

108TH CONGRESS  
1ST SESSION

# H. R. 724

To amend the Federal Food, Drug, and Cosmetic Act to require that manufacturers of dietary supplements register with the Food and Drug Administration, to require the submission to such Administration of reports on adverse experiences regarding such supplements, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 12, 2003

Mrs. DAVIS of California 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 to require that manufacturers of dietary supplements register with the Food and Drug Administration, to require the submission to such Administration of reports on adverse experiences regarding such supplements, and for other purposes.

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 Information Act”.

1 **SEC. 2. REGISTRATION, REPORTING, AND POSTMARKET**  
2 **SURVEILLANCE REGARDING DIETARY SUP-**  
3 **PLEMENTS.**

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 “REGISTRATION, REPORTING, AND POSTMARKET  
8 SURVEILLANCE REGARDING DIETARY SUPPLEMENTS

9 “SEC. 416. (a) REGISTRATION.—

10 “(1) ANNUAL REGISTRATION.—Each calendar  
11 year a person who in any State owns or operates an  
12 establishment engaged in the business of manufac-  
13 turing, packing, or distributing a dietary supplement  
14 shall register with the Secretary the name of the  
15 person, places of business, and all such establish-  
16 ments.

17 “(2) INITIAL MANUFACTURING.—A person,  
18 upon first engaging in a business described in para-  
19 graph (1) in an establishment that the person owns  
20 or operates in any State, shall immediately register  
21 with the Secretary the name of the person, place of  
22 business, and such establishment.

23 “(3) ADDITIONAL ESTABLISHMENTS.—A person  
24 duly registered in accordance with paragraph (1) or  
25 (2), upon engaging in the business involved in any  
26 additional establishment that the person owns or op-

1 erates in any State, shall immediately register with  
2 the Secretary the additional establishment.

3 “(4) IMPORTS.—Any establishment within any  
4 foreign country engaged in the manufacture of a die-  
5 tary supplement that is imported or offered for im-  
6 port into the United States shall register with the  
7 Secretary the name and place of business of the es-  
8 tablishment and the name of the United States  
9 agent for the establishment.

10 “(5) PRODUCT INFORMATION.—

11 “(A) LABELING; OTHER INFORMATION.—  
12 In addition to information that under any of  
13 paragraphs (1) through (4) is required to be  
14 provided in a registration, the registration shall  
15 provide the labeling of the dietary supplements  
16 involved (except to the extent that another reg-  
17 istration under this subsection provides the la-  
18 beling) and such other information describing  
19 the dietary supplements as the Secretary may  
20 by regulation require.

21 “(B) CHANGES IN UNDERLYING FACTS.—  
22 With respect to information that pursuant to  
23 subparagraph (A) is submitted in a registra-  
24 tion, if after submitting the registration to the  
25 Secretary any of the underlying facts change,

1 the person involved shall submit revised infor-  
2 mation to the Secretary in accordance with  
3 such criteria and procedures as the Secretary  
4 may establish, which may include requiring the  
5 submission of a substitute registration. The re-  
6 vised information shall be so submitted not  
7 later than 30 days after the date on which the  
8 factual changes occur.

9 “(C) PREMARKET SUBMISSION OF LABEL-  
10 ING FOR POSTENACTMENT PRODUCTS.—In the  
11 case of a dietary supplement that was not in  
12 commercial distribution as of the day before the  
13 date of the enactment of the Dietary Supple-  
14 ment Information Act, the manufacturer of  
15 such supplement shall submit the labeling for  
16 the supplement to the Secretary in accordance  
17 with subparagraph (A) before introducing the  
18 supplement into interstate commerce or deliv-  
19 ering the supplement for such introduction.

