

NOTICES

[DESI 4203]

CERTAIN GAMMA BENZENE HEXACHLORIDE TOPICAL PREPARATIONS**Drugs for Human Use; Drug Efficacy Study Implementation Follow-Up Notice**

In a notice (DESI 4203) published in the FEDERAL REGISTER of September 17, 1970 (35 F.R. 14576), the Commissioner of Food and Drugs announced his conclusions pursuant to evaluation of reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on Kwell Shampoo (NDA 10-718) and Kwell Cream (NDA 6-309) containing gamma benzene hexachloride marketed by Reed and Carnrick, 30 Boright Avenue, Kenilworth, NJ 07033.

The notice stated that the shampoo was effective or probably effective for its labeled indications and the cream was effective or possibly effective for its labeled indications. The indications classified as probably effective and possibly effective have been reclassified as lacking substantial evidence of effectiveness in that no new evidence of effectiveness has been submitted pursuant to the September 17, 1970 notice.

The holder of the above-listed new drug applications has satisfactorily supplemented the applications to delete from the labeling all indications other than those regarded as effective. Other holders of applications approved for these drugs should submit within 60 days following publication of this notice in the FEDERAL REGISTER, supplements to their new drug applications to provide for revised labeling in accord with this notice. Such supplements should be submitted under the provisions of § 130.9 (d) and (e) of the new drug regulations (21 CFR 130.9 (d) and (e)) which permit certain changes to be put into effect at the earliest possible time.

Any such preparation, for human use, introduced into interstate commerce after 60 days following publication of this notice in the FEDERAL REGISTER with labeling bearing indications for which the drugs lack substantial evidence of effectiveness, may be subject to regulatory proceedings.

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 authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: June 13, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-9467 Filed 6-22-72; 8:49 am]

[DESI 6343]

HYALURONIDASE**Drugs for Human Use; Drug Efficacy Study Implementation Follow-Up Notice**

In a notice (DESI 6343) published in the FEDERAL REGISTER of September 23, 1970 (35 F.R. 14800), the Commissioner of Food and Drugs announced his conclusions pursuant to an evaluation of reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following drugs containing hyaluronidase:

1. Wydase Solution and Wydase Lyophilized; Wyeth Laboratories, Inc., Post Office Box 8299, Philadelphia, Pa. 19101 (NDA 6-343).

2. Alidase; G. D. Searle & Co., Post Office Box 5110, Chicago, Ill. 60680 (NDA 6-714).

3. Hyazyme; Abbott Laboratories, North Chicago, Ill. 60064 (NDA 7-933).

The notice stated that the drugs were regarded as effective, probably effective, possibly effective, and lacking substantial evidence of effectiveness for their various labeled indications and allowed holders of the new drug applications, and persons marketing the drugs without approval, additional time to obtain and submit data to substantiate the claims classified as probably and possibly effective. Since no new evidence has been received, these drugs have been reclassified as lacking substantial evidence of effectiveness for labeled indications other than those appearing in the "Indications" section which follows:

INDICATIONS

Hyaluronidase is indicated as an adjunct to increase the absorption and dispersion of other injected drugs; for hypodermoclysis; as an adjunct in subcutaneous urography for improving the resorption of radiopaque agents.

The new drug applications held by the firms listed above have been satisfactorily supplemented to delete those claims for which substantial evidence of effectiveness is lacking and to be in accord with the "Indications" section above.

The holders of applications approved for hyaluronidase should submit, within 60 days following publication of this amended announcement in the FEDERAL REGISTER, supplements to their new drug applications to provide for revised labeling in accord with the "Indications" section above. Such supplements should be submitted under the provisions of § 130.9 (d) and (e) of the new drug regulations (21 CFR 130.9 (d) and (e)) which permit certain changes to be put into effect at the earliest possible time.

Any such preparation, for human use, introduced into interstate commerce after 60 days following publication of this notice in the FEDERAL REGISTER with labeling bearing indications that lack substantial evidence of effectiveness may be subject to regulatory proceedings.

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 authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: June 13, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-9468 Filed 6-22-72; 8:49 am]

[DESI 8583]

CERTAIN OPHTHALMIC/OTIC OINTMENTS**Drugs for Human Use; Drug Efficacy Study Implementation**

The Food and Drug Administration has evaluated reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following drugs for ophthalmic and/or otic use.

Terramycin Ophthalmic-Otic Ointment with Polymyxin B Sulfate containing oxytetracycline hydrochloride and polymyxin B sulfate; Pfizer Inc., 235 East 42d Street, New York, N.Y. 10017 (NDA 61-015).

Chloromycetin-Polymyxin Ophthalmic Ointment containing chloramphenicol and polymyxin B sulfate; Parke, Davis and Co., Joseph Campau at the River, Detroit, Mich. 48232 (NDA 50-203).

