

NDA No.	Drug name	NDA holder
10-811	Quilactin Tablets, containing oxanamide.	The William S. Merrell Co., Division Richardson Merrell, Inc., 110 East Amity Rd., Cincinnati, OH 45215.
13-261	Lenetran Tablets, containing mephenozone.	Lakeside Laboratories, Division Colgate-Palmolive Co., 1707 East North Ave., Milwaukee, WI 53201.
6-566	Tolserol Tablets, Capsules, Elixir, Injection, and Powder for Injection, containing mephensin.	E. R. Squibb & Sons, Inc., Division Olin Mathieson Chemical Corp., 745 Fifth Ave., New York, NY 10022.
9-157	Tolseram Tablets, and Suspension, containing mephensin carbamate.	Do.
6-934-10-801	Dioloxol Tablets, Capsules, and Elixir containing mephensin.	G. W. Carrick Co., 65 Horse Hill Rd., Cedar Knolls, NJ 07927.

¹ Although not specifically reviewed by the Academy, these are regarded as similarly affected.

Neither the holders of the new drug applications nor any other interested person have 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 an opportunity for hearing.

The Commissioner of Food and Drugs pursuant to provisions of the Federal Food, Drug, and Cosmetic Act 505(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 each of said drugs, evaluated together with the evidence available to him when each application was approved, 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the foregoing finding, approval of the above-listed new drug applications and all amendments and supplements thereto is withdrawn effective on the date of publication hereof in the FEDERAL REGISTER (2-12-72).

Dated: February 3, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-2136 Filed 2-11-72; 8:51 am]

[Docket No. FDC-D-426; NDA 8-245]

PARKE, DAVIS & CO.

Combination Drug Containing Diphenhydramine Hydrochloride and Scopolamine Hydrobromide; Notice of Opportunity for Hearing on Proposal to Withdraw Approval of New Drug Application

In a notice (DESI 8245) published in the FEDERAL REGISTER of October 15, 1970 (35 F.R. 16194) the Commissioner of Food and Drugs announced his conclusions pursuant to the evaluation of a

report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the drug described below, stating that the drug is regarded as possibly effective for the labeled indications. The possibly effective indications have been reclassified as lacking substantial evidence of effectiveness in that no new evidence of effectiveness of the drug has been submitted within the period provided.

NDA 8-245; Benacine Tablets containing diphenhydramine hydrochloride and scopolamine hydrobromide; Parke, Davis & Co., Joseph Campau at the River, Detroit, Mich. 48232.

Therefore, notice is given to Parke, Davis & Co. and to any interested person who may be adversely affected, 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 and all amendments and supplements thereto on the grounds that new information before him with respect to the drug, evaluated together with the evidence available to him when the application was approved, shows there is a lack of substantial evidence that the drug will have all the effects it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling.

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 will give the applicant, and any interested person who would be adversely affected by an order withdrawing such approval, an opportunity for a hearing to show why approval of the new drug application should not be withdrawn. Any related drug for human use, not the subject of an approved new drug application, may be affected by this action.

Within 30 days after publication hereof in the FEDERAL REGISTER such persons are 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:

1. To avail themselves of the opportunity for a hearing; or
2. Not to avail themselves of the opportunity for a hearing.

If such persons elect not to avail themselves of the opportunity for a hearing, the Commissioner without further notice will enter a final order withdrawing approval of the new drug application. Failure of such persons to file a written appearance of election within said 30 days will be construed as an election by such persons not to avail themselves of an opportunity for a hearing.

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.

If such persons elect to avail themselves of the opportunity for a hearing, they must file, within 30 days after publication of this notice in the FEDERAL REGISTER, a written appearance requesting the hearing, giving the reasons for approval of the new drug application should not be withdrawn, together with a well organized and full factual analysis of the clinical and other investigational data they are prepared to prove in support of their opposition.

A request for 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. When it clearly appears from the data in the application and from the reasons and factual analysis in the request for the hearing that no genuine and substantial issue of fact precludes the withdrawal of approval of the application, the Commissioner will enter an order on these data, making findings and conclusions on such data.

If a hearing is requested and justified by the response to this notice, 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. (35 F.R. 7250, May 8, 1970; 35 F.R. 16631, Oct. 27, 1970.)

Received 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. 1052-5, as amended; 21 U.S.C. 355) and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: February 3, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-2133 Filed 2-11-72; 8:50 am]

[DESI 12467; Docket No. FDC-D-415; NDA 12-467]

SMITH, KLINE & FRENCH LABORATORIES

Combination Containing Trimeprazine Tartrate, Phenylpropanolamine Hydrochloride, and Acetaminophen for Oral Use; Notice of Opportunity for Hearing on Proposal To Withdraw Approval of New Drug Application

In an announcement (DESI 12467) published in the FEDERAL REGISTER of May 22, 1971 (36 F.R. 9344), the Commissioner of Food and Drugs announced his conclusions pursuant to the evaluation of a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on Coplexen Liquid (NDA 12-467) containing trimeprazine tartrate, phenylpropanolamine hydrochloride, and