

**CRITERIA TO BE CONSIDERED IN DENYING A PETITION FOR
EXEMPTION OR REMOVING A DRUG PRODUCT EXEMPTION**

Rule 4729-12-10 [Effective 03/13/1995]

- (A) The board shall consider the following factors in determining whether a particular over-the-counter (OTC) drug product containing the schedule V controlled substance ephedrine is manufactured and distributed for legitimate use in a manner consistent with the pertinent OTC tentative or final monograph issued by the federal food and drug administration and in a manner that reduces the likelihood of inappropriate use and/or abuse:
- (1) The package size and the manner of packaging;
 - (2) Distribution, advertising, and promotion of the product;
 - (3) Labeling and the name of the product;
 - (4) The potential, duration, scope, and significance of inappropriate use and/or abuse;
 - (5) Other facts as may be relevant to and consistent with the public health and safety.
- (B) The board shall remove a drug product exception for a particular drug product if it determines that the drug product is not manufactured and distributed for legitimate use and in a manner that reduces the likelihood of abuse.

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