



of a new 56-foot length overall steel vessel to engage in the fishery for salmon, tuna, and crabs.

Notice is hereby given, pursuant to the provisions of 16 U.S.C. 742c, Fisheries Loan Fund Procedures (50 CFR Part 250, as revised), and Reorganization Plan No. 4 of 1970, that the above-entitled application is being considered by the National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Department of Commerce, Interior Building, Washington, DC 20235. Any person desiring to submit evidence that the contemplated operation of such vessel will cause economic hardship or injury to efficient vessel operators already operating in that fishery must submit such evidence in writing to the Director, National Marine Fisheries Service, within 30 days from the date of publication of this notice. If such evidence is received it will be evaluated along with such other evidence as may be available before making a determination that the contemplated operation of the vessel will not cause such economic hardship or injury.

JAMES F. MURDOCK,  
Chief,  
Division of Financial Assistance.  
[FR Doc. 71-691 Filed 1-18-71; 8:45 am]

## DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration  
[DESI 11-3157]

### CERTAIN DRUG PRODUCTS CONTAINING NEOMYCIN SULFATE

#### Drugs for Veterinary Use; Drug 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 oral and/or topical drug preparations:

1. Neomycin Veterinary; packets contain 10 grams or 25.6 grams of neomycin base (as neomycin sulfate); by The Gland-O-Lac Co., a subsidiary of E. R. Squibb & Sons, Inc., Agricultural Research Center, Three Bridges, N.J. 08887.

2. Neo-My-Sol Solution; each cubic centimeter contains neomycin sulfate equivalent in activity to 80 milligrams of neomycin base; by The Gland-O-Lac Co., a subsidiary of E. R. Squibb & Sons, Inc.

3. Gland-O-Lac Neomycin Veterinary; each 10 oz. packet contains 140 grams of neomycin base; by The Gland-O-Lac Co., a subsidiary of E. R. Squibb & Sons, Inc.

4. Neomycin Sulfate Penick; each pound contains 325 grams of neomycin sulfate (equivalent to 227.5 grams neomycin base per pound); by S. B. Penick & Co., Antibiotics Feed Division, 100 Church Street, New York, N.Y. 10007.

5. Neomycin Solution; each cubic centimeter contains 140 milligrams of

neomycin base U.S.P. (equivalent to approximately 200 milligrams neomycin sulfate); by Diamond Laboratories, Inc., 2538 Southeast 43d Street, Des Moines, Iowa 50304.

6. Neomycin Solution; each cubic centimeter contains 200 milligrams of neomycin sulfate, commercial grade, equivalent to 140 milligrams neomycin base; by The S. E. Massengill Co., Veterinary Division, Bristol, Tenn. 37620.

7. Neomycin Sulfate, Sterile; each cubic centimeter contains 140 milligrams of neomycin sulfate; by Maurry Biological Co., Inc., 6109 Southwestern Avenue, Los Angeles, Calif. 90047.

8. Biosol; each pound contains 10 grams neomycin sulfate (equivalent to U.S.P. activity) equivalent to 7 grams neomycin base; by The Upjohn Company, Kalamazoo, Mich. 49001.

The Academy evaluated these drugs as probably effective for use in the control and treatment of bacterial enteritis in cattle, horses, sheep, goats, swine, dogs, cats, turkeys, chickens, ducks, and mink, and as a wet antibacterial dressing in swine, cattle, sheep, and dogs. The Academy stated: (1) Claims made regarding "for prevention of" or "to prevent" should be replaced with "as an aid in the control of" or "to aid in the control of"; (2) the labeling should warn that treated animals must actually consume enough medicated feed or medicated water to provide a therapeutic dose under the conditions that prevail—as a precaution, the label should state the desired oral dose per unit of animal weight per day for each species as a guide to effective use of the preparation in drinking water or feed; (3) the labeling should warn that oral neomycin sulfate is not indicated if animals have developed a septicemia as systemic levels of neomycin are not obtained because of the low degree of absorption from the gastrointestinal tract; (4) the recommended dosages are inconsistent; (5) the labeling should caution that cutaneous sensitivity lesions have been reported (applicable when labeled for use as wet antibacterial dressing); (6) the disease claims for preparations administered orally must be restricted to disease involving the gastrointestinal tract because of the chemical and pharmacological properties of neomycin sulfate; and (7) each disease claim should be properly qualified as "appropriate for use in (name of disease) caused by pathogens sensitive to (name of drug)," and if the disease claim cannot be so qualified the claim must be dropped.

The Food and Drug Administration concurs with the Academy's findings.

This evaluation is concerned only with these drugs' effectiveness and safety to the animal to which administered. It does not take into account the safety for food use of food derived from drug-treated animals. Nothing herein will constitute a bar to further proceedings with respect to questions of safety of the drugs or their metabolites as residues in food products derived from treated animals.

This announcement is published (1) to inform manufacturers of the subject

drugs of the findings of the Academy and the Food and Drug Administration and (2) to inform all interested persons that such articles may be marketed provided they are the subject of approved new animal drug applications and otherwise comply with all other requirements of the Federal Food, Drug and Cosmetic Act.

Manufacturers of the subject drugs are provided 6 months from the date of publication hereof in the FEDERAL REGISTER to submit adequate documentation in support of the labeling used.

Each holder of a new animal drug application which became effective prior to October 10, 1962, is requested to submit updating information as needed to make the application current with regard to manufacture of the drug, including information on drug components and composition and also including information regarding manufacturing methods, facilities and controls, in accordance with the requirements of section 512 of the act.

Written comments regarding this announcement, including requests for an informal conference, may be addressed to the Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20852.

The manufacturers of the listed drugs have been mailed a copy of the NAS/NRC report. Any other interested person may obtain a copy by writing to the Food and Drug Administration, Press Relations Staff, 200 C Street SW., Washington, D.C. 20204.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 512, 52 Stat. 1050-51, as amended, 82 Stat. 343-51; 21 U.S.C. 352, 350b) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: January 5, 1971.

SAM D. FINE,  
Associate Commissioner  
for Compliance.

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[Docket No. FDC-D-135; NDA Nos. 0-604  
0-751]

### CARTER-WALLACE, INC.

#### Nair Depilatory; Notice of Withdrawal of Approval of New-Drug Appli- cations

A notice of opportunity for hearing on the proposed withdrawal of approval of new-drug applications No. 0-604 and No. 0-751, both for the drug Nair Depilatory, and all amendments and supplements thereto held by Wallace Laboratories, a division of Carter-Wallace, Inc., 767 Fifth Avenue, New York, N.Y. 10022, was published in the FEDERAL REGISTER of February 6, 1970 (35 F.R. 2674-2696).

Carter-Wallace, Inc., filed a letter requesting a 60-day extension of the time permitted to request a hearing and requested further information on both new-drug applications. Subsequently, the firm filed a letter agreeing to withdrawal