

by McDonald Laboratories without an effective new drug application and Frommes Method, Inc., did not have a new drug application for the repacked articles.

LIBELED: 5-2-60, Dist. Minn.

CHARGE: 505(a)—the articles were new drugs within the meaning of the law, and applications filed pursuant to the law were not effective with respect to the drugs.

DISPOSITION: 6-14-60. Default—destruction.

6202. Pega Palo. (F.D.C. No. 42518. S. No. 14-916 P.)

QUANTITY: 68 ½-lb. paper bags at Canton, Ohio.

SHIPPED: On an unknown date from the Dominican Republic.

LABEL IN PART: "PEGA PALO Bring to a boil one gallon of water, add one teaspoon of powder, cook for one hour in stainless pot with lid, take one ounce with each meal."

RESULTS OF INVESTIGATION: The article was being distributed by Durwood Drew Roberts during the course of lectures given by him at Canton, Ohio.

LIBELED: 12-2-58, N. Dist. Ohio.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use as a gland aid, which was the condition for which it was offered orally by Durwood Drew Roberts; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application pursuant to law was not effective with respect to such drug.

DISPOSITION: On 1-3-59, Durwood Drew Roberts, claimant, filed an answer denying that the article was misbranded or a new drug. In addition, the claimant filed a motion to quash service on the grounds that the "Summons on Libel of Information and Forfeiture" and unsigned "Libel of Information" was served in the M. Dist. Pa., by the United States Marshal of that district and was therefore without force and effect. The court overruled the motion to quash on 3-6-59.

Thereafter, the Government filed requests for admissions, which were not answered, and on 6-13-60, a default decree was entered ordering the destruction of the article.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

DRUG FOR VETERINARY USE

6203. Trace's Poultry and Animal Booster. (F.D.C. No. 44410. S. No. 69-006 P.)

QUANTITY: 37 3½-lb. tins at Slayton, Minn., in possession of the Slayton Drug Store.

SHIPPED: 1-23-60, from Madison, S. Dak.

LABEL IN PART: (Tin) "Trace's Hi-Potency Water Soluble Poultry and Animal Booster * * * Guaranteed Analysis Penicillin 3.25 gm. per lb. Streptomycin Sulphate 2 gm. per lb. Terramycin Oxytetracycline Hydrochloride 1.25 gm. per lb. Vitamin B₁₂ 1 mg. per lb. Vitamin A 500,000 USP Units per lb. Vitamin D₃ 400,000 ICU per lb. Niacin 2,000 mg. per lb. Riboflavin 500 mg. per lb. Pantothenic Acid 500 mg. per lb. Menadione (Vitamin K) 100 mg. per lb. Pyridoxine Hydrochloride 100 mg. per lb. Thiamine Hydrochloride B₁ 2,000

mg. per lb. Alphatocopherol (Vit. E) 200 mg. per lb. Ascorbic Acid (Vit. C) 200 mg. per lb."

RESULTS OF INVESTIGATION: The article was shipped unlabeled as described above and after its receipt by the dealer at Slayton, Minn., the tins containing the article were labeled with the above-mentioned labels.

LIBELED: 3-28-60, Dist. Minn.

CHARGE: 502(a)—the label of the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment and preventive of all diseases in poultry, hogs, calves, lambs, dogs, cats, and mink; and 502(1)—the article was a drug composed in part of penicillin and streptomycin sulfate and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507 in that certification of the article under the above-mentioned label had not been obtained.

DISPOSITION: 5-11-60. Consent—claimed by Tracy L. Hafner, t/a Tracy Hafner Slayton Drug Store, and released for relabeling.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6204. Seconal Sodium capsules and amphetamine tablets. (F.D.C. No. 43585. S. No. 66-005 P.)

QUANTITY: 50,000 tablets of amphetamine and 1,000 capsules of Seconal Sodium at Stamford, Conn.

SHIPPED: On or about 10-8-59, from New Jersey to Connecticut, by Charles W. Christiansen, also known as Charlie Benjamin.

LIBELED: On or about 10-8-59, Dist. Conn.

CHARGE: 502(b)—the articles failed to bear labels containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents in terms of weight, measure, or numerical count; 502(d)—the *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, and their label failed to bear the name, and quantity, or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; 502(e)(1)—the labels of the articles failed to bear the common or usual names of the articles; 502(f)(1)—the labeling of the articles failed to bear adequate directions for use and they were not exempt from such requirement since the articles were in possession of persons who were not regularly and lawfully engaged in the manufacture, transportation, storage or wholesale distribution of prescription drugs and since the articles were not to be dispensed as required by 503(b)(1); and 503(b)(4)—the articles were subject to 503(b)(1) and their labeling failed to bear the mandatory statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 6-28-60. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

6205. Various drugs. (F.D.C. No. 44590. S. Nos. 19-841 R, 19-843 R, 19-846 R, 19-851/4 R, 19-856 R, 19-858/9 R, 19-861 R, 19-864 R, 19-868/70 R, 19-872 R, 19-875 R, 19-877 R, 19-881 R, 21-067/71 R, 21-073/4 R, 21-077 R, 21-079 R, 21-083 R, 21-087/8 R, 21-093/4 R, 21-097 R, 21-099/100 R, 21-103 R, 21-107 R, 21-110/11 R, 21-113 R, 21-117/19 R, 21-122 R.)

*See also Nos. 6202, 6204.