II

111TH CONGRESS
2D SESSION

S. 3414

To ensure that the Dietary Supplement Health and Education Act of 1994 and other requirements for dietary supplements under the jurisdiction of the Food and Drug Administration are fully implemented and enforced, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 25, 2010

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

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A BILL

To ensure that the Dietary Supplement Health and Education Act of 1994 and other requirements for dietary supplements under the jurisdiction of the Food and Drug Administration are fully implemented and enforced, 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 Full Implementation and Enforcement Act of 2010''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) Each year, more than 150,000,000 Americans regularly consume dietary supplements to maintain and improve their health.

(2) Consumer expenditures on dietary supplements exceeded $25,000,000,000 in 2008.

(3) Given the growing awareness of the importance of prevention and wellness in the health care system of the United States, it is vital that laws governing the safety of, and education about, dietary supplements be fully implemented and enforced.

(4) In 1994, Congress approved, and the President signed into law, the Dietary Supplement Health and Education Act of 1994 (Public Law 103–417) (referred to in this Act as ''DSHEA''). DSHEA balanced the importance of continuing consumer access to vitamins, minerals, and other dietary supplements, promoting scientific research on the benefits and risks of dietary supplements, and fostering public education on the benefits and risks of supplement use with the need for regulatory safeguards to protect consumer health, including a new standard for safety, penalties for mislabeled or adulterated dietary supplements, rules to ensure scientific substantiation of the claims made regarding dietary supplements, and a notification requirement to the Food

and Drug Administration before dietary supplements that contain certain new dietary ingredients may be marketed.

(5) DSHEA requires that claims made on dietary supplement labels, packaging, and accompanying material be truthful, non-misleading, and substantiated. Manufacturers are prohibited from making claims that products are intended to diagnose, treat, mitigate, cure, or prevent a disease.

(6) DSHEA requires that dietary supplements comply with good manufacturing practice (referred to in this section as ''GMP'') requirements, and authorizes the Food and Drug Administration to establish such requirements.

(7) In 2007, after many years of delay, the Food and Drug Administration published regulations detailing the GMP requirements for dietary supplements, including requirements for identity, purity, strength, sanitary conditions, and recordkeeping. The Food and Drug Administration began to enforce those requirements in 2008.

(8) DSHEA requires that, before marketing a dietary supplement containing certain new dietary ingredients, the manufacturer or distributor must submit notice to the Food and Drug Administration

that includes information showing that the dietary supplement will reasonably be expected to be safe. According to the Food and Drug Administration, the Food and Drug Administration has raised objections to more than 70 percent of all new dietary ingredient notifications submitted to the agency.

(9) The Food and Drug Administration has successfully used the adulteration provisions of DSHEA to remove from the marketplace dietary supplements that present an unreasonable risk of injury or illness.

(10) In 2002, Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act (Public Law 107–188). This law requires any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States, including dietary supplements, to be registered with the Food and Drug Administration.

(11) In 2006, Congress supplemented DSHEA by approving the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109–462). This law requires dietary supplement manufacturers, packers, and distributors to report promptly to the Food and Drug Administration

any reports the manufacturer or other responsible person receives of serious adverse events associated with the use of the products of such manufacturer or other responsible person. Information the Food and Drug Administration receives under this reporting requirement may help the agency detect possible safety problems related to dietary supplement products or ingredients.

(12) DSHEA created the Office of Dietary Supplements within the National Institutes of Health to expand research and consumer information about the health effects of dietary supplements. The Office of Dietary Supplements has greatly expanded the number of scientific studies of dietary supplements and the availability of reliable information to consumers.

(13) While the Food and Drug Administration has taken some important steps to implement and enforce DSHEA and the other laws governing the regulation of dietary supplements, the agency has not fully implemented and enforced DSHEA and the other laws governing the regulation of dietary supplements.

(14) Both the public and regulated industry would benefit from more guidance from the Food

and Drug Administration on the procedures and definitions concerning the regulation of new dietary ingredients under section 413 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350b).

(15) If the Food and Drug Administration determines that a product labeled as a dietary supplement includes an anabolic steroid or an analogue of an anabolic steroid, the Food and Drug Administration does not systematically notify the Drug Enforcement Administration of that determination.

