

107TH CONGRESS
1ST SESSION

H. R. 3066

To amend the Federal Food, Drug, and Cosmetic Act to establish labeling and advertising requirements for dietary supplements containing ephedrine alkaloids, to prohibit sales of such supplements to individuals under the age of 18, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 9, 2001

Mrs. DAVIS of California introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish labeling and advertising requirements for dietary supplements containing ephedrine alkaloids, to prohibit sales of such supplements to individuals under the age of 18, 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 “Ephedrine Alkaloid
5 Consumer Protection Act”.

1 **SEC. 2. REQUIREMENTS REGARDING DIETARY SUPPLE-**
2 **MENTS CONTAINING EPHEDRINE ALKALOIDS.**

3 (a) FOOD LABELING AND ADVERTISING.—Section
4 403 of the Federal Food, Drug, and Cosmetic Act (21
5 U.S.C. 343) is amended by adding at the end the fol-
6 lowing:

7 “(t) If it is a dietary supplement containing ephed-
8 rine alkaloids, unless its labeling and advertising are in
9 accordance with the following, as applicable:

10 “(1) The label bears, in at least $\frac{1}{16}$ inch type,
11 a notice as follows:

12 ‘WARNING: (A) Not for use by individ-
13 uals under the age of 18. Do not use if preg-
14 nant or nursing. Consult a physician or licensed
15 qualified health care professional before using
16 this product if you have, or have a family his-
17 tory of, heart disease, thyroid disease, diabetes,
18 asthma, high blood pressure, recurrent head-
19 aches, depression or other psychiatric condition,
20 glaucoma, difficulty in urinating, prostate en-
21 largement, or seizure disorder, or if you are
22 using monoamine oxidase inhibitor (MAOI) or
23 any other dietary supplement, prescription
24 drug, or over-the-counter drug containing
25 ephedrine, pseudoephedrine, caffeine, or phenyl-
26 propanolamine (ingredients found in certain al-

1 lergy, asthma, cough or cold, and weight control
2 products).

3 ‘(B) Consuming this product may cause se-
4 rious adverse health effects, including heart at-
5 tack, stroke, and death.

6 ‘(C) Discontinue use and call a physician
7 or licensed qualified health care professional im-
8 mediately if you experience rapid heartbeat, diz-
9 ziness, severe headache, shortness of breath, or
10 other similar symptoms.

11 ‘(D) Individuals who consume additional
12 caffeine with this product may experience seri-
13 ous adverse health effects.

14 ‘(E) This product contains ____ milli-
15 grams concentrated ephedrine group alkaloids
16 per serving in the form of herbal extracts.’.

17 In lieu of the blank, the number of milligrams shall
18 be identified.

19 “(2) The label bears standardized nomenclature
20 for the ephedrine ingredient such that the ephedrine
21 group alkaloid name is used when referring to the
22 active ingredients in place of or in addition to the
23 botanical name of the ephedrine group alkaloid.

24 “(3) The label bears the amount in milligrams
25 of caffeine alkaloids and other ingredients per serv-

1 ing that have a known stimulant effect (ex yohim-
2 bine).

3 “(4) The label bears the toll-free telephone
4 number, and the address of the Internet site, main-
5 tained by the Secretary for purposes of the medical
6 product reporting program (MedWatch or any suc-
7 cessor program).

8 “(5) The labeling (other than the label), and all
9 prerecorded or scripted radio or television adver-
10 tising, provide a notice as follows: ‘This product con-
11 tains ephedrine group alkaloids and may cause seri-
12 ous adverse health effects. Read the label and follow
13 directions.’”.

14 (b) SALES TO MINORS.—Chapter IV of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.)
16 is amended by inserting after section 403C the following
17 section:

18 “SALE OF DIETARY SUPPLEMENTS CONTAINING
19 EPHEDRINE ALKALOIDS

20 “SEC. 403D. The sale of a dietary supplement con-
21 taining ephedrine alkaloids shall be deemed to be an act
22 that results in such supplement being misbranded while
23 held for sale if—

24 “(1) the sale of the supplement is made to an
25 individual under the age of 18; or

1 “(2) in the case of a sale at retail, the pur-
2 chaser has direct access to the supplement at the re-
3 tail establishment involved, rather than the supple-
4 ment being held at a portion of the establishment
5 not intended to be accessible to customers of the es-
6 tablishment.”.

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