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.)

LIBEL 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.

composed of so-called "sea vegetation," imported from various foreign countries, in combination with drug chemicals and vitamins, and marketed under the names of *West's Imported Sea Vegetable Tablets, West's Sea-Vo-Kra Tablets, West's D-X Tablets, West's Kalseom Tablets, West's Sodeom Tablets, Ferrolene Tablets, F Y A Tablets, West-Aid Tablets, West-Lax, West's Sea Vegecene (Powder), Mar-Glo Tablets, Ten In One, West-Co, West's Vi-Linn (Choc. Flavored), West's Vi-Linn (Banana Flavored), West's Imported Sea Vegetation Vitaminized,* and *West's Pro-Pi-Pa Tablets.* The products were misbranded within the meaning of Section 502 (f) (1), in that their labeling failed to bear adequate directions for use, since their labeling contained no statement or reference to diseases or conditions for which they were to be used and failed to bear adequate directions for use in all conditions for which they were recommended and suggested in their advertising. The advertising referred to was disseminated and sponsored by the defendants and consisted of a series of lectures conducted by Nathan S. West throughout the United States, and the distribution of the booklet "Excerpts from 'Diet Daily or Die Early'" and other media, in which he recommended and suggested the drugs for use in the treatment, prevention, or cure of arthritis, neuritis, angina pectoris, apoplexy, heart diseases, cerebral hemorrhages, arteriosclerosis, high and low blood pressure, pain in the bones and bone marrow, brain and nerve disturbances, lassitude, nausea, vomiting, headache, sleeplessness, loss of appetite, damage to teeth, cancer, tooth decay, rickets, scurvy, softening of the bones, hairlessness, paralysis, bone and joint disease, malnutrition, leg weakness, roup, stiff neck, beriberi, black tongue, ulcerated gums, falling teeth, sores, dropsy, rheumatism, heart condition, nervousness, frequent colds, kidney conditions, constipation, migraine headache, skin conditions, poor eyesight, hay fever, asthma, sinus infection, continual tiredness, underweight and overweight, stomach and intestinal ulcers, anemia, general weakness, diabetes, painful and irregular menstruation, dropsy, swollen limbs, gall bladder conditions, supersensitivity, brittle fingernails, stiff joints, poor memory, poor circulation, mucous condition, low energy, glandular disturbances, varicose veins, epilepsy, palsy, cataracts, catarrhal conditions, tooth malformation, excessive acid, stomach trouble, and other degenerative diseases; for use as an aid in lengthening life; for providing resistance to infection and epidemics; for improving the health of people suffering from a wide variety of nutritional diseases; for helping nutritionally to relieve, ease, and lessen excessive acid pains in arthritis; for increasing resistance to the causative factors of disease; and for aiding in preventing flu, such as was prevalent in the 1918 epidemic.

The complaint alleged also that the defendants had been repeatedly informed that the drugs manufactured and distributed in interstate commerce by them were misbranded; that this information had been imparted to the defendants through a number of seizure actions, as well as by opportunities afforded them to present their views in respect to alleged criminal violations as provided for in Section 305 of the Act; that there had been much correspondence and numerous interviews between the defendants and officials of the Food and Drug Administration involving the labeling of the drugs; that at the inception of the defendants' operations, Mineralized Foods, Inc., through its president, Nathan S. West, sought to promote the sales of the drugs in question through false and misleading representations placed on the labels of the drugs; that as the result of regulatory action these representations were removed from the labels and incorporated in booklets accompanying the articles when shipped in interstate commerce; and that continued seizures of the articles misbranded in such manner had resulted in the defendants turning to the promotion of sales of the drugs by means of the stated oral advertising and the distribution of the above-mentioned booklet and other media.

PRAYER OF COMPLAINT: That the defendants he perpetually enjoined from commission of the acts complained of.

DISPOSITION: March 15, 1948. The defendants having filed an answer denying the allegations of the complaint, but having consented subsequently to the entry of a decree, the court issued an order enjoining the defendants from directly or indirectly introducing or delivering for introduction in interstate commerce, any drug the labeling of which omitted in whole or in part the disease or condition and the directions for use for the disease or condition for which the drug was intended to be used, recommended, or suggested in the oral or written advertising disseminated or sponsored by or on behalf of the defendants, or any drug which was otherwise misbranded within the meaning of Section 502 (f) (1).