

NOTICES

Corp. of America (RCA) at the time the applicant ordered the foreign article, but which is currently being manufactured by Forglfo Corp. (Forgflo). In the domestic electron microscope, the airlock is not evacuated before introducing the specimen, thus requiring the cutoff of the high voltage with each specimen change and a restabilization of the high voltage after it is restored. We are advised by the Department of Health Education, and Welfare (HEW) in its memorandum of June 25, 1969, that the procedures inherent in the domestic electron microscope would affect the accomplishment of the research objectives of the program in which the foreign article is intended to be used. (2) The foreign article permits a continuous change from 400 to 500,000 magnifications without the need to change pole pieces, whereas the domestic instrument requires a change in pole pieces to produce distortion-free micrographs. We are also advised by HEW that the 3-minute delay required each time the pole piece was changed, which also involves breaking the vacuum in the column, would tend to affect the specimen and thus impair the achievement of the purposes for which the foreign article is intended to be used.

For the foregoing reasons, we find that the RCA Model ZMU-4B is not of equivalent scientific value to the foreign article for such purposes as this article is intended to be used.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for the purposes for which such article is intended to be used, which is being manufactured in the United States.

CHARLEY M. DENTON,
Assistant Administrator for Industry Operations, Business and Defense Services Administration.

[F.R. Doc. 69-10819, Filed Sept. 10, 1969; 8:46 a.m.]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[DESI 11-300]

CHLORZOXAZONE BY ITSELF OR IN COMBINATION WITH ACETAMINOPHEN; CODEINE PHOSPHATE AND ACETAMINOPHEN; OR PREDNISOLONE AND ACETAMINOPHEN

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, and other available evidence on the following drugs:

1. Chlorzoxazone 250 milligrams per tablet (Paraflex); marketed by McNeil Laboratories, Inc., Camp Hill Road, Fort

Washington, Pa. 19034 (NDA 11-300)

2. Chlorzoxazone 125 milligrams and acetaminophen 300 milligrams per tablet (Parafon); Chlorzoxazone 250 milligrams and acetaminophen 300 milligrams per tablet (Parafon Forte); marketed by McNeil Laboratories, Inc. (NDA 11-529).

3. Chlorzoxazone 125 milligrams, codeine phosphate 15 milligrams, and acetaminophen 300 milligrams per tablet (Parafon with Codeine); marketed by McNeil Laboratories, Inc. (NDA 11-985).

4. Chlorzoxazone 125 milligrams, acetaminophen 300 milligrams, and prednisolone 1 milligram per tablet (Parafon with Prednisolone); marketed by McNeil Laboratories, Inc. (NDA 11-529).

These drugs are regarded as new drugs. The Food and Drug Administration's conclusions as to their effectiveness classification and marketing status are described below.

A. Effectiveness classification. 1. On the basis of the Academy reports the articles containing chlorzoxazone with acetaminophen, and with acetaminophen and prednisolone or codeine phosphate are considered to be possibly effective for all of their labeled indications.

2. Chlorzoxazone alone has been evaluated as lacking substantial evidence of effectiveness for reducing spasticity associated with neurological disease and traumatic spinal cord injuries. For its other labeled indications it has been evaluated as possibly effective.

B. Marketing status. 1. Holders of previously approved new drug applications and any person marketing any such drug without approval will be allowed 6 months from the date of publication of this announcement in the FEDERAL REGISTER to obtain and to submit in a supplemental or original new drug application data to provide substantial evidence of effectiveness for those indications for which these drugs have been classified as possibly effective: *Provided*, That, in regard to chlorzoxazone alone, the claim for which substantial evidence of effectiveness is lacking (as described in paragraph A above) is deleted within 60 days of the date of this publication. The holder of the previously approved application for chlorzoxazone alone (Paraflex) is requested to submit within the 60-day period a supplement containing revised labeling deleting the claim. The supplement should be submitted under the provisions of 130.9 (d) and (e) of the new-drug regulations (21 CFR 130.9 (d), (e)) which permit certain changes to be put into effect at the earliest possible time. Failure to do so may result in a proposal to withdraw approval of the new drug application.

