

6. Chlx Mix;
7. ABD Pheasant Premix;
8. Special Stress Vitamin Premix, Poultry Finisher Premix No. 19, and Poultry Finisher Premix No. 17;
9. Poultry and Turkey Premix, Zacky Broiler Premix, Poultry and Turkey Premix No. 2524, Kobernik-Barnes Laying Mash Premix, Bell Starter Broiler Premix, Honaker Thrifty Premix, Custom Turkey Premix, Yukon Utility Poultry Premix, and Special Poultry and Turkey Premix;

10. P.B. Turkey Fortifier;
11. Procaine Penicillin "10";
12. Broiler Premix;
13. Procaine Penicillin "4";
14. Custom Premix WC2;
15. Vilas Chicken Premix No. 1;
16. Chick Starter Premix; and
17. Stress Premix.

B. DESI 0180NV; Premixes containing Penicillin and other Drugs.

1. Premix No. 677 Medicated;
2. Ballard Laying Premix Medicated;
3. Custom Vitamin Premix for Pig Starter "A";
4. Acco Cage Layer Vitamin Premix Medicated;
5. Vilas Turkey Premix No. 1;
6. Premix No. 675 Medicated;
7. Comfort Poultry and Turkey Medicated;
8. Mid Continent Poultry Vitamin Premix Medicated; and
9. Special Starter Broiler Grower Premix Medicated.

C. DESI 0175V; Certain Feed Premixes containing Manganese Bacitracin and other drugs.

1. Medicated Swine Premix "H" 12139;
2. Custom Swine Premix;
3. Special Turkey Grow Premix;
4. Turkey Starter;
5. Custom Mix WC3;
6. Antibiotic Premix;
7. Hog Grower-Finisher Premix 7251;
8. Turkey Starter Premix No. 4076;
9. Special Swine Premix;
10. Turkey Grower Finisher;
11. Ark-La Layer Breeder Premix;
12. P.G.C. Prime Broiler Premix Starter Finisher No. 2800 Medicated; and

13. Swine Premix No. 11136.
D. DESI 0181NV; Certain Premixes containing Bacitracin.

1. Turkey Grower Premix No. 13410;
2. P-G-Q Turkey Premix ZB;
3. Turkey Starter Premix No. 10735;
4. Johnson Turkey No. 1;
5. 1-66 Pullet Starter Premix;
6. Kimber No. 112-M Starter Grower Premix;
7. Chick Starter and Grower F-1163;
8. Broiler Finisher Premix No. 11043;
9. Starter & Broiler Premix;
10. Grower Premix;
11. Vilas Turkey Premix No. 3;
12. Custom Vitamin & Antibiotic Premix for Swine Finishing Feed A; and
13. Premix No. 12 Medicated.

E. DESI 0176NV; Certain Feed Premixes containing Oxytetracycline.

1. Calf Premix 10108; and
2. Pig Supplement Premix Medicated.
F. DESI 0064; Certain Premixes containing Bacitracin.

1. 4-66 Turkey Grower Premix;
2. Turkey Grower Premix 6357;
3. Turkey Grower Premix;
4. Turkey Premix 6937;
5. Turkey Starter Premix No. 13680;
6. Turkey Grower Premix;
7. Broiler Premix 6398;
8. Turkey Finisher Premix 6391;
9. Amerine Turkey Starter Premix;
10. Turkey Starter Premix;
11. Turkey Starter Premix;
12. Turkey Starter Premix 6361;
13. Turkey Starter Premix P.P.A. No. 211;
14. Special Pullet Grow Premix;
15. Chick Starter-Grower Premix 6370;
16. Direct Services Turkey Premix;
17. Starter Broiler Grower Premix 7153;
18. Turkey Starter Premix; and
19. Turkey Starter Premix.

Said announcements provided the manufacturer and all interested parties a 6-month period in which to submit new animal drug applications.

Hoffman-La Roche, Inc., did not submit new animal drug applications for the above named products. However, they responded to said announcements by advising the Commissioner that these premixes have been discontinued and that these drugs are no longer marketed.

Therefore, based on information before him, the Commissioner concludes that the named premixes are adulterated within the meaning of section 501(a)(5) or (6) of the Federal Food, Drug, and Cosmetic Act, in that they are not the subject of approved new animal drug applications pursuant to section 512 of the Act. Notice is given to Hoffman-La Roche, Inc., and all interested persons that all stocks of the above named drugs for use in animal feed and all animal feeds bearing or containing these products within the jurisdiction of the Federal Food, Drug, and Cosmetic 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 (secs. 501(a)(5), (6), 512, 52 Stat. 1049) as amended, 82 Stat. 343-351; 21 U.S.C. 351(a)(5) and (6), 360(b) and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: December 15, 1972.

SAM D. FINE,
Associate Commissioner for
Compliance.

[FR Doc. 72-22089 Filed 12-22-72; 8:47 am]

[DESI 6566; Docket No. FDC-D-557; NDA No. 10-723]

MERCK SHARP & DOHME

Benactyzine Hydrochloride; Opportunity for Hearing on Proposal To Withdraw Approval of New Drug Application

In a notice (DESI 6566) published in the FEDERAL REGISTER of June 25, 1970 (35 F.R. 10394), the Commissioner of Food and Drugs announced his conclu-

sions 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 and lacking substantial evidence of effectiveness for the various 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 pursuant to the notice.

NDA 10-723; Suavitil tablets containing 1 milligram benactyzine hydrochloride per tablet; Merck Sharp & Dohme, Division Merck & Co., Inc., West Point, Pa. 19486.

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 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 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 Ad-

ministrative 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. 72-22094 Filed 12-22-72; 8:47 am.]

[DESI 11524; Docket No. FDC-D-544;
NDA 11-524]

STEROID COMBINATION PREPARATION FOR ORAL USE

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 drug:

Prednal tablets containing prednisone, mephenesin, and mephobarbital; USV Pharmaceutical Corp., 1 Scarsdale Road, Tuckahoe, N.Y. 10707 (NDA 11-524).

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 this fixed combination drug will have the effect that it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling and that each component of such combination contributes to the total effects claimed.

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, 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