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(Original Signature of Member)

112TH CONGRESS
1ST SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act concerning safe dietary ingredients in dietary supplements.

IN THE HOUSE OF REPRESENTATIVES

Mr. BURTON of Indiana introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act concerning safe dietary ingredients in dietary supplements.

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 Protection Act of 2011”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

8 (1) Improving the health status of United
9 States citizens ranks at the top of the national prior-

1 ities of the Federal Government. The importance of
2 nutrition and the benefits of dietary supplements to
3 health promotion and disease prevention are well
4 known and have been documented in scientific stud-
5 ies.

6 (2) Since enactment of the Dietary Supplement
7 Health and Education Act of 1994 (DSHEA), die-
8 tary supplements have had an exemplary public
9 health safety record. Based on national surveys, in
10 1994, 50 percent of the 260,000,000 Americans reg-
11 ularly consumed dietary supplements. In 2006,
12 232,000,000 adults over the age of 18 alone con-
13 sumed dietary supplements, 53 percent of the
14 United States adult population.

15 (3) There were 4,000 dietary supplements in
16 the marketplace in 1994, and in 2006 an estimated
17 29,000 dietary supplements were being consumed
18 daily by Americans. Since the enactment of
19 DSHEA, there has been 17 years of additional his-
20 torical use-safety experience conducted by millions of
21 Americans. Over 17 years, approximately 25,000
22 new supplements with new dietary ingredients have
23 been approved by the Food and Drug Administra-
24 tion (FDA) under DSHEA and have and are being
25 safely consumed by Americans.

1 (4) Since January 2007, FDA regulations gov-
2 erning dietary supplement manufacturer good manu-
3 facturing practices, dietary supplement adverse
4 event reporting, and private sector voluntary testing
5 and auditing for supplement quality and purity have
6 improved postmarketing consumer safety. Before
7 DSHEA, these mechanisms did not exist.

8 (5) There are DSHEA “grandfathered” supple-
9 ments, dietary ingredients, and classified products
10 which were on the market before October 15, 1994,
11 and “generally recognized as safe” for human con-
12 sumption. FDA regulatory policy, industry practices,
13 and consumer marketplace paradigms have dras-
14 tically changed over 17 years, but this policy has
15 not.

16 (6) The definition of a new dietary ingredient
17 in section 413 of the Federal Food, Drug and Cos-
18 metic Act (21 U.S.C. 350b) does not recognize the
19 current safe market in supplements, nor how inten-
20 sively supplements have been regulated over the 17
21 years since enactment of DSHEA to protect public
22 health and safety, and should be updated to reflect
23 this reality.

1 **SEC. 3. NEW DIETARY INGREDIENT DEFINITION.**

2 Section 413(d) of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 350b(d)) is amended by striking
4 “October 15, 1994” each place it appears and inserting
5 “January 1, 2007”.