so adulterated.

5               “(2) DISTRIBUTION OF PRODUCT PENDING  
6       COMPLETION OF PROCESS.—

7               “(A) IN GENERAL.—Subject to subpara-  
8       graph (B), a dietary supplement may not be  
9       considered adulterated under section 402(f)(1)  
10       during the pendency of a demonstration under  
11       paragraph (1) by the manufacturer of the sup-  
12       plement and during the pendency of the review  
13       under paragraph (4) by the Secretary with re-  
14       spect to the demonstration.

15               “(B) IMMINENT HAZARD TO PUBLIC  
16       HEALTH OR SAFETY.—This subsection does not  
17       affect the authority of the Secretary under sec-  
18       tion 402(f)(1)(C).

19               “(3) TIMEFRAME FOR DEMONSTRATION.—

20               “(A) IN GENERAL.—An order under para-  
21       graph (1) shall provide that the demonstration  
22       under such paragraph by a manufacturer is re-  
23       quired to be completed not later than the expi-  
24       ration of 180 days after the date on which the  
25       order is issued, except that the Secretary may

1 extend such period if the Secretary determines  
2 that an extension is appropriate. Any informa-  
3 tion submitted for such purpose by the manu-  
4 facturer after the expiration of the applic-  
5 able period under the preceding sentence may not be  
6 considered by the Secretary, except to the ex-  
7 tent that the Secretary requests the manufac-  
8 turer to provide additional information after  
9 such period.

10 “(B) COMPLETION DATE OF DEMONSTRA-  
11 TION.—A demonstration under paragraph (1)  
12 shall be considered complete on the expiration  
13 of the applicable period under subparagraph  
14 (A), or on such earlier date as the manufac-  
15 turer informs the Secretary that the manufac-  
16 turer has completed the demonstration, or on  
17 such earlier date as the Secretary reasonably  
18 concludes that the manufacturer has no further  
19 information to provide to the Secretary as part  
20 of the demonstration or that the manufacturer  
21 is not in substantial compliance with the order  
22 under paragraph (1).

23 “(4) REVIEW BY SECRETARY.—Once a dem-  
24 onstration under paragraph (1) by a manufacturer is  
25 completed, the Secretary shall review all relevant in-

1 formation received by the Secretary pursuant to the  
2 demonstration or otherwise available to the Sec-  
3 retary and make a determination of whether the  
4 Secretary considers the dietary supplement involved  
5 to be adulterated under section 402(f)(1). Such de-  
6 termination shall be made not later than 180 days  
7 after the completion of the demonstration.

8 “(5) REQUIREMENTS REGARDING DEMONSTRA-  
9 TIONS.—The Secretary may, by order or by regula-  
10 tion, establish requirements for demonstrations  
11 under paragraph (1).

12 “(6) RELATION TO OTHER PROCEDURES.—In  
13 the case of a dietary supplement with respect to  
14 which the Secretary has not issued an order under  
15 paragraph (1), this subsection may not be construed  
16 as preventing the Secretary from acting pursuant to  
17 section 402(f)(1) to the same extent and in the same  
18 manner as would apply in the absence of this sub-  
19 section. In the case of a dietary supplement with re-  
20 spect to which the Secretary has issued an order  
21 under paragraph (1), a determination under para-  
22 graph (4) that the supplement is not adulterated  
23 under section 402(f)(1) does not prevent the Sec-  
24 retary from making a determination, on the basis of

1 additional information obtained by the Secretary,  
2 that the supplement is so adulterated.

3 “(f) SALES TO MINORS; SIGNIFICANT RISK.—

4 “(1) CRITERIA.—Not later than the expiration  
5 of the two-year period beginning on the date of the  
6 enactment of the Dietary Supplement Access and  
7 Awareness Act, the Secretary shall by regulation es-  
8 tablish criteria for making a determination that a di-  
9 etary supplement may pose a significant risk to indi-  
10 viduals who are under the age of 18 (referred to in  
11 this section individually as a ‘minor’).

12 “(2) PRODUCT DETERMINATION; PROHIBITED  
13 ACT.—The Secretary may, by order or by regulation,  
14 make a determination described in paragraph (1)  
15 with respect to a dietary supplement. Effective upon  
16 the expiration of a period designated by the Sec-  
17 retary in publishing such determination in the Fed-  
18 eral Register, the act of selling the dietary supple-  
19 ment to a minor shall be deemed to be an act which  
20 results in such supplement being misbranded while  
21 held for sale. During the two-year period referred to  
22 in paragraph (1), an order making such a deter-  
23 mination may be issued notwithstanding that criteria  
24 have not yet been established in accordance with  
25 such paragraph.

1 “(g) RECORDKEEPING ON SAFETY ISSUES.—

2 “(1) IN GENERAL.—The Secretary shall by reg-  
3 ulation require manufacturers of dietary supple-  
4 ments to maintain records regarding reports of seri-  
5 ous adverse experiences under subsection (c) and  
6 records regarding compliance with section 402.

