I

109TH CONGRESS
1ST SESSION

H. R. 2485

To ensure that the goals of the Dietary Supplement Health and Education Act of 1994 are met by authorizing appropriations to fully enforce and implement such Act and the amendments made by such Act, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 19, 2005

Mr. BURTON of Indiana (for himself and Mr. PALLONE) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To ensure that the goals of the Dietary Supplement Health and Education Act of 1994 are met by authorizing appropriations to fully enforce and implement such Act and the amendments made by such Act, 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 ''DSHEA Full Implementation and Enforcement Act of 2005''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) Over 158,000,000 Americans regularly consume dietary supplements to maintain and improve their health.

(2) Consumer expenditures on dietary supplements reached a reported $17,100,000,000 in 2000, double the amount spent in 1994.

(3) According to a recent report issued by the Food and Drug Administration (in this Act referred to as the ''FDA'') the use of dietary supplements is likely to grow due to factors such as the aging of the baby boom generation, increased interest in self-sufficiency, and advances in science that are uncovering new relationships between diet and disease.

(4) In 1994, the Dietary Supplement Health and Education Act of 1994 (Public Law 103–417) (in this Act referred to as ''DSHEA'') was enacted. This Act balanced continued consumer access to vitamins, minerals, and other dietary supplements, increased scientific research on the benefits and risks of dietary supplements, public education on dietary supplements, and needed consumer protections.

(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 provides for good manufacturing practice standards setting requirements for potency, purity, sanitary conditions, and recordkeeping for dietary supplements.

(7) DSHEA requires that manufacturers submit adequate information as to the safety of any new ingredients contained in dietary supplements before those products can be sold.

(8) The FDA has updated and expanded its system for the reporting, collection, and analysis of dietary supplement adverse events reports.

(9) DSHEA provides the FDA with a number of authoritites to remove unsafe dietary supplements from the marketplace.

(10) 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.

(11) The FDA has not adequately used its authority to enforce DSHEA.

(12) The FDA needs adequate resources to appropriately implement and enforce DSHEA. Congress has appropriated additional funds over the last

several years beyond those requested in the President's budget to implement and enforce DSHEA, reaching $9,700,000 in fiscal year 2003.

(13) However, according to the FDA, full implementation of DSHEA would require substantial additional resources. The FDA asserts that between $24,000,000 and $65,000,000 per year will be needed to fully implement DSHEA.

SEC. 3. AUTHORIZATION AND APPROPRIATION OF RESOURCES.

(a) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out the Dietary Supplement Health and Education Act of 1994 (Public Law 103–417), the amendments made by such Act, and all applicable regulatory requirements for dietary supplements under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)—

(1) $20,000,000 for fiscal year 2006;

(2) $30,000,000 for fiscal year 2007;

(3) $40,000,000 for fiscal year 2008;

(4) $50,000,000 for fiscal year 2009; and

(5) $65,000,000 for fiscal year 2010.

(b) APPROPRIATION OF FUNDS FOR FISCAL YEAR 2006.—There are appropriated, out of any money in the Treasury not otherwise appropriated, to carry out the Die-

tary Supplement Health and Education Act of 1994 (Public Law 103–417), the amendments made by such Act, and all applicable regulatory requirements for dietary supplements under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), $20,000,000 for fiscal year 2006.

(c) OFFICE OF DIETARY SUPPLEMENTS.—There are authorized to be appropriated and there are appropriated, out of any money in the Treasury not otherwise appropriated, for expanded research and development of consumer information on dietary supplements by the Office of Dietary Supplements at the National Institutes of Health—

(1) $30,000,000 for fiscal year 2006; and

(2) such sums as may be necessary for each of the fiscal years 2007 through 2010.

(d) USE OF FUNDS.—The Food and Drug Administration shall fully and appropriately use the funds appropriated in subsections (b) and (c) and pursuant to subsection (a) to regulate dietary supplements.

SEC. 4. ANNUAL ACCOUNTABILITY REPORT ON THE REGULATION OF DIETARY SUPPLEMENTS.

(a) IN GENERAL.—Not later than January 31, 2006, and annually thereafter, the Secretary of Health and Human Services shall submit a report to Congress on the implementation and enforcement of the Dietary Supple-

ment Health and Education Act of 1994 (Public Law 103–417).

(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 over 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 they relate to dietary supplement regulation over 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 over the prior fiscal year and an explanation of their activities.

(4) The total funding and number of full-time equivalent personnel in the Food and Drug Administration dedicated to good manufacturing practices inspections of dietary supplement manufacturers over the prior fiscal year and an explanation of their activities.

(5) The number of good manufacturing practices inspections of dietary supplement manufacturers by the Food and Drug Administration over the prior fiscal year and a summary of the results.

(6) The number of new ingredient reviews and safety reviews related to dietary supplements and the results of those reviews.

(7) An explanation of all enforcement actions taken by the Food and Drug Administration and the Department of Health and Human Services related to dietary supplements over the prior fiscal year, including the number and type of actions.

(8) The number of dietary supplement claims for which the Food and Drug Administration requested substantiation from the manufacturer over the prior fiscal year, and the agency's response.

(9) The number of dietary supplement claims determined to be false, misleading, or nonsubstantiated by the Food and Drug Administration over the prior fiscal year.

(10) The research and consumer education activities supported by the Office of Dietary Supplements of the National Institutes of Health.

(11) Any recommendations for administrative or legislative actions regarding the regulation of dietary supplements.

(12) 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.

○