

harmless and suitable for use in drugs in accordance with regulations and was other than one from a batch that had been certified.

Misbranding, Section 502 (a), the label statements "For the relief of rheumatic pains \* \* \* one drop at a time upon the pain area until the desired relief is effected" were false and misleading since the article would not be effective for the relief of rheumatic pains.

DISPOSITION: April 14, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

### DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS\*

**2159. Adulteration and misbranding of Dwarfies 10-Vitamin Tablets. U. S. v. Dwarfies Corporation and James John Oberdin. Pleas of guilty. Each defendant fined \$200 and costs. (F. D. C. No. 17831. Sample No. 26455-H.)**

INFORMATION FILED: October 1, 1946, Southern District of Iowa, against the Dwarfies Corporation, Council Bluffs, Iowa, and James John Oberdin, secretary and treasurer.

ALLEGED SHIPMENT: On or about March 14, 1945, from the State of Iowa into the State of Colorado. The article was accompanied by a leaflet entitled "Vitamin Chart," a letter entitled "Dear Friend," and a circular entitled "Thousands of Folks use Dwarfies 10-Vitamin Tablets Daily . . . and live a more healthy life because of it." The Vitamin Chart was shipped with the drug, and the other material was delivered to the consignee on or about March 19, 1945.

PRODUCT: Examination of a sample showed that it contained 2,760 U. S. P. units of vitamin A per tablet.

LABEL, IN PART: "Dwarfies 10 Vitamins All-In-One Daily Tablet Each tablet contains: Vitamin A, D, B<sub>1</sub>, B<sub>6</sub>, C, E, Niacin, Calcium Pantothenate, Paraminobenzoic Acid \* \* \* Each tablet contains the following proportion of established minimum requirements: A, 125% \* \* \* A . . . 5000 U. S. P. Units."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from, and its quality fell below, that which it purported and was represented to possess since it contained less than 5,000 U. S. P. units of vitamin A per tablet.

Misbranding, Section 502 (a), the label statements "Each Tablet Contains \* \* \* A 5000 USP Units" and "Each Tablet Contains the Following Proportion of Established minimum Requirements \* \* \* A, 125%" were false and misleading. Certain statements in the accompanying letter, circular, and leaflet were misleading. These statements represented and suggested that the following conditions are frequently caused by lack of the vitamin substances contained in the article, and that the reader might reasonably expect correction and relief from those conditions by use of a product containing such substances: Abnormal vitality of mucous membrane or epithelial cells, low resistance to infection, abnormal functioning of the visual purple (bad eyesight), abnormal glandular function, abnormal lactation, improper formation of bone and teeth, poor appetite, poor utilization of carbohydrates, abnormal intestinal function, improper nerve function and cell respiration, abnormal nerve tissues, unclear, dull eyes, improper healing of wounds and repair tissue, faulty control of collagen formation, abnormalities of the vascular system, poor health, abnormal function of the gastrointestinal tract, poor utilization of unsaturated fatty acids, lack of virility, unsound muscle functioning and general well-being, poor intestinal motility, lack of growth, loss of natural hair color, abnormal blood calcium level, lack of vigor and well-being, loss of characteristics of youth, and a shortened life span. The stated conditions commonly and usually result from causes other than lack of the vitamin substances contained in the article, and the article would not ordinarily correct and relieve such conditions.

Further misbranding, Section 502 (a), certain statements in the labeling were misleading since they represented and suggested that the following conditions are frequently caused by lack of the vitamin substances contained in

\*See also No. 2152.

