

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

drug(s), evaluated together with the evidence available to him at the time of approval of the application(s), shows there is a lack of substantial evidence that the drug(s) will have all the effects purported or represented to have under the conditions of use prescribed, recommended, or suggested in the labeling.

All identical, related, or similar products, not the subject of an approved new drug application, are covered by the new drug application(s) reviewed. See 21 CFR 130.40 (37 F.R. 23185 October 31, 1972). Any manufacturer or distributor of such an identical, related, or similar product is an interested person who may in response to this notice submit data and information, request that the new drug application(s) not be withdrawn, request a hearing, and participate as a party in any hearing. 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.

In accordance with the provisions of section 505 of the Act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Part 130), the Commissioner hereby gives the applicant(s) and any other interested person an opportunity for a hearing to show why approval of the new drug application(s) should not be withdrawn.

Within 30 days after publication hereof in the FEDERAL REGISTER the applicant(s) and any other interested person is required to file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, a written appearance electing whether or not to avail himself of the opportunity for a hearing. Failure of an applicant or any other interested person to file a written appearance of election within said 30 days will constitute an election by him not to avail himself of the opportunity for a hearing.

If no person elects to avail himself of the opportunity for a hearing, the Commissioner without further notice will enter a final order withdrawing approval of the application(s).

If an applicant or any other interested person elects to avail himself of the opportunity for a hearing, he must file, within 30 days after publication of this notice in the FEDERAL REGISTER, a written appearance requesting the hearing, giving the reasons why approval of the new drug application(s) should not be withdrawn, together with a well-organized and full-factual analysis of the clinical and other investigational data he is prepared to prove in support of his opposition. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that a genuine and substantial issue of fact requires a hearing (21 CFR 130.14(b)).

If review of the data submitted by an applicant or any other interested person warrants the conclusion that there exists substantial evidence demonstrating the effectiveness of the product(s) for the labeling claims involved, the Commissioner will rescind this notice of opportunity for hearing.

If review of the data in the application(s) and data submitted by the applicant(s) or any other interested person in a request for a hearing, together with the reasoning and factual analysis in a request for a hearing, warrants the conclusion that no genuine and substantial issue of fact precludes the withdrawal of approval of the application(s), the Commissioner will enter an order of withdrawal making findings and conclusions on such data.

If, upon the request of the new drug applicant(s) or any other interested person, a hearing is justified, the issues will be defined, a hearing examiner will be named, and he shall issue, as soon as practicable after the expiration of such 30 days, a written notice of the time and place at which the hearing will commence. All persons interested in identical, related, or similar products covered by the new drug application(s) will be afforded an opportunity to appear at the hearing, file briefs, present evidence, cross-examine witnesses, submit suggested findings of fact, and otherwise participate as a party. The hearing contemplated by this notice will be open to the public except that any portion of the hearing that concerns a method or process the Commissioner finds entitled to protection as a trade secret will not be open to the public, unless the respondent specifies otherwise in his appearance.

Requests for a hearing and/or elections not to request a hearing may be seen in the Office of the Hearing Clerk (address given above) during regular business hours, Monday through Friday.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052-53, as amended; 21 U.S.C. 355); and the Administrative Procedure Act (5 U.S.C. 554), and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: November 21, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-20468 Filed 11-28-72; 8:49 am]

[Dockets Nos. FDC-D-438; NADA 3-161V and NADA 3-162V]

HAVER-LOCKHART LABORATORIES

Certain Phenothiazine-Containing Products; Notice of Withdrawal of Approval of New Animal Drug Applications

In the FEDERAL REGISTER of September 27, 1972 (37 F.R. 20189), the Com-

missioner of Food and Drugs published a notice proposing to withdraw approval of new animal drug application (NADA) No. 3-161V for Phenothiazine tablet and NADA No. 3-162V for Phenothiazine Suspension (Red); marketed by Haver-Lockhart Laboratories, Box 390, Shawnee Mission, KS 66201.

Haver-Lockhart Laboratories waived an opportunity for a hearing. Therefore, based on the grounds set forth in the cited notice of opportunity for a hearing, the Commissioner concludes that approval of said new animal drug applications should be withdrawn. Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512, 82 Stat. 343-351; 21 U.S.C. 360b) and under authority delegated to the Commissioner (21 CFR 2.120), approval of NADA No. 3-161V and NADA No. 3-162V, including all amendments and supplements thereto, is hereby withdrawn effective on the date of publication of this document (11-29-72).

Dated: November 21, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-20470 Filed 11-28-72; 8:49 am]

[Docket No. FDC-D-507; NADA 7-461V, 9-009V]

NELSON LABORATORIES, INC., AND MERCK SHARP & DOHME RESEARCH LABORATORIES

Certain Drug Products Containing S-faquinaxaline; Notice of Withdrawal of Approval of New Animal Drug Applications

In the FEDERAL REGISTER of September 22, 1972 (37 F.R. 19839), the Commissioner of Food and Drugs published a notice proposing to withdraw approval of new animal drug application (NADA) No. 7-461V for Sulfafloxazine Solution; marketed by Nelson Laboratories, Inc., 404 East 12th Street, Sioux Falls, SD 57101 and NADA No. 9-009V for S. Q. Tablet and Bolus; marketed by Merck Sharp & Dohme Research Laboratories, Division of Merck & Co., Inc., Rahway, NJ 07065.

Neither the above named firms nor any other interested persons have filed a written appearance in response to the above cited notice within said 30 days. This is construed as an election by said persons not to avail themselves of the opportunity for a hearing.

Therefore, based on the grounds set forth in said notice of opportunity for a hearing, the Commissioner concludes that approval of said new animal drug applications should be withdrawn. Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512, 82 Stat. 343-351; 21 U.S.C. 360b) and under authority delegated to