

112TH CONGRESS
1ST SESSION

H. R. 2045

To amend the Federal Trade Commission Act concerning the burden of proof in false advertising cases involving dietary supplements and dietary ingredients.

IN THE HOUSE OF REPRESENTATIVES

MAY 26, 2011

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

A BILL

To amend the Federal Trade Commission Act concerning the burden of proof in false advertising cases involving dietary supplements and dietary ingredients.

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 “Freedom of Health
5 Speech Act”.

6 **SEC. 2. HEALTH INFORMATION.**

7 Section 5 of the Federal Trade Commission Act (15
8 U.S.C. 45) is amended by adding at the end the following:

1 “(o) ADVERTISING OF DIETARY SUPPLEMENTS AND
2 DIETARY INGREDIENTS.—

3 “(1) DEFINITIONS.—In this subsection—

4 “(A) the term ‘dietary supplement’ has the
5 meaning given to that term in section 201(ff)
6 (21 U.S.C. 321(ff)) of the Federal Food, Drug,
7 and Cosmetic Act; and

8 “(B) the term ‘dietary ingredient’ means
9 an ingredient listed in subparagraphs (A)
10 through (F) of section 201(ff)(1) (21 U.S.C.
11 321(ff)(1)) of the Federal Food, Drug, and
12 Cosmetic Act that is included in, or that is in-
13 tended to be included in, a dietary supplement.

14 “(2) EXEMPTIONS FROM REGULATION AS AD-
15 VERTISING.—No content of any publication shall be
16 considered advertising regulated under this Act un-
17 less the content is intended by the seller of a prod-
18 uct to promote the sale of that product and the con-
19 tent includes—

20 “(A) the name of the product offered for
21 sale;

22 “(B) an express offer to sell the named
23 product; and

24 “(C) a purchase price for the product.

1 No content excerpted in whole or part from a peer-
2 reviewed scientific publication shall be considered
3 advertising regulated under this Act.

4 “(3) NO IMPLIED CLAIMS.—In any investiga-
5 tion commenced by the Commission and in any adju-
6 dicative proceeding in which the Commission is a
7 party, the Commission shall not attribute to an ad-
8 vertiser accused of false advertisement any adver-
9 tising statement not actually made by that adver-
10 tiser.

11 “(4) NOTICE, OPPORTUNITY TO CURE, AND
12 BURDEN OF PROOF FOR INVESTIGATION.—Before
13 the Commission authorizes an investigation of false
14 advertisement by an advertiser of a dietary supple-
15 ment or a dietary ingredient, the Commission shall
16 send the advertiser a written ‘Notice of Suspected
17 Violation and Opportunity to Cure’ informing the
18 advertiser of—

19 “(A) the precise advertising statement that
20 the Commission suspects may be false or mis-
21 leading;

22 “(B) the scientific basis for the Commis-
23 sion’s view that any statement of health benefit
24 may be false or misleading; and

1 “(C) a date certain, not less than 30 days
2 after the date of the advertiser’s receipt of the
3 notice, by which the advertiser may voluntarily
4 discontinue further use of the statement the
5 Commission suspects may be false or mis-
6 leading and, upon so doing, the advertiser shall
7 not be subject to an investigation of false adver-
8 tisement by the Commission for the statement.

9 The Commission shall not commence any investiga-
10 tion of an advertiser of a dietary supplement or a di-
11 etary ingredient to determine whether the advertiser
12 has disseminated a false advertisement unless it pos-
13 sesses before the commencement of such investiga-
14 tion clear and convincing evidence that the advertise-
15 ment is false and misleading.

16 “(5) BURDEN OF PROOF FOR FALSE ADVER-
17 TISEMENT CASES.—In every proceeding before a
18 court or the Commission in which an advertiser of
19 a dietary supplement or a dietary ingredient is
20 charged with false advertising, the burden of proof
21 shall be on the Commission to establish by clear and
22 convincing evidence that the advertisement is false,
23 that the advertisement actually caused consumers to
24 be misled into believing to be true that which is
25 false, and that but for the false advertising content

1 the consumer would not have made the purchase at
2 the price paid. If a claimed health benefit of a die-
3 tary supplement or dietary ingredient is alleged to
4 be false advertising, the Commission must addition-
5 ally establish based on expert scientific opinion and
6 published peer-reviewed scientific evidence that the
7 claim is false. No order adverse to the advertiser
8 shall be entered except upon the Commission satis-
9 fying this burden of proof.”.

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