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at which time such persons may produce evidence and arguments to show why approval of NADA No. 11-346V should not be withdrawn.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appearance requesting a hearing and giving the reasons why approval of the new animal drug application should not be withdrawn together with a well-organized and full-factual analysis of the clinical and other investigational data they are prepared to prove in support of their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 that 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 pipradrol 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 pipradrol 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 pipradrol hydrochloride, in liquid or solid dosage form, the Food and Drug Administration 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 Meclizine and Niacin; Notice of Withdrawal of Approval

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

14411) extending to the holder of the new drug application listed below, 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 the listed application and all amendments and supplements thereto. The basis of the proposed action was the lack of substantial evidence that (1) the drug was effective as a fixed combination in the treatment of, vertigo, Meniere's syndrome, and in conditions of apprehension and mental confusion that may arise from niacin deficiency and (2) each component of the drug contributes to the total effects claimed.

NDA 10-721, Antivert Tablets containing 12.5 milligrams meclizine hydrochloride and 50 milligrams niacin; J. B. Roerig and Co., Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017.

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 Pfizer nor any other interested person has 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 an opportunity for hearing.

Currently pending before the Administration is a supplemental application submitted by the NDA holder to provide for a reformulated product. Agency action on that supplement will be taken upon completion of review of the data submitted.

Accordingly, 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 respect to the combination drug, evaluated together with the evidence available to him when the application was approved, there is a lack of substantial evidence that the combination 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 findings, approval of the above-listed new drug application and all amendments and supplements thereto pertaining to the combination drug product is withdrawn effective on the date of publication hereof in the FEDERAL REGISTER. Shipment in interstate commerce of the above drug product or of any identical, related, or similar product, not the subject of an approved new drug application is henceforth unlawful.

Dated: December 7, 1972.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.72-21313 Filed 12-8-72;10:00 am]

HOFFMAN-TAFF, INC.

Aklo-3 Premix Medicated; Notice of Withdrawal of Approval of New Animal Drug Application

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512, 82 Stat. 343-51; 21 U.S.C. 360b) and under authority delegated to the Commissioner (21 CFR 2.120), the following notice is issued:

At the request of Hoffman-Taff, Inc., Post Office Box 1246 S.S.S., Springfield, MO 65805, and in accordance with § 135.-28(d) (21 CFR 135.28(d)), notice is given that approval of NADA (new animal drug application) No. 40-298V for Aklo-3 Premix Medicated, which contains aklomode (2-chloro-4-nitrobenzamide) and roxarsone (3-nitro-4-hydroxyphenylarsonic acid), is hereby withdrawn.

Effective date. This order shall be effective upon publication in the FEDERAL REGISTER (12-12-72).

(Sec. 512, 82 Stat. 343-51; 21 U.S.C. 360b)

Dated: November 30, 1972.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.72-21303 Filed 12-11-72;8:48 am]

HOFFMAN-TAFF, INC.

Broiler Premix Medicated; Notice of Withdrawal of Approval of New Animal Drug Application

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512, 82 Stat. 343-51; 21 U.S.C. 360b) and under authority delegated to the Commissioner (21 CFR 2.120), the following notice is issued:

At the request of Hoffman-Taff, Inc., Post Office Box 1246 S.S.S., Springfield, MO 65805, and in accordance with § 135.-28(d) (21 CFR 135.28(d)), notice is given that approval of NADA (new animal drug application) No. 38-740V for Broiler Premix Medicated, which contains erythromycin thiocyanate, is hereby withdrawn.

Effective date. This order shall be effective upon publication in the FEDERAL REGISTER (12-12-72).

(Sec. 512, 82 Stat. 343-51; 21 U.S.C. 360b)

Dated: November 30, 1972.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.72-21302 Filed 12-11-72;8:48 am]

OVER-THE-COUNTER TOPICAL ANALGESIC, INCLUDING ANTIRHEUMATIC, OTIC, BURN, SUNBURN TREATMENT AND PREVENTION DRUG PRODUCTS

Safety and Efficacy Review; Request for Data and Information

The FDA is undertaking a review of all over-the-counter (OTC) drug products currently marketed in the United States, to determine that these OTC products are safe and effective for their labeled indications. This review will utilize expert panels working with FDA personnel.

A notice outlining procedures for this review was published in the FEDERAL REGISTER of May 11, 1972 (37 F.R. 9464).

To facilitate this review and a determination as to whether an OTC drug for human use is generally recognized as safe and effective and not misbranded under its recommended conditions of use, and to provide all interested persons an opportunity to present for the consideration of the reviewing experts the best data and information available to support the stated claims for all dosage forms of topical analgesic, including antirheumatic, otic, burn, sunburn prevention and treatment drug products, the administration invites submission of data, published and unpublished, and other information pertinent to all active ingredients utilized in such preparations.

FDA is aware that the following active ingredients are used in such products and has conducted a literature search on each of them.

Benzocaine.	Menthyl Anthranilate.
Camphor.	Methyl Salicylate.
Capsicum Oleoresin.	Oil of Mustard.
Cinoxate.	Oxybenzone.
Digalloyl Trioleate.	p-Aminobenzoate.
Dioxybenzone.	Red Veterinary Petrolatum.
Eucalyptol.	Sulisobenzone.
Glyceryl p-Aminobenzoate.	Thymol.
Homosalate.	Titanium Dioxide.
Lidocaine.	Zinc Oxide.
Menthol.	

FDA's literature search covered the United States of America literature and other leading English language literature published since 1950 from the following sources:

Medlars (NLM and SUNY).
FDA Clinical Experience Abstracts.
Quarterly Cumulative Index Medicus.
Current List of Medical Literature.
Index Medicus.
JAMA Subject Index.
DeHaen Drugs in Use.
RINGDOC.
VETDOC.
International Pharmaceutical Abstracts.
Excerpta Medica.
Abstracts of World Medicine.
Biological Abstracts.
Chemical Abstracts.

The bibliography of the literature search is available to interested persons.

Interested persons are also invited to submit data on any other active ingredients for topical analgesic, including antirheumatic, otic, burn, sunburn prevention and treatment drug products.