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

initiated to withdraw approval of the new drug applications for the above mentioned drugs, pursuant to the provisions of section 505(e) of the Federal Food, Drug, and Cosmetic Act. Withdrawal of approval of the applications will cause any such drugs on the market to be new drugs for which an approval is not in effect.

The above-named holder of the new drug applications for these drugs has been mailed a copy of the NAS-NRC report. Any interested person may obtain a copy of these reports by writing to the office named below.

Communications forwarded in response to this announcement should be identified with the reference number, DESI 11-300, and be directed to the attention of the following appropriate office and addressed to the Food and Drug Administration, 200 C Street, SW., Washington, D.C. 20204:

Requests for NAS-NRC reports: Press Relations Office (CE-300).

Supplements (Identify with NDA number): Office of Marketed Drugs (MD-300), Bureau of Medicine.

Original new-drug applications: Office of New Drugs (ND-100), Bureau of Medicine. All other communications regarding this announcement: Special Assistant for Drug Efficacy Study Implementation (MD-16), Bureau of Medicine.

This notice is issued pursuant to the 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: August 28, 1969.

WINTON B. RANKIN,
Deputy Commissioner
of Food and Drugs.

[F.R. Doc. 69-10822; Filed, Sept. 10, 1969; 8:46 a.m.]

[DESI 2853]

CERTAIN SULFATHIAZOLE-CONTAINING DRUGS

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 sulfonamide-containing drugs for systemic use.

1. Coco-Sulfonamides Triplex Suspension; each 5 cc. containing 0.167 gram each of sulfathiazole, sulfadiazine, and sulfamerazine; Eli Lilly and Co., Post Office Box 618, Indianapolis, Ind. 46206 (NDA 6-317).

2. Sulfonamides Triplex Tablets; 0.167 gram each of sulfathiazole, sulfadiazine, and sulfamerazine; Eli Lilly and Co. (NDA 6-317).

3. Sulfathiazole, 0.5 gram per tablet; Eli Lilly and Co. (NDA 2-853).

4. Sulfathiazole, 0.5 gram per tablet; Bowman, Meil and Co., 1334-48 Howard Street, Harrisburg, Pa. 17105 (NDA 4-734).

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5. Sulfathiazole, 0.5 gram per tablet; The Vale Chemical Co., Inc., 1201 Liberty Street, Allentown, Pa. 18102 (NDA 2-583).

The Academy commented that the imbalance between benefit and risk of serious untoward effects with sulfathiazole does not warrant its continued use inasmuch as other available sulfonamides have equivalent benefit and much less risk. The Academy also observed that the incidence of serious reactions (including renal complications, rash, fever, blood dyscrasias, and liver damage) is 18.6 percent for sulfathiazole versus 6.5 percent for sulfadiazine. The Food and Drug Administration concludes that there is a lack of evidence that the effectiveness of sulfathiazole is sufficient to justify its use systemically in view of known serious hazards associated with such use. Accordingly, the Commissioner intends to initiate proceedings to withdraw approval of the above-listed new drug applications and all other new drug applications for drugs which contain sulfathiazole for systemic use in man.

Prior to initiating such action, however, the Commissioner invites the holders of new drug applications for such sulfathiazole-containing drugs and any interested person who may be adversely affected by the removal of such articles from the market to submit any pertinent data bearing on the proposal within 30 days after publication of this notice in the FEDERAL REGISTER. The only material which will be considered acceptable for review must be well-organized and consist of adequate and well-controlled studies bearing on both the safety and efficacy of the products, and not previously submitted.

This announcement of the proposed action and implementation of the NAS-NRC reports for these drugs is made to give notice to persons who might be adversely affected by their withdrawal from the market. Promulgation of any order withdrawing approval of the new drug applications will cause any such drug on the market to be a new drug for which an approved new drug application is not in effect and will make it subject to regulatory action.

The above-named holders of the subject new drug applications have been mailed a copy of the NAS-NRC report, and any interested person may obtain a copy on request from the office named below.

