[DESI 11562; Docket No. FDC-D-511; NDA 11-562]

PFIZER LABORATORIES

Carbetapentane Citrate Jel; Notice of Withdrawal of Approval of New Drug Application

On August 25, 1972 there was published in the FEDERAL REGISTER (37 F.R. 17227) a notice of opportunity for hearing (DESI 11562) in which the Commissioner of Food and Drugs proposed to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) withdrawing approval of the new drug application for the following drug:

NDA 11-562; Candette Cough Jel containing carbetapentane citrate; Pfizer Laboratories Division, Pfizer Inc., 235 East 42d Street, New York, NY 10017.

All identical, related, or similar products, not the subject of an approved new drug application, are covered by the new drug application reviewed and are subject to this notice. See 21 CFR 130.40 (37 F.R. 23165, October 31, 1972). Any person who wished to determine whether a specific product is covered by this notice should write to the Food and Drug Administration, Bureau of Drugs, Office of Compliance (BD-300), 5600 Fishers Lane, Rockville, Md. 20852.

Neither Pfizer Laboratories nor any other interested person has filed a written appearance of election as provided by said notice. The failure to file such an appearance constitutes an election by such persons not to avail themselves of the opportunity for a hearing.

The Commissioner of Food and Drugs, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1053, as amended; 21 U.S.C. 355), and the Administrative Procedure Act (5 U.S.C. 554), and under authority delegated to him (21 CFR 2.120), finds that new evidence not contained in the new drug application or not available to the Commissioner until after the application was approved, evaluated together with the evidence available to him when the application was approved, reveals that the drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved. Specifically, the risks involved in its use outweigh any expected benefits in that inexact methods of determining dosage (of a gel) are potentially dangerous, particularly in the care of small children.

Therefore, pursuant to the foregoing findings, approval of new drug application 11-562 and all amendments and supplements applying thereto is withdrawn effective on the date of publication hereof in the FEDERAL REGISTER. Shipment in interstate commerce of the above-listed drug product or of any identical, related, or similar product, not the subject of an approved new drug application, is henceforth unlawful.

Dated: November 21, 1972.

SAM D. FINE,
Associate Commissioner for Compliance.

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