

as amended; 21 U.S.C. 355) and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: May 19, 1970.

SAM D. FINE,  
Acting Associate Commissioner  
for Compliance.

[F.R. Doc. 70-6604; Filed, May 27, 1970;  
8:48 a.m.]

[Docket No. FDC-D-180; NDA No. 10-559]

**WARNER-LAMBERT PHARMA-  
CEUTICAL CO.**

**Drugs for Human Use; Drug Efficacy  
Study Implementation; Pacatal Tab-  
lets and Injections; Withdrawal of  
Approval of New-Drug Application**

In the FEDERAL REGISTER of November 29, 1969 (34 F.R. 19037), the Commissioner of Food and Drugs announced (DESI 10539) his conclusions pursuant to evaluating reports received from the National Academy of Sciences—National Research Council, Drug Efficacy Study Group, concerning the safety and efficacy of mepazine for human use, and stated his intention to initiate proceedings to withdraw approval of new-drug application No. 10-559 for Pacatal (tablets containing 25, 50, and 100 milligrams of mepazine and injection containing 25 milligrams of mepazine (as acetate) per milliliter).

The Warner-Lambert Pharmaceutical Co., Morris Plains, N.J. 07950, holder of said application, by letter of January 12, 1970, waived opportunity for a hearing on the proposed withdrawal of approval of the application. No data or objections were filed by other interested persons.

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), the Commissioner finds on the basis of new information, evaluated together with the evidence available when the application was approved, that: (1) Mepazine is not shown to be safe for use under the conditions of use upon the basis of which the application was approved, in view of the adverse effects associated with its use, and (2) there is a lack of substantial evidence that mepazine will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling.

Therefore, pursuant to the foregoing finding, approval of new-drug application No. 10-559, and all amendments and supplements applying thereto, is withdrawn effective on publication hereof in the FEDERAL REGISTER. This causes any mepazine-containing drug to be a new drug for which an approved new-drug application is not in effect and makes it subject to regulatory action.

Dated: May 19, 1970.

SAM D. FINE,  
Acting Associate Commissioner  
for Compliance.

[F.R. Doc. 70-6606; Filed, May 27, 1970;  
8:48 a.m.]

[Docket No. FDC-D-173; NDA 4-350, etc.]

**CERTAIN SULFONAMIDE - DECON-  
GESTANT NASAL PREPARATIONS**

**Drugs for Human Use; Drug Efficacy  
Study Implementation; Opportunity  
for Hearing on Proposal To With-  
draw Approval of New-Drug Appli-  
cations**

In the FEDERAL REGISTER of September 9, 1969 (34 F.R. 14181), pursuant to evaluations by the National Academy of Sciences—National Research Council, Drug Efficacy Study Group, of certain sulfonamide-decongestant drugs for nasal instillation, the Food and Drug Administration concluded (DESI 4850) there is a lack of substantial evidence that such drugs will have the effects they purport or are represented, expressly or by implications, to have. The Commissioner of Food and Drugs gave notice of his intention to initiate proceedings to withdraw approval of the new-drug applications for those and similar drugs.

Holders of new-drug applications for such drugs, and any interested person who might be adversely affected by their removal from the market, were invited to submit pertinent data bearing on the proposal within 30 days after said publication date. Responses were received from Lederle Laboratories concerning Rhinazine and from Smith, Kline & French Laboratories concerning Paredrine Sulfathiazole Suspension. The material submitted, considered with other available information, does not provide substantial evidence of effectiveness of the drugs for their recommended uses.

Therefore, notice is given to:

1. Roche Laboratories, Division of Hoffmann-La Roche, Inc., 340 Kingsland Street, Nutley, N.J. 07110, holder of new-drug application (NDA 8-603) for Chantarin Nasal Solution (sulfisoxazole and phenylephrine hydrochloride);

2. Parke, Davis & Co., Joseph Campau at the River, Detroit, Mich. 48232, holder of new-drug applications (NDA 5-329, 5-180, 5-559, 5-563) for (1) Gluco-Pedrin with sulfathiazole (sulfathiazole and ephedrine lactate); (2) Sulfamone Drops (sulfathiazole sodium and methamphetamine); (3) Gluco-Pedrin with Sulfadiazine Drops (sulfadiazine and ephedrine); and (4) Sulfamone with Sulfadiazine Drops (sodium sulfadiazine and methamphetamine hydrochloride);

3. Smith, Kline & French Laboratories, 1300 Spring Garden Street, Philadelphia, Pa. 19101, holder of new-drug application (NDA 4-350) for Paredrine Sulfathiazole Suspension (sulfathiazole and hydroxyamphetamine hydrochloride);

