U.S. CONSUMER PRODUCT SAFETY COMMISSION

WASHINGTON, D.C. 20207

CPSC Executive Session
April 15, 1976

1750 K Street, N.W.
Washington, D.C.

Presiding: Chairman Simpson

Present : Commissioner Franklin
Commissioner Kushner
Commissioner Pittle

ITEM

Petition of Warren-Teed Pharmaceuticals, Inc., to Exempt Four Liquid Potassium Supplements from the Child Protection Packaging Standards for Oral Prescription Drugs (CPSC Petition No. PP 74-42)

(Briefing material transmitted by Office of Secretary April 9, 1976)

DECISION

On March 18, 1974, the Commission received a petition (dated March 13, 1974) from Warren-Teed Pharmaceuticals, Inc., requesting exemption from the Child Protection Packaging Standards for Human Prescription Drugs in Oral Dosage Form (16 CFR 1700.14(a)(10)) for four liquid potassium supplements in 15 ml unit dose package sizes: (1) Kaochlor Liquid (potassium chloride salt); (2) Kaochlor S-F (potassium chloride salt); (3) grape-flavored Kaon Elixir (potassium gluconate salt); and (4) lemon-lime flavored Kaon Elixir (potassium gluconate salt). The firm based its petition on the alleged low toxicity of potassium salts and the fact that its unit dose packages are designed primarily for institutional use.

Upon review of information available to the Commission, the Commission denies the subject petition. The Commission notes that although these drugs may be designed primarily for institutional use, a minimum of 25 unit

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dosage vials of these products would be dispensed at one time for outpatient use. Based on the animal toxicity data submitted by the petitioner, when extrapolated to humans, the Commission concludes that the minimum amount of the drugs dispensed to an outpatient would not provide a sufficient margin of safety to protect young children from serious personal harm or injury. Further, the products are supplied in highly-flavored, palatable dosage forms which may facilitate ingestion by children.

Attached is a copy of the letter sent to the petitioner containing the above information. The letter also calls to the petitioner's attention the fact that products intended and carefully distributed only for institutional use need not be packaged by the manufacturer in child-resistant packaging.

VOTE

Concurring: Chairman Simpson *

Commissioner Franklin B. Franklin

Commissioner Kushner

Commissioner Pittle R. David Pittle

* Minute approved in draft

Attachment

Submitted by: Office of the Secretary

APR 3 0 1976

Mr. A.S. Bauman
Director of Manufacturing
Warren-Teed Pharmaceuticals, Inc.
582 West Goodale Street
Columbus, Ohio 43215

Re: PP-74-42, Petition for Exemption of Kaochlor Liquid, Kaochlor S-F, Kaon Elixir (Grape), and Kaon Elixir (Lemon-Lime) from the Child Protection Packaging Standards for Prescription Drugs in Oral Dosage Form.

Dear Mr. Bauman:

The Consumer Product Safety Commission has reviewed your petition for liquid potassium supplements dated March 13, 1974, and your additional submissions dated June 18, 1974, July 30, 1974 and August 9, 1974, requesting exemption from the special packaging standards for Oral Prescription Drugs (16 CFR 1700.14(a)(10)). This is to advise you that the Commission has denied this petition.

The Commission has observed that, although these drugs may be designed primarily for institutional use, a minimum of 25 unit dosage vials of these products would be dispensed at one time for outpatient use. Review of the animal toxicity data submitted by Warren-Teed Pharmaceuticals indicated, upon conversion to milliequivalents potassium per kg of body weight, an oral LD50 of 27 mEq/kg for potassium gluconate (Kaon Elixirs), and an average oral LD50 of 26 mEq/kg for potassium chloride (Kaochlor liquids). If these values were extrapolated to humans, they would reveal that 13 units (about half the minimum number dispensed to an outpatient) represent an LD50 dosage for a 22-pound child. Information available to the Commission suggests that this amount would not provide a sufficient margin of safety to protect young children from serious personal harm or injury.

In addition, the products are supplied in highly flavored, palatable dosage forms which may facilitate ingestion by children.

The Commission wishes to call to your attention the fact that oral prescription drug products intended and carefully distributed only for institutional use need not be packaged by the manufacturer in child resistant packaging. However, a pharmacist who dispensed these products to patients or purchasers (other than in-patients) would be required to dispense these products in child resistant packaging, unless the purchaser requested non-complying packaging or the prescribing physician ordered non-complying packaging. As a result, if the products for which you have requested an exemption are intended by you to be dispensed only for institutional use, you may wish to further amplify this intent by specifically informing pharmacists that these products are in non-child resistant packaging and should be dispensed only for institutional (i.e., in-patient) use in this type of packaging.

Sincerely,
ORIGINAL SIGNED BY
SADYE DUNN

Sadye E. Dunn
Secretary

PBechtel:mli:4/29/76

cc: PBechtel
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