

108TH CONGRESS  
2D SESSION

# H. R. 4747

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 HOUSE OF REPRESENTATIVES

JUNE 25, 2004

Mr. PALLONE introduced the following bill; which was referred to the Committee on Energy and Commerce

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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 “Dietary Supplement  
5 Regulatory Implementation Act of 2004”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

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 (“FDA”) the use of  
9           dietary supplements is likely to grow due to factors  
10          such as the aging of the baby boom generation, in-  
11          creased interest in self-sufficiency, and advances in  
12          science that are uncovering new relationships be-  
13          tween diet and disease.

14          (4) In 1994, the Dietary Supplement Health  
15          and Education Act of 1994 (Public Law 103–417)  
16          (“DSHEA”) was enacted. That Act balanced contin-  
17          ued consumer access to vitamins, minerals, and  
18          other dietary supplements, increased scientific re-  
19          search on the benefits and risks of dietary supple-  
20          ments, public education on dietary supplements, and  
21          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 provides that dietary supplements  
8 are to be regulated like foods and not drugs or food  
9 additives.

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

14 (9) DSHEA provides the FDA with a number  
15 of powers 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) \$30,000,000 for fiscal year 2006;
- 19 (2) \$40,000,000 for fiscal year 2007;
- 20 (3) \$50,000,000 for fiscal year 2008; and
- 21 (4) \$65,000,000 for fiscal year 2009.

22 (b) APPROPRIATION OF FUNDS FOR FISCAL YEAR  
 23 2005.—There is appropriated, out of any money in the  
 24 Treasury not otherwise appropriated, to carry out the Die-  
 25 tary Supplement Health and Education Act of 1994 (Pub-

1 lie Law 103–417), the amendments made by such Act, and  
2 all applicable regulatory requirements for dietary supple-  
3 ments under the Federal Food, Drug, and Cosmetic Act  
4 (21 U.S.C. 301 et seq.), \$20,000,000 for fiscal year 2005.

5 (c) OFFICE OF DIETARY SUPPLEMENTS.—

6 (1) AUTHORIZATION OF APPROPRIATIONS.—

7 There are authorized to be appropriated for ex-  
8 panded research and development of consumer infor-  
9 mation, including information on safety and bene-  
10 ficial effects, of dietary supplements by the Office of  
11 Dietary Supplements at the National Institutes of  
12 Health such sums as may be necessary for each of  
13 the fiscal years 2006 through 2009.

14 (2) APPROPRIATION OF FUNDS FOR FISCAL  
15 YEAR 2005.—There is appropriated, out of any  
16 money in the Treasury not otherwise appropriated,  
17 for expanded research and development of consumer  
18 information, including information on safety and  
19 beneficial effects, of dietary supplements by the Of-  
20 fice of Dietary Supplements at the National Insti-  
21 tutes of Health \$30,000,000 for fiscal year 2005.

22 (d) USE OF FUNDS.—The Secretary of Health and  
23 Human Services shall fully and appropriately use the  
24 funds appropriated in subsections (b) and (c) and pursu-  
25 ant to subsection (a) to regulate dietary supplements.

1 **SEC. 4. ANNUAL ACCOUNTABILITY REPORT ON THE REGU-**  
2 **LATION OF DIETARY SUPPLEMENTS.**

3 (a) IN GENERAL.—Not later than January 31, 2006,  
4 and annually thereafter, the Secretary shall submit a re-  
5 port to Congress on the implementation and enforcement  
6 of the Dietary Supplement Health and Education Act of  
7 1994 (Public Law 103–417).

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

10 (1) The total funding and number of full-time  
11 equivalent personnel in the Food and Drug Adminis-  
12 tration dedicated to dietary supplement regulation  
13 over the prior fiscal year.

14 (2) The total funding and number of full-time  
15 equivalent personnel in the Food and Drug Adminis-  
16 tration dedicated to administering adverse event re-  
17 porting systems as they relate to dietary supplement  
18 regulation over the prior fiscal year.

