

first dose (1 tablet) in the morning and second dose (1 tablet) in the evening after meals on 2 days of each week. Skip 2 or 3 days between days of taking Atabrine. Start to take Atabrine on first day you are in a malarial area and continue to take it as long as you are in a malarial area" and (case label) "Malaria (chills and fever) (prevention) * * * ." [Directions substantially the same as those on vial.]

Amphetamine sulfate tablets, misbranding, Section 502 (j), the article would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, as follows: (Vial label) "Directions: Take 1 tablet if sleepy or 2 tablets if extremely fatigued. Repeat this dose in 6 hours if necessary, but do not take more than 6 tablets in any 1 week" and (kit label) [Directions substantially the same as those on vial.]

Wound tablets, misbranding, Section 502 (j), the article would be dangerous to health when used in the dosage prescribed, recommended, and suggested in the labeling, as follows: (Vial label) "Use—when hit: take all tablets. Drink lots of water * * *" and (case label) "Wounds—take internally by mouth, followed by a large amount of water, 8 Sulfadiazine tablets."

DISPOSITION: November 14, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to the Department of Hospitals of the City of New York, for use in the medical care and treatment of sick persons, conditioned that the recipient remove the articles from the kits and containers and relabel them in compliance with the law, or that the recipient itself distribute and administer the articles to patients, under the supervision of proper medical authorities.

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

2155. Misbranding of Tru-Lax Tablets, Natural B Complex Tablets, Nurex Tablets, Vitamin Minerals Tablets, Sleen Tablets, Sleen Pellets, and Sleen Herb Tea. U. S. v. 14 Bottles, etc. (F. D. C. No. 14661. Sample Nos. 81582-F to 81585-F, incl., 81587-F to 81589-F, incl.)

LABEL FILED: On or about December 26, 1944, Western District of Missouri.

ALLEGED SHIPMENT: On or about October 23 and 25, 1944, by the Pavo Co., from Minneapolis, Minn.

PRODUCT: 14 bottles of *Tru-Lax Tablets*, 9 bottles of *Natural B Complex Tablets*, 21 bottles of *Nurex Tablets*, 21 bottles of *Vitamin Minerals Tablets*, 34 bottles of *Sleen tablets*, 22 bottles of *Sleen Pellets*, and 21 bottles of *Sleen Herb Tea* at Kansas City, Mo., together with a number of circulars entitled "Slenderize by the 'Sleen' System" and "Are You Below Par?"

The *Sleen Herb Tea* was in 2½-ounce-size bottles, and the other products were contained in 65-, 75-, 80-, 85-, 150-, 185-, 250-, 270-, and 285-tablet-size bottles. Examination showed that the *Tru-Lax Tablets* contained laxative drugs, such as cascara sagrada, aloe, and senna, flavored with anise, peppermint, and juniper berries; that the *Natural B Complex Tablets* contained vitamin B₁, riboflavin, and niacin; that the *Nurex Tablets* contained vitamin B₁, calcium, magnesium, iron, sodium, and potassium; that the *Vitamin Minerals Tablets* contained calcium, phosphorus, and iron compounds, vitamin C and organic matter, and traces of iodides and copper; that the *Sleen Tablets* contained compounds of calcium, phosphorus, iron, and iodine, and green plant matter; that the *Sleen Pellets* consisted of pink compressed tablets such as would be made from milk sugar and phytolacca berry juice; and that the *Sleen Herb Tea* consisted essentially of a large proportion of senna leaves with other plant material, including fennel seed, anise, peppermint and bark, and stem and leaf fragments.

