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109TH CONGRESS
1ST SESSION

H. R. 3156

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

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.

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 Access and Awareness Act''.

SEC. 2. DIETARY SUPPLEMENTS; PRODUCT LISTING; REPORTING, POSTMARKET SURVEILLANCE, AND OTHER PROVISIONS REGARDING SAFETY.

(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:

"SEC. 416. DIETARY SUPPLEMENTS; PRODUCT LISTING; REPORTING, POSTMARKET SURVEILLANCE, AND OTHER PROVISIONS REGARDING SAFETY.

''(a) LIMITATION ON APPLICABILITY.—Notwithstanding the other subsections of this section, this section does not apply to any dietary supplement that meets the conditions described in paragraphs (1) and (2), as follows:

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

''(A) A vitamin.

''(B) A mineral.

''(C) A concentrate, metabolite, constituent, extract, or combination of any vitamin or mineral.

''(2) The supplement does not bear or contain—

''(A) an herb or other botanical, an amino acid, or a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

"(B) a concentrate, metabolite, constituent, extract, or combination of any ingredient specified in subparagraph (A).

"(b) PRODUCT LISTING.—Every person who is required under section 415 to register with the Secretary with respect to manufacturing or processing a dietary supplement shall, in the form and manner prescribed by the Secretary, report to the Secretary twice each year, once during the month of June and once during the month of December, the following information:

"(1) A list of each dietary supplement manufactured or processed by the person for commercial distribution in the United States, other than dietary supplements previously included on a list reported under this subsection by the person.

"(2) The labeling for each of the dietary supplements on the list.

"(3) A listing of the major ingredients of each dietary supplement on the list (including active ingredients, as applicable), except that the Secretary may require the submission of a quantitative listing of all ingredients in such a supplement if the Secretary finds that such submission is necessary to carry out the purposes of this Act.

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

''(A) notice of such discontinuance;

''(B) the date of such discontinuance; and

''(C) the identity of such supplement.

''(5) Such other information describing the dietary supplements as the Secretary may by regulation require.

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

''(1) SERIOUS EXPERIENCES.—Each person who is a manufacturer or distributor of a dietary supplement shall report to the Secretary any information received by such person on serious adverse experiences regarding the supplement. Such a report shall be submitted to the Secretary not later than 15 days after the date on which the person receives such information.

''(2) INVESTIGATION AND FOLLOW-UP.—A person submitting a report under paragraph (1) 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.

''(3) 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.

''(4) DEFINITIONS.—For purposes of this subsection:

''(A) 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.

"(B) The term 'serious', with respect to an adverse experience regarding a dietary supplement, means an adverse experience that—

"(i) results in death; a life-threatening condition; inpatient hospitalization or prolongation of 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; or

"(ii) requires medical or surgical intervention to prevent one of the outcomes described in clause (i).

"(d) POSTMARKET SURVEILLANCE.—The Secretary may by order require a manufacturer of a dietary supplement to conduct postmarket surveillance for the supplement if the Secretary determines that there is a reasonable possibility that a use or expected use of the supplement may have serious adverse health consequences.

"(e) AUTHORITY TO ORDER DEMONSTRATION OF SAFETY.—

"(1) IN GENERAL.—If the Secretary has reasonable grounds for believing that a dietary supple-

ment may be adulterated under section 402(f)(1), the Secretary may by order require the manufacturer to demonstrate to the Secretary that the supplement is not so adulterated.

''(2) DISTRIBUTION OF PRODUCT PENDING COMPLETION OF PROCESS.—

''(A) IN GENERAL.—Subject to subparagraph (B), a dietary supplement may not be considered adulterated under section 402(f)(1) during the pendency of a demonstration under paragraph (1) by the manufacturer of the supplement and during the pendency of the review under paragraph (4) by the Secretary with respect to the demonstration.

''(B) IMMINENT HAZARD TO PUBLIC HEALTH OR SAFETY.—This subsection does not affect the authority of the Secretary under section 402(f)(1)(C).

''(3) TIMEFRAME FOR DEMONSTRATION.—

''(A) IN GENERAL.—An order under paragraph (1) shall provide that the demonstration under such paragraph by a manufacturer is required to be completed not later than the expiration of 180 days after the date on which the order is issued, except that the Secretary may

extend such period if the Secretary determines that an extension is appropriate. Any information submitted for such purpose by the manufacturer after the expiration of the applicable period under the preceding sentence may not be considered by the Secretary, except to the extent that the Secretary requests the manufacturer to provide additional information after such period.

''(B) COMPLETION DATE OF DEMONSTRATION.—A demonstration under paragraph (1) shall be considered complete on the expiration of the applicable period under subparagraph (A), or on such earlier date as the manufacturer informs the Secretary that the manufacturer has completed the demonstration, or on such earlier date as the Secretary reasonably concludes that the manufacturer has no further information to provide to the Secretary as part of the demonstration or that the manufacturer is not in substantial compliance with the order under paragraph (1).

