

111TH CONGRESS
2^D 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

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.

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 Full Implementation and Enforcement Act of 2010”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

1 (1) Each year, more than 150,000,000 Ameri-
2 cans regularly consume dietary supplements to
3 maintain and improve their health.

4 (2) Consumer expenditures on dietary supple-
5 ments exceeded \$25,000,000,000 in 2008.

6 (3) Given the growing awareness of the impor-
7 tance of prevention and wellness in the health care
8 system of the United States, it is vital that laws gov-
9 erning the safety of, and education about, dietary
10 supplements be fully implemented and enforced.

11 (4) In 1994, Congress approved, and the Presi-
12 dent signed into law, the Dietary Supplement Health
13 and Education Act of 1994 (Public Law 103–417)
14 (referred to in this Act as “DSHEA”). DSHEA bal-
15 anced the importance of continuing consumer access
16 to vitamins, minerals, and other dietary supple-
17 ments, promoting scientific research on the benefits
18 and risks of dietary supplements, and fostering pub-
19 lic education on the benefits and risks of supplement
20 use with the need for regulatory safeguards to pro-
21 tect consumer health, including a new standard for
22 safety, penalties for mislabeled or adulterated die-
23 tary supplements, rules to ensure scientific substan-
24 tiation of the claims made regarding dietary supple-
25 ments, and a notification requirement to the Food

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

4 (5) DSHEA requires that claims made on die-
5 tary supplement labels, packaging, and accom-
6 panying material be truthful, non-misleading, and
7 substantiated. Manufacturers are prohibited from
8 making claims that products are intended to diag-
9 nose, treat, mitigate, cure, or prevent a disease.

10 (6) DSHEA requires that dietary supplements
11 comply with good manufacturing practice (referred
12 to in this section as “GMP”) requirements, and au-
13 thORIZES the Food and Drug Administration to estab-
14 lish such requirements.

15 (7) In 2007, after many years of delay, the
16 Food and Drug Administration published regula-
17 tions detailing the GMP requirements for dietary
18 supplements, including requirements for identity, pu-
19 rity, strength, sanitary conditions, and record-
20 keeping. The Food and Drug Administration began
21 to enforce those requirements in 2008.

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

1 that includes information showing that the dietary
2 supplement will reasonably be expected to be safe.
3 According to the Food and Drug Administration, the
4 Food and Drug Administration has raised objections
5 to more than 70 percent of all new dietary ingre-
6 dient notifications submitted to the agency.

7 (9) The Food and Drug Administration has
8 successfully used the adulteration provisions of
9 DSHEA to remove from the marketplace dietary
10 supplements that present an unreasonable risk of in-
11 jury or illness.

12 (10) In 2002, Congress passed the Public
13 Health Security and Bioterrorism Preparedness and
14 Response Act (Public Law 107–188). This law re-
15 quires any facility engaged in manufacturing, proc-
16 essing, packing, or holding food for consumption in
17 the United States, including dietary supplements, to
18 be registered with the Food and Drug Administra-
19 tion.

20 (11) In 2006, Congress supplemented DSHEA
21 by approving the Dietary Supplement and Non-
22 prescription Drug Consumer Protection Act (Public
23 Law 109–462). This law requires dietary supple-
24 ment manufacturers, packers, and distributors to re-
25 port promptly to the Food and Drug Administration

1 any reports the manufacturer or other responsible
2 person receives of serious adverse events associated
3 with the use of the products of such manufacturer
4 or other responsible person. Information the Food
5 and Drug Administration receives under this report-
6 ing requirement may help the agency detect possible
7 safety problems related to dietary supplement prod-
8 ucts or ingredients.

9 (12) DSHEA created the Office of Dietary
10 Supplements within the National Institutes of
11 Health to expand research and consumer informa-
12 tion about the health effects of dietary supplements.
13 The Office of Dietary Supplements has greatly ex-
14 panded the number of scientific studies of dietary
15 supplements and the availability of reliable informa-
16 tion to consumers.

17 (13) While the Food and Drug Administration
18 has taken some important steps to implement and
19 enforce DSHEA and the other laws governing the
20 regulation of dietary supplements, the agency has
21 not fully implemented and enforced DSHEA and the
22 other laws governing the regulation of dietary sup-
23 plements.

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

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

5 (15) If the Food and Drug Administration de-
6 termines that a product labeled as a dietary supple-
7 ment includes an anabolic steroid or an analogue of
8 an anabolic steroid, the Food and Drug Administra-
9 tion does not systematically notify the Drug En-
10 forcement Administration of that determination.

