

The determination of the Secretary on the application will be published in the **FEDERAL REGISTER**. A separate notice will be sent to each interested party of record.

If circumstances warrant it, a public hearing will be held at a convenient time and place which will be announced.

The lands involved in the application are:

ST. JOE NATIONAL FOREST

HIGH MOUNTAIN LAKES, MALLARD-LARKINS AREA—BOISE MERIDIAN

Devil's Lake

T. 42 N., R. 6 E.,
Sec. 25, E $\frac{1}{2}$ SW $\frac{1}{4}$ NE $\frac{1}{4}$, W $\frac{1}{2}$ SE $\frac{1}{4}$ NE $\frac{1}{4}$, NW $\frac{1}{4}$ NE $\frac{1}{4}$ SE $\frac{1}{4}$, and NE $\frac{1}{4}$ NW $\frac{1}{4}$ SE $\frac{1}{4}$.

Total area—80 acres.

Fawn Lake

T. 42 N., R. 7 E.,
Sec. 25, S $\frac{1}{2}$ SW $\frac{1}{4}$ NE $\frac{1}{4}$ NE $\frac{1}{4}$, S $\frac{1}{2}$ SE $\frac{1}{4}$ NW $\frac{1}{4}$ NE $\frac{1}{4}$, E $\frac{1}{2}$ SW $\frac{1}{4}$ NE $\frac{1}{4}$, E $\frac{1}{2}$ W $\frac{1}{2}$ SW $\frac{1}{4}$ NE $\frac{1}{4}$, and SE $\frac{1}{4}$ NE $\frac{1}{4}$.

Total area—80 acres.

Skyland Lake

T. 42 N., R. 7 E.,
Sec. 25, S $\frac{1}{2}$ SW $\frac{1}{4}$ NW $\frac{1}{4}$ SW $\frac{1}{4}$ and W $\frac{1}{2}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$;
Sec. 26, SE $\frac{1}{4}$ NE $\frac{1}{4}$ SE $\frac{1}{4}$ and SE $\frac{1}{4}$ SE $\frac{1}{4}$;
Sec. 35, NE $\frac{1}{4}$ NE $\frac{1}{4}$ NE $\frac{1}{4}$, and N $\frac{1}{2}$ NW $\frac{1}{4}$ NE $\frac{1}{4}$ NE $\frac{1}{4}$;
Sec. 36, N $\frac{1}{2}$ NW $\frac{1}{4}$ NW $\frac{1}{4}$ NW $\frac{1}{4}$.

Total area—95 acres.

Northbound Lake

T. 42 N., R. 7 E.,
Sec. 34, SE $\frac{1}{4}$ SW $\frac{1}{4}$ NW $\frac{1}{4}$, SW $\frac{1}{4}$ SE $\frac{1}{4}$ NW $\frac{1}{4}$, W $\frac{1}{2}$ SE $\frac{1}{4}$ NE $\frac{1}{4}$ NW $\frac{1}{4}$, W $\frac{1}{2}$ NE $\frac{1}{4}$ NE $\frac{1}{4}$ SW $\frac{1}{4}$, NW $\frac{1}{4}$ NE $\frac{1}{4}$ SW $\frac{1}{4}$, N $\frac{1}{2}$ SW $\frac{1}{4}$ NE $\frac{1}{4}$ SW $\frac{1}{4}$, E $\frac{1}{2}$ NW $\frac{1}{4}$ SW $\frac{1}{4}$, and E $\frac{1}{2}$ NW $\frac{1}{4}$ NW $\frac{1}{4}$ SW $\frac{1}{4}$.

Total area—70 acres.

Hero Lake and Gnat Lake

T. 42 N., R. 7 E.,
Sec. 21, S $\frac{1}{2}$ S $\frac{1}{2}$ SW $\frac{1}{4}$ NW $\frac{1}{4}$ and W $\frac{1}{2}$ SW $\frac{1}{4}$;
Sec. 28, N $\frac{1}{2}$ NE $\frac{1}{4}$ NW $\frac{1}{4}$ NW $\frac{1}{4}$ and NW $\frac{1}{4}$ NW $\frac{1}{4}$ NW $\frac{1}{4}$.

Total area—105 acres.

