NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION*

6085. Pabacaine. (F.D.C. No. 44147. S. No. 66–712 P.)

QUANTITY: 1,550 ampuls at Los Angeles, Calif., in possession of Brown Pharmaceutical Co.

SHIPPED: 10–19–59, from Philadelphia, Pa., by the Philadelphia Ampule Laboratories, Inc.

LABEL IN PART: (Ampul) "5 cc Ampule Pabacaine each ampule contains: Pabacaine 100 mg. Ascorbic Acid 50 mg. * * * Glutamic Acid 50 mg * * * Exclusive U.S. Distributors–The Brown Pharmaceutical Co., Los Angeles, Calif. 9966."

ACCOMPANYING LABELING: Brochures entitled "Research On The Use of H3 In The Treatment Of Old Age And Other Diseases."

RESULTS OF INVESTIGATION: The brochures were printed locally for the dealer.

LIBELED: 12–31–59, S. Dist. Calif.

CHARGE: 502(a)—while held for sale, the labeling which accompanied the article contained statements that the article appeared to make old people younger than their natural age; usually they experienced a marked improvement in general health; some elderly patients found their new hair growth was youthfully dark in color; in certain kinds of baldness, hair growth was restored dramatically; often the patients showed a marked improvement in their skin texture; a large percentage became strong enough to resume work again; many people crippled with arthritis had been strikingly helped; heart action and blood circulation were usually much improved; treatment had cured many cases of stomach ulcers; profound effects were shown in the central nervous system, with some men and women achieving greater improvement in eyesight and hearing; the brain functions frequently improved, with most elderly patients exhibiting notable strengthening of memory and attention; and treatment was also given to younger men and women suffering from arthritis, neuralgia, stomach ulcers, premature baldness, and other ailments; which statements were false and misleading since the article was not capable of fulfilling the promises of benefit stated and implied; 505(a)—the article was a new drug within the meaning of the law, since its safety for use in the treatment of old age and other conditions mentioned in its accompanying labeling had not been established and an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: 1–26–60. Default—destruction.

6086. Hope's Worm-Rid. (F.D.C. No. 43458. S. No. 69–683 P.)

QUANTITY: 12 cases, each containing 1 display ctn. which contained 12 btls., at Minneapolis, Minn.

SHIPPED: 9–4–59, from Clayton, Mo., by Hope Co.

LABEL IN PART: (Btl.) "Hope's Worm-Rid 4 ounces * * * A Safe * * * Syrup for the eradication of Pin and Roundworms Each Teaspoonful (5 cc) Contains: Piperazine Citrate Equivalent to 500 mg. Piperazine Hexahydrate * * * The Hope Company, Clayton 5, Missouri."

LIBELED: 10–1–59, Dist. Minn.

---

*See also No. 6081.

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 11-13-59. Default—destruction.

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

DRUG FOR VETERINARY USE

6087. Entero-Sol Powder. (F.D.C. No. 43323. S. No. 71-708 P.)

QUANTITY: 10 cases, 12 btls. each, at Gainesville, Ga.

SHIPPED: 5-25-59, from Vineland, N.J., by Eastern Laboratories, Inc.

LABEL IN PART: (Btl.) "Rollins Entero-Sol Powder For the treatment of Enteritis, Air-Sac, Colds and Blue Comb in Chickens and Turkeys * * * Contents 156 Gms. Each Pound Contains: 24,000,000 units of Penicillin G. Potassium 24,000 mg. of Dihydrostreptomycin Base as sulphate, and 3,600 mg. of Menadione Sodium Bisulfite (Synthetic Vitamin K) In addition each pound contains: * * * Manufactured for Ben C. Rollins Company 602 Grove Street, Gainesville, Georgia."

LIBELED: 8-4-59, N. Dist. Ga.

CHARGE: 502(a)—when shipped, the label of the article contained false and misleading representations that the article was an adequate and effective treatment for colds in chickens and turkeys; and 502(l)—the article consisted in part of penicillin and dihydrostreptomycin and it was not from a batch with respect to which a certificate or release had been issued.

DISPOSITION: 9-23-59. Default—destruction.

DRUG IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6088. Dextro-amphetamine sulfate tablets and amphetamine sulfate tablets. (F.D.C. No. 43391. S. Nos. 73-809/10 P.)

QUANTITY: 5 1,000-tablet btls. at Bay Saint Louis, Miss.

SHIPPED: Prior to 7-7-59, from outside the State of Mississippi.

RESULTS OF INVESTIGATION: The bottles were unlabeled. Analysis showed that 3 bottles contained *dextro-amphetamine sulfate tablets* and 2 bottles contained *amphetamine sulfate tablets.*

LIBELED: 7-13-59, S. Dist. Miss.

CHARGE: 502(b)—while held for sale, the article failed to bear (1) a label containing 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 count; 502(e)(1)—the label failed to bear the common or usual name of the drug; 502(f)(1)—the label of the article failed to bear adequate directions for use and it was not exempt from such requirement since it was in possession of a person or persons not authorized to dispense a prescription drug; and 503(b)(4)—the label of the article failed to bear the statement "Caution—Federal law prohibits dispensing without prescription."

DISPOSITION: 8-18-59. Default—destruction.