

Data available to the Commissioner fail to establish the absence of unsafe residues of this product in the edible tissue of food producing animals when this product is administered in accordance with the conditions of use prescribed, recommended, or suggested in its labeling.

In accordance with the provisions of section 512 of the act (21 U.S.C. 360b), the Commissioner will give the applicant and any other interested persons who would be adversely affected by an order withdrawing such approval, an opportunity for a hearing at which time such persons may produce evidence and arguments to show why approval of NADA No. 11-346V should not be withdrawn. Promulgation of the order will cause any drug similar in composition to the above cited drug product and recommended for similar conditions of use to be a new animal drug for which an approved new animal drug application is not in effect. Any such drug then on the market will be subject to appropriate regulatory action.

Within 30 days after publication hereof in the FEDERAL REGISTER, such persons are required to file with the Hearing Clerk, Food and Drug Administration, 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 animal 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 the 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 which the Commissioner finds is 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 a written appearance requesting a hearing and giving the reasons why approval of the new animal drug application should not be withdrawn together with a well-organized and full-factual analysis of the clinical and other investigational data they are prepared to prove in support of their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 to the grounds for this notice. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact which 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 there is no genuine and substantial issue

of fact which precludes the withdrawal of approval of the application, the Commissioner will enter an order stating his findings and conclusions on such data. If a hearing is requested and is justified by the response to this notice, the issues will be defined, an administrative law judge will be named, and he shall issue a written notice of the time and place at which the hearing will commence.

Response to this notice will be available for public inspection 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. 512, 82 Stat. 343-351; 21 U.S.C. 360b) and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: December 4, 1972.

SAM D. FINE,
Associate Commissioner for
Compliance.

[FR Doc.72-21304 Filed 12-11-72; 8:53 am]

[DESI 1002; Docket No. FDC-D-211; NDA 10-740]

PIPRADROL HYDROCHLORIDE

Drugs for Human Use; Drug Efficacy Study Implementation; Follow-Up Notice

In a notice published in the FEDERAL REGISTER of October 21, 1970 (35 F.R. 16421), the Commissioner of Food and Drugs offered Merrell-National Laboratories (formerly Wm. S. Merrell Co.), Division of Richardson-Merrell, Inc., 110 Amity Road, Cincinnati, OH 45215, holder of the following new drug application, and other interested persons, an opportunity for a hearing on a proposal to withdraw approval of the application and all amendments and supplements thereto. The basis of the proposal was a lack of substantial evidence that the drug will have the effects it purported or was represented to have under the conditions of use prescribed, recommended, or suggested in its labeling.

NDA 10-740; Alertonic Elixir containing piperadrol hydrochloride, thiamine hydrochloride, riboflavin, pyridoxine hydrochloride, niacinamide, choline, inositol, calcium glycerophosphate, alcohol, maganous sulfate, magnesium acetate, zinc acetate, and ammonium molybdate.

Data submitted thereafter by the NDA holder did not constitute substantial evidence of effectiveness of the combination drug product. Subsequently the NDA holder submitted a supplement for a reformulated product and revised labeling. The reformulated product is a liquid dosage form of piperadrol hydrochloride, a drug for which, in solid dosage form, a Drug Efficacy Study announcement was published on May 15, 1970 (35 F.R. 7616, DESI 9366).

In reviewing available data pertaining to piperadrol hydrochloride, in liquid or solid dosage form, the Food and Drug Ad-

ministration concludes that the drug is less than effective (possibly effective) for fatigue, apathy, or lack of energy and activity accompanying mild depression or occurring by themselves without sufficient physical cause.

Any data submitted in response to this notice to support indications for which a drug is classified as other than effective must be previously unsubmitted and include data from adequate and well-controlled clinical investigations (identified for ready review) and described in § 130.12(a)(5) of the regulations published in the FEDERAL REGISTER of May 8, 1970 (35 F.R. 7250). Carefully conducted and documented clinical studies obtained under uncontrolled or partially controlled situations are not acceptable as a sole basis for approval of claims of effectiveness, but such studies may be considered on their merits for corroborative support of efficacy and evidence of safety.

All identical, related, and similar drug products, not the subject of an approved new drug application, are covered by the 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 the Food and Drug Administration, Bureau of Drugs, Office of Compliance (BD-300), 5600 Fishers Lane, Rockville, MD 20852.

Communications forwarded in response to this notice should be identified with the reference number DESI 1002, directed to the attention of the appropriate office listed below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852: Supplements (Identify with NDA number): Office of Scientific Evaluation (BD-100), Bureau of Drugs.

Original new drug applications (Identify as such): Office of Scientific Evaluation (BD-100), Bureau of Drugs.

All other communications regarding this announcement: Drug Efficacy Study Implementation Project Office (BD-60), Bureau of Drugs.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-53, as amended; 21 U.S.C. 352, 355) and the Administrative Procedure Act (5 U.S.C. 554), and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: December 7, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-21312 Filed 12-8-72; 10:00 am]

[DESI 10721; Docket No. FDC-D-234; NDA 10-721]

PFIZER, INC.

Combination Drug Containing Mecizine and Niacin; Notice of Withdrawal of Approval

A notice was published in the FEDERAL REGISTER of September 12, 1970 (35 F.R.