

(35 F.R. 13602), and amended in the FEDERAL REGISTER of April 2, 1971 (36 F.R. 6118), 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 polymyxin B sulfate preparations, stating that these drugs are regarded as effective and possibly effective for their various labeled indications.

1. Aerosporin Sterile Powder for preparation of solutions (NDA 60-757); Burroughs Wellcome & Co., Inc., Research Triangle Park, N.C. 27709.
2. Polymyxin B Sulfate Sterile Powder for preparation of solutions (NDA 60-716); Pfizer Inc., 235 East 42d Street, New York, NY 10017.

The previously announced possibly effective indications have been reclassified as lacking substantial evidence of effectiveness in that no new evidence of effectiveness of these drugs has been submitted pursuant to the notices of August 26, 1970, and April 2, 1971.

Consequently, these drugs lack substantial evidence of effectiveness for labeled indications other than those appearing below. The above-listed firms have satisfactorily amended their antibiotic applications to be in accord with the indications which follow:

INDICATIONS

Acute infections caused by susceptible strains of *Pseudomonas aeruginosa*. Polymyxin B sulfate is a drug of choice in the treatment of infections of the urinary tract, meningitis, and blood stream caused by susceptible strains of *Ps. aeruginosa*. It may also be used topically and subconjunctivally in the treatment of infections of the eye caused by susceptible strains of *Ps. aeruginosa*.

It may be indicated in serious infections caused by susceptible strains of the following organisms, when less potentially toxic drugs are ineffective or contraindicated:

- H. influenzae*, specifically meningitis infections.
- Escherichia coli*, specifically urinary tract infections.
- Aerobacter aerogenes*, specifically bacteremia.
- Klebsiella pneumoniae*, specifically bacteremia.

NOTE: In meningitis infections, Polymyxin B sulfate should be administered only by the intrathecal route.

Batches of drugs with labeling bearing indications for which substantial evidence of effectiveness is lacking are no longer acceptable for certification or release.

Any person who will be adversely affected by the deletion from labeling of the indications for which the drug has been reclassified from possibly effective to lacking substantial evidence of effectiveness may within 30 days after the date of publication of this notice in the FEDERAL REGISTER, petition for the issuance of a regulation providing for other certification of the drug 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.

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

Dated: June 15, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-9640 Filed 6-26-72;8:45 am]

[Docket No. FDC-D-412; NDA No. 8-836 etc.]

GEIGY PHARMACEUTICALS AND ROCHE LABORATORIES

Notice of Withdrawal of Approval of New Drug Applications

A notice was published in the FEDERAL REGISTER of February 12, 1972 (37 F.R. 3198) extending to each holder of a new drug application listed below, and to any interested person who may be adversely affected, an opportunity for hearing on the proposal of the Commissioner of Food and Drugs to issue an order under section 505 (e) of the Federal Food, Drug, and Cosmetic Act, withdrawing approval of each listed application and all amendments and supplements thereto. The basis of the proposed action was the lack of substantial evidence that the drugs are effective for their labeled indications.

NDA No.	Drug	NDA holder
NDA 8-836...	Sterosan Cream and Ointment containing chlorquinaldol.	Geigy Pharmaceuticals, Division of Ciba-Geigy Corp., Saw Mill River Rd., Ardsley, NY 10502.
NDA 11-675...	Triburon Ointment containing tribolbionium chloride.	Roche Laboratories, Division of Hoffmann-La Roche, Inc., 340 Kingsland Ave., Nutley, NJ 07110.
NDA 11-925...	Triburon Cream containing tribolbionium chloride.	Roche Laboratories.

Hoffmann-LaRoche has waived opportunity for hearing stating that marketing of the above drugs (NDAs 11-675 and 11-925) has been discontinued. Neither Geigy Pharmaceuticals, the holder of NDA 8-836, nor any other interested persons have filed a written appearance of election as provided by said notice. The failure to file such an appearance is construed as an election by such persons not to avail themselves of an opportunity for hearing.

The Commissioner of Food and Drugs pursuant to provisions of the Federal Food, Drug, and Cosmetic Act 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 each of said drugs, evaluated together with the evidence available to him when each application was approved, there is a lack of substantial evidence that each of the drugs 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 findings, approval of the above-listed new drug applications and all amendments and supplements thereto is withdrawn effective on the date of publication hereof in the FEDERAL REGISTER (6-26-72).

Dated: June 15, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-9641 Filed 6-26-72;8:46 am]

[Docket No. FDC-D-360; NADA 33-803V]

SHELL CHEMICAL CO.

Task; Order Vacating Notice of Opportunity for Hearing

A notice of opportunity for hearing on a proposal by the Commissioner of Food and Drugs to withdraw approval of the new animal drug application for Task (NADA No. 33-803V) was published in the FEDERAL REGISTER of October 14, 1971 (36 F.R. 19996).

In response to this notice, Shell Chemical Co., Division of Shell Oil Co., 3401 Crow Canyon Road, San Ramon, CA 94583, holder of new animal drug application No. 33-803V, has submitted a supplemental new animal drug application containing new information and revised labeling with respect to Task. The Commissioner concludes that the new information submitted evaluated together with the evidence available when the application was approved shows that this drug is safe and effective for the treatment of dogs under the conditions of use prescribed, recommended, or suggested in the revised labeling.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512, 82 Stat. 343-51; 21 U.S.C. 360b) and under authority delegated to the Commissioner (21 CFR 2.120), said notice of opportunity for hearing is vacated.

Dated: June 15, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-9642 Filed 6-26-72;8:46 am]

[Docket No. FDC-D-360; NADA 33-803V]

SCHERING CORP. DESI 3726

Sulfacetamide for Oral Administration; Notice of Withdrawal of Approval of New-Drug Application

A notice was published in the FEDERAL REGISTER of February 11, 1972 (37 F.R. 3079), extending to Schering Corp., 60 Orange Street, Bloomfield, NJ 07003, and