

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-

nized in the United States Pharmacopoeia, an official compendium, and the amount of powdered digitalis contained in the article varied more than 25 percent from the labeled amount of powdered digitalis. The tablets contained less than 75 percent of the labeled amount of powdered digitalis, whereas the compendium provides that "Digitalis tablets shall be considered to conform to the Pharmacopoeia requirement if the result of the assay does not vary more than 25 percent from the labeled amount of powdered digitalis." The difference in the strength of the article from the standard set forth in the official compendium was not plainly stated, or stated at all, on the label.

**DISPOSITION:** March 31, 1947. A plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$500, plus costs.

**2161. Adulteration of Diet Tablets. U. S. v. 63 Bottles \* \* \*. (F. D. C. No. 21974. Sample Nos. 65559-H, 65571-H, 65572-H.)**

**LABEL FILED:** December 12, 1946, Eastern District of Pennsylvania.

**ALLEGED SHIPMENT:** April 29 and May 6, 1946, by National Drug Laboratories, Inc., from Chicago, Ill.

**PRODUCT:** 63 1,000-tablet bottles of *Diet Tablets* at Philadelphia, Pa.

**LABEL, IN PART:** "Diet Tablets (Pink) \* \* \* Atropine Sulphate 1/360 Grain."

**NATURE OF CHARGE:** Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess since some tablets of the article contained 13/360 grain of atropine sulfate, although the label declared 1/360 grain of atropine sulfate to be present in each tablet.

**DISPOSITION:** March 4, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**2162. Adulteration of histamine acid phosphate. U. S. v. 84 Vials \* \* \*. (F. D. C. No. 22156. Sample No. 66109-H.)**

**LABEL FILED:** January 6, 1947, Eastern District of Pennsylvania.

**ALLEGED SHIPMENT:** On or about October 30, 1946, by Medicinals, Inc., from Richmond Hill, N. Y.

**PRODUCT:** 84 10-cc. vials of *histamine acid phosphate* at Philadelphia, Pa. Examination showed that the product was contaminated with undissolved material. The United States Pharmacopoeia requires that injections be free of any turbidity or undissolved material which can be detected readily under certain specified conditions.

**LABEL, IN PART:** "Sterile Solution Histamine Acid Phosphate."

**NATURE OF CHARGE:** Adulteration, Section 501 (b), the article purported to be and was represented as "Histamine Acid Phosphate Injection," the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth in that compendium.

**DISPOSITION:** March 4, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**2163. Adulteration and misbranding of Lactobacillus acidophilus. U. S. v. 34 Bottles \* \* \*. (F. D. C. No. 22446. Sample No. 59467-H.)**

**LABEL FILED:** January 30, 1947, Western District of Washington.

**ALLEGED SHIPMENT:** Shipment on or about December 3, 1946, by Kovac Laboratories, from Los Angeles, Calif.

**PRODUCT:** 34 8-fluid-ounce bottles of *Lactobacillus acidophilus* at Seattle, Wash.

**LABEL, IN PART:** "Kovac Type Lactobacillus Acidophilus A condensed culture in whey broth."

**NATURE OF CHARGE:** Adulteration, section 501 (b), a substance, streptococci, had been mixed with the article so as to reduce its quality and strength and had been substituted in part for the article.

Misbranding, Section 502 (a), the label statement "culture Lactobacillus Acidophilus A condensed culture" was false and misleading as applied to this product which contained relatively few bacillus acidophilus organisms and large numbers of streptococci.