

108TH CONGRESS  
1ST SESSION

# S. 1538

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.

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## IN THE SENATE OF THE UNITED STATES

JULY 31 (legislative day, JULY 21), 2003

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 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.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “DSHEA Full Imple-  
5 mentation and Enforcement Act of 2003”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

1           (1) Over 158,000,000 Americans regularly con-  
2           sume dietary supplements to maintain and improve  
3           their health.

4           (2) Consumer expenditures on dietary supple-  
5           ments reached a reported \$17,100,000,000 in 2000,  
6           double the amount spent in 1994.

7           (3) According to a recent report issued by the  
8           Food and Drug Administration (in this Act referred  
9           to as the “FDA”) the use of dietary supplements is  
10          likely to grow due to factors such as the aging of the  
11          baby boom generation, increased interest in self-suf-  
12          ficiency, and advances in science that are uncovering  
13          new relationships between diet and disease.

14          (4) In 1994, the Dietary Supplement Health  
15          and Education Act of 1994 (Public Law 103–417)  
16          (in this Act referred to as “DSHEA”) was enacted.  
17          This Act balanced continued consumer access to vi-  
18          tamins, minerals, and other dietary supplements, in-  
19          creased scientific research on the benefits and risks  
20          of dietary supplements, public education on dietary  
21          supplements, and needed consumer protections.

22          (5) DSHEA requires that claims made on die-  
23          tary supplement labels, packaging, and accom-  
24          panying material be truthful, non-misleading, and  
25          substantiated. Manufacturers are prohibited from

1 making claims that products are intended to diag-  
2 nose, treat, mitigate, cure, or prevent a disease.

3 (6) DSHEA provides for good manufacturing  
4 practice standards setting requirements for potency,  
5 purity, sanitary conditions, and recordkeeping for di-  
6 etary supplements.

7 (7) DSHEA requires that manufacturers sub-  
8 mit adequate information as to the safety of any  
9 new ingredients contained in dietary supplements be-  
10 fore those products can be sold.

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

14 (9) DSHEA provides the FDA with a number  
15 of authorities to remove unsafe dietary supplements  
16 from the marketplace.

17 (10) DSHEA created the Office of Dietary  
18 Supplements within the National Institutes of  
19 Health to expand research and consumer informa-  
20 tion about the health effects of dietary supplements.

21 (11) The FDA has not adequately used its au-  
22 thority to enforce DSHEA.

23 (12) The FDA needs adequate resources to ap-  
24 propriately implement and enforce DSHEA. Con-  
25 gress has appropriated additional funds over the last

1 several years beyond those requested in the Presi-  
 2 dent's budget to implement and enforce DSHEA,  
 3 reaching \$9,700,000 in fiscal year 2003.

4 (13) However, according to the FDA, full im-  
 5 plementation of DSHEA would require substantial  
 6 additional resources. The FDA asserts that between  
 7 \$24,000,000 and \$65,000,000 per year will be need-  
 8 ed to fully implement DSHEA.

9 **SEC. 3. AUTHORIZATION AND APPROPRIATION OF RE-**  
 10 **SOURCES.**

11 (a) AUTHORIZATION OF APPROPRIATIONS.—There  
 12 are authorized to be appropriated to carry out the Dietary  
 13 Supplement Health and Education Act of 1994 (Public  
 14 Law 103–417), the amendments made by such Act, and  
 15 all applicable regulatory requirements for dietary supple-  
 16 ments under the Federal Food, Drug, and Cosmetic Act  
 17 (21 U.S.C. 301 et seq.)—

18 (1) \$20,000,000 for fiscal year 2004;

19 (2) \$30,000,000 for fiscal year 2005;

20 (3) \$40,000,000 for fiscal year 2006;

21 (4) \$50,000,000 for fiscal year 2007; and

22 (5) \$65,000,000 for fiscal year 2008.

23 (b) APPROPRIATION OF FUNDS FOR FISCAL YEAR  
 24 2004.—There are appropriated, out of any money in the  
 25 Treasury not otherwise appropriated, to carry out the Die-

1 tary Supplement Health and Education Act of 1994 (Pub-  
2 lic Law 103–417), the amendments made by such Act, and  
3 all applicable regulatory requirements for dietary supple-  
4 ments under the Federal Food, Drug, and Cosmetic Act  
5 (21 U.S.C. 301 et seq.), \$20,000,000 for fiscal year 2004.

6 (c) OFFICE OF DIETARY SUPPLEMENTS.—There are  
7 authorized to be appropriated and there are appropriated,  
8 out of any money in the Treasury not otherwise appro-  
9 priated, for expanded research and development of con-  
10 sumer information on dietary supplements by the Office  
11 of Dietary Supplements at the National Institutes of  
12 Health—

13 (1) \$30,000,000 for fiscal year 2004; and

14 (2) such sums as may be necessary for each of  
15 the fiscal years 2005 through 2008.

16 (d) USE OF FUNDS.—The Food and Drug Adminis-  
17 tration shall fully and appropriately use the funds appro-  
18 priated in subsections (b) and (c) and pursuant to sub-  
19 section (a) to regulate dietary supplements.

20 **SEC. 4. ANNUAL ACCOUNTABILITY REPORT ON THE REGU-**  
21 **LATION OF DIETARY SUPPLEMENTS.**

22 (a) IN GENERAL.—Not later than January 31, 2004,  
23 and annually thereafter, the Secretary of Health and  
24 Human Services shall submit a report to Congress on the  
25 implementation and enforcement of the Dietary Supple-

1 ment Health and Education Act of 1994 (Public Law  
2 103–417).

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

5 (1) The total funding and number of full-time  
6 equivalent personnel in the Food and Drug Adminis-  
7 tration dedicated to dietary supplement regulation  
8 over the prior fiscal year.

9 (2) The total funding and number of full-time  
10 equivalent personnel in the Food and Drug Adminis-  
11 tration dedicated to administering adverse event re-  
12 porting systems as they relate to dietary supplement  
13 regulation over the prior fiscal year.

14 (3) The total funding and number of full-time  
15 equivalent personnel in the Food and Drug Adminis-  
16 tration dedicated to enforcement of dietary supple-  
17 ment labeling and claims requirements over the prior  
18 fiscal year and an explanation of their activities.

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

1           (5) The number of good manufacturing prac-  
2           tices inspections of dietary supplement manufactur-  
3           ers by the Food and Drug Administration over the  
4           prior fiscal year and a summary of the results.

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

8           (7) An explanation of all enforcement actions  
9           taken by the Food and Drug Administration and the  
10          Department of Health and Human Services related  
11          to dietary supplements over the prior fiscal year, in-  
12          cluding the number and type of actions.

13          (8) The number of dietary supplement claims  
14          for which the Food and Drug Administration re-  
15          quested substantiation from the manufacturer over  
16          the prior fiscal year, and the agency's response.

17          (9) The number of dietary supplement claims  
18          determined to be false, misleading, or nonsubstan-  
19          tiated by the Food and Drug Administration over  
20          the prior fiscal year.

21          (10) The research and consumer education ac-  
22          tivities supported by the Office of Dietary Supple-  
23          ments of the National Institutes of Health.

1           (11) Any recommendations for administrative  
2           or legislative actions regarding the regulation of die-  
3           tary supplements.

4           (12) Any other information regarding the regu-  
5           lation of dietary supplements determined appropriate  
6           by the Secretary of Health and Human Services or  
7           the Commissioner of Food and Drugs.

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