20 “(6) FEES.—The Secretary may by regulation  
21 establish a requirement that a registration under  
22 this subsection is subject to a fee to be assessed and  
23 collected by the Secretary. Subject to the extent of  
24 amounts approved in advance by an appropriation  
25 Act for the fiscal year involved, amounts collected by

1 the Secretary under the preceding sentence are  
2 available to the Secretary for the purpose of car-  
3 rying out the responsibilities of the Secretary under  
4 this subsection and subsection (b). The Secretary  
5 may waive the requirement that a person pay such  
6 a fee if the Secretary determines that the waiver is  
7 justified on the basis that the person is a small busi-  
8 ness.

9 “(b) REPORTING OF INFORMATION ON ADVERSE EX-  
10 PERIENCES.—

11 “(1) SERIOUS EXPERIENCES.—Each person  
12 who is a manufacturer of a dietary supplement, or  
13 a packer or distributor of the supplement whose  
14 name appears on the labeling of the supplement,  
15 shall—

16 “(A) report to the Secretary in accordance  
17 with paragraph (2) any information received by  
18 such person on serious adverse experiences re-  
19 garding the supplement; and

20 “(B) develop written procedures regarding  
21 the submission to the Secretary of such reports,  
22 including procedures for surveillance, receipt,  
23 and evaluation of information on such experi-  
24 ences.

25 “(2) REPORTING OF SERIOUS EXPERIENCES.—

1           “(A) INITIAL REPORT.—With respect to  
2 the initial receipt of information on a serious  
3 adverse experience, a person with reporting re-  
4 sponsibility under paragraph (1) shall submit  
5 the report to the Secretary as soon as is pos-  
6 sible, but in no case later than 15 calendar days  
7 after the initial receipt of the information. Such  
8 report shall be accompanied by a copy of the  
9 current labeling for the dietary supplement in-  
10 volved.

11           “(B) INVESTIGATION AND FOLLOW-UP.—A  
12 person submitting an initial report under sub-  
13 paragraph (A) on a serious adverse experience  
14 shall promptly investigate the experience, and if  
15 additional information is obtained, shall report  
16 the information to the Secretary not later than  
17 15 days after obtaining the information. If no  
18 additional information is obtained, records of  
19 the steps taken to seek additional information  
20 shall be maintained by the person.

21           “(C) DUPLICATIVE REPORTING.—In order  
22 to avoid duplicative reporting under this para-  
23 graph, the Secretary may provide for proce-  
24 dures under which persons who are packers or  
25 distributors described in paragraph (1) submit

1 reports under this paragraph to the manufac-  
2 turer involved rather than the Secretary, with  
3 the manufacturers then submitting the required  
4 reports to the Secretary, subject to the Sec-  
5 retary establishing requirements to ensure that  
6 the Secretary receives reports within the appli-  
7 cable period of time specified in subparagraph  
8 (A) or (B).

9 “(3) CLINICAL EVALUATIONS BY SECRETARY.—

10 The Secretary shall conduct a clinical evaluation of  
11 each serious adverse experience reported to the Sec-  
12 retary under paragraph (2) (except to the extent  
13 that the patient involved or the next of kin for the  
14 patient, as the case may be, elects not to cooperate  
15 with the Secretary).

16 “(4) ADDITIONAL REQUIREMENTS FOR MANU-  
17 FACTURERS.—

18 “(A) GENERAL REVIEW REGARDING AD-  
19 VERSE EXPERIENCES.—A manufacturer of a di-  
20 etary supplement shall promptly review all in-  
21 formation on adverse experiences regarding the  
22 supplement obtained or otherwise received by  
23 the manufacturer. The preceding sentence ap-  
24 plies to information without regard to the  
25 source of the information, foreign or domestic,

1 and includes information derived from sources  
2 such as commercial marketing experience, post-  
3 marketing investigations, postmarketing surveil-  
4 lance, studies, reports in the scientific lit-  
5 erature, and unpublished scientific papers.

