Criteria to be considered in denying a petition for exception or removing a drug product exception.

(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.
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CERTIFIED ELECTRONICALLY

Certification

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