7 “(2) RETENTION PERIOD.—Regulations under  
8 paragraph (1) shall specify the number of years for  
9 which records required in such paragraph are re-  
10 quired to be retained, except that, if under section  
11 402(g)(1) the Secretary makes a determination that  
12 expiration date labeling is necessary for dietary sup-  
13 plements, records regarding dietary supplements in  
14 a lot shall be retained for not less than one year  
15 after the expiration date of supplements in the lot.”.

16 (b) PROHIBITED ACTS.—

17 (1) IN GENERAL.—Section 301 of the Federal  
18 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is  
19 amended by adding at the end the following:

20 “(hh) The failure of a person to comply with any re-  
21 quirement under section 416, other than an order under  
22 subsection (e)(1) of such section.”.

23 (2) ADULTERATED DIETARY SUPPLEMENTS.—

24 (A) ORDER REGARDING DEMONSTRATION  
25 OF SAFETY.—Section 402 of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 342) is  
2 amended by adding at the end the following:

3 “(i) If it is a dietary supplement and the manufac-  
4 turer of the supplement fails to comply with an order of  
5 the Secretary under section 416(e)(1) that is issued with  
6 respect to the supplement.”.

7 (B) CERTAIN COURT PROCEDURES; DE-  
8 TERMINATION OF UNREASONABLE RISK.—Sec-  
9 tion 402(f) of the Federal Food, Drug, and  
10 Cosmetic Act (21 U.S.C. 342(f)) is amended—

11 (i) in subparagraph (1), by striking  
12 the matter after and below clause (D) of  
13 such subparagraph; and

14 (ii) by adding at the end the following  
15 subparagraph:

16 “(3)(A) For purposes of clause (A) or (B) of subpara-  
17 graph (1), the Secretary shall consider a dietary supple-  
18 ment or dietary ingredient as presenting an unreasonable  
19 risk of illness or injury if the Secretary determines that  
20 the risks of such product outweighs its benefits, as indi-  
21 cated by a relative weighing of the known and reasonably  
22 likely risks of the product against its known and reason-  
23 ably likely benefits. In the absence of a sufficient benefit,  
24 the presence of even a relatively small risk of a serious

1 adverse health effect to a user may be considered by the  
2 Secretary as unreasonable.

3 “(B) A determination by the Secretary under clause  
4 (A) with respect to the risk of a product may be made  
5 on the basis of any science-based evidence of risk, without  
6 the need to prove that the substance has actually caused  
7 harm in particular cases. The Secretary shall consider any  
8 relevant evidence including but not limited to scientific  
9 data about the toxicological properties of a dietary ingre-  
10 dient or its mechanism of action; known effects of pharma-  
11 cologically related compounds, including those regulated  
12 as drugs; the results of clinical studies, including observa-  
13 tional studies; and adverse event reports.

14 “(C) A determination that a product presents an un-  
15 reasonable risk may be made under clause (A) by the Sec-  
16 retary even though there are uncertainties as to the levels  
17 of a dietary ingredient that may present a risk.”

18 (3) TRADE SECRETS.—Section 301(j) of the  
19 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
20 331(j)) is amended by inserting “416,” after  
21 “414,”.

22 (c) INSPECTION AUTHORITY.—Section 704(a) of the  
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a))  
24 is amended—

1 (1) in paragraph (1), by inserting after the sec-  
2 ond sentence the following: “In the case of any per-  
3 son who manufactures, processes, packs, transports,  
4 distributes, holds, or imports a dietary supplement  
5 with respect to which an order under section  
6 416(e)(1) has been issued, the inspection shall ex-  
7 tend to all records, files, papers, processes, controls,  
8 and facilities bearing on whether the dietary supple-  
9 ment is adulterated under section 402(f)(1).”; and

10 (2) in paragraph (2), in the matter preceding  
11 subparagraph (A), by striking “third sentence” and  
12 inserting “fourth sentence”.

13 **SEC. 3. EDUCATION PROGRAMS REGARDING DIETARY SUP-**  
14 **PLEMENTS.**

15 (a) **HEALTH CARE PROFESSIONALS.—**

16 (1) **IN GENERAL.—**The Secretary of Health and  
17 Human Services (referred to in this section as the  
18 “Secretary”), acting through the Commissioner of  
19 Food and Drugs, shall carry out a program to edu-  
20 cate health professionals on the importance of re-  
21 porting to the Food and Drug Administration ad-  
22 verse health experiences that are associated with die-  
23 tary supplements.

24 (2) **AUTHORIZATION OF APPROPRIATIONS.—**For  
25 the purpose of carrying out paragraph (1), there is

1 authorized to be appropriated \$5,000,000 for fiscal  
2 year 2006, in addition to any other authorization of  
3 appropriations that is available with respect to such  
4 purpose.

5 (b) CONSUMERS.—

6 (1) IN GENERAL.—The Secretary, acting  
7 through the Commissioner of Food and Drugs, shall  
8 carry out a program to educate consumers of dietary  
9 supplements on the importance of informing their  
10 health professionals of the dietary supplements and  
11 drugs the consumers are taking.

12 (2) AUTHORIZATION OF APPROPRIATIONS.—For  
13 the purpose of carrying out paragraph (1), there is  
14 authorized to be appropriated \$5,000,000 for fiscal  
15 year 2006, in addition to any other authorization of  
16 appropriations that is available with respect to such  
17 purpose.

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