



## COMPLIANCE ALERT

TO: ALL SALONS LICENSED BY THE COSMETOLOGY BOARD

DATE: 08/08/97

RE: PRODUCTS CONTAINING EPHEDRINE (also known as MA HUANG; EPHEDRA) --  
CLASSIFICATION AS A SCHEDULE V CONTROLLED SUBSTANCE

It has come to the attention of the Pharmacy Board that many Ohio salons have been approached to sell or are selling products containing Ephedrine (Ma Huang; Ephedra). As of July 21, 1994, Ephedrine (Ma Huang; Ephedra) was placed in the Schedule V Controlled Substance classification, which means it can only be sold by a pharmacist in a licensed pharmacy unless excepted by the Pharmacy Board (see reverse side for list of excepted products).

Many changes have occurred in the laws since July 21, 1994. A salon **MAY** continue to sell these products **ONLY IF** the products meet the requirements set forth in Division (K)(2)(a) of Ohio Revised Code Section 3719.44 as follows:

(K)(2)(a) A product containing ephedrine shall not be considered a controlled substance if the product is a food product or dietary supplement that meets **ALL** of the following criteria: *[emphasis added]*

- (i) it 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.
- (ii) it contains no hydrochloride or sulfate salts of ephedrine alkaloids. *[i.e., ephedrine hydrochloride or ephedrine sulfate]*
- (iii) it is packaged with a prominent label securely affixed to each package that states all of the following:
  - the amount in milligrams of ephedrine in a serving or dosage unit;
  - the amount of the food product or dietary supplement that constitutes a serving or dosage unit;
  - 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 *[emphasis added]*
  - 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 a licensed pharmacy.

PRODUCTS EXCEPTED BY THE OHIO STATE BOARD OF PHARMACY:

The Pharmacy Board, 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 (Ma Huang; Ephedra), 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]*
- (6) "SnoreStop™" tablets. *[exception effective 07/01/97]*

**Additional requirements** for the legal sale of Ephedrine (Ma Huang; Ephedra) products excepted from Schedule V either by the Pharmacy Board or by meeting all of the criteria set forth in Division (K)(2)(a) are as follows:

(K)(2)(b)(i) Subject to division (K)(2)(b)(ii) of this section, no person shall dispense, sell, or otherwise give a product described in division (K)(2)(a) of this section *[3719.44]* to any individual under eighteen years of age.

(ii) Division (K)(2)(b)(i) of this section *[3719.44]* does not apply to a physician or pharmacist who dispenses, sells, or otherwise gives a product described in division (K)(2)(a) of this section to an individual under eighteen years of age, to a parent or guardian of an individual under eighteen years of age who dispenses, sells, or otherwise gives a product of that nature to the individual under eighteen years of age, or to a person who, as authorized by the individual's parent or legal guardian, dispenses, sells, or otherwise gives a product of that nature to an individual under eighteen years of age.

(K)(2)(c) No person in the course of selling, offering for sale, or otherwise distributing a product described in division (K)(2)(a) of this section shall advertise or represent in any manner that the product causes euphoria, ecstasy, a "buzz" or "high," or an altered mental state; heightens sexual performance; or, because it contains ephedrine alkaloids, increased muscle mass.

Please check the labeling of any products your salon may be selling which contain Ephedrine (Ma Huang; Ephedra) and determine if the products are in compliance with the law.

If you find a product that does not meet all of the requirements described in (K)(2)(a)(i), (ii), or (iii) on the front page of this alert or does not meet the requirements shown in (K)(2)(c) above, please call (614/466-4143) the Pharmacy Board with the name of the product, the company, and the non-law conforming attributes and/or fax (614/752-4836) a copy of the label and any accompanying sales material you have received.

If you have any questions or concerns, please contact the Pharmacy Board office by any means listed in the heading of this communication.

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