Craig Lake

T. 42 N., R. 7 E.,
Sec. 23, S $\frac{1}{2}$ NE $\frac{1}{4}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$, E $\frac{1}{2}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$, SE $\frac{1}{4}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$, and SW $\frac{1}{4}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$;
Sec. 33, NW $\frac{1}{4}$ NE $\frac{1}{4}$ NW $\frac{1}{4}$ and N $\frac{1}{2}$ NW $\frac{1}{4}$ NW $\frac{1}{4}$.

Total area—80 acres.

Heart Lake

T. 42 N., R. 7 E.,
Sec. 33, SW $\frac{1}{4}$ NE $\frac{1}{4}$, S $\frac{1}{2}$ NW $\frac{1}{4}$ SE $\frac{1}{4}$ NE $\frac{1}{4}$, SW $\frac{1}{4}$ SE $\frac{1}{4}$ NE $\frac{1}{4}$, E $\frac{1}{2}$ SE $\frac{1}{4}$ NW $\frac{1}{4}$, SW $\frac{1}{4}$ SE $\frac{1}{4}$ NW $\frac{1}{4}$, NE $\frac{1}{4}$ NE $\frac{1}{4}$ SW $\frac{1}{4}$, N $\frac{1}{2}$ SE $\frac{1}{4}$ NE $\frac{1}{4}$ SW $\frac{1}{4}$, W $\frac{1}{2}$ NW $\frac{1}{4}$ NE $\frac{1}{4}$ SE $\frac{1}{4}$, and NW $\frac{1}{4}$ SE $\frac{1}{4}$.

Total area—145 acres.

Mudd Lake

T. 42 N., R. 7 E.,
Sec. 29, S $\frac{1}{2}$ SW $\frac{1}{4}$ NW $\frac{1}{4}$ NE $\frac{1}{4}$, N $\frac{1}{2}$ SW $\frac{1}{4}$ NE $\frac{1}{4}$, SW $\frac{1}{4}$ SW $\frac{1}{4}$ NE $\frac{1}{4}$, N $\frac{1}{2}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$ NE $\frac{1}{4}$, E $\frac{1}{2}$ NE $\frac{1}{4}$ SE $\frac{1}{4}$ NW $\frac{1}{4}$, and NE $\frac{1}{4}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$ NW $\frac{1}{4}$.

Total area—47.50 acres.

Larkins Lake

T. 42 N., R. 7 E.,
Sec. 29, SW $\frac{1}{4}$ NE $\frac{1}{4}$ SW $\frac{1}{4}$, SW $\frac{1}{4}$ SE $\frac{1}{4}$ NE $\frac{1}{4}$ SW $\frac{1}{4}$, SE $\frac{1}{4}$ NW $\frac{1}{4}$ SW $\frac{1}{4}$, NE $\frac{1}{4}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$, NE $\frac{1}{4}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$, and SE $\frac{1}{4}$ SW $\frac{1}{4}$.

Total area—75 acres.

NOTICES

Bacon Lake

T. 42 N., R. 9 E.,
Sec. 24, SW $\frac{1}{4}$ SW $\frac{1}{4}$ NE $\frac{1}{4}$, SW $\frac{1}{4}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$ NE $\frac{1}{4}$, SE $\frac{1}{4}$ SE $\frac{1}{4}$ NW $\frac{1}{4}$, E $\frac{1}{2}$ NE $\frac{1}{4}$ SW $\frac{1}{4}$, N $\frac{1}{2}$ NW $\frac{1}{4}$ SE $\frac{1}{4}$, SW $\frac{1}{4}$ NW $\frac{1}{4}$ SE $\frac{1}{4}$, and NW $\frac{1}{4}$ SE $\frac{1}{4}$ NW $\frac{1}{4}$ SE $\frac{1}{4}$.

Total area—75 acres.

Forage Lake

T. 42 N., R. 9 E.,
Sec. 13, NE $\frac{1}{4}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$, N $\frac{1}{2}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$, SE $\frac{1}{4}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$, SE $\frac{1}{4}$ SW $\frac{1}{4}$, SW $\frac{1}{4}$ NW $\frac{1}{4}$ SW $\frac{1}{4}$ SE $\frac{1}{4}$, and W $\frac{1}{2}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$ SE $\frac{1}{4}$.

Total area—65 acres.

Halo Lake

T. 42 N., R. 9 E.,
Sec. 13, S $\frac{1}{2}$ NE $\frac{1}{4}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$, SE $\frac{1}{4}$ NW $\frac{1}{4}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$, and S $\frac{1}{2}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$;
Sec. 24, N $\frac{1}{2}$ NE $\frac{1}{4}$ NE $\frac{1}{4}$.

