

mately 1,500 International Units of estrogens as estrone over an extended and indefinite period of time, an amount which could cause injury to health.  
DISPOSITION: 9-23-55. Default—destruction.

#### NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

4882. Broiler Pre-Mix. (F. D. C. No. 38248. S. No. 16-247 M.)

QUANTITY: 10 50-lb. bags at Seattle, Wash.

SHIPPED: 5-27-55, from Pasadena, Calif., by Ray Ewing Co.

LABEL IN PART: (Bag) "A Ray Ewing Custom Mix \* \* \* Broiler Pre-Mix Guaranteed Potencies \* \* \* Nicarbazin, Grams 90.80 Per Pound."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 7 percent of the declared amount of nicarbazin.

LIBELED: 7-27-55, W. Dist. Wash.

CHARGE: 502 (a)—the label statement "Guaranteed Potencies \* \* \* Nicarbazin, Grams 90.80 Per Pound" was false and misleading; 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess; and 505 (a)—the article was a new drug which could not lawfully be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 11-30-55. Default—destruction.

4883. Serpina tablets. (F. D. C. No. 38244. S. No. 24-721 M.)

QUANTITY: 1 unlabeled drum containing 5,000 tablets at Seattle, Wash.

SHIPPED: 3-30-55, from Bombay, India, by Himalaya Drug Co.

RESULTS OF INVESTIGATION: The article was shipped from India in a bulk container labeled in part "Serpina Each tablet contains 4 mg. of the total alkaloids of Rauwolfia serpentina (Benth)."

LIBELED: 7-26-55, W. Dist. Wash.

CHARGE: 505 (a)—the article was a new drug which could not lawfully be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 11-30-55. Default—destruction.

#### DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

4884. Halazone tablets and Dramamine tablets. (F. D. C. No. 38184. S. Nos. 30-203/4 M.)

QUANTITY: 59 btls. containing 1,000 tablets of *Dramamine*, and 1,100 cases, 300 100-tablet btls. each, of *halazone* at Memphis, Tenn.

SHIPPED: The articles were shipped in interstate commerce to Memphis, Tenn.; however, the name of the shipper and the date of shipment are unknown.

LABEL IN PART: (Btl.) "1,000 Tablets \* \* \* Dramamine Brand of Dimenhydrinate 100 mg. Caution: to be dispensed only by or on the prescription of a physician," "Tablets Water Purification Individual (Halazone) \* \* \* Each tablet contains P-Sulfonedichloramido Benzoic Acid (1/16 Grain) Sodium Carbonate Sodium Chloride Boric Acid," "Halazone Tablets (p-sulfonedichloramido benzoic acid 0.004 gm.; sodium borate and chloride)," or "Water Purification Tablets \* \* \* Each Tablet Contains 0.004 Gm. (1/16 Grain) of Halazone."

**RESULTS OF INVESTIGATION:** Analysis showed that the *halazone tablets* contained from 19 percent to 67 percent of the labeled amount of halazone. The National Formulary requires that halazone tablets contain not less than 90 percent of the labeled amount of halazone.

**LIBELED:** 6-14-55; amended 6-15-55, W. Dist. Tenn.

**CHARGE:** *Halazone tablets.* 501 (b)—the article, while held for sale, purported to be and was represented as "Halazone Tablets," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the standard set forth in such compendium.

*Dramamine tablets.* 503 (b) (4)—the article, when shipped, was a drug subject to 503 (b) (1) (C), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

**DISPOSITION:** 6-21-55. Consent—destruction.

**4885. First aid packets and halazone tablets.** (F. D. C. No. 38179. S. Nos. 18-374/5 M.)

**QUANTITY:** 13,775 *first aid packets* and 73 cases, 300 100-tablet btls. each, of *halazone tablets* at New York, N. Y.

**SHIPPED:** 10-21-52 and 3-22-55, from Louisville, Ky., and Memphis, Tenn.

**RESULTS OF INVESTIGATION:** An examination of 7 *first aid packets* showed that 4 contained an envelope holding 5 grams of sulfanilamide.

Analysis showed that the *halazone tablets* contained less than 90 percent of the labeled amount of halazone. The National Formulary requires that halazone tablets contain not less than 90 percent of the labeled amount of halazone.

**LIBELED:** 6-10-55, S. Dist. N. Y.

**CHARGE:** *Halazone tablets.* 501 (b)—the article purported to be and was represented as "Halazone Tablets," a drug the name of which is recognized in the National Formulary, an official compendium; and while held for sale, its strength differed from the standard set forth in such compendium.

*First aid packets.* 503 (b) (4)—a component of the article, sulfanilamide, was a drug which was subject to 21 U. S. C. 503 (b) (1); and, while held for sale, its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

**DISPOSITION:** 7-14-55. Default—destruction.

**4886. First aid packets.** (F. D. C. No. 38215. S. No. 18-378 M.)

**QUANTITY:** 2,668 packets at New York, N. Y.

**SHIPPED:** 3-27-52 and 3-31-52, from Austin, Tex., and Memphis, Tenn.

**RESULTS OF INVESTIGATION:** Examination showed that a substantial number of the *first aid packets* contained an envelope holding 5 grams of sulfanilamide, none of which bore the prescription legend.

**LIBELED:** 7-1-55, S. Dist. N. Y.

**CHARGE:** 503 (b) (4)—the article, while held for sale, contained a drug to which 503 (b) (1) (B) applied, and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

**DISPOSITION:** 7-22-55. Default—destruction.