Ohio Administrative Code

Rule 4729:9-3-01 Sale or Distribution of Ephedrine-Containing Products.

Effective: July 7, 2025

(A) As used in this rule, "ephedrine" is alpha-[-(Methylamino)ethyl]benzene-methanol; alpha-[1-(methylamino) ethyl]benzyl alcohol; 2-methylamino-1-phenyl-1-propanol; 1-phenyl-1-hydroxy-2-methylaminopropane; 1-phenyl-2- methylaminopropanol; alpha- hydroxy-beta-methylaminopropylbenzene; a product which occurs in the Chinese herb Ma Huang (Ephedra vulgaris, Ephedra sinica Stapf., Ephedra equisetina Bunge, Gnetaceae) and in several other Ephedra spp. Isomeric forms include d- and l-ephedrine as well as d-and l-pseudoephedrine with l-ephedrine and d-pseudoephedrine as the naturally occurring isomers.

(B) Each of the following products containing ephedrine, its salts, its isomers, or the salts of its isomers is excepted from classification as a schedule V controlled substance:

(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.

(2) "Breathe Easy" herb tea.

(3) "Bronkaid Dual Action" caplets.

(4) "Hydrosal" hemorrhoidal ointment.

(5) "Primatene Dual Action Formula" tablets.

(6) "Primatene" tablets.

(7) "SnoreStop" tablets.

(8) Drug products listed in division (K)(1) of section 3719.44 of the Revised Code.

(C) Except for products listed in paragraph (B) of this rule or products excepted in accordance within paragraph (D) of this rule, any person who manufactures, sells at wholesale or retail, dispenses, imports or exports products containing ephedrine, its salts or isomers, or who proposes to engage in such activities, shall:

(1) Hold a category III license in accordance with section 4729.52 of the Revised Code or section 4729.54 of the Revised Code.

(2) Comply with all applicable security and storage requirements in accordance with Chapters 3719. and 4729. of the Revised Code and agency 4729 of the Administrative Code.

(3) Conduct an inventory of all products containing ephedrine pursuant to rule 4729:5-3-07 or 4729:6-3-06 of the Administrative Code.

(4) Maintain all records required in accordance with Chapters 3719. and 4729. of the Revised Code and agency 4729 of the Administrative Code.

(5) The requirements listed in this paragraph do not apply if the ephedrine product is a food product or a dietary supplement that is specifically excepted in division (K)(1) of section 3719.44 of the Revised Code or paragraph (B) of this rule.

(D) A petition requesting that a drug product containing ephedrine be excepted by the board of pharmacy from being legally classified as a schedule V controlled substance stimulant may be submitted by any person engaged in the legitimate manufacture or wholesale sale of such products in the United States. The petition shall include the following information:

(1) Full name, address, and telephone number of the manufacturer.

(a) If incorporated, the petition must include copies of the incorporation papers and the names, dates of birth, addresses, and social security numbers of the officers of the corporation and all stockholders holding more than ten percent of the corporation's stock.

(b) If a proprietorship, the petition must include the name, address, date of birth, and social security

number of the owner(s).

(c) If a partnership, the petition must include the names, addresses, dates of birth, and social security numbers of the partners.

(2) A description of the package sizes and the manner of packaging of the drug product.

(3) A limited number of samples of each dosage form marketed in the final marketed packages.

(4) The manner of distribution, advertising, and promotion of the product including the following:

(a) The full name and address of all accounts located in Ohio to which the products have been or will be distributed at wholesale based on other products marketed by the petitioner.

(b) Copies of all advertisements used to promote the product within the last twelve months shall be included with the petition. A list of the publications in which the advertisements appeared or will appear if not presently marketed. If the product has not yet been marketed, copies of other products marketed by the petitioner shall be submitted with the petition.

(5) A listing of all ingredients in the product, indicating the quantity of each ingredient, whether or not it has any therapeutic value, and its purpose for being included in the product. Documentation of the therapeutic value of all active ingredients in the product shall be included with the petition.

(6) A list of all names the product is marketed or will be marketed under in the United States or any other country.

(7) Any information regarding the product's abuse or potential for abuse in the United States or other countries where the product is marketed or will be marketed under any of the names listed in paragraph (D)(6) of this rule.

(E) 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.

(F) 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.