Communications forwarded in response to this announcement should refer to DESI No. 2853 which identifies this announcement and should be directed to the following appropriate office and addressed to the Food and Drug Administration, 200 C Street SW., Washington, D.C. 20204:

Request for NAS-NRC report: Press Relations Office (CE-300).

All other communications regarding this announcement: Special Assistant for Drug Efficacy Study Implementation (MD-16), Bureau of Medicine.

This announcement is issued pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sections 502,

505, 52 Stat. 1050-53, as amended; 21 U.S.C. (352, 355)) and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: September 4, 1969.

HERBERT L. LEY, Jr.,

Commissioner of Food and Drugs.

[P.R. Doc. 98-10823; Filed, Sept. 10, 1969; 8:46 a.m.]

[DESI 2800]

ULTRASHORT ACTION BARBITURATES: SODIUM METHOHEXITAL - AND SODIUM THIAMYLAL

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 ultrashort acting barbiturates for intravenous injection:

1. Sodium Methohexital, marketed as Brevital Sodium Ampoules, containing 500 mg., 2.5 grams, and 5 grams of sodium methohexital, by Eli Lilly and Co., Indianapolis, Ind. 46206 (NDA 11-559); and
2. Sodium Thiamylal, marketed as Surital in ampoules and vials containing 0.5 Gm., 1 Gm., 5 Gm., and 10 Gm. of sodium thiamylal, by Parke, Davis and Co., Detroit, Mich. 48232 (NDA 7-600).

The drugs are regarded as new drugs (21 U.S.C. 321(p)). Supplemental new drug applications are required to revise the labeling and to update previously approved applications providing for such drugs. A new drug application is required from any person marketing such drugs without approval.

The Food and Drug Administration is prepared to approve new drug applications and supplements to previously approved new drug applications under conditions described in this announcement.

SODIUM METHOHEXITAL AND SODIUM THIAMYLAL

A. Effectiveness classification. 1. The Food and Drug Administration has considered the Academy reports, and additional available evidence, and concludes that sodium methohexital is effective as an intravenous anesthetic agent for short surgical procedures, for the induction of anesthesia, in combination with other agents for more prolonged anesthesia, and for inducing a hypnotic state.

2. The Food and Drug Administration also concludes on the basis of the NAS-NRC, Drug Efficacy Study Group reports and other available evidence that sodium thiamylal is effective as an intravenous anesthetic agent for short surgical procedures, for the induction of anesthesia, in combination with other agents for more prolonged anesthesia, and for inducing a hypnotic state.

Sodium thiamylal is regarded as possibly effective for its recommended use in terminating convulsions of unknown cause.

B. Form of the drug. Sodium methohexital and sodium thiamylal preparations are in dry sterile form suitable for

reconstitution and intravenous administration and contain per dosage amount appropriate for administration as described in the labeling conditions of this announcement.

C. Labeling conditions. 1. The label bears the statement "Caution: Federal law prohibits dispensing without prescription."

2. The drug is labeled to comply with all requirements of the Act and Regulations and those parts of its labeling which are substantially as indicated below: (Optional additional information applicable to the drug, may be provided under other appropriate paragraph headings and should follow the information set forth below.)

SODIUM METHOHEXITAL

WARNING

This drug should be administered by persons qualified in the use of intravenous anesthetics and with the ready availability of appropriate resuscitative equipment for prevention and treatment of anesthetic emergencies.

DESCRIPTION

(Descriptive information to be included by the manufacturer or distributor should be confined to an appropriate description of the physical and chemical properties of the drug and its formulation.)

ACTIONS

Sodium methohexital is a ultrashort acting barbiturate anesthetic agent.

INDICATIONS

For induction of anesthesia, for supplementing other anesthetic agents, intravenous anesthesia for short surgical procedures with minimal painful stimulation or as an agent for inducing a hypnotic state.

CONTRAINDICATIONS

Sodium methohexital is contraindicated when general anesthesia is contraindicated, in patients with latent or manifest porphyria, or in patients with a known hypersensitivity to barbiturates.

WARNINGS

Repeated and continuous use may cause cumulative effects resulting in prolonged somnolence, respiratory and circulatory depression.

