DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

3141. Misbranding of first aid kits. U. S. v. 118 Kits * * *. (F. D. C. No. 29094. Sample No. 80874–K.)

LIBEL FILED: May 2, 1950, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about October 6, 1949, by the All State Iron Scrap & Metal Co., from Middletown, Del.

PRODUCT: 118 first aid kits containing various items of drugs including, in each, an envelope of *sulfanilamide powder* (5 grams) and a package of 7.7 gr. *sulfadiazine tablets* (8 tablets), at Philadelphia, Pa. Some of the kits contained also a package of two tubes (¾-ounce size) of *tannic acid-sulfadiazine ointment* (sulfadiazine 5%).

These products could not be used safely and efficaciously in self-medication. They should be dispensed only on prescription, and they were in the hands of a dealer who was not authorized to fill prescriptions.

NATURE OF CHARGE: Misbranding, Section 502 (j), the products were dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in their labelings, as follows: (*Sulfanilamide powder*) "For Topical Use Warning—Absorption of this drug applied locally varies with the tissue and degree of injury but may be sufficiently great to cause systemic toxic reactions. Dyspnoea, vertigo, cyanosis, and methemoglobinemia are signs that indicate a reduction of dosage. Constant observation of the patient is essential. Caution: To be used only by or on the prescription of a physician," (*tannic acid-sulfadiazine ointment*) "For local application only not to be used on face, hands or genitals. Ointment is removable with water or saline solution * * * for U. S. Army Use Only," and (*sulfadiazine tablets*) "See back label for directions Caution—To be used only by or on the prescription of a physician. Warning—This is a dangerous drug which may cause serious or fatal injury unless taken under adequate and continuous medical supervision. Directions 1. If wounded, take two (2) tablets every five (5) minutes until all are taken. 2. It is important that you drink large quantities of water when taking the drug. 3. Caution—Do not take otherwise except under specific direction of Medical Officer."

DISPOSITION: June 22, 1950. Default decree of condemnation and destruction.

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

3142. Misbranding of Benadryl capsules, Nembutal capsules, sulfonamides triplex tablets, Dexedrine sulfate tablets, and Seconal sodium capsules. U. S. v. Central Drug Co. and Harlan C. Bopp. Pleas of guilty. Fine of $1,000 against each defendant. (F. D. C. No. 28124. Sample Nos. 45943–K, 45948–K, 45951–K, 45952–K, 45977–K, 45978–K, 45980–K, 45981–K, 45985–K.)

INFORMATION FILED: February 17, 1950, Eastern District of Illinois, against the Central Drug Co., a corporation, East St. Louis, Ill., and Harlan C. Bopp, president of the corporation.

INTERSTATE SHIPMENT: Between the approximate dates of June 3, 1948, and March 28, 1949, from the State of Missouri into the State of Illinois, of quantities of *Benadryl capsules, Nembutal capsules, sulfonamides triplex tablets, Dexedrine sulfate tablets,* and *Seconal sodium capsules.*

ALLEGED VIOLATION: On or about January 6, 19, and 21, March 29, and April 7, 11, and 13, 1949, while the drugs were being held for sale after shipment in interstate commerce, the Central Drug Co. and Harlan C. Bopp caused various quantities of the drugs to be repacked and sold without a prescription, which acts of the defendants resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged *Nembutal capsules* and *sulfonamides triplex tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing statements of the quantity of the contents; and Section 502 (e) (2), the repackaged *sulfonamides triplex tablets* bore no label containing the common or usual name of each active ingredient, namely, sulfathiazole, sulfadiazine, and sulfamerazine.

Further misbranding, Section 502 (d), the *Nembutal capsules* and the *Seconal sodium capsules* contained chemical derivatives of barbituric acid, which derivatives had been by the Administrator of the Federal Security Agency, found to be, and by regulations designated as, habit forming; and when repackaged, their labels failed to bear the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drugs, with the exception of the *sulfonamides triplex tablets*, failed to bear adequate directions for use in that the directions on the labeling of the *Seconal sodium capsules*, namely, "One as needed," were not adequate directions for use, and that the labeling of the *Nembutal capsules*, *Benadryl capsules*, and *Dexedrine sulfate tablets* bore no directions for use; and, Section 502 (f) (2), the repackaged *sulfonamides triplex tablets* bore no labeling containing warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: May 23, 1950. Pleas of guilty having been entered, the court imposed a fine of $1,000 against each of the defendants.

3143. Misbranding of dextro-amphetamine phosphate tablets, sulfadiazine tablets, Tuinal capsules, Seconal sodium capsules, and Dexedrine sulfate Tablets. U. S. v. Weipert Drug Co., a corporation, and James V. Cockrum, Clyde Frick, and Alfred Hoffman. Plea of guilty for corporation; pleas of nolo contendere for individual defendants. Fine of $2,000 against corporation; sentences suspended against individual defendants and these defendants placed on probation for 1 year. (F. D. C. No. 28141. Sample Nos. 60870-K, 60905-K, 60919-K, 60941-K, 60951-K, 60953-K, 60957-K, 60960-K.)

INFORMATION FILED: March 8, 1950, Eastern District of Missouri, against the Weipert Drug Co., a corporation, St. Louis, Mo., and against James V. Cockrum, secretary and pharmacist, and Clyde Frick and Alfred Hoffman, pharmacists, for the corporation.

INTERSTATE SHIPMENT: From the States of New York, Indiana, and Pennsylvania, into the State of Missouri, of quantities of *dextro-amphetamine phosphate tablets*, *sulfadiazine tablets*, *Tuinal capsules*, *Seconal sodium capsules*, and *Dexedrine sulfate tablets*.