

the Commissioner (21 CFR 2.120), approval of NADA No. 7-461V and NADA No. 9-009V, including all amendments and supplements thereto, is hereby withdrawn effective on the date of publication of this document (11-29-72).

Dated: November 21, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc. 72-20471 Filed 11-28-72; 8:49 am]

[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. 23185, 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.

[FR Doc. 72-20469 Filed 11-28-72; 8:49 am]

[DESI 97; Docket No. FDC-D-509; NDA 97 etc.]

ROCHE LABORATORIES AND AMERICAN PHARMACEUTICAL CO.

Certain OTC Multiple-Vitamin Preparations for Oral Use; Notice of Withdrawal of Approval of New Drug Applications

On September 13, 1972 there was published in the FEDERAL REGISTER (37 F.R. 18576) an announcement and notice of opportunity for hearing (DESI 97) 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 applications for the following products:

1. NDA 97; Cal-C-Tose Powder containing in each serving 2,000 units vitamin A, 2 mg. vitamin B₁, 1 mg. vitamin B₂, 75 mg. vitamin C, 500 units vitamin D, and 5 mg. niacinamide; formerly marketed by Roche Laboratories, Division of Hoffmann La Roche Inc., Nutley, NJ 07110.

2. NDA 336; Codanol Vitamin Liquid, each 5 ml., containing 4,000 USP units vitamin A palmitate, 1,000 USP units ergocalciferol, 2 mg. thiamine mononitrate, 2 mg. sodium riboflavin phosphate, 1 mg. pyridoxine hydrochloride, 3 mcgm. cyanocobalamin, 50 mg. ascorbic acid and 5 mg. niacinamide; formerly marketed by American Pharmaceutical Co., 120 Bruckner Boulevard, Bronx, NY 10454.

All identical, related, or similar products, not the subject of an approved new drug application, are covered by the new drug applications reviewed and are subject to this notice. See 21 CFR 130.40 (37 F.R. 23185, October 31, 1972). Any person who wishes 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.

The notice stated that, formulated as described, the benefit-to-risk ratio associated with the products is unfavorable.

Neither the holders of the applications nor any other person have 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 applications or not available to the Commissioner until after the applications were approved, evaluated together with the evidence available to him when the applications were approved, reveals that the products are not shown to be safe for use under the conditions of use upon the basis of which the applications were approved.

Therefore, pursuant to the foregoing findings, approval of the above new drug applications and all amendments and supplements applying thereto, is withdrawn effective on the date of publication hereof in the FEDERAL REGISTER (11-29-72). Shipment in interstate commerce of any of the above-listed drug products 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.

[FR Doc. 72-20462 Filed 11-28-72; 8:49 am]

[FAP 1H2621]

OLIN CHEMICALS

Notice of Filing of Petition for Food Additive

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786; 21 U.S.C. 348(b)(5)), notice is given that a petition (FAP 1H2621) has been filed by Olin Chemicals, 120 Long Ridge Road, Stamford, CT 06904, proposing that § 121.2520 Adhesives (21 CFR 121.2520) be amended to provide for the safe use of sodium salt of 1-hydroxy-2(1H)-pyridinethione as a preservative in food packaging adhesives.

Dated: November 20, 1972.

ALBERT C. KOLBYE, JR.,
Acting Director, Bureau of Foods.

[FR Doc. 72-20472 Filed 11-28-72; 8:49 am]

Health Services and Mental Health Administration

NATIONAL ADVISORY COUNCIL ON HEALTH MANPOWER SHORTAGE AREAS AND NATIONAL ADVISORY MENTAL HEALTH COUNCIL

Notice of Meetings

Pursuant to Executive Order 11671, the Administrator, Health Services and Mental Health Administration, announces the meeting dates and other required information for the following