6 “(B) PERIODIC REPORTS ON NONSERIOUS  
7 EXPERIENCES.—With respect to the receipt of  
8 information on adverse experiences that are not  
9 serious, a manufacturer of the dietary supple-  
10 ment involved shall submit reports to the Sec-  
11 retary annually, or at such shorter intervals as  
12 the Secretary may require. Each such report  
13 shall meet such requirements as the Secretary  
14 may establish.

15 “(5) AUTHORITY OF SECRETARY.—In addition  
16 to requirements established in this subsection, the  
17 Secretary may establish such requirements regarding  
18 the reporting of information on adverse experiences  
19 as the Secretary determines to be appropriate to  
20 protect the public health. The Secretary may estab-  
21 lish waivers from requirements under this subsection  
22 regarding such information if the Secretary deter-  
23 mines that compliance with the requirement involved  
24 is not necessary to protect the public health regard-  
25 ing such supplements.

1           “(6) SYSTEM FOR COORDINATING REPORTS RE-  
2           CEIVED BY SECRETARY.—With respect to reports of  
3           adverse health experiences submitted to the Sec-  
4           retary (whether required under this subsection or  
5           otherwise), the Secretary shall establish a system to  
6           receive the reports, refer the reports to the appro-  
7           priate officials within the Food and Drug Adminis-  
8           tration, store and retrieve the reports, store and re-  
9           trieve records of activities carried out in response to  
10          the reports, and carry out such other administrative  
11          functions regarding the reports as the Secretary de-  
12          termines to be appropriate.

13           “(7) DATA COLLECTION BY SECRETARY.—The  
14          Secretary shall carry out a program to collect data  
15          on serious adverse experiences, in addition to receiv-  
16          ing reports required in this subsection. In carrying  
17          out such program, the Secretary shall seek the co-  
18          operation of appropriate public and private entities,  
19          including entities that respond to medical emer-  
20          gencies.

21           “(8) DEFINITIONS.—For purposes of this sec-  
22          tion:

23                   “(A) The term ‘adverse experience’ means  
24                   an adverse experience regarding a dietary sup-  
25                   plement.

1           “(B) The term ‘adverse experience regard-  
2           ing a dietary supplement’ means any adverse  
3           event associated with the use of such supple-  
4           ment in humans, whether or not such event is  
5           considered to be related to the supplement by a  
6           person referred to in paragraph (1) who obtains  
7           the information.

8           “(C) The term ‘serious’, with respect to an  
9           adverse experience, means an adverse experi-  
10          ence to which any of clauses (i) through (iii)  
11          applies, as follows:

12                 “(i) The experience is associated with  
13                 any of the following outcomes: Death; a  
14                 life-threatening condition; inpatient hos-  
15                 pitalization or prolongation of existing hos-  
16                 pitalization; a persistent or significant dis-  
17                 ability or incapacity; or a congenital anom-  
18                 aly, birth defect, or other effect regarding  
19                 pregnancy, including premature labor or  
20                 low birth weight.

21                 “(ii) The experience requires medical  
22                 or surgical intervention to prevent one of  
23                 the outcomes specified in clause (i).

24                 “(iii) There is reason to believe that a  
25                 factor associated with the experience is the

1 interaction of the dietary supplement in-  
2 volved with a drug, without regard to  
3 whether clause (i) or (ii) applies to the ex-  
4 perience.

5 “(c) POSTMARKET SURVEILLANCE.—

6 “(1) AUTHORITY TO REQUIRE SURVEIL-  
7 LANCE.—The Secretary may by order require a  
8 manufacturer of a dietary supplement to conduct  
9 postmarket surveillance for such supplement if the  
10 Secretary determines that there is a reasonable pos-  
11 sibility that a use or expected use of the supplement  
12 by a significant number of consumers may have seri-  
13 ous adverse health consequences.

14 “(2) SURVEILLANCE PLAN.—

15 “(A) IN GENERAL.—Not later than 30  
16 days after receiving from the Secretary an  
17 order under paragraph (1) to conduct surveil-  
18 lance for a dietary supplement, the manufac-  
19 turer involved shall submit to the Secretary, for  
20 the approval of the Secretary, a plan for the re-  
21 quired surveillance.