the article, and that the reader might reasonably expect correction and relief from such conditions by use of a product containing such substances: Lack of body strength, sleeplessness, body aches, neuritis, indigestion, poor body function, a run-down, tired, and worn-out feeling, arthritis, back ailment, poor appetite, heart disease, disability of the legs, retarded growth, diarrhea, intestinal disorders, poor appetite, poor teeth and gums, lack of vigor, a dry skin, night blindness, poor resistance to infection, xerophthalmia (eye disease), hyperkeratosis of the skin, weakness, sterility, loss of weight, atrophy of glands, calculi (stones) in kidneys and bladder, nerve degeneration, infections entering through epithelia, eyes, tear ducts, tongue, alimentary tract, ear canal, sinuses, bladder, and kidneys, colitis, weakness (fatigue), slow heartbeat, poor appetite, retarded growth, cardiovascular disturbances, poor assimilation, nervousness, decreased peristalsis, impaired reproductive functioning, heaviness of legs, burning feet, pain in legs, paresthesia of toes, calf muscle cramps, anorexia, paralysis, loss of weight, atrophy of glands, atrophy of musculature, gastric atony, convulsions, enlarged heart, serious effusions and colitis, lesions of the lips, cracks at the angles of the mouth and other facial lesions, abnormal changes in the eyes which result in failing vision, digestive disturbances, lack of vigor, poor lactation, impaired growth, photophobia (evidenced by easy watering of the eyes in sun-glare), small blood vessels advance into the corneal area of the eyes, clouding the vision, itching, burning, a sensation of roughness of the eyes, weakness, atrophy of intestines, atony, loss of body weight, cataract (in eyes), keratitis, "sharkskin," glossitis, cheilosis, dermatitis (seborrheic), breakdown of central nervous system, anemia, hemorrhage, pyorrhea, defective teeth, tender joints, poor bone knitting, headache, poor resistance to infection, retarded growth, weakened blood capillaries, weakness, restlessness, tendency to bruise easily, as evidenced by dark discolor of skin, anemia, swollen joints, swollen, bleeding gums, loose teeth, fragile bones, lesions in bone marrow, sterility, respiratory and intestinal infections, paralysis, hypertrophy of adrenals, gastric ulcers, colitis, erythema, soreness of mouth, indigestion, constipation, headache, anorexia, dermatitis, redness of tongue, glossitis, diarrhea, insanity, poor memory, muscular derangements and disorders, retarded growth, edema, muscle incoordination, "fatty" livers, microcytic hypochromic anemia, lesions of various tissues, ophthalmia, abscesses, epileptiform fits, low fertility, impaired placental function, muscle dystrophy, degenerative diseases of the nervous system, graying of the hair, hemorrhagic adrenals, low blood calcium, low blood phosphate, "bow legs," poor deposition of lime and phosphorus in teeth and bones, restlessness, lack of vigor, poor growth, enlarged joints, curved spine, beaded ribs, retarded growth, lesions in bones and teeth, and tetany. These conditions commonly and usually result from causes other than lack of the vitamin substances contained in the article, and the article would not ordinarily correct and relieve such conditions.

**DISPOSITION:** October 1, 1946. Pleas of guilty having been entered, the defendants were each fined \$200, plus costs.

**2160. Adulteration of digitalis tablets. U. S. v. Strong, Cobb and Company, Inc. Plea of guilty. Fine, \$500 and costs. (F. D. C. No. 21498. Sample No. 10590-H.)**

**INFORMATION FILED:** December 19, 1946, Northern District of Ohio, against Strong, Cobb and Company, Inc., a corporation, Cleveland, Ohio, charging the defendant with the giving of a false guaranty. The guaranty was given by the defendant to the Buffalo Pharmacal Company, Buffalo, N. Y., on or about August 11, 1941. It provided that the article comprising each shipment or delivery made by Strong, Cobb and Company, Inc., would be neither adulterated nor misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act.

On or about August 7, 1945, the defendant sold and delivered a quantity of *digitalis tablets* to the Buffalo Pharmacal Company, and on or about September 25, 1945, the Buffalo Pharmacal Company shipped a bottle containing a quantity of these *digitalis tablets* from the State of New York into the State of Pennsylvania. The tablets so guaranteed and shipped were adulterated and misbranded.

**LABEL, IN PART:** "Tablets Digitalis U. S. P. XII 1½ grs."

**NATURE OF CHARGE:** Adulteration, Section 501 (b), the article purported to be and was represented as "Digitalis Tablets," a drug the name of which is recog-