SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS 5201–5220

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its strength differed from, or its quality fell below, the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess; Section 501 (d), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b) (1), the article was in package form, and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 503 (b) (4), the article was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DRUG IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

5201. R-20 hair treatment. (F. D. C. No. 39640. S. No. 40-913 M.)

QUANTITY: 2 btls., containing 20 oz. total, of *R-20 hair treatment*, and 2 jugs, 1 containing 1 gal. and the other containing 28 oz., of diluted *R-20 hair treatment*, at Minneapolis, Minn.

SHIPPED: 8-23-56, from Rouses Point, N. Y., by Dr. R. E. Liefmann.

LABEL IN PART: (Btl.) "R-20 Batch #17, 8–27–56 Regular"; (jug) "the Frommes formula R-20 by Frommes Scalp Specialists Minneapolis."

RESULTS OF INVESTIGATION: Analysis showed that the drug consisted of an isopropyl alcohol solution of alpha-estradiol. The drug was shipped unlabeled, and, upon arrival, the handwritten bottle labeled "R-20 Batch #17 8–27–56 Regular" was affixed by the consignee, Frommes Method, Inc.

The diluted material was prepared by the consignee by adding an additional quantity of isopropyl alcohol to a portion of the shipped drug. The "Frommes formula R-20" labels were printed locally for the consignee, who applied them to the diluted material.

LIBELED: 10–24–56, Dist. Minn.

CHARGE: 502 (b) (1)—the label of the article, when shipped, failed to bear the name and place of business of the manufacturer, packer, or distributor; 502 (e) (2)—the article was fabricated from 2 or more ingredients, and its label, when shipped, failed to bear the common or usual name of each active ingredient; 502 (f) (1)—the labeling of the article, when shipped, failed to bear adequate directions for use; and 503 (b) (4)—the article was a drug which was not safe for use except under the supervision of a practitioner li-

censed by law to administer such drug, and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 12–14–56. Default—destruction.

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

5202. Hoxsey treatment for internal cancer. (Inj. No. 311.) *See also* N. J. No. 5212 in this supplement.

COMPLAINT FOR INJUNCTION FILED: 5–28–57, W. Dist. Pa., against Hoxsey Cancer Clinic, a corporation, Portage, Pa., John J. Haluska, president and administrator, Philip Stager, treasurer, Samuel Einhorn, secretary, John H. Benko, vice president, and Delmar Randall and Harold Galbraith, osteopathic physicians employed by the corporation.

An amended complaint was filed on 8–22–57.

ACCOMPANYING LABELING: Booklet entitled "What is Cancer? How Does It Function?"; pamphlet entitled "Procedure and Information, Hoxsey Cancer Clinic, Inc."; miscellaneous reprints of articles and letters written and distributed by John J. Haluska; monthly publication entitled "Globe Gazette"; and book entitled "The Pittsburgh Trial."

NATURE OF DRUGS: The original complaint alleged that the essential part of the *Hoxsey treatment for internal cancer* was either a combination of green and red tablets or a combination of yellow and red tablets.

The complaint alleged also that the green tablets were composed of licorice, burdock root, stillingia root, berberis root, pokeroot, cascara sagrada, prickly ash bark, buckthorn bark, and red clover; that the yellow tablets were composed of red clover, buckthorn bark, stillingia root, berberis root, pokeroot, and pepsin; and that the red tablets were composed of potassium iodide.

The complaint alleged further that at times the potassium iodide was furnished as a liquid solution or omitted entirely.

METHOD OF OPERATION: The original complaint alleged that a typical method used by the defendants in the promotion, sale, and distribution of the treatment, in interstate commerce, was as follows: Interest in the treatment was promoted by articles appearing in the Globe Gazette, edited by John J. Haluska, and by articles published in the Defender magazine, edited by Gerald B. Winrod. In response to an inquiry concerning the treatment, from a person living outside Pennsylvania, an invitation to visit the clinic was issued in a letter bearing the facsimile signature of defendant Harold L. Galbraith as medical director of the clinic. When the prospective out-of-state customer arrived on the premises of the clinic, he was interviewed by the employees, at which time there was a discussion of his symptoms and ailments. This was followed by laboratory tests of the blood and urine, X-rays, and a physical examination of the customer. On that basis, the prospective customer's condition was diagnosed as cancer without a biopsy. The customer then was sold the *Hoxsey treatment for internal cancer*, comprised essentially of the above-described tablets, and the treatment was delivered to the customer for transportation outside Pennsylvania.

On 8–22–57, the complaint was amended to include the allegation that, upon entry of the temporary restraining order as described below, the defendants did the following: With no notice to the persons going to the

*See also No. 5201.