ular business hours, Monday through Friday.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052–53, as amended; 21 U.S.C. 355) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: August 17, 1972.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.72-14450 Filed 8-24-72;8:48 am]

PAREGORIC

Notice Placing Certain Paregoric and Other Opium-Containing Preparations for Veterinary Use on Prescription Dispensing Basis

An order published in the FEDERAL REGISTER of April 4, 1972 (37 F.R. 6734), provided for removal of the exemption for certain paregoric and other opium-containing preparations from the prescription dispensing requirements of section 503(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act under § 165.5(a)(1) of the habit-forming drug regulations (21 CFR 165.5(a)(1)).

This action was taken based upon potential for abuse of the drug by addicts who process it into a form for intravenous administration and was based upon a consideration of a recommendation from the Bureau of Narcotics and Dangerous Drugs, Department of Justice.

Commissioner of Food and Drugs concludes that, consistent with the aim of placing such drug under prescription dispensing for use in man as provided in section 503(b)(1)(A) of the act, its veterinary use should likewise be on a prescription basis under section 502(f)(1) of the act.

Therefore, paregoric and other preparations containing more than 100 milligrams of opium per 100 milliliters or per 100 grams and intended for veterinary use shall be labeled with the statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502(f), 701(a), 52 Stat. 1051 and 1055; 21 U.S.C. 352(f), 371(a)) and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: August 17, 1972.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.72-14451 Filed 8-24-72;8:48 am]

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

PFIZER LABORATORIES

Carbetapentane Citrate Gel; Notice of Opportunity for Hearing on Proposal To Withdraw Approval of New-Drug Application

In an announcement (DESI 11562) published in the FEDERAL REGISTER of July 17, 1971 (36 F.R. 13281), the Commissioner of Food and Drugs announced his conclusions pursuant to the evaluation of a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group on Candette Cough Jel, containing carbetapentane citrate. The announcement stated that the risks involved in its use outweigh any benefits that might be derived from such use and it is regarded as unsafe for its recommended use because inexact methods of determining dosage are potentially dangerous, particularly in the care of children, and that the Commissioner of Food and Drugs intended to initiate proceedings to withdraw approval of the new-drug application for the drug. Interested persons were invited to submit any pertinent data bearing on the proposal within 30 days following publication of the announcement. No data have been received.

Therefore, notice is given to Pfizer Laboratories Division, Pfizer, Inc., 235 East 42d Street, New York, N.Y. 10017, holder of NDA 11-562 for Candette Cough Jel and to any interested person who may be adversely affected, that the Commissioner proposes 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 said application and all amendments and supplements thereto on the grounds that new evidence of clinical experience, not contained in the application or not available until after the application was approved, evaluated together with the evidence available when the application was approved, reveals that the drug is not shown to be safe under the conditions of use upon the basis of which the application was approved.

In accordance with the provisions of section 505 of the Act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Part 130), the Commissioner will give the applicant, and any interested person who would be adversely affected by an order withdrawing such approval, an opportunity for a hearing to show why approval of the new-drug application should not be withdrawn. Any related drug for human use, not the subject of an approved new-drug application, may be affected by this action.

Within 30 days after publication hereof in the FEDERAL REGISTER, such persons are required to file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, a written appearance electing whether:

1. To avail themselves of the opportunity for a hearing; or

2. Not to avail themselves of the opportunity for a hearing.

If such persons elect not to avail themselves of the opportunity for a hearing, the Commissioner without further notice will enter a final order withdrawing approval of the new-drug application. Failure of such persons to file a written appearance of election within said 30 days will be construed as an election by such persons not to avail themselves of the opportunity for a hearing.

The hearing contemplated by this notice will be open to the public except that any portion of the hearing that concerns a method or process the Commissioner finds entitled to protection as a trade secret will not be open to the public, unless the respondent specifies otherwise in his appearance.

If such persons elect to avail themselves of the opportunity for a hearing, they must file, within 30 days after publication of this notice in the FEDERAL REGISTER, a written appearance requesting the hearing, giving the reasons why approval of the new-drug application should not be withdrawn, together with a well organized and full factual analysis of the clinical and other investigational data they are prepared to prove in support of their opposition. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that a genuine and substantial issue of fact requires a hearing. When it clearly appears from the data in the application and from the reasons and factual analysis in the request for a hearing that no genuine and substantial issue of fact precludes the withdrawal of approval of the application, the Commissioner will enter an order on these data, making findings and conclusions on such data.

If a hearing is requested and justified by the response to this notice, the issues will be defined, a hearing examiner will be named, and he shall issue, as soon as practicable after the expiration of such 30 days, a written notice of the time and place at which the hearing will commence (35 F.R. 7250, May 8, 1970; 35 F.R. 16631, October 7, 1970).

Received requests for a hearing and/or elections not to request a hearing, may be seen in the office of the Hearing Clerk (address given above) during regular business hours, Monday through Friday.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052–53, as amended; 21 U.S.C. 355) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: August 17, 1972.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.72-14445 Filed 8-24-72;8:48 am]

[Docket No. FDC-D-197; NDA 5025]

PROTAMIDE

Final Order on Objections and Request for a Hearing Regarding Withdrawal of Approval of New-Drug Application

In the FEDERAL REGISTER of March 27, 1969 (34 F.R. 5753), the Food and Drug Administration announced its evaluation of a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the preparation Protamide (colloidal solution of denatured proteolytic enzyme) Injection; Sherman Laboratories, 5031 Grandy Avenue, Detroit, Mich. 48221