T. 42 N., R. 10 E.,
Sec. 18, SW $\frac{1}{4}$ NW $\frac{1}{4}$ of lot 4 and SW $\frac{1}{4}$ of lot 4;

Sec. 19, NW $\frac{1}{4}$ of lot 1.

Total area—69.10 acres.

The above areas aggregate 946.60 acres more or less within Shoshone County, Idaho.

CLEARWATER NATIONAL FOREST

HIGH MOUNTAIN LAKES, MALLARD-LARKINS AREA—BOISE MERIDIAN

T. 41 N., R. 7 E.,
Sec. 23, E $\frac{1}{2}$ E $\frac{1}{2}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$, W $\frac{1}{2}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$, and W $\frac{1}{2}$ E $\frac{1}{2}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$.

T. 42 N., R. 7 E.,
Sec. 34, E $\frac{1}{2}$ NE $\frac{1}{4}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$, NE $\frac{1}{4}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$, NW $\frac{1}{4}$ SW $\frac{1}{4}$ SE $\frac{1}{4}$, and N $\frac{1}{2}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$ SE $\frac{1}{4}$;

Sec. 36, S $\frac{1}{2}$ SW $\frac{1}{4}$ SE $\frac{1}{4}$ NE $\frac{1}{4}$, SW $\frac{1}{4}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$ NE $\frac{1}{4}$, NW $\frac{1}{4}$ NE $\frac{1}{4}$ SE $\frac{1}{4}$, and W $\frac{1}{2}$ NE $\frac{1}{4}$ NE $\frac{1}{4}$ SE $\frac{1}{4}$.

T. 41 N., R. 8 E., Unsurveyed, but which when surveyed will be:

Sec. 19, W $\frac{1}{2}$ E $\frac{1}{2}$ NE $\frac{1}{4}$ SE $\frac{1}{4}$, W $\frac{1}{2}$ NE $\frac{1}{4}$ SE $\frac{1}{4}$, NE $\frac{1}{4}$ SW $\frac{1}{4}$ SE $\frac{1}{4}$, and E $\frac{1}{2}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$;

Sec. 20, W $\frac{1}{2}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$;
Sec. 29, SW $\frac{1}{4}$ NE $\frac{1}{4}$ NW $\frac{1}{4}$ SW $\frac{1}{4}$, S $\frac{1}{2}$ NW $\frac{1}{4}$ NW $\frac{1}{4}$ SW $\frac{1}{4}$, SW $\frac{1}{4}$ NW $\frac{1}{4}$ SW $\frac{1}{4}$, SW $\frac{1}{4}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$, and W $\frac{1}{2}$ SE $\frac{1}{4}$ NW $\frac{1}{4}$ SW $\frac{1}{4}$;

Sec. 30, S $\frac{1}{2}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$;
Sec. 31, NE $\frac{1}{4}$ NE $\frac{1}{4}$ NE $\frac{1}{4}$ and N $\frac{1}{2}$ SE $\frac{1}{4}$ NE $\frac{1}{4}$ NE $\frac{1}{4}$;

Sec. 32, W $\frac{1}{2}$ NW $\frac{1}{4}$ NW $\frac{1}{4}$ NW $\frac{1}{4}$.

The above areas aggregate approximately 185 acres located in Shoshone and Clearwater Counties, Idaho.

RICHARD H. PETRIE,
Chief,

Division of Technical Services.

[FR Doc.72-2761 Filed 2-24-72; 8:46 am]

National Park Service

[Order No. 66, Amdt. No. 1]

CHIEF, DIVISION OF PROPERTY MANAGEMENT AND GENERAL SERVICES ET AL.

Limitations on Redlegation of Authority

Order No. 66, Revised, approved October 29, 1971, and published in the **FEDERAL REGISTER** of November 4, 1971 (36 F.R. 21218) set forth in section 2 the limitations on redelegations of authority.

Section 2 is hereby amended to read as follows:

Sec. 2. *Redelegation.* Subject to the following exceptions; the Directors of

the Regions may, in writing redelegate to their officers and employees, the authority delegated in this order and may authorize written redelegations of such authority:

(1) Master Plan approval authority may not be redelegated.