Usage in pregnancy: Safe use of sodium methohexital has not been established with respect to adverse effects upon fetal development. Therefore, sodium methohexital should not be used in women of childbearing potential, particularly during early pregnancy, unless in the judgment of the physician the expected benefits outweigh the potential hazards.

PRECAUTIONS

Respiratory depression, apnea, hypotension may occur due to variation in tolerance from individual to individual or to physical status of patient. Caution should be exercised in the use of this drug in patients with respiratory depression, hypotension, or in patients with a known hypersensitivity to barbiturates.

fonamides have equivalent benefit and involve must less risk; and (2) new information, evaluated together with the evidence available when the applications were approved, shows there is a lack of substantial evidence that the drugs will have the effect they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling.

The following firms, listed with their address, respective drug, and new-drug application number, have waived opportunity for a hearing on the proposed withdrawal of said new-drug applications, in that no response has been received.

1. Sulfathiazole, 0.5 gram per tablet, and Lacto-Thiazole Suspension containing sulfathiazole 10 grams per 100 milliliters and sodium lactate (NDA 2-353); Coco-Sulfonamides Triplex Suspension containing 0.167 gram each of sulfathiazole, sulfadiazine, and sulfamerazine; Sulfonamides Triplex Tablets containing 0.167 gram each of sulfathiazole, sulfadiazine, and sulfamerazine (NDA 6-317); Eli Lilly & Co., Post Office Box 618, Indianapolis, Ind. 46206. (This notice does not apply to those formulations provided for in NDA 6-317 which do not contain sulfathiazole.)

2. Sulfathiazole, 0.5 gram per tablet (NDA 4-734); Bowman, Mell & Co., 1334-48 Howard Street, Harrisburg, Pa. 17105.

3. Sulfathiazole, 0.5 gram per tablet (NDA 2-976); Sulfathiazole, 0.5 gram per tablet (NDA 2-774); Sulfathiazole sodium sesquihydrate, 3-gram vial (NDA 3-724); Tresamide Tablets containing 0.2 gram each of sulfathiazole and sulfadiazine, 0.1 gram of sulfamerazine (NDA 5-301); Merck Sharp & Dohme, Division of Merck & Co., Inc., Sonneytown Pike, West Point, Pa. 19486.

4. Sulfathiazole, 0.5 gram per tablet (NDA 2-713); Sulfathiazole, 0.5 gram per tablet (NDA 3-457); Wallace & Tierman, Inc., 25 Main Street, Bellevue, N.J. 07189.

5. Sulfathiazole, 0.5 gram per tablet (NDA 2-729); Sulfathiazole, 0.5 gram per tablet and 25 percent ampul (NDA 2-730); Sulfathiazole sodium 25 percent ampul (NDA 3-430); American Cyanamid Co., Post Office Box 400, Princeton, N.J. 08540.

6. Sulfathiazole, 0.25 gram and 0.5 gram per tablet (NDA 2-856); Sulfathiazole Suspension containing 2.6 grams per fluid ounce (NDA 5-646); Parke, Davis & Co., Joseph Campau Avenue at the River, Detroit, Mich. 48232.

7. Sulfathiazole, 0.5 gram per tablet (NDA 2-975); The Upjohn Co., 7171 Portage Road, Kalamazoo, Mich. 49002.

8. Sulfathiazole, 0.5 gram per tablet (NDA 3-949); Wyeth Laboratories, Inc., Post Office Box 3299, Philadelphia, Pa. 19101.

9. Sulfathiazole, 0.5 gram per tablet (NDA 3-194); William S. Merrell Co., Division of Richardson-Merrell, Inc., 101 East Amity Street, Cincinnati, Ohio 45215.

10. Sulfathiazole, 0.25 gram and 0.5 gram per tablet (NDA 3-399); Rexall

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[Docket No. FDC-D-175; NDA No. 2-353
etc.]