NATURE OF CHARGE: *Tru-Lax Tablets*, misbranding, Section 502 (a), certain statements in the labeling were false and misleading since they represented and suggested that the article would be efficacious in the treatment of headaches, constipation, auto-intoxication, nervousness, tiredness, discharge from the ears, nose, throat, navel, and rectum, and many other common ailments; and that the article would cleanse the alimentary canal, regulate the flow of bile

* See also Nos. 2151, 2153, 2154.

from the liver, cleanse and strengthen the kidneys, purify the blood stream, and tone up the entire system. The article would not fulfill the promises of benefit stated and implied. Further misbranding, Section 502 (f) (2), the labeling failed to bear adequate warning against unsafe duration of administration, since the warning "Laxatives should not be taken regularly over an extended period of time as they may become a habit" had been made inadequate by the direction "Directions for best results. For the first 10 to 15 days on retiring take one or two tablets with a full glass of water; then as needed."

Natural B Complex Tablets, misbranding, Section 502 (a), certain statements in the labeling were false and misleading since the article would not fulfill the promises of benefit stated and implied. The statements represented and implied that the article would be of value to persons who were below par and always tired, sleepy, and listless; and that it would make one feel like a new person and enable one to live his life in a way to enjoy it.

Nurex Tablets, misbranding, Section 502 (a), certain statements in the labeling were false and misleading since they represented and suggested that the article was of nutritional and therapeutic value because of the presence of sodium, potassium, and magnesium; that it would be of value to ones who were nervous, irritable, despondent, blue, and unable to sleep nights; and that it would relax taut nerves. The article was of no nutritional or therapeutic value by reason of the minerals mentioned, and it would not be effective to fulfill the promises of benefit stated and implied.

Vitamin Minerals Tablets, misbranding, Section 502 (a), certain statements in the labeling were false and misleading since they represented and suggested that the article would enable persons to keep healthy, young, and beautiful, and to keep their skin, hair, and nails in youthful condition. The article would not fulfill the promises of benefit stated and implied.

Sleen Tablets, *Sleen Pellets*, and *Sleen Herb Tea*, misbranding, Section 502 (a), certain statements in the labeling were false and misleading since they represented and suggested that the articles would be effective to reduce the weight of the user, to provide important amounts of essential food elements, to supply nutritional balance, to build physically while getting rid of excess weight, and to help in gradually changing body processes to a normal state. The article would not be effective for such purposes.

The *Natural B Complex Tablets*, *Nurex Tablets*, and *Vitamin Minerals Tablets* were alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: October 18, 1945. Jack G. Pavo, trading as the Pavo Co., having appeared as claimant and having filed an answer denying that the products were misbranded, and the court having found that the articles were misbranded within the meaning of the law, judgment of condemnation was entered. The products were ordered released under bond to be brought into compliance with the law by relabeling or destruction, as the circumstances might require, under the supervision of the Food and Drug Administration.

2156. Misbranding of West's preparations. U. S. v. 56 Bottles * * *. (F. D. C. No. 22747. Sample Nos. 90326-H to 90336-H, incl.)

LIBEL FILED: March 28, 1947, District of Columbia.

ALLEGED SHIPMENT: On or about March 24, 1947, and on prior dates by Mineralized Foods, Inc., from Baltimore, Md.

PRODUCT: 62 bottles of *West's Imported Sea Vegetable Tablets*, 42 bottles of *West's Sea Vegecene (Powder)*, 38 bottles of *Ferrolene Tablets*, 42 bottles of *West's Sodeom Tablets*, 20 bottles of *West's Sodeom (Vitaminized Sodeom Tablets)*, 45 bottles of *West-Aid Tablets*, 32 bottles of *West's Kalseom Tablets*, 16 bottles of *West's Sea-Vo-Kra Tablets*, 16 bottles of *West's Imported Sea Vegetation Tablets (Vitaminized with added Vitamin A)*, 35 bottles of *F Y A Tablets*, and 46 bottles of *West's Pro-Pi-Ya Tablets*.

The products were located at Washington, D. C. The *West's Sea Vegecene (Powder)* was contained in 5- and 8-ounce-size bottles, and the other products were contained in 100-, 240-, 400-, or 500-tablet-size bottles. The products consisted preponderantly of sea vegetation, such as kelp, seaweed, etc., with added vitamins in some instances.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use in arthritis, neuritis, angina