Polysporin Ophthalmic Ointment containing polymyxin B sulfate and zinc bacitracin; Burroughs Wellcome & Co., 3030 Cornwallis Road, Research Triangle Park, N.C. 27709 (NDA 61-229).

The Food and Drug Administration concludes that these drugs for ophthalmic and/or otic use are effective for the indications described in the labeling conditions in this announcement.

Preparations containing these drugs are subject to the antibiotic procedures pursuant to section 507 of the Federal Food, Drug, and Cosmetic Act. After 60 days following publication of this announcement in the FEDERAL REGISTER, drugs in the dosage forms described above, for which certification is requested should contain labeling information in accord with this reevaluation of the drugs published in this announcement.

The above-named firms and any other holders of applications approved for a drug of the kinds described above are requested to submit within 60 days following publication of this announcement in the FEDERAL REGISTER, amendments to their antibiotic applications to provide for revised labeling. The label for ointments for ophthalmic use should state whether the product is or is not sterile. The labeling should comply with all requirements of the Act and regulations, bear adequate information for safe and effective use of the drug, and be in accord with the guidelines for uniform labeling published in the FEDERAL REGISTER of February 6, 1970. The "Indications" section of the labeling should be as follows:

INDICATIONS

Oxytetracycline Hydrochloride with Polymyxin B Sulfate Ophthalmic/Otic Ointment

For the treatment of superficial ocular infections involving the conjunctiva and/or cornea caused by (insert drug name) susceptible organisms.

For the treatment of superficial infections the external auditory canal caused by (insert drug name) susceptible organisms.

Chloramphenicol with Polymyxin B Sulfate Ophthalmic Ointment; Polymyxin B Sulfate with Zinc Bacitracin Ophthalmic Ointment.

For the treatment of superficial ocular infections involving the conjunctiva and/or cornea caused by (insert drug name) susceptible organisms.

Except for the indications described in the "Indications" sections above, these drugs are regarded as possibly effective for their other labeled indications. Batches of the drugs which bear labeling with these indications and are otherwise in accord with the labeling conditions herein will continue to be accepted for certification or release by the Food and Drug Administration for a period of 6 months from the publication date of this announcement to allow any applicant to obtain and submit data to provide substantial evidence of effectiveness of the drugs for use in these conditions for which they have been evaluated as possibly effective.

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 § 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 with labeling bearing such indications.

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 directed to the attention of the appropriate office listed below, 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 the 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 8, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-9469 Filed 6-22-72; 8:49 am]

[DESI 9152]

OXYTETRACYCLINE HYDROCHLORIDE WITH HYDROCORTISONE ACETATE FOR OPHTHALMIC/OTIC USE

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 Terra-Cortril Eye/Ear Suspension containing oxytetracycline hydrochloride and hydrocortisone acetate; Pfizer Laboratories, Division Chas. Pfizer and Co., Inc., 235 East 42d Street, New York, N.Y. 10017 (NDA 60-016).

The Food and Drug Administration concludes that oxytetracycline hydrochloride with hydrocortisone acetate for ophthalmic or otic administration lacks substantial evidence of effectiveness for use in furunculosis and for use in spastic entropion caused by local irritation and is possibly effective for other labeled indications. Preparations containing these drugs are subject to the antibiotic procedures pursuant to section 507 of the Federal Food, Drug, and Cosmetic Act.

To allow applicants time to obtain and submit data to provide substantial evidence of the effectiveness of the drugs in those conditions for which they have been evaluated as possibly effective, batches of preparations containing oxytetracycline hydrochloride with hydrocortisone acetate which bear labeling with those indications will 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.

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, any such drug will not be eligible for release or certification.

Preparations containing oxytetracycline hydrochloride with hydrocortisone acetate with labeling bearing claims for use in furunculosis and for use in spastic entropion caused by local irritation will no longer be acceptable for certification or release after 40 days following the publication date of this announcement.

Any person who would be adversely affected by deletion of the claims for which the drug lacks substantial evidence of effectiveness may, within 30 days following the publication date of this announcement, submit comments or pertinent data bearing on the effectiveness for such use.

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 § 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.

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 9152, 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, if known): Division of Anti-Infective Drug Products (BD-140), Office of Scientific Evaluation, Bureau of Drugs.

Request 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, 50 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 7, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-9470 Filed 6-22-72; 8:49 am]

Office of the Secretary

PRINTING AND PUBLICATIONS MANAGEMENT STAFF, OFFICE OF THE DEPUTY ASSISTANT SECRETARY FOR ADMINISTRATION

Statement of Organization, Functions, and Delegations of Authority

Correction

In F.R. Doc. 72-9180 appearing on page 12071 in the issue for Saturday, June 17, 1972, in section 1T040903.10, paragraph F, line 3, the word "regulations" should read "operations".