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

18 (17) According to the Food and Drug Adminis-
19 tration, full implementation of DSHEA and the
20 other laws governing the regulation of dietary sup-
21 plements would require substantial additional re-
22 sources. In 2002, the Food and Drug Administra-
23 tion reported to Congress in writing that the agency
24 would need between \$24,000,000 and \$65,000,000
25 per year to fully implement DSHEA.

1 **SEC. 3. SENSE OF CONGRESS.**

2 It is the sense of Congress that:

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

6 (A) providing Congress with a professional
7 judgment estimate of the annual costs during
8 the 5-year period beginning on the date of en-
9 actment of this Act to fully implement and en-
10 force DSHEA and other dietary supplement
11 laws and regulations under the jurisdiction of
12 the Food and Drug Administration;

13 (B) conducting inspections, using appro-
14 priately trained inspection personnel, of all fa-
15 cilities in which a dietary supplement is manu-
16 factured, processed, packed, or held to ensure
17 compliance with the new dietary supplement
18 good manufacturing practices regulations;

19 (C) using the authority under DSHEA to
20 protect the public from unsafe dietary supple-
21 ment products and ingredients and to ensure
22 that claims made are truthful, non-misleading,
23 and substantiated, with highest regulatory pri-
24 ority given to cases of clear violations of the law
25 (including the intentional adulteration and spik-
26 ing of products);

1 (D) implementing the recommendations
2 contained in the January 2009 report of the
3 Government Accountability Office, entitled,
4 “Dietary Supplements: FDA Should Take Fur-
5 ther Actions To Improve Oversight and Con-
6 sumer Understanding”, (GAO 09–250) that the
7 Food and Drug Administration—

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

13 (ii) promptly issue guidance to clarify
14 when a dietary supplement ingredient is a
15 new dietary ingredient, the evidence needed
16 to document the safety of new dietary in-
17 gredients, and appropriate methods for es-
18 tablishing the identity of a new dietary in-
19 gredient; and

20 (iii) coordinate with stakeholder
21 groups involved in consumer outreach to
22 identify, implement, and evaluate the effec-
23 tiveness of additional mechanisms for edu-
24 cating consumers about the safety, effi-

1 cacy, and labeling of dietary supplements;
2 and

3 (E) notifying the Drug Enforcement Ad-
4 ministration if the Food and Drug Administra-
5 tion determines that the information in a new
6 dietary ingredient notification submitted under
7 section 413 of the Federal Food, Drug, and
8 Cosmetic Act (21 U.S.C. 350b) is inadequate to
9 establish that the new dietary ingredient will
10 reasonably be expected to be safe, because the
11 dietary supplement may contain an anabolic
12 steroid or an analogue of an anabolic steroid.

13 (2) The manufacturers, packers, retailers, and
14 distributors of dietary supplements and dietary sup-
15 plement ingredients should increase efforts to—

16 (A) comply fully with all requirements of
17 DSHEA and the Dietary Supplement and Non-
18 prescription Drug Consumer Protection Act;

19 (B) cooperate fully and appropriately with
20 the Food and Drug Administration in imple-
21 mentation and enforcement of Federal laws and
22 regulations; and

23 (C) provide the Food and Drug Adminis-
24 tration with appropriate input on known and

1 suspected violations of such laws and regula-
2 tions.

3 **SEC. 4. AUTHORIZATION OF APPROPRIATIONS AND ALLO-**
4 **CATION OF RESOURCES.**

5 (a) AUTHORIZATION OF APPROPRIATIONS.—There
6 are authorized to be appropriated to carry out the Dietary
7 Supplement Health and Education Act of 1994, the
8 amendments made by such Act, and other provisions
9 under the Federal Food, Drug, and Cosmetic Act (21
10 U.S.C. 301 et seq.) that apply to dietary supplements,
11 \$30,000,000 for fiscal year 2011 and such sums as may
12 be necessary for each of fiscal years 2012 through 2014.

13 (b) ALLOCATION OF FUNDS FOR FISCAL YEAR
14 2010.—From funds appropriated to the Food and Drug
15 Administration for fiscal year 2010 for the purpose of en-
16 hancing food safety, not less than \$20,000,000 shall be
17 expended to effectively and fully implement and enforce
18 the Dietary Supplement Health and Education Act of
19 1994, the amendments made by such Act, and other provi-
20 sions under the Federal Food, Drug, and Cosmetic Act
21 (21 U.S.C. 301 et seq.) that apply to dietary supplements.

