

been removed from the incomplete kits. These kits contained a bottle of *mild tincture of iodine*. The kits were intended to be incorporated into certain emergency equipment for utilization by the Army.

LABEL, IN PART: (First aid kits) "First Aid Instructions Vest, Emergency, Sustenance Type C-1."

NATURE OF CHARGE: *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: (case and vial label) "Directions: Take one tablet if sleepy or two tablets if extremely fatigued. Repeat this dose in six hours if necessary but do not take more than * * * " (vial label) " * * * six tablets in any one week" and (case label) " * * * four tablets in any 12 hour period."

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."

Atabrine tablets, misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use, since the following directions appearing in the labeling were not adequate directions for use in the prevention or treatment of malaria: (vial label) "Use: For prevention of Symptoms of Malaria. Take first dose (1 tablet) in the morning and second dose (1 tablet) in the evening after meals on two days of each week. Skip 2 or 3 days between days of taking Atabrine. Start to take Atabrine on first day you are in 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 similar to those on vial.]

Mild tincture of iodine, misbranding, Section 502 (a), the statement "50% isopropyl alcohol" on the label was false and misleading since the article contained no isopropyl alcohol.

DISPOSITION: On November 20, 1946, the Ever Ready First Aid Company, New York, N. Y., claimant for the products, with the exception of 2,500 complete first aid kits, having admitted the allegations of the libel, judgment of condemnation was entered and it was ordered that the products be released under bond to be relabeled and repackaged as specified in the order, so as to comply with the law, under the supervision of the Food and Drug Administration. On November 6, 1946, the claim for the 2,500 remaining kits having been withdrawn, judgment of condemnation was entered and the product was ordered delivered to the Department of Hospitals of the City of New York.

2154. Misbranding of first aid kits. U. S. v. 13,500 * * *. (F. D. C. No. 20586. Sample No. 63805-H.)

LIBEL FILED: August 9, 1946, Southern District of New York.

ALLEGED SHIPMENT: Between the approximate dates of May 22 and August 14, 1945, by Burke Drug Supply, from Dayton, Ohio.

PRODUCT: 13,500 complete *first aid kits* at New York, N. Y. These kits were intended for use as part of emergency equipment for the Army. When the war ended, the contract was terminated and the kits were sold separately as surplus to a private dealer. Each of the kits contained, among other items, vials of tablets designated as "Amphetamine Sulfate— 5 MG.," "Atabrine Tablets," and "Wound Tablets," and a small bottle of a solution designated as "Mild Tincture Iodine 2 cc. U.S.P. * * * 50% Isopropyl Alcohol." The *wound tablets* contained sulfadiazine. The *mild tincture iodine* contained no isopropyl alcohol.

LABEL, IN PART: "First Aid Instructions Vest, Emergency, Sustenance Type C-1."

NATURE OF CHARGE: *Mild tincture iodine*, misbranding, Section 502 (a), the label statement "50% Isopropyl Alcohol" was false and misleading since the article contained no isopropyl alcohol.

Atabrine tablets, misbranding, Section 502 (f) (1), the label failed to bear adequate directions for use since the following directions appearing in the labeling were not adequate directions for use in the prevention or treatment of malaria: (Vial label) "Use: for prevention of Symptoms of Malaria. Take

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.