SULFATHIAZOLE - CONTAINING DRUGS FOR SYSTEMIC USE IN HUMANS

Notice of Withdrawal of Approval of New-Drug Application

On May 28, 1970, there was published in the FEDERAL REGISTER (35 F.R. 8403) a notice of opportunity for hearing in which the Commissioner of Food and Drugs proposed to issue an order under the provisions of section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) withdrawing approval of the new-drug applications listed therein on the grounds that: (1) New evidence of clinical experience not contained in the applications or not available until after the applications were approved, evaluated together with the evidence available when the applications were approved, reveal that the drug is not shown to be safe for use upon the basis of which the applications were approved. In view of the known serious hazards associated with such use and the imbalance between benefit and risk of serious untoward effects from such drugs, their continued use systemically is not warranted as other available sul-

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Drug Co., 3480 Beverly Boulevard, Los Angeles, Calif. 90054.

11. Sulfathiazole, 0.25 gram and 0.5 gram per tablet (NDA 3-467); Premo Pharmaceutical Laboratories, Inc., 111 Leaning Street, South Hackensack, N.J. 07606.
12. Sulfathiazole, 0.5 gram per tablet (NDA 3-447); American Pharmaceutical Co., 120 Bruckner Boulevard, Bronx, N.Y. 10454.
13. Sulfathiazole, 0.5 gram per tablet (NDA 3-459); Flint Laboratories, Division Baxter Laboratories, Inc., 6301 Lincoln Avenue, Morton Grove, Ill. 60053.
14. Sulfathiazole, 0.5 gram per tablet (NDA 3-501); Purity Drug Co., 173-204 River Drive, Passaic, N.J. 07055.
15. Sulfathiazole, 2.0 grains and 0.5 gram per tablet (NDA 3-517); Warren Teed Pharmaceuticals, Inc., 532 West Goodale Street, Columbus, Ohio 43215.
16. Sulfathiazole, 0.5 gram per tablet (NDA 3-520); Sulfathiazole-Sodium Injection, 0.5 gram per ampul (NDA 4-523); Lakeside Laboratories, Inc., 1707 East North Avenue, Milwaukee, Wis. 53291.
17. Sulfathiazole, 0.5 gram per tablet (NDA 3-535); Schieffelin & Co., Apex, N.C. 27502.
18. Sulfathiazole, 0.5 gram per tablet (NDA 3-559); Standard Chemical Co., Inc., 1017 High Street, Des Moines, Iowa 50309.
19. Sulfathiazole, 0.5 gram per tablet (NDA 3-540); Central Pharmacal Co., 116-123 East Third Street, Seymour, Ind. 47274.
20. Sulfathiazole, 0.5 gram per tablet (NDA 3-552); Horton and Converse, 621 West Pico Boulevard, Los Angeles, Calif. 90015.
21. Sulfathiazole, 0.5 gram per tablet (NDA 3-592); The G. F. Harvey Co., Inc., 99-101 Saw Mill Road, Yonkers, N.Y. 10701.
22. Sulfathiazole, 0.5 gram per tablet (NDA 3-519); Ziegler Pharmacal Corp., 484 Delaware Avenue, Buffalo, N.Y. 14202.
23. Sulfathiazole, 0.5 gram per tablet (NDA 3-512); Blue Line Pharmacal Co., 302 South Broadway, St. Louis, Mo. 63102.
24. Sulfathiazole, 0.5 gram per tablet (NDA 3-338); American Chemical Co., 432 East Erie Street, Chicago, Ill. 60611.
25. Sulfathiazole, 0.5 gram per tablet (NDA 3-545); Sulfathiazole, 0.25 gram per tablet (NDA 4-322); Spersoid Sulfathiazole Suspension containing sulfathiazole 0.5 gram per 5 cubic centimeters (NDA 5-204); Sulfathiazole, 0.25 and 0.5 gram per tablet; Sulfathiazole, 0.5 gram and sodium bicarbonate 5 grains per tablet; Sulfathiazole, 0.25 gram and sodium bicarbonate 2½ grains per tablet; Marmoid Sulfathiazole Suspension containing sulfathiazole 0.5 gram per 5 cubic centimeters (NDA 5-572); Pitman-Moore Co., Division of Dow Chemical Co., Post Office Box 1656, Indianapolis, Ind. 46206.
26. Sulfathiazole, 0.5 gram per tablet (NDA 3-559); First Texas Pharmaceutical, Inc., 1810 North Lamar Street, Dallas, Tex. 75202.
27. Sulfathiazole, 0.5 gram per tablet (NDA 3-339); Brewer and Co., Division

of Cooper Laboratories, Inc., 67 Union Street, Worcester, Mass. 01608.

