Dated: June 28, 2000.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for food Safety and Applied Nutrition.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 83N–0118; DESI 6514]

Oral Prescription Drugs Offered for Relief of Symptoms of Cough, Cold, or Allergy; Drug Efficacy Study Implementation; Caramiphen Edisylate; Final Actions on Supplemental New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) refuses to approve supplemental new drug applications (NDA's) for Tuss-Ornade Spansules and Liquid containing caramiphen edisylate and phenylpropanolamine hydrochloride. The basis for FDA's refusal to approve these products is that there is a lack of substantial evidence that caramiphen edisylate is effective.

DATES: Effective July 7, 2000.

ADDRESSES: Requests for applicability of this notice to a specific product should be identified with Docket No. 83N–0118 and reference number DESI 6514 and directed to the Division of Prescription Drug Compliance and Surveillance (HFD–330), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: David T. Read, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 9, 1973 (38 FR 4006), FDA classified the following drug products as less than effective for their labeled indications:

1. NDA 12–903; Tuss-Ornade Spansules containing caramiphen edisylate 20 milligrams (mg), chlorpheniramine maleate 8 mg, phenylpropanolamine hydrochloride 50 mg, and isopropamide iodide 2.5 mg; SmithKline Beecham Pharmaceuticals, P.O. Box 7929, Philadelphia, PA 19101–7929 (SmithKline).

2. NDA 13–068; Tuss-Ornade Liquid containing caramiphen edisylate 5 mg, chlorpheniramine maleate 2 mg, phenylpropanolamine hydrochloride 15 mg, and isopropamide iodide 0.75 mg; SmithKline.

In a notice published in the **Federal Register** of December 14, 1973 (38 FR 34481), FDA granted a temporary exemption from the time limits established for completing certain phases of the drug efficacy study implementation (DESI) program, for certain oral prescription drugs offered for relief of cough, cold, allergy, and related symptoms, including the aforementioned products. The exemption was granted because of the close relationship between drugs sold over the counter (OTC)—and thus subject to the ongoing OTC drug review (21 CFR part 330)—and prescription drugs offered for relief of cough, cold, allergies, and related symptoms.

In 1980 SmithKline submitted supplements proposing to reformulate the products listed above and marketed the following reformulated products pending a final determination of effectiveness:

1. NDA 12–903; caramiphen edisylate 40 mg and phenylpropanolamine hydrochloride 25 mg.

2. NDA 13–068; caramiphen edisylate 6.7 mg and phenylpropanolamine hydrochloride 12.5 mg.

In 1976 the OTC drug review panel for cold, cough, allergy, bronchodilator, and antiasthmatic drugs concluded that there were no well-controlled, objective, clinical studies documenting the effectiveness of caramiphen edisylate as an antitussive (41 FR 38312, September 9, 1976). The OTC monograph on antitussives was finalized in 1987 (52 FR 30042 at 30054, August 12, 1987).

Because of the lack of evidence that caramiphen edisylate is an effective antitussive, the Director of what was then the National Center for Drugs and Biologics concluded that there was a lack of substantial evidence that Tuss-Ornade Spansules and Liquid, either as previously formulated or as proposed for reformulation, would have all the effects they purported or were represented to have under the conditions of use prescribed, recommended, or suggested in the labeling. The Director issued a notice of opportunity for hearing on two proposals: (1) To withdraw approval of the original formulations of Tuss-Ornade Spansules and Liquid, and (2) to refuse approval of the supplemental reformulations of the same products (48 FR 40322, September 6, 1983).

Neither SmithKline nor any other interested party requested a hearing on the proposal to withdraw approval of the original formulations of Tuss-Ornade Spansules and Liquid; therefore, approval of the old formulations was withdrawn (49 FR 10707, March 22, 1984). However, in response to the agency's September 6, 1983, proposal to refuse to approve the reformulated products, SmithKline and National Pharmaceutical Manufacturing Company (National) requested hearings. SmithKline submitted data and information in support of its hearing request.

FDA has reviewed these data and determined that there is not substantial evidence of the effectiveness of caramiphen edisylate. SmithKline and National no longer market the products named in their 1983 hearing requests and have withdrawn those hearing requests.

This notice applies to any drug product that is identical, related, or similar to the products named above and is not the subject of an approved NDA (21 CFR 310.6). Any person who wishes to determine whether a specific product is covered by this notice should write to the Division of Prescription Drug Compliance and Surveillance (address above).

The Director of the Center for Drug Evaluation and Research, under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and under the authority delegated to her (21 CFR 5.70 and 5.82) finds that, on the basis of new information before her with respect to Tuss-Ornade Spansules and Liquid, evaluated together with the evidence available to her when the applications were approved, there is a lack of substantial evidence that the products as proposed for reformulation will have the effect they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling.

Therefore, based on the foregoing finding, approvals and all the amendments and supplements thereto of NDA 12–903 and NDA 13–068 are withdrawn and refused effective July 7, 2000. Shipment in interstate commerce of the products listed above or of any identical, related, or similar product that is not the subject of an approved NDA will then be unlawful.

Dated: June 20, 2000.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

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