

**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS
REPORTED IN D. D. N. J. NOS. 5321-5340**

Adulteration, Section 501 (a) (2), the article had been held under insanitary conditions; Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (National Formulary or United States Pharmacopeia), 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 purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; 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 label of the article bore the statement "Caution: Federal law prohibits dispensing without prescription," and it was a drug to which Section 503 (b) (1) did not apply.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

5321. Glandular preparations. (F. D. C. No. 36806. S. Nos. 88-806/21 L.)

QUANTITY: 32 boxes, 6 cartoned 1-cc. ampuls each, of *corpora lutea soluble extract*; 11 btl., 100 5-grain Emplets each, and 19 btl., 50 5-grain tablets each, of *corpora lutea desiccated*; 30 btl., 100 5-grain Emplets each, of *ovarian residue*; 28 1-oz. btl. of *ovarian substance desiccated*; 15 boxes, 12 cartoned 1-cc. ampuls each, of *ovarian substance soluble extract*; 111 btl., 100 5-grain Emplets each, and 44 btl., 100 5-grain tablets each, of *ovarian substance desiccated*; 27 btl., 100 $\frac{1}{10}$ -grain Emplets each, and 16 btl., 100 $\frac{1}{10}$ -grain tablets each, of *parathyroid gland desiccated*; 4 1-oz. btl. of *pituitary body anterior lobe desiccated* and 23 btl., 100 $2\frac{1}{2}$ -grain Emplets each, 42 btl., 100 5-grain Emplets each, 9 btl., 100 $2\frac{1}{2}$ -grain tablets each, and 20 btl., 100 5-grain tablets each, of *pituitary body anterior lobe desiccated*; 10 1-oz. btl., 40 btl., 100 1-grain Emplets each, and 13 btl., 100 1-grain tablets each, of *pituitary body whole gland desiccated*, at Chicago, Ill.

SHIPPED: Between 8-13-53 and 3-17-54, from Detroit, Mich., by Parke, Davis & Co.

LIBELED: 5-27-54, N. Dist. Ill.

CHARGE: (502) (f) (1)—the labeling of the articles, when shipped, failed to bear adequate directions for use; and 503 (b) (4)—all articles, except the 32-box lot of *corpora lutea soluble extract* and the 15-box lot of *ovarian substance soluble extract*, bore on their labels prior to dispensing the statement "Caution: Federal law prohibits dispensing without prescription," and such articles were drugs to which 503 (b) (1) did not apply.

DISPOSITION: 4-23-57. Upon the representation of the claimant, Parke, Davis & Co., that the intrinsic value of the article was negligible, and with the consent of the claimant and the Government that a decree might be entered pursuant

to the provisions of the Federal Food, Drug, and Cosmetic Act without adjudication as to any issue of fact or law, the court entered an order directing that the article be turned over to the United States Department of Health, Education, and Welfare, pursuant to the provisions of such Act.

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

5322. Immun capsules (3 seizure actions). (F. D. C. Nos. 37699, 37700, 37898. S. Nos. 4-034 M, 15-959 M, 16-185 M.)

QUANTITY: 60 btl. at Seattle, Wash., 44 btl. at Pittsburgh, Pa., and 21 btl. at Spokane, Wash.

SHIPPED: Between 12-1-54 and 2-8-55, from New York, N. Y., by Universal Nutritions, Inc.

LABEL IN PART: (Btl.) "Immun Capsules Improved with Activator X Each Capsule Contains: Vitamin A (fish liver oils) 2,000 U. S. P. Units 50% Minimum daily requirement Vitamin D (fish liver oils) 200 U. S. P. Units 50% Minimum daily requirement Activator X 6 Minims Vitamin E 0.68 I. U. * * * Manufactured Exclusively for Nu-Health Laboratories, Inc., Lynbrook, New York A Nutrient Supplement with Naturally Occurring Antioxidant. Dosage: Adults And Children one capsule twice a day with meals. Contents 60 Capsules Activator X is Nu-Health Laboratories' Trade Mark for the essential unsaturated fatty acids, oleic, linoleic, linolenic, arachidonic, hexaenoic, and pantaenoid derived from mammalian oils."

ACCOMPANYING LABELING: Leaflet entitled "Read How Immun Capsules with 'Activator X' Helped Many People."

LIBELED: 3-9-55, W. Dist. Pa.; 3-15-55, W. Dist. Wash.; 3-30-55, E. Dist. Wash.

CHARGE: 502 (a)—when shipped, the labeling of the article contained the following false and misleading representations:

(a) The name "Immun Capsules" represented that the article would increase immunity to disease;

(b) The name of the ingredient "Activator X" represented that the ingredient so designated was effective to activate and make effective the nutritive elements obtained from common foods; and

(c) The leaflet represented that the article would be effective to provide immunity to disease, to increase vigor, to prolong life, and to prolong sex potency; and, further, that the article would be effective in the prevention and treatment of dental caries, colds, arthritis, joint and muscle stiffness, general debility, loss of appetite, underweight, gastritis, belching, anemia, insomnia, low blood pressure, disturbed calcium and phosphorus metabolism, impaired vision, painful menses, constipation, general fatigue, irregular heart, chest pains, and bronchitis; and

502 (f) (1)—the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended.

DISPOSITION: Nu-Health Laboratories, Inc., Lynbrook, N. Y., entered all 3 actions as claimant and petitioned for the removal of these actions to the Southern District of New York for trial. Pursuant to such petitions, the 3 seizure actions were removed and consolidated for trial in that District.

On 9-26-56, the answer and claim of Nu-Health Laboratories, Inc., were withdrawn; and on 3-8-57, a default decree providing for destruction of the article was entered.

*See also No. 5321.