(2) In the Regional Offices, procurement and contracting authority in excess of \$2,000 may only be redelegated to the Chief, Division of Property Management and General Services and the Chief, Office of Finance and Control. Authority to contract for supplies, equipment and services may be redelegated by the Directors to Superintendents as follows: Superintendents, Grade GS-12 and below not to exceed \$2,000; Superintendents, Grade GS-13 not to exceed \$50,000; Superintendents, Grade GS-14 not to exceed \$100,000; Superintendents, Grade GS-15 not to exceed \$200,000. The limitations in this subsection (2) of section 2 apply only to open market or nonmandatory sources of supply. Employees and officers who are otherwise authorized may continue to issue orders to GSA Centers and sources under established Federal Supply Schedules of Contracts in amounts exceeding \$2,000.

(3) Authority to approve land acquisition priorities may not be redelegated. Authority to execute the land acquisition program, including contracting for acquisition of lands and related property, and options and offers to sell related thereto, may be redelegated only to the Chief land acquisition officer in the Regional Office and field land acquisition officers.

Each redelegation shall be published in the **FEDERAL REGISTER**.

(205 DM, as amended; 245 DM, as amended; sec. 2 of Reorganization Plan No. 3 of 1950)

Dated: February 16, 1972.

GEORGE P. HARTZOG, Jr.,
Director, National Park Service.

[FR Doc.72-2783 Filed 2-24-72; 8:48 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[DESI 1786]

CERTAIN DRUGS FOR HUMAN USE CONTAINING ORGANIC NITRATES

Efficacy Study Implementation

The Food and Drug Administration has evaluated reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following "coronary vasodilator" drug:

1. Metamine Tablets containing troinitrate phosphate; Charles Pfizer & Co., Inc., 235 East 42d Street, New York, N.Y. 10017 (NDA 8-294).

2. Metamine Sustained Tablets containing troinitrate phosphate; Charles Pfizer & Co., Inc (NDA 10-131).

3. Nitretamine and Nitretamine-10 Tablets containing troinitrate phosphate; E. R. Squibb & Sons, Inc., Georges

Road, New Brunswick, N.Y. 08903 (NDA 9-196).

4. Metamine with Butabarbital Tablets containing troinitrate phosphate and butabarbital; Charles Pfizer & Co., Inc. (NDA 8-798).

5. Metamine with Butabarbital Sustained Tablets containing troinitrate phosphate and butabarbital; Charles Pfizer & Co. (NDA 11-420).

6. Penta-Erythritol Tetranitrate Nyscaps containing pentaerythritol tetranitrate; Nysco Laboratories, Inc., 34-24 Vernon Boulevard, Long Island City, N.Y. 11106 (NDA 12-317).

7. Timed Pentrylate Stronger Capsules containing pentaerythritol tetranitrate; Fellows-Testagar, Division Fellows Medical Manufacturing Co., Inc., 12741 Capital Avenue, Oak Park, Mich. 48237 (NDA 12-646).

8. Pentestian-80 Stancaps containing pentaerythritol tetranitrate; Standex Laboratories, Inc., 585 West Second Avenue, Columbus, Ohio 43215 (NDA 12-488).

9. Pentritol Tempules containing pentaerythritol tetranitrate; Armour Pharmaceutical Co., Box 511, Kankakee, Ill. 60901 (NDA 12-311).

10. Duotrate 45 Plateau Caps containing pentaerythritol tetranitrate; Marion Laboratories, Inc., 10236 Bunker Ridge Road, Kansas City, Mo. 64137 (NDA 12-748).

11. Petritrate SA Tablets containing pentaerythritol tetranitrate; Warner-Chilcott Laboratories, Division Warner-Lambert Pharmaceutical Co., 201 Tabor Road, Morris Plains, N.J. 07950 (NDA 11-109).

12. Peritrate Tablets containing pentaerythritol tetranitrate; Warner-Chilcott Laboratories (NDA 8-072).

13. Metranil Duracap containing pentaerythritol tetranitrate; Meyer Laboratories, Inc., 22601 Mack Avenue, St. Clair Shores, Mich. 48080 (NDA 12-529).

14. Tetrasule-80 Timesules containing pentaerythritol tetranitrate; Storck Pharmaceuticals, Inc., Division Arnar-Stone Laboratories, Inc., 601 East Kensington Road, Mount Prospect, Ill. 60056 (NDA 12-450).

15. Duotrate 45 with Phenobarbital Plateau Caps containing pentaerythritol tetranitrate and phenobarbital; Marion Laboratories, Inc. (NDA 12-749).

