



Ohio State Board of Pharmacy; 77 S. High Street, 17th Floor; Columbus, Ohio 43266-0320  
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## COMPLIANCE BULLETIN 97-001

TO: MANUFACTURERS/WHOLESALERS/PHARMACISTS

DATE: 03/17/97

RE: O-T-C PRODUCTS CONTAINING EPHEDRINE -- EXCEPTIONS TO  
CLASSIFICATION AS A SCHEDULE V CONTROLLED SUBSTANCE

**Effective March 31, 1997**, pursuant to enactment of Sub. H. B. 523, Food Products or Dietary Supplements that contain ephedrine are not Schedule V controlled substances **if they meet** all of the following criteria:

- (1) the product contains, per dosage unit or serving, not more than the lesser of twenty-five milligrams of ephedrine alkaloids or the maximum amount of ephedrine alkaloids provided in applicable regulations adopted by the United States Food and Drug Administration, and no other controlled substance.
- (2) the product contains no hydrochloride or sulfate salts of ephedrine alkaloids.
- (3) the product is packaged with a prominent label securely affixed to each package that states all of the following:
  - (a) the amount in milligrams of ephedrine in a serving or dosage unit;
  - (b) the amount of the food product or dietary supplement that constitutes a serving or dosage unit;
  - (c) that the maximum recommended dosage of ephedrine for a healthy adult human is the lesser of one hundred milligrams in a twenty-four-hour period for not more than twelve weeks or the maximum recommended dosage or period of use provided in applicable regulations adopted by the United States Food and Drug Administration; and
  - (d) that improper use of the product may be hazardous to a person's health.

Food products and dietary supplements that contain ephedrine and **do not meet** the above criteria continue to be Schedule V controlled substances and may not be sold in Ohio by anyone other than a pharmacist in accordance with Ohio Administrative Code Rule 4729-11-09 (Sale of Schedule V controlled substance products without a prescription).

The Board of Pharmacy, pursuant to authority granted in division (K) of section 3719.44 of the Revised Code effective July 21, 1994, has excepted (by Rule 4729-12-09 of the Ohio Administrative Code) the following products which contain ephedrine, its salts, its isomers, or the salts of its isomers and, thereby, do not require sale by a pharmacist:

- (1) All products that contain the isomer known as pseudoephedrine or its salts, but do not also contain any of the isomer known as ephedrine or its salts. *[exception effective 08/24/94]*
- (2) "Breathe Easy®" herb tea. *[exception effective 12/15/94]*
- (3) "Bronkaid® Dual Action" caplets. *[exception effective 12/15/94]*
- (4) "Hydrosal®" hemorrhoidal ointment. *[exception effective 12/15/94]*
- (5) "Primatene® Dual Action Formula" tablets. *[exception effective 01/10/96]*

If you have any questions, please call the Board office.

NOTE: Sub. H.B. 523 provides additional requirements for the legal sale of food products or dietary supplements excepted from Schedule V. Please see paragraphs (K)(2)(b) and (K)(2)(c) of Section 3719.44 of the Ohio Revised Code.