LIBELED: 7–13–61, S. Dist. N.Y.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use as a treatment for and preventive of migraine headache, impaired hearing, prostate gland trouble, internal cancer, tumors, receding gums, poor vision, poor digestion, varicose veins, and hardening of the arteries; and to clear sinuses; remove wrinkles; rejuvenate personality glands; remove cobwebs from the brain; and for spot reducing, which were the diseases, conditions, and purposes for which the articles were recommended in oral statements made by Adolphus Hohensee during the course of 3 lectures given at New York, N.Y., on or about June 28 and 29, 1961.

DISPOSITION: 8–22–61. Default—delivered to the Food and Drug Administration.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS FOR HUMAN USE

6710. Sal-Amino C tablets. (F.D.C. No. 45745. S. No. 62–717 R.)

QUANTITY: 95 100-tablet btls. and 149 1,000-tablet btls. at Columbus, Ohio, in possession of Columbus Hospital Supply Co.

SHIPPED: In March or April 1953, from Philadelphia, Pa.

LABEL IN PART: (Btl.) "List No. 2083 Sal-Amino C Tablets Control No. 9431 Distributed by Columbus Hospital Supply Company Columbus 15, Ohio Caution: * * * Each tablet Represents: Sodium Salicylate (3 gr.) 200.0 mg. Calcium Succinate (2 gr.) 133.3 mg. Para Aminobenzoic Acid (1 gr.) 66.7 mg. Vitamin C (0.3 gr.) 20.0 mg."

RESULTS OF INVESTIGATION: Examination showed that the article contained 47 percent of the declared amount of ascorbic acid (vitamin C) and 75 percent of the declared amount of para-aminobenzoic acid.

LIBELED: 4–26–61, S. Dist. Ohio.

CHARGE: 501(c)—while held for sale, the strength of the article differed from and its quality fell below that which it purported or was represented to possess; and 502(a)—the label statements "Each Tablet Represents: * * * Para Aminobenzoic Acid (1 gr.) 66.7 mg. Vitamin C (0.3 gr.) 20.0 mg." were false and misleading as applied to an article that contained less than the declared amounts of these ingredients.

DISPOSITION: 6–16–61. Default—destruction.

6711. Secobarbital sodium capsules. (F.D.C. No. 46140. S. No. 97–334 R.)

QUANTITY: 1 100-capsule btl., 12 500-capsule btls., and 45 1,000-capsule btls., at Buffalo, N.Y.

SHIPPED: From Philadelphia, Pa., by Richlyn Laboratories.

LABEL IN PART: (Btl.) "No. 4090 * * * Secobarbital Sodium * * * 1½ Grain * * * Distributed by Direct Laboratories, Inc., Buffalo 4, New York, Control 9228."

RESULTS OF INVESTIGATION: The article was repacked and labeled by the dealer after its shipment in bulk as described above. Analysis showed that the article failed to meet the United States Pharmacopeia requirement for *secobarbital sodium capsules* in that its weight variation was not in accordance with the Pharmacopeia.

LIBELED: 7–27–61, W. Dist. N.Y.

CHARGE: 501(b)—when shipped and while held for sale, the article purported to be and was represented as *secobarbital sodium capsules*, a drug which is recognized in the United States Pharmacopeia, an official compendium, and its quality differed from the standard set forth in such compendium; and 502(a)—the label statement "*Secobarbital Sodium Capsules*" was false and misleading as applied to an article which failed to meet the requirements of the United States Pharmacopeia for such drug.

DISPOSITION: 8–31–61. Default—destruction.

6712. Reserpine tablets. (F.D.C. No. 45812. S. No. 66–906 R.)

QUANTITY: 900 tablets at Oklahoma City, Okla.

SHIPPED: Prior to 4–26–61, by an unknown shipper, from outside the State of Oklahoma.

LIBELED: 5–25–61, W. Dist. Okla.

CHARGE: 501(d)(2)—while held for sale, an imitation drug had been substituted for an authentic drug; 502(a)—the label statements "Serpasil" and "Ciba" were false and misleading as applied to a product which was an imitation of Serpasil; 502(i)(2)—the article was an imitation of another drug; 502(i)(3)—the article was offered for sale under the name of another drug namely, Serpasil.

DISPOSITION: 6–19–61. Default—destruction.

6713. Vitamin B complex with vitamin B_{12} injection. (F.D.C. No. 46467. S. No. 79–855 R.)

QUANTITY: 42 individually cartoned 30-cc. vials at Baltimore, Md.

SHIPPED: 1–30–61, from New Rochelle, N.Y.

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 22 percent of the declared amount of vitamin B_{12}.

LIBELED: 9–22–61, Dist. Md.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported to possess; and 502(a)—the label statement "Each cc. contains: Vitamin B_{12} 30 mg." was false and misleading as applied to an article which contained less than the declared amount of vitamin B_{12}.

DISPOSITION: 10–25–61. Default—destruction.

6714. Rubber prophylactics. (F.D.C. No. 45792. S. No. 80–921 R.)

QUANTITY: 38 ctns., each containing 48 3-unit boxes, at Natchitoches, La.

SHIPPED: 3–15–61, from Kansas City, Mo., by M & M Rubber Manufacturing Co.

LABEL IN PART: (Ctn.) "One Gross Viking Super Thin Transparent Prophylactics Threes."

RESULTS OF INVESTIGATION: Examination showed that 2.8 percent of the units examined were defective in that they contained holes.

LIBELED: 5–11–61, W. Dist. La.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "Sold for Prevention of Disease" was false and misleading as applied to an article containing holes.

DISPOSITION: 6–27–61. Default—destruction.