19 (3) The total funding and number of full-time  
20 equivalent personnel in the Food and Drug Adminis-  
21 tration dedicated to enforcement of dietary supple-  
22 ment labeling and claims requirements over the prior  
23 fiscal year and an explanation of their activities.

24 (4) The total funding and number of full-time  
25 equivalent personnel in the Food and Drug Adminis-  
26 tration dedicated to good manufacturing practices

1 inspections of dietary supplement manufacturers  
2 over the prior fiscal year and an explanation of their  
3 activities.

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

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

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

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

20 (9) The number of dietary supplement claims  
21 determined to be false, misleading, or unsubstan-  
22 tiated by the Food and Drug Administration over  
23 the prior fiscal year.

1           (10) The research and consumer education ac-  
2           tivities supported by the Office of Dietary Supple-  
3           ments of the National Institutes of Health.

4           (11) Any recommendations for administrative  
5           or legislative actions regarding the regulation of die-  
6           tary supplements.

7           (12) Any other information regarding the regu-  
8           lation of dietary supplements determined appropriate  
9           by the Secretary.

10 **SEC. 5. DIETARY SUPPLEMENTS CONTAINING EPHEDRINE**  
11 **ALKALOIDS.**

12       (a) FINDINGS.—The Congress finds that—

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

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

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



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

3 (1) all dietary supplements containing such  
 4 alkaloids should be declared to be adulterated in ac-  
 5 cordance with such section; and

6 (2) the Secretary should take all necessary ac-  
 7 tions to remove all such supplements from the mar-  
 8 ket.

9 (c) SENSE OF CONGRESS REGARDING BOTANICAL  
 10 SOURCES.—It is the sense of the Congress that the Sec-  
 11 retary should take steps to assure the continued avail-  
 12 ability of botanical sources of ephedrine alkaloids that—

13 (1) are in forms that have not been manipu-  
 14 lated or chemically altered to increase their ephed-  
 15 rine alkaloid concentration or content;

16 (2) are marketed at dosages that are substan-  
 17 tiated to be at levels used in traditional herbal for-  
 18 mulas; and

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

21 **SEC. 6. EDUCATION PROGRAMS REGARDING DIETARY SUP-**  
 22 **PLEMENTS.**

23 (a) HEALTH CARE PROFESSIONALS.—

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

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

4 (2) AUTHORIZATION OF APPROPRIATIONS.—For  
5 the purpose of carrying out paragraph (1), there is  
6 authorized to be appropriated \$5,000,000 for fiscal  
7 year 2005, in addition to any other authorization of  
8 appropriations that is available with respect to such  
9 purpose.

10 (b) CONSUMERS.—

11 (1) IN GENERAL.—The Secretary shall carry  
12 out a program to educate consumers of dietary sup-  
13 plements on the safety and health benefits of the di-  
14 etary supplements, including the potential for die-  
15 tary supplement/drug interactions through public  
16 education forums, advertisements, and the Internet.

17 (2) AUTHORIZATION OF APPROPRIATIONS.—For  
18 the purpose of carrying out paragraph (1), there is  
19 authorized to be appropriated \$5,000,000 for fiscal  
20 year 2005, in addition to any other authorization of  
21 appropriations that is available with respect to such  
22 purpose.

23 **SEC. 7. ADVERSE EVENT REPORTING SYSTEM.**

24 The Secretary shall establish a system for the re-  
25 quirements for the reporting of serious adverse experi-

1 ences associated with the use of a dietary supplement re-  
2 ceived by the manufacturer, packer, or distributor whose  
3 name appears on the label of the product.

4 **SEC. 8. DEFINITION.**

5 For purposes of this Act, the term “Secretary”  
6 means the Secretary of Health and Human Services, act-  
7 ing through the Commissioner of Food and Drugs.

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