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

1 ments by the Office of Dietary Supplements at the Na-
2 tional Institutes of Health—

3 (1) \$40,000,000 for fiscal year 2010; and

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

6 **SEC. 5. ANNUAL ACCOUNTABILITY REPORT ON THE REGU-**
7 **LATION OF DIETARY SUPPLEMENTS.**

8 (a) IN GENERAL.—Not later than January 31, 2011,
9 and annually thereafter, the Secretary of Health and
10 Human Services shall submit a report to Congress on the
11 implementation and enforcement of the Dietary Supple-
12 ment Health and Education Act of 1994 and the amend-
13 ments made by such Act.

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

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

20 (2) The total funding and number of full-time
21 equivalent personnel in the Food and Drug Adminis-
22 tration dedicated to administering adverse event re-
23 porting systems, as such systems relate to dietary
24 supplement regulation, during the prior fiscal year.

1 (3) The total funding and number of full-time
2 equivalent personnel in the Food and Drug Adminis-
3 tration dedicated to enforcement of dietary supple-
4 ment labeling and claims requirements during the
5 prior fiscal year and a brief explanation of the activi-
6 ties of such personnel.

7 (4) The total funding and number of full-time
8 equivalent personnel in the Food and Drug Adminis-
9 tration dedicated to the review and enforcement of
10 good manufacturing practice requirements with re-
11 spect to dietary supplements during the prior fiscal
12 year.

13 (5) The number of inspections at which the
14 Food and Drug Administration evaluated or re-
15 viewed the compliance of a manufacturer with good
16 manufacturing practices for dietary supplements
17 during the prior fiscal year, and the number of times
18 the Food and Drug Administration issued a warning
19 letter because it determined that such manufacturer
20 was not in compliance with some aspect of such re-
21 quirements.

22 (6) The number of new dietary ingredient noti-
23 fication reviews that the Food and Drug Administra-
24 tion performed during the prior fiscal year and the
25 number of times the Food and Drug Administration

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

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

9 (8) A brief summary and explanation of all en-
10 forcement actions taken by the Food and Drug Ad-
11 ministration and the Department of Health and
12 Human Services related to dietary supplements dur-
13 ing the prior fiscal year, including the number and
14 type of actions.

15 (9) The number of times the Food and Drug
16 Administration requested substantiation of dietary
17 supplement claims from a manufacturer during the
18 prior fiscal year, the number of times a manufac-
19 turer refused to provide such information, and the
20 response of the agency in such situations.

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

1 (11) The research and consumer education ac-
2 tivities supported by the Office of Dietary Supple-
3 ments of the National Institutes of Health during
4 the prior fiscal year.

5 (12) Any recommendations for administrative
6 or legislative actions to improve the regulation of di-
7 etary supplements.

8 (13) Any other information regarding the regu-
9 lation of dietary supplements determined appropriate
10 by the Secretary of Health and Human Services or
11 the Commissioner of Food and Drugs.

12 **SEC. 6. NEW DIETARY INGREDIENTS.**

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

16 (1) by redesignating subsection (c) as sub-
17 section (e); and

18 (2) by inserting after subsection (b) the fol-
19 lowing:

20 “(c) GUIDELINES.—Not later than 180 days after the
21 date of enactment of the Dietary Supplement Full Imple-
22 mentation and Enforcement Act of 2010, the Secretary
23 shall publish guidance that clarifies when a dietary supple-
24 ment ingredient is a new dietary ingredient, when the
25 manufacturer or distributor of a dietary ingredient or die-

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

6 “(d) NOTIFICATION TO DEA.—

7 “(1) IN GENERAL.—If the Secretary determines
8 that the information in a new dietary ingredient no-
9 tification submitted under this section for an article
10 purported to be a new dietary ingredient is inad-
11 equate to establish that a dietary supplement con-
12 taining such article will reasonably be expected to be
13 safe because the article may be, or may contain, an
14 anabolic steroid or an analogue of an anabolic ster-
15 oid, the Secretary shall notify the Drug Enforcement
16 Administration of such determination. Such notifica-
17 tion by the Secretary shall include, at a minimum,
18 the name of the product or article, the name of the
19 person or persons who marketed the product or
20 made the submission of information regarding the
21 article to the Secretary under this section, and any
22 contact information for such person or persons that
23 the Secretary has.

24 “(2) DEFINITIONS.—For purposes of this sub-
25 section—

1 “(A) the term ‘anabolic steroid’ has the
2 meaning given such term in section 102(41) of
3 the Controlled Substances Act; and

4 “(B) the term ‘analogue of an anabolic
5 steroid’ means a substance whose chemical
6 structure is substantially similar to the chem-
7 ical structure of an anabolic steroid.”.

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