(16) The Food and Drug Administration needs adequate resources to implement and enforce DSHEA and other laws governing the regulation of dietary supplements appropriately. Congress has appropriated additional funds over the last several years to implement and enforce DSHEA, reaching more than $14,000,000 for fiscal year 2009.

(17) According to the Food and Drug Administration, full implementation of DSHEA and the other laws governing the regulation of dietary supplements would require substantial additional resources. In 2002, the Food and Drug Administration reported to Congress in writing that the agency would need between $24,000,000 and $65,000,000 per year to fully implement DSHEA.

SEC. 3. SENSE OF CONGRESS.

It is the sense of Congress that:

(1) The Food and Drug Administration should increase efforts to implement DSHEA more fully and effectively, by—

(A) providing Congress with a professional judgment estimate of the annual costs during the 5-year period beginning on the date of enactment of this Act to fully implement and enforce DSHEA and other dietary supplement laws and regulations under the jurisdiction of the Food and Drug Administration;

(B) conducting inspections, using appropriately trained inspection personnel, of all facilities in which a dietary supplement is manufactured, processed, packed, or held to ensure compliance with the new dietary supplement good manufacturing practices regulations;

(C) using the authority under DSHEA to protect the public from unsafe dietary supplement products and ingredients and to ensure that claims made are truthful, non-misleading, and substantiated, with highest regulatory priority given to cases of clear violations of the law (including the intentional adulteration and spiking of products);

(D) implementing the recommendations contained in the January 2009 report of the Government Accountability Office, entitled, ''Dietary Supplements: FDA Should Take Further Actions To Improve Oversight and Consumer Understanding'', (GAO 09–250) that the Food and Drug Administration—

(i) require all dietary supplement manufacturers, packers, and distributors to identify themselves specifically as such under existing registration requirements and to update such information annually;

(ii) promptly issue guidance to clarify when a dietary supplement ingredient is a new dietary ingredient, the evidence needed to document the safety of new dietary ingredients, and appropriate methods for establishing the identity of a new dietary ingredient; and

(iii) coordinate with stakeholder groups involved in consumer outreach to identify, implement, and evaluate the effectiveness of additional mechanisms for educating consumers about the safety, effi-

cacy, and labeling of dietary supplements; and

(E) notifying the Drug Enforcement Administration if the Food and Drug Administration determines that the information in a new dietary ingredient notification submitted under section 413 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350b) is inadequate to establish that the new dietary ingredient will reasonably be expected to be safe, because the dietary supplement may contain an anabolic steroid or an analogue of an anabolic steroid.

(2) The manufacturers, packers, retailers, and distributors of dietary supplements and dietary supplement ingredients should increase efforts to—

(A) comply fully with all requirements of DSHEA and the Dietary Supplement and Nonprescription Drug Consumer Protection Act;

(B) cooperate fully and appropriately with the Food and Drug Administration in implementation and enforcement of Federal laws and regulations; and

(C) provide the Food and Drug Administration with appropriate input on known and

suspected violations of such laws and regulations.

SEC. 4. AUTHORIZATION OF APPROPRIATIONS AND ALLOCATION OF RESOURCES.

(a) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out the Dietary Supplement Health and Education Act of 1994, the amendments made by such Act, and other provisions under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) that apply to dietary supplements, $30,000,000 for fiscal year 2011 and such sums as may be necessary for each of fiscal years 2012 through 2014.

(b) ALLOCATION OF FUNDS FOR FISCAL YEAR 2010.—From funds appropriated to the Food and Drug Administration for fiscal year 2010 for the purpose of enhancing food safety, not less than $20,000,000 shall be expended to effectively and fully implement and enforce the Dietary Supplement Health and Education Act of 1994, the amendments made by such Act, and other provisions under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) that apply to dietary supplements.

(c) OFFICE OF DIETARY SUPPLEMENTS.—There are authorized to be appropriated for expanded research and development of consumer information on dietary supple-

ments by the Office of Dietary Supplements at the National Institutes of Health—

(1) $40,000,000 for fiscal year 2010; and

(2) such sums as may be necessary for each of the fiscal years 2011 through 2014.

SEC. 5. ANNUAL ACCOUNTABILITY REPORT ON THE REGULATION OF DIETARY SUPPLEMENTS.

(a) IN GENERAL.—Not later than January 31, 2011, and annually thereafter, the Secretary of Health and Human Services shall submit a report to Congress on the implementation and enforcement of the Dietary Supplement Health and Education Act of 1994 and the amendments made by such Act.