''(4) REVIEW BY SECRETARY.—Once a demonstration under paragraph (1) by a manufacturer is completed, the Secretary shall review all relevant in-

formation received by the Secretary pursuant to the demonstration or otherwise available to the Secretary and make a determination of whether the Secretary considers the dietary supplement involved to be adulterated under section 402(f)(1). Such determination shall be made not later than 180 days after the completion of the demonstration.

''(5) REQUIREMENTS REGARDING DEMONSTRATIONS.—The Secretary may, by order or by regulation, establish requirements for demonstrations under paragraph (1).

''(6) RELATION TO OTHER PROCEDURES.—In the case of a dietary supplement with respect to which the Secretary has not issued an order under paragraph (1), this subsection may not be construed as preventing the Secretary from acting pursuant to section 402(f)(1) to the same extent and in the same manner as would apply in the absence of this subsection. In the case of a dietary supplement with respect to which the Secretary has issued an order under paragraph (1), a determination under paragraph (4) that the supplement is not adulterated under section 402(f)(1) does not prevent the Secretary from making a determination, on the basis of

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

''(f) SALES TO MINORS; SIGNIFICANT RISK.—

''(1) CRITERIA.—Not later than the expiration of the two-year period beginning on the date of the enactment of the Dietary Supplement Access and Awareness Act, the Secretary shall by regulation establish criteria for making a determination that a dietary supplement may pose a significant risk to individuals who are under the age of 18 (referred to in this section individually as a 'minor').

''(2) PRODUCT DETERMINATION; PROHIBITED ACT.—The Secretary may, by order or by regulation, make a determination described in paragraph (1) with respect to a dietary supplement. Effective upon the expiration of a period designated by the Secretary in publishing such determination in the Federal Register, the act of selling the dietary supplement to a minor shall be deemed to be an act which results in such supplement being misbranded while held for sale. During the two-year period referred to in paragraph (1), an order making such a determination may be issued notwithstanding that criteria have not yet been established in accordance with such paragraph.

''(g) RECORDKEEPING ON SAFETY ISSUES.—

''(1) IN GENERAL.—The Secretary shall by regulation require manufacturers of dietary supplements to maintain records regarding reports of serious adverse experiences under subsection (c) and records regarding compliance with section 402.

''(2) RETENTION PERIOD.—Regulations under paragraph (1) shall specify the number of years for which records required in such paragraph are required to be retained, except that, if under section 402(g)(1) the Secretary makes a determination that expiration date labeling is necessary for dietary supplements, records regarding dietary supplements in a lot shall be retained for not less than one year after the expiration date of supplements in the lot.''.

(b) PROHIBITED ACTS.—

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

''(hh) The failure of a person to comply with any requirement under section 416, other than an order under subsection (e)(1) of such section.''.

(2) ADULTERATED DIETARY SUPPLEMENTS.—

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

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

''(i) If it is a dietary supplement and the manufacturer of the supplement fails to comply with an order of the Secretary under section 416(e)(1) that is issued with respect to the supplement.''.

(B) CERTAIN COURT PROCEDURES; DETERMINATION OF UNREASONABLE RISK.—Section 402(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(f)) is amended—

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

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

''(3)(A) For purposes of clause (A) or (B) of subparagraph (1), the Secretary shall consider a dietary supplement or dietary ingredient as presenting an unreasonable risk of illness or injury if the Secretary determines that the risks of such product outweighs its benefits, as indicated by a relative weighing of the known and reasonably likely risks of the product against its known and reasonably likely benefits. In the absence of a sufficient benefit, the presence of even a relatively small risk of a serious

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

''(B) A determination by the Secretary under clause (A) with respect to the risk of a product may be made on the basis of any science-based evidence of risk, without the need to prove that the substance has actually caused harm in particular cases. The Secretary shall consider any relevant evidence including but not limited to scientific data about the toxicological properties of a dietary ingredient or its mechanism of action; known effects of pharmacologically related compounds, including those regulated as drugs; the results of clinical studies, including observational studies; and adverse event reports.

''(C) A determination that a product presents an unreasonable risk may be made under clause (A) by the Secretary even though there are uncertainties as to the levels of a dietary ingredient that may present a risk.''.

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

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

(1) in paragraph (1), by inserting after the second sentence the following: ''In the case of any person who manufactures, processes, packs, transports, distributes, holds, or imports a dietary supplement with respect to which an order under section 416(e)(1) has been issued, the inspection shall extend to all records, files, papers, processes, controls, and facilities bearing on whether the dietary supplement is adulterated under section 402(f)(1).''; and

(2) in paragraph (2), in the matter preceding subparagraph (A), by striking ''third sentence'' and inserting ''fourth sentence''.

SEC. 3. EDUCATION PROGRAMS REGARDING DIETARY SUPPLEMENTS.

(a) HEALTH CARE PROFESSIONALS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall carry out a program to educate health professionals on the importance of reporting to the Food and Drug Administration adverse health experiences that are associated with dietary supplements.

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

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

(b) CONSUMERS.—

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

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

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