16. Pentaerythritol tetranitrate and phenobarbital; Nysco Laboratories, Inc. (NDA 12-538).

17. Peritrate with Phenobarbital SA Tablets containing pentaerythritol tetranitrate and phenobarbital; Warner-Chilcott Laboratories (NDA 12-266).

18a. Pencard and Pencard No. 2 Tablets containing pentaerythritol tetranitrate;

b. Pencard with Phenobarbital and Pencard No. 2 with Phenobarbital Tablets containing pentaerythritol tetranitrate and phenobarbital; and

c. Pencard-A Capsules containing pentaerythritol tetranitrate and theophylline; Cole Pharmacal Co., Inc., 3721 Laclede Avenue, St. Louis, Mo. 63108 (NDA 8-852).

19. Pentraline Tablets containing pentaerythritol tetranitrate, sodium buta-

barbital, and reserpine; McNeil Laboratories, Inc., Camp Hill Road, Fort Washington, Pa. 19034 (NDA 10-972).

20. Maxitate Tablets containing mannitol hexanitrate; Strassenburgh Prescription Products Division, Pennwalt Corp., 755 Jefferson Road, Rochester, N.Y. 14623 (NDA 1-786).

21. Nitranitol Tablets containing mannitol hexanitrate; The Wm. S. Merrell Co., Division of Richardson-Merrell, Inc., 110 East Amity Road, Cincinnati, Ohio 45215 (NDA 3-193).

22. Mannitol Hexanitrate Tablets; S. F. Durst & Co., Inc., 5317 North Third Street, Philadelphia, Pa. 19120 (NDA 4-730).

23. Nitranitol with Phenobarbital Tablets containing mannitol hexanitrate and phenobarbital; the Wm. S. Merrell Co. (NDA 4-353).

24. Maxitrate with Phenobarbital Tablets containing mannitol hexanitrate and phenobarbital; Strassenburgh Prescription Products (NDA 2-779).

25. Nitroglyn Sustained Action Tablets containing nitroglycerin; Key Pharmaceuticals, Inc., 50 Northwest 176th Street, Post Office Box 3670, Norland Beach, Miami, Fla. 33169 (NDA 9-599).

26. Isordil Tablets containing isosorbide dinitrate; Ives Laboratories, Inc., 685 Third Avenue, New York, N.Y. 10017 (NDA 12-093).

27. Isordil Tembids containing isosorbide dinitrate; Ives Laboratories, Inc. (NDA 12-882).

28. Isordil Sublingual Tablets containing isosorbide dinitrate; Ives Laboratories, Inc. (NDA 12-940).

29. Isordil with Phenobarbital Tablets containing isosorbide dinitrate and phenobarbital; Ives Laboratories, Inc. (NDA 12-093).

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). The effectiveness classification and marketing status are described below.

On April 19, 1966, a statement of policy (21 CFR 3.21) was published by the Food and Drug Administration concerning the status of these drugs and seven other drugs (amyl nitrite, erythryl tetranitrate, potassium nitrite, sodium nitrite, inositol hexanitrate, octyl nitrite, and nitroglycerine) offered for use as "coronary vasodilators." This DESI notice preempts that statement insofar as any inconsistency may exist between the two. The statement of policy, § 3.21, remains in effect otherwise. The effectiveness of the other drugs named therein is under review.

A. *Effectiveness classification.* The Food and Drug Administration has considered the Academy's reports, as well as other available evidence, and concludes that:

1. Sublingual tablets of isosorbide dinitrate are (a) probably effective for the treatment of an angina pectoris attack and for prophylaxis in situations likely to provoke such attacks when they are administered by the sublingual route; and (b) possibly effective for these same indications when administered orally, i.e., swallowed.

2. Conventional or extended action oral dosage forms of troinitrate phosphate,

pentaerythritol tetranitrate, mannitol hexanitrate, and isosorbide dinitrate, alone or in combination, are possibly effective for their labeled indications relating to the management, prophylaxis, or treatment of anginal attacks.

3. Sustained action tablets of nitroglycerin are possibly effective for indications relating to the management, prophylaxis, or treatment of anginal attacks.