4. Eli Lilly & Co., Post Office Box 618, Indianapolis, Ind. 46206, holder of new-drug applications (NDA 5-179, 5-365) for (1) Thiodrin Solution (sulfathiazole sodium and methamphetamine hydrochloride); and (2) Sulfathiazole with Tuamine Sulfate Suspension (sulfathiazole and tuaminoheptane sulfate);

5. Winthrop Laboratories, Div. of Sterling Drug, Inc., 90 Park Avenue, New York, N.Y. 10016, holder of new-drug application (NDA 5-225) for Neo-Synephrine Sulfathiazolate Nose Drops (phenylephrine sulfathiazolate);

6. Lederle Laboratories, Div. American Cyanamid Co. West Middletown Road, Pearl River, N.Y. 10965, holder of new-drug appli-

cation (NDA 5-588) for Rhinazine (sodium sulfadiazine, sulfathiazole, sodium, and dimethamphetamine hydrochloride);

7. J. R. Squibb & Sons, Georges Road, New Brunswick, N.J. 08902, holder of new-drug application (NDA 5-177) for Sulmeirin Drops (sulfathiazole sodium, sodium sulfadiazine, and methamphetamine);

8. Mallinckrodt Chemical Works, Second and Mallinckrodt Street, St. Louis, Mo. 63100, holder of new-drug application (NDA 5-281) for Sulfadrine Drops (sulfathiazole and ephedrine sulfate);

9. Conal Pharmaceuticals, Inc., 5547 West Ravenswood Avenue, Chicago, Ill. 60640, holder of new-drug application (NDA 5-334) for Sulfed Solution (sulfathiazole and ephedrine sulfate);

10. William H. Rorer, Inc., 500 Virginia Drive, Fort Washington, Pa. 19034, holder of new-drug application (NDA 5-370) for Sulfamidazole-Ephedrine Suspension (sulfamidamide, sulfathiazole, and ephedrine sulfate);

and to any interested person who may be adversely affected, that the Commissioner proposes to issue an order under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) withdrawing approval of the above-specified new-drug applications, and all amendments and supplements thereto, on the grounds that new information, evaluated 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. Specifically, substantial evidence is lacking to show (1) that the drugs are effective in the local treatment of intranasal bacterial infection and resultant postnasal drip, (2) that the sulfonamide component makes any contribution to the claimed effect for decongestion of nasal and pharyngeal mucosa in the treatment of rhinitis and sinusitis, and (3) that the sulfonamide component has a favorable effect in the treatment or prevention of the uncomplicated common cold or the simple, acute non-bacterial respiratory disease.

In addition to the new-drug applications listed above, a number of others provide for sulfonamide-decongestant nasal preparations for use in humans. Since the holders of those applications have already voluntarily requested their withdrawal, thereby waiving opportunity for a hearing, they are not listed in this notice.

In accordance with section 505 of the act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Part 130), the Commissioner will give the applicants, 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 any new-drug application listed herein should not be withdrawn. Promulgation of the proposed order will cause any drug for human use containing the same active ingredients and offered for the same conditions of use to be a new drug for which an approved new-drug application is not in effect. Any such drug then on the market would be subject to regulatory proceedings.

## DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[DESI 10659]

### MEPAZINE

#### 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:

Pacatal Tablets containing 25 milligrams and 50 milligrams mepazine, present as the hydrochloride, per tablet; previously marketed by Warner-Chilcott Laboratories, Division of Warner-Lambert Pharmaceutical Co., 201 Tabor Road, Morris Plains, N.J. 07960 (NDA 10-559). (The company reported in October 1966 that the drug had been withdrawn.)

The Food and Drug Administration concurs with the comment of the Academy panel that mepazine should not be marketed. Serious adverse effects associated with the use of the drug have included granulocytopenia and agranulocytosis, paralytic ileus, urinary retention, seizures, hypotension, and jaundice.

The Food and Drug Administration concludes that there is a lack of substantial evidence of effectiveness of mepazine for the claims which it purported or was represented to have. It is further concluded that the drug is not shown to be safe, in that the hazards associated with its use present risks which are unwarranted in view of its lack of effectiveness. Accordingly, the Commissioner intends to initiate proceedings to withdraw approval of the above listed new-drug application which provides for oral and injectable forms of mepazine.

Prior to initiating such action, however, the Commissioner invites the holder of the new-drug application for this drug and any interested person who may

be adversely affected by the removal of such article 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 product, and not previously submitted.

This announcement of the proposed action and implementation of the NAS-NRC report for this drug is made to give notice to persons who might be adversely affected by its withdrawal from the market. Promulgation of an order withdrawing approval of the new-drug application 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 holder of the subject new-drug application has 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. 10559, 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-18), Bureau of Medicine.

This announcement is issued pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 302, 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: November 20, 1969.

HERBERT L. LEE, Jr.,  
Commissioner of Food and Drugs.