

**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 ($\frac{3}{4}$ -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*.