



Ohio Administrative Code

Rule 4729:9-3-08 Criteria to be considered in denying a petition for exception or removing a drug product exception.

Effective: August 1, 2019

(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 United States 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 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.
