

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: December 18, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-22097 Filed 12-22-72; 8:47 am]

[DESI 10899; Docket No. FDC-D-472; NDA 10-899]

CIBA PHARMACEUTICAL CO.

Methylphenidate Hydrochloride Parenteral; Notice of Withdrawal of Approval of New Drug Application

A notice was published in the FEDERAL REGISTER of July 6, 1972 (37 F.R. 13281), extending to Ciba Pharmaceutical Co., 556 Morris Avenue, Summit, NJ 07901, and to any interested person, 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 NDA 10-899 for Ritalin Hydrochloride lyophilized powder for injection (methylphenidate

hydrochloride). The basis of the proposed action was the lack of substantial evidence that the drug is effective for its labeled indications.

All identical, related, or similar products, not the subject of an approved new drug application, are covered by the new drug application 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.

Neither the holder of the application nor any other person filed a written appearance of election within the 30 days provided by said notice. The failure to file such an appearance constitutes election by such person 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 (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 that on the basis of new information before him with regard to the 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. 10-899 and all amendments and supplements thereto is withdrawn effective on the date of publication hereof in the FEDERAL REGISTER (12-23-72).

Shipment in interstate commerce of the above-listed drug product or of any identical, related, or similar product, not the subject of an approved new drug application, is henceforth unlawful.

Dated: December 15, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-22099 Filed 12-22-72; 8:48 am]

[DESI 1730; Docket No. FDC-D-534; NDA's 1730, etc.]

CERTAIN DRUGS CONTAINING AMOBARBITAL AND DIOXYLINE PHOSPHATE; PHENOBARBITAL AND THEOBROMINE CALCIUM SALICYLATE; OR BUTABARBITAL AND HYDROCHLOROTHIAZIDE, WITH AND WITHOUT RESERPINE

Opportunity for Hearing on Proposal To Withdraw Approval of New Drug Applications; Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated reports received from the

National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following drugs for oral use:

1. Phenobarb Theocalcin tablets containing phenobarbital and theobromine calcium salicylate; Knoll Pharmaceutical Co., 377 Crane Street, Orange, N.J. 07051 (NDA 1-730).

2. Paveril Phosphate and Amytal tablets containing dioxyline phosphate and amobarbital; Eli Lilly and Co., Post Office Box 618, Indianapolis, Ind. 46206 (NDA 9-047).

3. Butiserpazide-25 and Butiserpazide-50 Prestabs, prolonged action tablets containing butabarbital, hydrochlorothiazide, and reserpine; McNeil Laboratories, Inc., Camp Hill Road, Fort Washington, Pa. 19034 (NDA 13-313).

4. Butizide-25 and Butizide-50 Prestabs, prolonged action tablets containing butabarbital and hydrochlorothiazide; McNeil Laboratories, Inc. (NDA 13-312).

The Food and Drug Administration has considered the Academy's reports, as well as other available evidence, and concludes that there is a lack of substantial evidence, within the meaning of the Federal Food, Drug, and Cosmetic Act, that these fixed combination drugs will have the effect that they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in the labeling and that each component of such drugs contributes to the total effects claimed.

Therefore, notice is given to be 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 partici-

pate 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, business hours, Monday through Friday, 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: December 18, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-22090 Filed 12-22-72; 8:47 am]

[DESI 12373; Docket No. FDC-D-536; NDA 12-373]

CERTAIN DRUGS CONTAINING POLY-UNSATURATED FATTY ACIDS WITH OR WITHOUT NIACIN

Opportunity for Hearing on Proposal To Withdraw Approval of New Drug Application 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 drugs:

1. Lenic capsules containing 100 mg. total of tetraenoic, pentaenoic, and hexaenoic acids and 500 mg. linoleic acid;
2. Lenic H.P. capsules containing 350 mg. total of tetraenoic, pentaenoic, and hexaenoic acids and 300 mg. linoleic acid; and
3. Lenic with Niacin capsules containing a total of 90 mg. of tetraenoic, pentaenoic, and hexaenoic acids, 450 mg. linoleic acid, and 100 mg. niacin; all previously marketed by Cooper Laboratories, oleic acid, and 100 mg. niacin; all pre-2900 North 17th Street, Philadelphia, Pa. 19132 (NDA 12-373).

The Food and Drug Administration has considered the Academy's report, as well as other available evidence, and concludes that there is a lack of substantial evidence, within the meaning of the Federal Food, Drug, and Cosmetic Act that these drugs are effective for use in lowering blood cholesterol levels at the recommended dosages.

Cooper Laboratories, the holder of NDA 12-373, has discontinued marketing of the above listed drugs.

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, Oct. 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