

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[DESI 10866; Docket No. FDC-D-363; NDA 10-866, etc.]

CENTRAL PHARMACAL CO. AND MERRELL-NATIONAL LABORATORIES

Neoparbel Tablets and Tace With Ergonovine Capsules; Notice of Withdrawal of Approval of New- Drug Applications

On October 5, 1971, there was published in the FEDERAL REGISTER (36 F.R. 19418) a notice of opportunity for hearing (DESI 10866) 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 following new-drug applications in the absence of substantial evidence that the drugs will have the effect they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling:

1. NDA 10-866, Neoparbel Tablets (pamabrom, pyrillamine maleate, homatropine methylbromide, hyoscyamine sulfate, scopolamine hydrobromide, and methamphetamine hydrochloride); Central Pharmacal Co., 116-128 East Third Street, Seymour, Indiana 47274.

2. NDA 11-444: That part of the NDA providing for TACE with Ergonovine Capsules (chlorotriamisene and ergonovine maleate), Merrell-National Laboratories, Div. of Richardson-Merrell Inc., 110 East Amity Road, Cincinnati, Ohio 45215, formerly the Wm. S. Merrell Co.

The Merrell-National Co., by letter of October 26, 1971, voluntarily requested withdrawal of approval of that portion of their NDA pertaining to TACE with Ergonovine, and thereby waived their opportunity for a hearing, stating that the product is no longer marketed.

Neither Central Pharmacal Co., the holder of NDA 10-866; nor any other interested person has 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 the opportunity for a hearing.

The Commissioner of Food and Drugs, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505(e), 52 Stat. 1053, as amended, 21 U.S.C. 355(e)) and under authority delegated to him (21 CFR 2.120), finds 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, that 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 NDA 10-866 and that part of NDA 11-444 pertaining to TACE with Ergonovine Capsules, and all amendments and supplements thereto, is withdrawn effective on the date of publication hereof in the FEDERAL REGISTER (3-30-72).

Dated: March 20, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-4829 Filed 3-29-72; 8:50 am]

[Docket No. FDC-D-482]

DIAMOND LABORATORIES, INC.

Penicillin, Streptomycin, Vitamins Preparations; Notice of Drugs Deemed Adulterated

An announcement concerning the productions Vistrepain and Vistrepain 5X was published in the FEDERAL REGISTER of July 23, 1970, (35 F.R. 11825, DESI 018(NV)). The announcement set forth the findings of the Food and Drug Administration following evaluation of reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, that the drugs are probably not effective for their intended use as a water dispersible antibiotic-vitamin powder for enteric infections in calves and swine or for complicated chronic respiratory disease and blue comb in turkeys and chickens.

Said announcement informed the manufacturer and all interested persons that such drugs to be marketed must be the subject of approved new animal drug applications. Diamond Laboratories, Inc., Post Office Box 863, Des Moines, Iowa 50304, manufacturer of the above-listed drugs, did not respond or submit new animal drug applications for the above-named drugs.

Based on the foregoing, and on the information before him, the Commissioner of Food and Drugs concludes that the above named drugs are adulterated within the meaning of section 501(a)(5) of the Federal Food, Drug, and Cosmetic Act, in that they are not the subjects of approved new animal drug applications pursuant to section 512 of the act. Therefore, notice is given to Diamond Laboratories, Inc., and to all interested persons, that all stocks of said drugs within the jurisdiction of the act are deemed adulterated within the meaning of the act and are subject to appropriate regulatory action.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 501(a)(5), 512, 52 Stat. 1049, as amended, 82 Stat. 343-51; 21 U.S.C. 351(a)(5), 360b) and under the authority delegated to the Commissioner (21 CFR 2.120).

Dated: March 23, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

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license. The entry of the parenthetical digit on Declarations covering general export shipments will confirm the exporter's representation that the license being used is applicable to the intended shipment.

7. *Entry of validated license number.* For shipments made under the authority of a validated export license, the exporter or forwarder will continue to enter the license number on the shipper's export declaration. It should be entered below the "description of commodities" and be clearly identifiable.

8. *Summary.* The proposed change in export clearance procedures will result in relieving the exporter of his responsibility for the entry of a destination control statement on his Shipper's Export Declaration and of the necessity of having these Declarations authenticated by the Bureau of Customs. He will also be relieved of the requirement that validated export licenses be presented to the Customs Office at the port of export (or an authorized inland port of origin) or to the Post Office at the time of mailing. On the other hand, the entry of the parenthetical digit on the Declaration will apply to most shipments whether made under a validated or general license.

The simplified export clearance system will not affect shipments made under the Monthly Reporting Procedure (ECR 3863(x) and FTSR 30.39). As in the past, authorized exporters will annotate bills of lading or air waybills properly and either file with the Bureau of Customs each month a report of their shipments on the Summary Shipper's Export Declaration or forward their report in the form of punch cards or magnetic tape directly to the Foreign Trade Division of the Bureau of the Census. Shipments will continue to be recorded on licenses by exporters and upon their completion or expiration the licenses will be returned to the Office of Export Control.

Persons interested in the changes described in substance in this notice are urged to submit their written data, views, or comments to the Office of Export Control (Attention: 840), U.S. Department of Commerce, Washington, D.C. 20230, not later than 30 days from the publication of this notice. All such material received on or before that date will be considered before the adoption of the proposed changes in the regulations. Copies of all material submitted will be available for inspection during normal business hours at the address given above. If, after the written data, views, and comments have been received and considered, it is decided to adopt the proposed procedures, the changes in the Export Control Regulations necessary and appropriate to give effect to the proposals described in this notice will be published in a forthcoming edition of the FEDERAL REGISTER.

RAUER H. MEYER,
Director, Office of Export Control,
Bureau of International Commerce.

[FR Doc.72-4995 Filed 3-29-72; 9:59 am]