

Avenue, Garden City, Long Island, N.Y. 11530.

The announcement stated that the drug was regarded as possibly effective for the labeled indication, rheumatoid arthritis. Six months from the date of that publication were allowed for the holder of the application and any person marketing such drug without approval to obtain and submit data providing substantial evidence of effectiveness of the drug for the possibly effective indication. No such data have been received and the holder of said new drug application has requested withdrawal of approval of its new drug application and thereby has waived opportunity for a hearing, stating that marketing of the drug was discontinued in 1968.

The Commissioner of Food and Drugs, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505 (e), 52 Stat. 1053, as amended; 21 U.S.C. 355 (e)), and under authority delegated to him (21 CFR 2.120), finds that on the basis of new information before him with respect to said drug, evaluated together with the evidence available to him when the application was approved, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof.

Therefore, pursuant to the foregoing finding, approval of new drug application No. 5-714, and all amendments and supplements thereto, is withdrawn effective on the date of publication hereof in the FEDERAL REGISTER (2-12-72).

Dated: February 3, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-2126 Filed 2-11-72; 8:50 am]

[DESI 50223]

CERTAIN NEOMYCIN TOPICAL DERMATOLOGIC PREPARATIONS

Drugs for Human Use; Efficacy Study Implementation; Follow-up Notice

In a notice (DESI 50223) published in the FEDERAL REGISTER of April 6, 1971 (36 F.R. 6531), 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 the following preparations:

1. Ultimycin Cream, containing neomycin palmitate and allantoin; Walker Corp. & Co., Inc., Easthampton Place and North Collingwood Avenue, Post Office Drawer 1320, Syracuse, N.Y. 13206 (NDA 50-223).
2. Neo-Mantle Lotion and Neo-Mantle Creme, both containing neomycin sulfate; Dome Laboratories Division, Miles Laboratories, Inc., 400 Morgan Lane, West Haven, Conn. 06516 (NDA 50-239 and NDA 50-240).

The notice stated that these drugs were regarded as possibly effective for their

labeled indications. The possibly effective indications have been reclassified as lacking substantial evidence of effectiveness in that such evidence has not been submitted pursuant to the notice of April 6, 1971.

Batches of such drugs with labeling bearing indications for which substantial evidence of effectiveness is lacking are no longer acceptable for release. There is no antibiotic drug regulation which provides for certification of these preparations.

Any person who will be adversely affected by this action may, within 30 days after the date of publication of this notice in the FEDERAL REGISTER, petition for the issuance of regulation providing for certification of the drugs for such indications. The petition must be supported by a full factual and well-documented medical analysis which shows reasonable grounds for the issuance of such regulation.

A petition for issuance of said regulation should be filed (preferably in quintuplicate) with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852.

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

Dated: February 3, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-2129 Filed 2-11-72; 8:50 am]

[DESI 3684; Docket No. FDC-D-420; NDA 4-924, etc.]

CERTAIN SULFONAMIDE-CONTAINING PREPARATIONS FOR TOPICAL OR OPHTHALMIC USE

Notice of Withdrawal of Approval of New Drug Applications

In an announcement (DESI 3684) published in the FEDERAL REGISTER on September 25, 1970 (35 F.R. 14954), 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 subject drugs, stating that these drugs are regarded as possibly effective and lacking substantial evidence of effectiveness for the various labeled indications. The possibly effective indications have been reclassified as lacking substantial evidence of effectiveness in that no new evidence of effectiveness of the drugs has been submitted within the period provided.

The holders of the following new drug applications have requested withdrawal of approval of their new drug applications and have thereby waived their opportunity for hearing, stating that the drugs are no longer marketed. (NDA's identified by an asterisk were not reviewed by

the Academy and not included in the notice of September 25, 1970, but are regarded as similarly affected.):

1. NDA 4-924*; Sulfadiazine Ointment 5 percent and Sulfadiazine Ophthalmic Ointment 5 percent; Lederle Laboratories, Division American Cyanamid Co., Pearl River, N.Y. 10965.

2. NDA 4-988*; Sulfathiazole-Urantoin Ointment; Mallinckrodt Chemical Works, 3600 North Second Street, St. Louis, Mo. 63160.

3. NDA 5-069*; Sulthigel Ointment and Jelly; Breon Laboratories, Inc., Subsidiary Sterling Drug, Inc., 90 Park Avenue, New York, N.Y. 10016.

4. NDA 5-122; Sulfathiazole Crystals; Breon Laboratories, Inc.

5. NDA 6-813; Sulfamylon (mafenide hydrochloride) Solutions; Otomyon (mafenide hydrochloride) Ear Drops; and Sulfamylon Hydrochloride with Streptomycin Sulfate; Winthrop Laboratories, Division of Sterling Drug, Inc., 90 Park Avenue, New York, N.Y. 10016.

A notice published in the FEDERAL REGISTER of July 24, 1970 (35 F.R. 11947), withdrew approval of NDA 3-756 Sulfalantoin Ointment 2 percent and Powder; S. F. Durst and Co., Inc., 5317 North Third Street, Philadelphia, Pa. 19120 (this new drug application held by Schuylkill Chemical Co., 2436 West Sedgley Avenue, Philadelphia, Pa. 19132). Another notice published in the FEDERAL REGISTER of August 6, 1971 (36 F.R. 14493), withdrew approval of NDA 5-114; Morumide Ointment; The S. E. Massengill Co., 527 Fifth Street, Bristol, Tenn. 37620. Approval of both of these new drug applications was withdrawn on the grounds that the applicants had failed to make reports under section 505 (j) and §§ 130.13 and 130.35 (e) and (f) of the new drug regulations (21 CFR 130.13 and 130.35).

The Commissioner of Food and Drugs, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505 (e), 52 Stat. 1053, as amended; 21 U.S.C. 355 (e)) and under the authority delegated to him (21 CFR 2.120) finds on the basis of new information before him with respect to such drugs evaluated together with the evidence available to him when the applications were approved, that there is a lack of substantial evidence that the drugs will have the effects they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof.

Therefore, pursuant to the foregoing finding, approval of the above-listed new drug applications and all amendments and supplements applying thereto is withdrawn effective on date of publication hereof in the FEDERAL REGISTER (2-12-72).

Dated: February 3, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-2127 Filed 2-11-72; 8:50 am]