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107TH CONGRESS
1ST SESSION

H. R. 3065

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.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 9, 2001

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.

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 Information Act''.

SEC. 2. REGISTRATION, REPORTING, AND POSTMARKET SURVEILLANCE REGARDING DIETARY SUPPLEMENTS.

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

''REGISTRATION, REPORTING, AND POSTMARKET SURVEILLANCE REGARDING DIETARY SUPPLEMENTS

''SEC. 414. (a) REGISTRATION.—

''(1) ANNUAL REGISTRATION.—Each calendar year a person who in any State owns or operates an establishment engaged in the business of manufacturing, packing, or distributing a dietary supplement shall register with the Secretary the name of the person, places of business, and all such establishments.

''(2) INITIAL MANUFACTURING.—A person, upon first engaging in a business described in paragraph (1) in an establishment that the person owns or operates in any State, shall immediately register with the Secretary the name of the person, place of business, and such establishment.

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

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

''(4) IMPORTS.—Any establishment within any foreign country engaged in the manufacture of a dietary supplement that is imported or offered for import into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.

''(5) PRODUCT INFORMATION.—

''(A) LABELING; OTHER INFORMATION.—In addition to information that under any of paragraphs (1) through (4) is required to be provided in a registration, the registration shall provide the labeling of the dietary supplements involved (except to the extent that another registration under this subsection provides the labeling) and such other information describing the dietary supplements as the Secretary may by regulation require.

''(B) CHANGES IN UNDERLYING FACTS.—With respect to information that pursuant to subparagraph (A) is submitted in a registration, if after submitting the registration to the Secretary any of the underlying facts change,

the person involved shall submit revised information to the Secretary in accordance with such criteria and procedures as the Secretary may establish, which may include requiring the submission of a substitute registration. The revised information shall be so submitted not later than 30 days after the date on which the factual changes occur.

''(C) PREMARKET SUBMISSION OF LABELING FOR POSTENACTMENT PRODUCTS.—In the case of a dietary supplement that was not in commercial distribution as of the day before the date of the enactment of the Dietary Supplement Information Act, the manufacturer of such supplement shall submit the labeling for the supplement to the Secretary in accordance with subparagraph (A) before introducing the supplement into interstate commerce or delivering the supplement for such introduction.

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

the Secretary under the preceding sentence are available to the Secretary for the purpose of carrying out the responsibilities of the Secretary under this subsection and subsection (b). The Secretary may waive the requirement that a person pay such a fee if the Secretary determines that the waiver is justified on the basis that the person is a small business.

''(b) REPORTING OF INFORMATION ON ADVERSE EXPERIENCES.—

''(1) SERIOUS EXPERIENCES.—Each person who is a manufacturer of a dietary supplement, or a packer or distributor of the supplement whose name appears on the labeling of the supplement, shall—

''(A) report to the Secretary in accordance with paragraph (2) any information received by such person on serious adverse experiences regarding the supplement; and

''(B) develop written procedures regarding the submission to the Secretary of such reports, including procedures for surveillance, receipt, and evaluation of information on such experiences.

''(2) REPORTING OF SERIOUS EXPERIENCES.—

"(A) INITIAL REPORT.—With respect to the initial receipt of information on a serious adverse experience, a person with reporting responsibility under paragraph (1) shall submit the report to the Secretary as soon as is possible, but in no case later than 15 calendar days after the initial receipt of the information. Such report shall be accompanied by a copy of the current labeling for the dietary supplement involved.

"(B) INVESTIGATION AND FOLLOW-UP.—A person submitting an initial report under subparagraph (A) on a serious adverse experience shall promptly investigate the experience, and if additional information is obtained, shall report the information to the Secretary not later than 15 days after obtaining the information. If no additional information is obtained, records of the steps taken to seek additional information shall be maintained by the person.

"(C) DUPLICATIVE REPORTING.—In order to avoid duplicative reporting under this paragraph, the Secretary may provide for procedures under which persons who are packers or distributors described in paragraph (1) submit

reports under this paragraph to the manufacturer involved rather than the Secretary, with the manufacturers then submitting the required reports to the Secretary, subject to the Secretary establishing requirements to ensure that the Secretary receives reports within the applicable period of time specified in subparagraph (A) or (B).

''(3) CLINICAL EVALUATIONS BY SECRETARY.—The Secretary shall conduct a clinical evaluation of each serious adverse experience reported to the Secretary under paragraph (2) (except to the extent that the patient involved or the next of kin for the patient, as the case may be, elects not to cooperate with the Secretary).

''(4) ADDITIONAL REQUIREMENTS FOR MANUFACTURERS.—

''(A) GENERAL REVIEW REGARDING ADVERSE EXPERIENCES.—A manufacturer of a dietary supplement shall promptly review all information on adverse experiences regarding the supplement obtained or otherwise received by the manufacturer. The preceding sentence applies to information without regard to the source of the information, foreign or domestic,

and includes information derived from sources such as commercial marketing experience, postmarketing investigations, postmarketing surveillance, studies, reports in the scientific literature, and unpublished scientific papers.

''(B) PERIODIC REPORTS ON NONSERIOUS EXPERIENCES.—With respect to the receipt of information on adverse experiences that are not serious, a manufacturer of the dietary supplement involved shall submit reports to the Secretary annually, or at such shorter intervals as the Secretary may require. Each such report shall meet such requirements as the Secretary may establish.

