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112TH CONGRESS
1ST SESSION

H. R. 3380

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

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 4, 2011

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

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A BILL

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

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 Protection Act of 2011''.

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) Improving the health status of United States citizens ranks at the top of the national priorities of the Federal Government. The importance of

nutrition and the benefits of dietary supplements to health promotion and disease prevention are well known and have been documented in scientific studies.

(2) Since enactment of the Dietary Supplement Health and Education Act of 1994 (DSHEA), dietary supplements have had an exemplary public health safety record. Based on national surveys, in 1994, 50 percent of the 260,000,000 Americans regularly consumed dietary supplements. In 2006, 232,000,000 adults over the age of 18 alone consumed dietary supplements, 53 percent of the United States adult population.

(3) There were 4,000 dietary supplements in the marketplace in 1994, and in 2006 an estimated 29,000 dietary supplements were being consumed daily by Americans. Since the enactment of DSHEA, there has been 17 years of additional historical use-safety experience conducted by millions of Americans. Over 17 years, approximately 25,000 new supplements with new dietary ingredients have been approved by the Food and Drug Administration (FDA) under DSHEA and have and are being safely consumed by Americans.

(4) Since January 2007, FDA regulations governing dietary supplement manufacturer good manufacturing practices, dietary supplement adverse event reporting, and private sector voluntary testing and auditing for supplement quality and purity have improved postmarketing consumer safety. Before DSHEA, these mechanisms did not exist.

(5) There are DSHEA ''grandfathered'' supplements, dietary ingredients, and classified products which were on the market before October 15, 1994, and ''generally recognized as safe'' for human consumption. FDA regulatory policy, industry practices, and consumer marketplace paradigms have drastically changed over 17 years, but this policy has not.

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

SEC. 3. NEW DIETARY INGREDIENT DEFINITION.

Section 413(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350b(d)) is amended by striking ''October 15, 1994'' each place it appears and inserting ''January 1, 2007''.

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