

hereof in the FEDERAL REGISTER may cause the drug to be subject to regulatory proceedings.

3. The notice Conditions for Marketing New Drugs Evaluated in Drug Efficacy Study, published in the FEDERAL REGISTER, July 14, 1970 (35 F.R. 11273), describes in paragraphs (d), (e), and (f) the marketing status of a drug labeled with those indications for which it is regarded as possibly effective.

A copy of the Academy's report has been furnished to each firm referred to above. Communications forwarded in response to this announcement should be identified with the reference number DESI 8451, directed to the attention of the appropriate office listed below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20852:

Supplements (Identify with NDA number): Office of Scientific Evaluation (BD-100), Bureau of Drugs.

Original new-drug applications: Office of Scientific Evaluation (BD-100), Bureau of Drugs.

Requests for the Academy's report: Drug Efficacy Study Information Control (BD-67), Bureau of Drugs.

All other communications regarding this announcement: Drug Efficacy Study Implementation Project Office (BD-60), Bureau of Drugs.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-53, as amended; 21 U.S.C. 352, 355) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: June 26, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-10453 Filed 7-7-72;8:48 am]

[DESI 50020]

NEOMYCIN PALMITATE-TRYPSIN-CHYMOTRYPSIN TOPICAL PREPARATION

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following prescription drug for topical application:

Biozyme Ointment containing neomycin palmitate and trypsin-chymotrypsin concentrate; Armour Pharmaceutical Co., Division, Armour and Co., Post Office Box 511, Kankakee, Ill. 69901.

The Food and Drug Administration concludes that the above listed combination drug for topical administration is possibly effective for the claimed indications for treatment of localized infections or for suppressive therapy in such conditions.

Preparations containing neomycin sulfate in combination with trypsin-chymo-

trypsin are subject to antibiotic certification procedures under section 507 of the Federal Food, Drug, and Cosmetic Act. To allow applicants to obtain and submit data to provide substantial evidence of the effectiveness of the drug in those conditions for which it has been evaluated as possibly effective, such drug labeled with those indications will continue to be accepted for release or certification by the Food and Drug Administration for a period of 6 months after publication of this announcement in the FEDERAL REGISTER.

To be acceptable for consideration in support of the effectiveness of a drug, any such data must be previously unsubmitted, well-organized, and include data from adequate and well-controlled clinical investigations (identified for ready review) as described in section 130.12(a)(5) of the regulations published in the FEDERAL REGISTER of May 8, 1970 (35 F.R. 7250). Carefully conducted and documented clinical studies obtained under uncontrolled or partially controlled situations are not acceptable as a sole basis for the approval of claims of effectiveness, but such studies may be considered on their merits for corroborative support of efficacy and evidence of safety.

At the end of the 6-month period, any such data will be evaluated to determine whether there is substantial evidence of effectiveness for such uses. After that evaluation, the conclusions concerning the drug will be published in the FEDERAL REGISTER. If no studies have been undertaken, or if the studies do not provide substantial evidence of effectiveness, such drug will not be eligible for release or certification.

A copy of the Academy's report has been furnished to the firm referred to above. Communications forwarded in response to this announcement should be identified with the reference number DESI 50020 directed to the attention of the following appropriate office, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20852:

Amendments (Identify with NDA number) Division of Anti-Infective Drug Products (BD-140), Office of Scientific Evaluation, Bureau of Drugs.

Requests for the Academy's report: Drug Efficacy Study Information Control (BD-67), Bureau of Drugs.

All other communications regarding this announcement: Drug Efficacy Study Implementation Project Office (BD-60), Bureau of Drugs.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 507, 52 Stat. 1050-51, as amended, 59 Stat. 463, as amended; 21 U.S.C. 352, 357) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: June 27, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-10458 Filed 7-7-72;8:48 am]

[DESI 7909]

PREPARATION CONTAINING CARBACRYLAMINE RESINS

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following drug for oral use:

Carbo-Resin Powder containing carbacrylamine resin; Eli Lilly and Co., Post Office Box 618, Indianapolis, Ind. 46206 (NDA 7-909).

The Food and Drug Administration has considered the Academy's report, as well as other available evidence, and concludes that there is a lack of substantial evidence, within the meaning of the Federal Food, Drug, and Cosmetic Act, that this drug will have the effects it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling. The holder of the NDA has indicated that the preparation is no longer marketed.

A notice was published in the FEDERAL REGISTER of March 18, 1972 (37 F.R. 5711), withdrawing approval of NDA 7-909 on the grounds that reports required under section 505(j) of the Act and §§ 130.13 and 130.35 (e) and (f) of the new drug regulations (21 CFR 130.13 and 130.35) had not been submitted.

Accordingly, this notice is published to inform any person interested in similar or related products of the effectiveness classification of this article. If any related drug for human use, not the subject of an approved new drug application, is being marketed it may be affected by the above classification and be subject to appropriate action.

A copy of the Academy's report has been furnished to the firm referred to above. Communications forwarded in response to this announcement should be identified with the reference number DESI 7909, directed to the attention of the appropriate office listed below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20852:

Requests for the Academy's report: Drug Efficacy Study Information Control (BD-67), Bureau of Drugs.

All other communications regarding this announcement: Drug Efficacy Study Implementation Project Office (BD-60), Bureau of Drugs.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-53, as amended; 21 U.S.C. 352, 355) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: June 26, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-10452 Filed 7-7-72;8:47 am]