''(5) AUTHORITY OF SECRETARY.—In addition to requirements established in this subsection, the Secretary may establish such requirements regarding the reporting of information on adverse experiences as the Secretary determines to be appropriate to protect the public health. The Secretary may establish waivers from requirements under this subsection regarding such information if the Secretary determines that compliance with the requirement involved is not necessary to protect the public health regarding such supplements.

''(6) SYSTEM FOR COORDINATING REPORTS RECEIVED BY SECRETARY.—With respect to reports of adverse health experiences submitted to the Secretary (whether required under this subsection or otherwise), the Secretary shall establish a system to receive the reports, refer the reports to the appropriate officials within the Food and Drug Administration, store and retrieve the reports, store and retrieve records of activities carried out in response to the reports, and carry out such other administrative functions regarding the reports as the Secretary determines to be appropriate.

''(7) DATA COLLECTION BY SECRETARY.—The Secretary shall carry out a program to collect data on serious adverse experiences, in addition to receiving reports required in this subsection. In carrying out such program, the Secretary shall seek the cooperation of appropriate public and private entities, including entities that respond to medical emergencies.

''(8) DEFINITIONS.—For purposes of this section:

''(A) The term 'adverse experience' means an adverse experience regarding a dietary supplement.

''(B) The term 'adverse experience regarding a dietary supplement' means any adverse event associated with the use of such supplement in humans, whether or not such event is considered to be related to the supplement by a person referred to in paragraph (1) who obtains the information.

''(C) The term 'serious', with respect to an adverse experience, means an adverse experience to which any of clauses (i) through (iii) applies, as follows:

''(i) The experience is associated with any of the following outcomes: Death; a life-threatening condition; inpatient hospitalization or prolongation of existing hospitalization; a persistent or significant disability or incapacity; or a congenital anomaly, birth defect, or other effect regarding pregnancy, including premature labor or low birth weight.

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

''(iii) There is reason to believe that a factor associated with the experience is the

interaction of the dietary supplement involved with a drug, without regard to whether clause (i) or (ii) applies to the experience.

''(c) POSTMARKET SURVEILLANCE.—

''(1) AUTHORITY TO REQUIRE SURVEILLANCE.—The Secretary may by order require a manufacturer of a dietary supplement to conduct postmarket surveillance for such supplement if the Secretary determines that there is a reasonable possibility that a use or expected use of the supplement by a significant number of consumers may have serious adverse health consequences.

''(2) SURVEILLANCE PLAN.—

''(A) IN GENERAL.—Not later than 30 days after receiving from the Secretary an order under paragraph (1) to conduct surveillance for a dietary supplement, the manufacturer involved shall submit to the Secretary, for the approval of the Secretary, a plan for the required surveillance.

''(B) QUALIFICATIONS REGARDING SURVEILLANCE; DATA REGARDING ADVERSE EXPERIENCES.—Not later than 60 days after a plan is submitted to the Secretary under subpara-

graph (A), the Secretary shall determine whether—

"(i) the person designated to conduct the surveillance has appropriate qualifications and experience to conduct such surveillance; and

"(ii) the plan will result in the collection of useful data that can reveal adverse experiences or other information necessary to protect the public health.

"(3) SURVEILLANCE PERIOD.—In consultation with a manufacturer of a dietary supplement that is required to conduct surveillance under paragraph (1), the Secretary may by order require a prospective surveillance period for the manufacturer of up to 36 months. Any determination by the Secretary that a longer period is necessary shall be made by mutual agreement between the Secretary and the manufacturer or, if no agreement can be reached, after the completion of a dispute resolution process that is established by the Secretary by regulation.

"(d) REPORTING IN GENERAL.—In addition to requirements otherwise established under this section, a manufacturer of a dietary supplement shall establish and maintain such records, make such reports, and provide

such information as the Secretary may by regulation reasonably require to assure that such supplement is not adulterated or misbranded.''.

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

''(bb) The failure of a person to register, submit reports, or comply with any other requirement under section 414.''.

SEC. 3. INSPECTION AUTHORITY REGARDING RECORDS ON DIETARY SUPPLEMENTS.

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

(1) in subsection (a)(1)—

(A) in the second sentence, by striking ''or restricted devices'' each place such term appears and inserting ''restricted devices, or dietary supplements''; and

(B) in the third sentence—

(i) by striking ''and devices'' and inserting ''devices, and dietary supplements''; and

(ii) by striking ''section 505(i) or (k)'' and inserting ''section 414, section 505(i), section 505(k),''; and

(2) in subsection (e), by striking ''section 519'' and inserting ''section 414, 519,''.

SEC. 4. LABELING OF DIETARY SUPPLEMENTS.

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

(1) by striking ''and (2)'' and inserting the following: ''(2) the toll-free telephone number, and the address of the Internet site, maintained by the Secretary for purposes of the medical product reporting program (MedWatch or any successor program); and (3) ''; and

(2) by striking ''clause (2)'' and inserting ''clause (3)''.

SEC. 5. PUBLICATION OF PROPOSED RULE ON CURRENT GOOD MANUFACTURING PRACTICES FOR DIETARY SUPPLEMENTS.

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

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