

March 28

guaranteed resolving power of this stage is 8 angstroms. (The lower the numerical rating in terms of angstrom units, the better the resolving power.) We are advised by the Department of Health, Education, and Welfare in its memorandum dated December 17, 1971, that the guaranteed resolving power of the tilt stage of the foreign article is pertinent to the applicant's research studies. We, therefore, find that the Model EMU-4C electron microscope 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.

SETH M. BODNER,
Director,
Office of Import Programs.

[FR Doc. 72-4678 Filed 3-27-72; 8:51 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[Docket No. FDC-D-444; NDA No. 12-658]

ARMOUR PHARMACEUTICAL CO.

Hydroxyphenamate; Notice of Withdrawal of Approval of New-Drug Application

In the FEDERAL REGISTER of June 25, 1970 (35 F.R. 10394), the Commissioner of Food and Drugs announced (DESI 6566) his conclusions pursuant to evaluation of a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, concerning the following drug:

NDA 12-658; Listica Tablets, containing hydroxyphenamate; Armour Pharmaceutical Co., Box 511, Kankakee, Ill. 60901.

The announcement stated that the drug was regarded as either lacking substantial evidence of effectiveness or possibly effective for the various labeled indications. 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 indications. 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 1971.

The Commissioner of Food and Drugs, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 305(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. 12-658, and all amendments and supplements thereto, is withdrawn effective on the date of publication hereof in the FEDERAL REGISTER (3-28-72).

Dated: March 16, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc. 72-4689 Filed 3-27-72; 8:53 am]

[DESI 4054-4]

CERTAIN SHORT-ACTING AND INTERMEDIATE-ACTING SYSTEMIC SULFONAMIDES

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration published announcements in the FEDERAL REGISTER June 17, 1969 (34 F.R. 9464), August 30, 1969 (34 F.R. 13948), and November 28, 1970 (35 F.R. 18215), regarding the efficacy of certain short-acting and intermediate-acting systemic sulfonamides.

The notices stated that certain preparations containing sulfachlorpyridazine; sulfadiazine; sulfaethidole; sulfamerazine; sulfamethizole; sulfamethoxazole; sulfisomidine; sulfisoxazole; or sulfadiazine and sulfamerazine with or without sulfamethazine were regarded as effective, probably effective, possibly effective, and/or lacking substantial evidence of effectiveness for their various labeled indications.

Based on a further reevaluation of the reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, and other available evidence, the Commissioner of Food and Drugs finds it appropriate to amend the announcement of November 28, 1970 (35 F.R. 18215) by:

1. Reclassifying sulfisoxazole, sulfamethoxazole, sulfisomidine, sulfachlorpyridazine, sulfaethidole, sulfamethizole, and combinations of sulfadiazine, sulfamerazine, and sulfamethazine from probably effective to effective in the treatment of recurrent or chronic urinary tract infections (primarily pyelonephritis, pyelitis, and cystitis) due to susceptible organisms (usually *E. coli*, *Klebsiella-Aerobacter*, staphylococcus, *Proteus mirabilis*, and less frequently, *Proteus vulgaris*) in the absence of obstructive uropathy or foreign bodies.

2. Reclassifying the following probably effective indication for sulfonamides other than sulfadiazine as lacking substantial evidence of effectiveness in that no new evidence of effectiveness has been

received pursuant to the notices of August 30, 1969, and November 28, 1970: For use in the prophylaxis of rheumatic fever as an alternative to penicillin.

3. Reclassifying the possibly effective indications as lacking substantial evidence of effectiveness in that no new evidence of effectiveness has been received pursuant to the notices of August 30, 1969, and November 28, 1970, i.e.; the treatment of pneumococcal infections; gas gangrene; lymphogranuloma venereum; shigellosis; for suppressive therapy in patients with indwelling catheters, ureterostomies, urinary stasis, cord bladder, and before and after genitourinary surgery and instrumentation; and in "acute or chronic otitis media." Sulfachlorpyridazine, sulfaethidole, sulfamethizole, and sulfamethoxazole are, for the same reason, reclassified as lacking substantial evidence of effectiveness in the treatment of meningococcal meningitis and as adjunctive therapy in *Haemophilus influenzae* meningitis.

4. Adding information under the "Adverse Reactions" section relating to the goitrogenic effects of sulfonamides during long-term administration in the rat.

5. Rewording the "Indications" and "Adverse Reactions" sections to reflect the above findings, as follows:

INDICATIONS

Chancroid.
Trachoma.
Inclusion conjunctivitis.
Nocardiosis.

Acute urinary tract infections (primarily pyelonephritis, pyelitis, and cystitis) due to susceptible organisms (usually *E. coli*, *Klebsiella-Aerobacter*, staphylococcus, *Proteus mirabilis*, and less frequently, *Proteus vulgaris*) in the absence of obstructive uropathy or foreign bodies.

Toxoplasmosis as adjunctive therapy with pyrimethamine.

Malaria due to chloroquine-resistant strains of *Plasmodium falciparum*, when used as adjunctive therapy.

Meningococcal meningitis prophylaxis when sulfonamide-sensitive group A strains are known to prevail in family groups or larger closed populations. (The prophylactic usefulness of sulfonamides when group B or C infections are prevalent is not proven and in closed population groups may be harmful.)

In acute otitis media due to *Haemophilus influenzae* when used concomitantly with adequate doses of penicillin.

Add for: Sulfisoxazole, sulfamethoxazole, sulfisomidine, sulfachlorpyridazine, sulfaethidole, sulfamethizole, and combinations of sulfadiazine, sulfamerazine, and sulfamethazine only—The treatment of recurrent or chronic urinary tract infections (primarily pyelonephritis, pyelitis and cystitis) due to susceptible organisms (usually, *E. coli*, *Klebsiella-Aerobacter*, staphylococcus, *Proteus mirabilis*, and less frequently, *Proteus vulgaris*) in the absence of obstructive uropathy or foreign bodies.

Add for: Sulfadiazine only—Prophylaxis against recurrences of rheumatic fever as an alternative to penicillin.

Add for: Sulfadiazine, sulfamerazine, sulfisomidine, sulfisoxazole, and combinations of sulfadiazine and sulfamerazine with or without sulfamethazine only—

Haemophilus influenzae meningitis (as adjunctive therapy with parenteral streptomycin), and

Meningococcal meningitis (where the organism has been demonstrated to be susceptible).