22 “(B) QUALIFICATIONS REGARDING SUR-  
23 VEILLANCE; DATA REGARDING ADVERSE EXPE-  
24 RIENCES.—Not later than 60 days after a plan  
25 is submitted to the Secretary under subpara-

1 graph (A), the Secretary shall determine wheth-  
2 er—

3 “(i) the person designated to conduct  
4 the surveillance has appropriate qualifica-  
5 tions and experience to conduct such sur-  
6 veillance; and

7 “(ii) the plan will result in the collec-  
8 tion of useful data that can reveal adverse  
9 experiences or other information necessary  
10 to protect the public health.

11 “(3) SURVEILLANCE PERIOD.—In consultation  
12 with a manufacturer of a dietary supplement that is  
13 required to conduct surveillance under paragraph  
14 (1), the Secretary may by order require a prospec-  
15 tive surveillance period for the manufacturer of up  
16 to 36 months. Any determination by the Secretary  
17 that a longer period is necessary shall be made by  
18 mutual agreement between the Secretary and the  
19 manufacturer or, if no agreement can be reached,  
20 after the completion of a dispute resolution process  
21 that is established by the Secretary by regulation.

22 “(d) REPORTING IN GENERAL.—In addition to re-  
23 quirements otherwise established under this section, a  
24 manufacturer of a dietary supplement shall establish and  
25 maintain such records, make such reports, and provide

1 such information as the Secretary may by regulation rea-  
2 sonably require to assure that such supplement is not  
3 adulterated or misbranded.”.

4 (b) PROHIBITED ACTS.—Section 301 of the Federal  
5 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-  
6 ed by adding at the end the following:

7 “(hh) The failure of a person to register, submit re-  
8 ports, or comply with any other requirement under section  
9 416.”.

10 **SEC. 3. INSPECTION AUTHORITY REGARDING RECORDS ON**  
11 **DIETARY SUPPLEMENTS.**

12 Section 704 of the Federal Food, Drug, and Cosmetic  
13 Act (21 U.S.C. 374) is amended—

14 (1) in subsection (a)(1)—

15 (A) in the third sentence, by striking “or  
16 restricted devices” each place such term ap-  
17 pears and inserting “restricted devices, or die-  
18 tary supplements”; and

19 (B) in the fourth sentence—

20 (i) by striking “and devices” and in-  
21 serting “devices, and dietary supplements”;  
22 and

23 (ii) by striking “section 505(i) or (k)”  
24 and inserting “section 416, section 505(i),  
25 section 505(k),”; and

1 (2) in subsection (e), by striking “section 519”  
2 and inserting “section 416, 519,”.

3 **SEC. 4. LABELING OF DIETARY SUPPLEMENTS.**

4 Section 403(e) of the Federal Food, Drug, and Cos-  
5 metic Act (21 U.S.C. 343(e)) is amended—

6 (1) by striking “and (2)” and inserting the fol-  
7 lowing: “(2) the toll-free telephone number, and the  
8 address of the Internet site, maintained by the Sec-  
9 retary for purposes of the medical product reporting  
10 program (MedWatch or any successor program); and  
11 (3) ”; and

12 (2) by striking “clause (2)” and inserting  
13 “clause (3)”.

14 **SEC. 5. PUBLICATION OF PROPOSED RULE ON CURRENT**  
15 **GOOD MANUFACTURING PRACTICES FOR DI-**  
16 **ETARY SUPPLEMENTS.**

17 Not later than 30 days after the date of the enact-  
18 ment of this Act, the Secretary of Health and Human  
19 Services shall publish in the Federal Register a proposed  
20 rule for carrying out section 402(g) of the Federal Food,  
21 Drug, and Cosmetic Act.

○