(b) CONTENTS.—The report under subsection (a) shall include the following:

(1) The total funding and number of full-time equivalent personnel in the Food and Drug Administration dedicated to dietary supplement regulation during the prior fiscal year.

(2) The total funding and number of full-time equivalent personnel in the Food and Drug Administration dedicated to administering adverse event reporting systems, as such systems relate to dietary supplement regulation, during the prior fiscal year.

(3) The total funding and number of full-time equivalent personnel in the Food and Drug Administration dedicated to enforcement of dietary supplement labeling and claims requirements during the prior fiscal year and a brief explanation of the activities of such personnel.

(4) The total funding and number of full-time equivalent personnel in the Food and Drug Administration dedicated to the review and enforcement of good manufacturing practice requirements with respect to dietary supplements during the prior fiscal year.

(5) The number of inspections at which the Food and Drug Administration evaluated or reviewed the compliance of a manufacturer with good manufacturing practices for dietary supplements during the prior fiscal year, and the number of times the Food and Drug Administration issued a warning letter because it determined that such manufacturer was not in compliance with some aspect of such requirements.

(6) The number of new dietary ingredient notification reviews that the Food and Drug Administration performed during the prior fiscal year and the number of times the Food and Drug Administration

objected to the marketing of the dietary supplement described in such notification reviews.

(7) The number of times the Food and Drug Administration issued a warning letter or initiated an enforcement action against a manufacturer or distributor for failure to file a new dietary ingredient notification as required under section 413 of the Federal Food, Drug, and Cosmetic Act.

(8) A brief summary and explanation of all enforcement actions taken by the Food and Drug Administration and the Department of Health and Human Services related to dietary supplements during the prior fiscal year, including the number and type of actions.

(9) The number of times the Food and Drug Administration requested substantiation of dietary supplement claims from a manufacturer during the prior fiscal year, the number of times a manufacturer refused to provide such information, and the response of the agency in such situations.

(10) The number of dietary supplement claims determined by the Food and Drug Administration during the prior fiscal year to be false, misleading, or not substantiated, and a description of the follow-up action taken by the agency in such instances.

(11) The research and consumer education activities supported by the Office of Dietary Supplements of the National Institutes of Health during the prior fiscal year.

(12) Any recommendations for administrative or legislative actions to improve the regulation of dietary supplements.

(13) Any other information regarding the regulation of dietary supplements determined appropriate by the Secretary of Health and Human Services or the Commissioner of Food and Drugs.

SEC. 6. NEW DIETARY INGREDIENTS.

(a) GUIDELINES FOR INTRODUCING NEW DIETARY INGREDIENTS.—Section 413 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350b) is amended—

(1) by redesignating subsection (c) as subsection (e); and

(2) by inserting after subsection (b) the following:

''(c) GUIDELINES.—Not later than 180 days after the date of enactment of the Dietary Supplement Full Implementation and Enforcement Act of 2010, the Secretary shall publish guidance that clarifies when a dietary supplement ingredient is a new dietary ingredient, when the manufacturer or distributor of a dietary ingredient or die-

tary supplement should provide the Secretary with information as described in subsection (a)(2), the evidence needed to document the safety of new dietary ingredients, and appropriate methods for establishing the identity of a new dietary ingredient.

''(d) NOTIFICATION TO DEA.—

''(1) IN GENERAL.—If the Secretary determines that the information in a new dietary ingredient notification submitted under this section for an article purported to be a new dietary ingredient is inadequate to establish that a dietary supplement containing such article will reasonably be expected to be safe because the article may be, or may contain, an anabolic steroid or an analogue of an anabolic steroid, the Secretary shall notify the Drug Enforcement Administration of such determination. Such notification by the Secretary shall include, at a minimum, the name of the product or article, the name of the person or persons who marketed the product or made the submission of information regarding the article to the Secretary under this section, and any contact information for such person or persons that the Secretary has.

''(2) DEFINITIONS.—For purposes of this subsection—

"(A) the term 'anabolic steroid' has the meaning given such term in section 102(41) of the Controlled Substances Act; and

"(B) the term 'analogue of an anabolic steroid' means a substance whose chemical structure is substantially similar to the chemical structure of an anabolic steroid.".

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