

Commerce, and five members appointed by the organization they represent.

The agenda for the meeting is: (1) A tel discussion on Revenue Sharing; (2) Status report on the 1972 Census of Governments; and (3) Panel review of Current and Special Statistics of Governments.

A limited number of seats—approximately 15—will be available to the public. A brief period will be set aside for public comment and questions. Extensive questions or statements must be submitted in writing at least 3 days prior to the meeting.

Persons wishing to submit questions or statements, planning to attend the meeting, or wishing additional information should contact Mrs. Aileen Ashbaugh, Bureau of the Census, Room 2416, Federal Building 3, Suitland, MD. (Mail Address: Washington, D.C. 20233). Telephone: (301) 763-5262.

Dated: November 22, 1972.

HAROLD C. PASSER,
Assistant Secretary for
Economic Affairs.

[FR Doc.72-20513 Filed 11-28-72; 8:53 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[DESI 9861; Docket No. FDC-D-495; NDA 9-861, etc.]

CERTAIN CARDIOVASCULAR PREPARATIONS

Notice of Withdrawal of Approval of New Drug Applications

On August 25, 1972, there was published in the FEDERAL REGISTER (37 F.R. 17226) notice of opportunity for hearing (DESI 9861) in which the Commissioner of Food and Drugs proposed to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) withdrawing approval of the new drug applications for the subject drugs in the absence of substantial evidence that these fixed combination drugs will have the effect they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or that each component of the combinations contributes to the total effects claimed for the drugs.

On September 22, 1972, McNeil Laboratories, holder of NDA 9-921 Butiserpine tablets and NDA 10-646 Butiserpine R-A tablets, elected to avail itself of the opportunity for a hearing on the two drugs. This request for a hearing is under review and will be the subject of a future publication in the FEDERAL REGISTER.

Concerning Mephoserp tablets (reserpine and mephobarbital), reviewed by the National Academy of Sciences-

National Research Council, Drug Efficacy Group, and listed in the notice of August 25, 1972, Nysco Laboratories has stated that the drug has not been manufactured since 1965. It was not the subject of an approved new drug application.

None of the holders of the following new drug applications or any other interested person have filed a written appearance of election as provided by said notice. The failure to file such an appearance constitutes an election by such persons not to avail themselves of the opportunity for a hearing:

1. NDA 9-861; Nembu-Serpin tablets and Nembu-Serpin ½ strength tablets containing reserpine and calcium pentobarbital; Abbott Laboratories, 14th and Sheridan Road, North Chicago, IL 60064.

2. NDA 11-191; Harmony-N tablets and Harmony-N half-strength tablets containing deserpidine and calcium pentobarbital; Abbott Laboratories.

3. NDA 10-456; Butiserpine Elixir containing reserpine and sodium butabarbital; McNeil Laboratories, Inc., Camp Hill Road, Fort Washington, PA 19034.

All identical, related, or similar products, not the subject of an approved new drug application, are covered by the new drug applications reviewed and are subject to this notice. See 21 CFR 130.40 (37 F.R. 23185 October 31, 1972). Any person who wishes to determine whether a specific product is covered by this notice should write to the Food and Drug Administration, Bureau of Drugs, Office of Compliance (BD-300), 5600 Fishers Lane, Rockville, Md. 20852.

The Commissioner of Food and Drugs, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1053, as amended, 21 U.S.C. 355), and the Administrative Procedure Act (5 U.S.C. 554), and under authority delegated to him (21 CFR 2.120), finds on the basis of new information before him with respect to said 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 new drug applications, and all amendments and supplements applying thereto is withdrawn effective on the date of publication hereof in the FEDERAL REGISTER (11-29-72). Shipment in interstate commerce of any of the above-listed drug products or of any identical, related, or similar product, not the subject of an approved new drug application, is henceforth unlawful.

Dated: November 21, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-20463 Filed 11-28-72; 8:49 am]

[DESI 11255; Docket No. FDC-D-566; NDA 6-547, etc.]

CERTAIN COMBINATION DRUGS CONTAINING ANTACIDS WITH ANTICHOLINERGICS

Notice of Opportunity for Hearing on Proposal To Withdraw Approval of New Drug Applications

In an announcement (DESI 11255) published in the FEDERAL REGISTER of September 8, 1972 (37 F.R. 18225), the Commissioner of Food and Drugs announced his conclusions pursuant to the evaluation of reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group on the following drugs:

1. Modutrol tablets containing pipethanate hydrochloride, scopolamine methylnitrate, aluminum hydroxide, and magnesium hydroxide; Reed & Carnrick, 30 Boright Avenue, Kenilworth, NJ 07033 (NDA 11-255).

2. Estomul tablets containing orphenadrine hydrochloride, bismuth aluminate, magnesium oxide, aluminum hydroxide, and magnesium carbonate; Riker Laboratories, Inc., Division Dart Inc., 19901 Nordhoff Street, Northridge, CA 91324 (NDA 12-830).

3. Estomul liquid containing orphenadrine hydrochloride, bismuth aluminate, aluminum hydroxide, and magnesium carbonate; Riker Laboratories, Inc. (NDA 12-830).

4. Alzinox compound tablets and Magma containing dihydroxy-aluminum aminoacetate, phenobarbital, and homatropine methylbromide; Smith, Miller & Patch, Inc., 401 Joyce Kilmer Avenue, New Brunswick, NJ 08902 (NDA 6-547).

The announcement stated that these fixed combination drugs lack substantial evidence of effectiveness for their recommended uses and that drugs containing an anticholinergic with an antacid are not appropriate for administration as fixed-dose combinations within the guidelines set forth in the Statement of General Policy or Interpretation § 3.86 Fixed-combination prescription drugs for humans, published in the FEDERAL REGISTER of October 15, 1971 (36 F.R. 20037), and that the Commissioner of Food and Drugs intended to initiate proceedings to withdraw approval of the new drug applications for the drugs.

Interested persons were invited to submit pertinent data bearing on the proposal within 30 days following publication of the announcement. No data providing substantial evidence of effectiveness have been received.

Therefore, notice is given to the holder(s) of the new drug application(s) and to any other interested person that the Commissioner proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) withdrawing approval of the listed new drug application(s) and all amendments and supplements thereto on the grounds that new information before him with respect to the