

**ALLEGED VIOLATION:** On or about August 15 and September 17, 1951, the defendant caused a number of *Cal-D-Fer tablets* and *triple sulfa tablets* to be introduced and delivered for introduction into interstate commerce, at St. Louis, Mo., for delivery into the State of Ohio.

On or about May 22, 1951, the defendant gave to a firm engaged in the business of shipping drugs in interstate commerce, at St. Louis, Mo., an invoice containing a guaranty to the effect that no article listed in the invoice was adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act.

On or about May 22, 1951, the defendant caused to be delivered to the holder of the guaranty, at St. Louis, Mo., a number of *tablets of mannitol hexanitrate with phenobarbital*, which were covered by the guaranty and which were adulterated and misbranded.

**NATURE OF CHARGE:** *Cal-D-Fer tablets.* Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess in that each tablet of the article was represented to contain 5 grains of calcium phosphate (dibasic), whereas each tablet of the article contained less than 5 grains of calcium phosphate (dibasic). Misbranding, Section 502 (a), the label statement "Each tablet contains \* \* \* Calcium Phosphate (dibasic) 5 gr." was false and misleading.

*Triple sulfa tablets.* Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess in that the article was represented to supply to the body from each tablet 2.56 grains of sulfadiazine, 2.56 grains of sulfamerazine, and 2.56 grains of sulfamethazine, whereas the article would not supply to the body from each tablet such amounts of sulfadiazine, sulfamerazine, and sulfamethazine since the tablets would not completely disintegrate and thus part of each tablet would pass through the body, would be eliminated, and would not be used by the body.

*Tablets of mannitol hexanitrate with phenobarbital.* Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since each tablet was represented to contain  $\frac{1}{4}$  grain of phenobarbital and  $\frac{1}{2}$  grain of mannitol hexanitrate, whereas each tablet contained less than  $\frac{1}{4}$  grain of phenobarbital and less than  $\frac{1}{2}$  grain of mannitol hexanitrate. Misbranding, Section 502 (a), the label statement "Each tablet contains: Phenobarbital  $\frac{1}{4}$  gr. \* \* \* Mannitol Hexanitrate  $\frac{1}{2}$  gr." was false and misleading.

**DISPOSITION:** September 28, 1953. The defendant having entered a plea of guilty, the court fined it \$800.

**4130. Adulteration of iodophthalein, Ringer's solution tablets, ammoniated mercury ointment, and Atabrine Dihydrochloride, and adulteration and misbranding of quinine phosphate.** U. S. v. 9,000 Bottles, etc. (F. D. C. No. 34914. Sample Nos. 43981-L, 43985-L, 43987-L to 43989-L, incl., 44151-L, 44155-L to 44158-L, incl., 44162-L, 44163-L.)

**LIBEL FILED:** March 30, 1953, District of Kansas.

**ALLEGED SHIPMENT:** During the month of August 1952, by Chemical Commodities, Inc., from Kansas City, Mo.

**PRODUCT:** 9,000 100-gram bottles of *iodophthalein*, 1,000 100-tablet bottles of *Ringer's solution tablets*, 2,000 1-pound jars of *ammoniated mercury ointment*, 33 4-ounce jars of *quinine phosphate*, and 23 pounds of *Atabrine Dihydrochloride* contained in 1 unlabeled drum but originally shipped in 4-ounce bottles, at Olathe, Kans.

Examination showed that the *iodophthalein* contained insoluble material; that the caking and disintegrating of *Ringer's solution tablets* had rendered them unsuitable for their intended use of supplying an accurate amount of the salts contained in them, so that it was not possible to prepare Ringer's solution for injection by dilution of the tablets in accordance with the label directions; that the *ammoniated mercury ointment* in many of the jars had separated from the ointment base and settled to the bottom of the jars, so that the article was not uniform in composition; that the *quinine phosphate* showed evidence of fire and water damage, with the labels being largely obliterated by stains, abrasion, and soiling, and the bottles containing black, charred material under the caps; and that the *Atabrine Dihydrochloride* in its original containers showed evidence of fire damage, with the bulk material transferred from the original containers to the drum being contaminated with wood splinters, rust flakes, and other extraneous material.

**NATURE OF CHARGE:** *Iodophthalein*. Adulteration, Section 501 (b), the article purported to be and was represented as "Iodophthalein," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality and purity fell below the official standard since it contained insoluble material.

*Ringer's solution tablets*. 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.

*Ammoniated mercury ointment*. Adulteration, Section 501 (b), the article purported to be and was represented as "Ammoniated Mercury Ointment," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from, and its quality fell below, the official standard since the article was not of uniform composition.

*Quinine phosphate*. Adulteration, Section 501 (b), the article purported to be and was represented as "quinine phosphate," a drug the name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the official standard since it contained added foreign substances. Misbranding, Section 502 (c), the information required by Section 502 (b) to appear on the label of the *quinine phosphate* was not prominently placed thereon with such conspicuousness (as compared with other words and statements on the label) and in such terms as to render such information likely to be read by the ordinary individual under customary conditions of purchase and use since such information had become illegible by reason of fire, water, or other damage to the labels.

*Atabrine Dihydrochloride*. Adulteration, Section 501 (b), the article purported to be and was represented as "Quinacrine Hydrochloride," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality and purity fell below the official standard since it contained added foreign substances. The *Atabrine Dihydrochloride* was alleged to be adulterated when introduced into, while in, and while held for sale after shipment in, interstate commerce; the *quinine phosphate* was alleged to be adulterated and misbranded while held for sale after shipment in interstate commerce; and the other products were alleged to be adulterated while held for sale after shipment in interstate commerce.

**DISPOSITION:** May 14, 1953. Default decree of condemnation and destruction.