28. Sulfathiazole, 0.5 gram per tablet (NDA 3-392); Warner-Lambert Pharmaceutical Co., Morris Plains, N.J. 07950.
 29. Sulfathiazole, 0.5 gram per tablet (NDA 3-339); Chicago Pharmacal Division Conal Pharmaceutical, Inc., 5547 North Ravenswood Avenue, Chicago, Ill. 60640.
 30. Sulfathiazole, 0.5 gram per tablet (NDA 4-827); Ferndale Laboratories & Surgical, Inc., 700 West Eight Mile Road, Ferndale, Mich. 49229.
 31. Sulfathiazole, 0.5 gram per tablet (NDA 4-385); Mutual Pharmacal Co., 817-821 South State Street, Syracuse, N.Y. 13202.
 32. Sulfathiazole, 0.5 gram per tablet (NDA 4-100); Hart Drug Corp., 25th Street, Miami, Fla. 33137.
 33. Sulfathiazole, 0.5 gram per tablet (NDA 4-171); Mallinckrodt Chemical Works, 360 North Second Street, St. Louis, Mo. 63145.
 34. Sulfathiazole, 0.5 gram per tablet (NDA 4-251); S. F. Durst & Co., 3317 North Third Street, Philadelphia, Pa. 19120.
 35. Sulfathiazole, 0.5 gram per tablet; sodium sulfathiazole monohydrate, 5 grams per vial (NDA 4-490); Lex Laboratories, Inc., 3522 Linden Place, Flushing, N.Y. 11354.
 36. Sulfathiazole, 0.5 gram per tablet (NDA 4-424); Maynard Inc., Post Office Box 20246, Greensboro, N.C. 27420.
 37. Sulfathiazole, 0.5 gram per tablet (NDA 4-423); Shores Co., Inc., 712 16th Street NE, Cedar Rapids, Iowa 52402.
 38. Sulfathiazole, 0.5 gram per tablet (NDA 5-652); Specific Pharmaceuticals, Chemical Products Division, Chemetron Corp., 365 Park Avenue South, New York, N.Y. 10016.
 39. Gluco-Sulfathiazole Liquid containing sulfathiazole 2 grams per fluid ounce (NDA 5-759); Gluco-sulfas Liquid containing 3.7 grams each of sulfathiazole and sulfadiazine and 2.5 grams of sulfamerazine per 100 milliliters (NDA 6-455); Donley-Evans & Co., 5229 Brown Avenue, St. Louis, Mo. 63115.
- The Commissioner of Food and Drugs, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505 (e), 52 Stat. 1052, as amended; 21 U.S.C. 355-e), and under the authority delegated to him (21 CFR 2.120), finds: (1) That new evidence of clinical experience not contained in the applications or not available until after the applications were approved, evaluated together with the evidence available when the applications were approved, reveal that the drug is not shown to be safe for use upon the basis of which the applications were approved; (2) that because of the known serious hazards associated with such use and the imbalance between benefit and risk of serious untoward effects from such drugs, their continued use systematically is not warranted as other available sulfonamides have equivalent benefit and involve much less risk; and (3) that new information, evaluated together with the evidence available when the applications were approved, shows there is a lack of substantial evidence

that the drugs will have the effect they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling.

Therefore, pursuant to the foregoing findings, approval of the above-listed new-drug applications, and all amendments and supplements thereto, is withdrawn effective on the date of the signature of this document.

Dated: September 28, 1970.

SAM D. FINE,
Associate Commissioner
for Compliance.

[P.R. Doc. 70-13372; Filed, Oct. 14, 1970;
8:46 a.m.]