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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

**NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG,
AND COSMETIC ACT**

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2351-2400

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

J. DONALD KINGSLEY, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., October 29, 1948.

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NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

2351. Doctor's Prescription Rx 7-11. U. S. v. 11 Bottles, etc. (F. D. C. 23882. Sample Nos. 16802-K to 16804-K, incl.)

LIBEL FILED: October 30, 1947, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about May 8, June 5, and July 8 and 19, 1947, by Murrell Laboratories, from Norman, Okla.

PRODUCT: 11 1-gallon bottles, 6 cases, each containing 12 1-pint bottles, and 81 cases, each containing 12 8-ounce bottles, of *Doctor's Prescription Rx 7-11* at Milwaukee, Wis.

NATURE OF CHARGE: Section 505 (a), the article was a drug which should not have been introduced or delivered for introduction into interstate commerce, since it was a new drug and an application filed pursuant to the law was not effective with respect to the drug. It was a new drug in that its composition consisting essentially of a colored solution containing alcohol, glycerin, sulfanilamide, and sulfathiazole, was not generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions suggested in its labeling, i. e., "Doctor's

*For presence of a habit-forming narcotic without warning statement, see No. 2357; deceptive packaging and imitation of another drug, No. 2376; labeling information not likely to be understood by the ordinary individual under customary conditions of purchase and use, No. 2352; cosmetic, subject to the drug provisions of the Act, No. 2351.

Prescription Seven-11 Guarantee Guaranteed to remove loose dandruff or your money will be refunded. This preparation is not sold as a hair tonic, but is a special prepared medicine and sold only to remove itching, scaly dandruff. Caution: For External Use Only Directions for Treatment Use once a day for four days, then once every other day for one week, or as needed. Apply freely and massage into the scalp. For best results shampoo and dry hair thoroughly before first application. Murrell Laboratories Norman, Oklahoma."

DISPOSITION: February 5, 1948. Default decree of condemnation and destruction.

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

2352. Misbranding of penicillin sodium. U. S. v. 77 Cartons, etc. (F. D. C. No. 23648. Sample Nos. 88001-H, 88002-H, 88004-H to 88006-H, incl.)

LABEL FILED: August 20, 1947, Southern District of New York.

ALLEGED SHIPMENT: On or about May 26 and June 3 and 5, 1947, from Elkins, W. Va., by the Golden Clinic Pharmacy; from Ganado, Ariz., by the Sage Memorial Hospital; from Bradford, Pa., by the Bradford Hospital; from West Chester, Pa., by the Chester County Hospital; from Corpus Christi, Tex., by the Sizer Hospital; and from Washington, D. C., by the Garfield Memorial Hospital. These were returned shipments.

PRODUCT: 77 cartons, each containing 5 200,000-unit vials, and 294 cartons, each containing 5 500,000-unit vials, of *penicillin sodium* at New York, N. Y.

NATURE OF CHARGE: Misbranding, Section 502 (1), the article was represented as a drug composed wholly of penicillin sodium, a derivative of a kind of penicillin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to the law; Section 502 (c), the name and place of business of the manufacturer, packer, or distributor, which is required by law to appear on the label, was not placed on the label in such terms as to render such information likely to be understood by the ordinary individual under customary conditions of purchase and use, since the name and address borne on the label "Proctor Laboratories, 475 Fifth Avenue, New York 17, U. S. A." did not inform the reader that they were not the name and address of the manufacturer but were those of the distributor; and, Section 502 (a), the statements "Lot No. 75," "Lot No. 76," "Lot No. 82," "Lot No. 85," "Lot No. 86" appearing on the labels of various portions of the article were false and misleading, since these statements represented and suggested that the article had been certified by the Food and Drug Administration, Federal Security Agency, under such identifying numbers, when such was not the case.

Further misbranding, Section 502 (a), the labeling of a portion of the article consisting of a circular entitled "Penicillin Sodium-Proctor (Crystalline)" enclosed with the article, giving indications, contraindications, method of preparation of penicillin for treatment, directions for administration, dosage, storage directions, and description of the packaging, was misleading, since such labeling created the impression that the article was crystalline penicillin sodium, whereas the article was amorphous penicillin sodium; and, Section 502 (f) (1), the labeling of two lots of the article failed to bear adequate directions for use.

DISPOSITION: February 6, 1948. Default decree of condemnation. The product was ordered sold to the Heyden Chemical Corp., conditioned that it be redissolved and reprocessed under the supervision of the Food and Drug Administration.

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

2353. Action to enjoin and restrain the interstate shipment of West's Imported Sea Vegetable Tablets and various other drugs. U. S. v. Mineralized Foods, Inc. (Sea Vegetation Import Co.), and Nathan S. West. Consent decree granting injunction. (Inj. No. 167.)

COMPLAINT FILED: November 21, 1947, District of Maryland, against Mineralized Foods, Inc., also trading as the Sea Vegetation Import Co., Baltimore, Md., and Nathan S. West, president and general counsel of the corporation.

NATURE OF CHARGE: That the defendant had been from time to time introducing and delivering for introduction into interstate commerce quantities of drugs

*See also No. 2352.