B. *Marketing status of drugs for which the highest classification is possibly effective.* Marketing of such drugs with labeling which recommends or suggests their use for indications for which they have been classified as possibly effective may be continued for 6 months as described in paragraphs (d), (e), and (f) of the notice "Conditions for Marketing New Drugs Evaluated in Drug Efficacy Study," published in the FEDERAL REGISTER July 14, 1970 (35 F.R. 11273).

C. *Marketing status of the drug for which the highest classification is probably effective.* 1. Marketing of such drug with labeling which recommends or suggests its use for indications for which it has been classified as probably effective or possibly effective may be continued for 12 months, or 6 months, respectively, as described in paragraphs (c), (d), (e), and (f) of the notice "Conditions for Marketing New Drugs Evaluated in Drug Efficacy Study," published in the FEDERAL REGISTER July 14, 1970 (35 F.R. 11273).

2. Within 60 days from publication hereof in the FEDERAL REGISTER, the holder of any approved new drug application for such drug is requested to submit a supplement to his application to provide for revised labeling as needed which, taking into account the comment of the Academy, furnishes adequate information for safe and effective use of the drug; is in accord with the guidelines for uniform labeling published in the FEDERAL REGISTER of February 6, 1970 (21 CFR 3.74); and recommends use of the drug for the probably effective indications as follows: (The possibly effective indications may also be included for 6 months.)

INDICATIONS

Isosorbide dinitrate (sublingual tablets).

When taken by the sublingual route, isosorbide dinitrate is indicated for the treatment of acute anginal attack and for prophylaxis in situations likely to provoke such attacks.

The supplement should be submitted under the provisions of § 130.9 (d) and (e) of the new drug regulations (21 CFR 130.9 (d) and (e)) which permit certain changes to be put into effect at the earliest possible time, and the revised labeling should be put into use within the 60-day period.

3. After 60 days following publication hereof in the FEDERAL REGISTER, any such drug on the market without an approved new drug application and shipped within the jurisdiction of the Federal Food, Drug, and Cosmetic Act should be labeled in accord with this notice.

A copy of the Academy's report has been furnished to each firm referred to above. Communications forwarded in response to this announcement should

be identified with the reference number DESI 1786, directed to the attention of appropriate office listed below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852:

Supplements (identify with NDA number): Office of Scientific Evaluation (BD-100), Bureau of Drugs.

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

Requests for the Academy's report: Drug Efficacy Study Information Control (BD-87), 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 under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: February 22, 1972.

JAMES D. GRANT,
Deputy Commissioner
of Food and Drugs.

[FR Doc. 72-2798 Filed 2-24-72; 8:51 am]

[Docket No. FDC-D-274; NADA No. 9-664V]

ARMOUR PHARMACEUTICAL CO.

Dynafac; Notice of Withdrawal of Approval of New Animal Drug Application

A notice of opportunity for a hearing was published in the FEDERAL REGISTER of April 29, 1971 (36 F.R. 8065). Said notice gave the named holders of various NADA's (new animal drug applications) 30 days in which to request an opportunity for a hearing.

Armour Pharmaceutical Co., Box 3113, Omaha, Nebr. 68108 the holder of NADA No. 9-644V for the product Dynafac, filed a written appearance requesting an opportunity for a hearing. However, said written appearance was not supported by a well-organized and full-factual analysis of clinical and other investigational data to support their opposition to the grounds for said notice. Therefore, the firm's request for a hearing is denied.

The Commissioner of Food and Drugs, based on his evaluation of information before him with respect to said drug, finds that there is a lack of substantial evidence that the drug will have the effect it purports and is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling. Accordingly, the Commissioner concludes that approval of said new animal drug application should be withdrawn. Therefore, 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), approval of NADA No. 9-664V, including all amendments and supple-

ments thereto, is hereby withdrawn effective on the date of publication of this document.

Dated: February 16, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc. 72-2787 Filed 2-24-72; 8:49 am]

[Docket No. FDC-D-433; NDA No. 10-891]

AYERST LABORATORIES

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

In a notice (DESI 10891) published in the FEDERAL REGISTER of September 1, 1970 (35 F.R. 13853), 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 was regarded as possibly effective 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 within the period provided.

NDA 10-891; Suvren Tablets containing captodiame hydrochloride; Ayerst Laboratories, 685 Third Avenue, New York, N.Y. 10017.

Therefore, notice is given to Ayerst Laboratories, 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 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 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 why 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 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. When it clearly appears from the data in the applications 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. 1052-53, as amended; 21 U.S.C. 355) and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: February 17, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

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