I

109TH CONGRESS
1ST SESSION

H. R. 2510

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. 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 ''Dietary Supplement Regulatory Implementation Act of 2005''.

SEC. 2. FINDINGS.

The Congress finds as follows:

(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 $20,500,000,000 in 2004, more than double the amount spent in 1994.

(3) According to a recent report issued by the Food and Drug Administration (''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) (''DSHEA'') was enacted. That 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 provides that dietary supplements are to be regulated like foods and not drugs or food additives.

(8) 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.

(9) DSHEA provides the FDA with a number of powers 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 $10,800,000 in fiscal year 2005.

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

(2) $40,000,000 for fiscal year 2008;

(3) $50,000,000 for fiscal year 2009; and

(4) $65,000,000 for fiscal year 2010.

(b) APPROPRIATION OF FUNDS FOR FISCAL YEAR 2006.—There is appropriated, out of any money in the Treasury not otherwise appropriated, to carry out the Dietary Supplement Health and Education Act of 1994 (Pub-

lic 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.—

(1) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for expanded research and development of consumer information, including information on safety and beneficial effects, of dietary supplements by the Office of Dietary Supplements at the National Institutes of Health such sums as may be necessary for each of the fiscal years 2007 through 2010.

(2) APPROPRIATION OF FUNDS FOR FISCAL YEAR 2006.—There is appropriated, out of any money in the Treasury not otherwise appropriated, for expanded research and development of consumer information, including information on safety and beneficial effects, of dietary supplements by the Office of Dietary Supplements at the National Institutes of Health $30,000,000 for fiscal year 2006.

(d) USE OF FUNDS.—The Secretary of Health and Human Services 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, 2007, and annually thereafter, the Secretary shall submit a report to Congress on the implementation and enforcement of the Dietary Supplement 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 unsubstantiated 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.

SEC. 5. DIETARY SUPPLEMENTS CONTAINING EPHEDRINE ALKALOIDS.

(a) FINDINGS.—The Congress finds that—

(1) dietary supplements containing ephedrine alkaloids may present a significant or unreasonable risk of illness or injury; and

(2) through section 402(f) of the Federal Food, Drug, and Cosmetic Act (established by the Dietary Supplement Health and Education Act of 1994), the Congress has granted the Secretary the authority to remove from the market dietary supplements that present such a risk.

(b) SENSE OF CONGRESS REGARDING RISK OF ILLNESS OR INJURY.—It is the sense of the Congress that, in the event the Secretary determines under section 402(f) of the Federal Food, Drug, and Cosmetic Act that a die-

tary supplement containing ephedrine alkaloids presents a significant or unreasonable risk of illness or injury—

(1) all dietary supplements containing such alkaloids should be declared to be adulterated in accordance with such section; and

(2) the Secretary should take all necessary actions to remove all such supplements from the market.

(c) SENSE OF CONGRESS REGARDING BOTANICAL SOURCES.—It is the sense of the Congress that the Secretary should take steps to assure the continued availability of botanical sources of ephedrine alkaloids that—

(1) are in forms that have not been manipulated or chemically altered to increase their ephedrine alkaloid concentration or content;

(2) are marketed at dosages that are substantiated to be at levels used in traditional herbal formulas; and

(3) are labeled only for traditional uses and not for weight loss or energy.

SEC. 6. EDUCATION PROGRAMS REGARDING DIETARY SUPPLEMENTS.

(a) HEALTH CARE PROFESSIONALS.—

(1) IN GENERAL.—The Secretary shall carry out a program to educate health professionals on the

safety and health benefits of dietary supplements, including the potential for dietary supplement/drug interactions.

(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 shall carry out a program to educate consumers of dietary supplements on the safety and health benefits of dietary supplements, including the potential for dietary supplement/drug interactions through public education forums, advertisements, and the Internet.

(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.

SEC. 7. ADVERSE EVENT REPORTING SYSTEM.

The Secretary shall establish a system for the requirements for the reporting of serious adverse experi-

ences associated with the use of a dietary supplement received by the manufacturer, packer, or distributor whose name appears on the label of the product.

SEC. 8. DEFINITION.

For purposes of this Act, the term ''Secretary'' means the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs.

○