Ohio Administrative Code

Rule 4729:9-3-06 Petitions for exception of ephedrine-containing products.

Effective: August 1, 2019

(A) 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 (A)(6) of this rule.

(B) This rule does not apply if the ephedrine product is a food product or a dietary supplement that is specifically excepted in division (K)(2) of section 3719.44 of the Revised Code or agency 4729 of the Administrative Code.