SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 5441–5460

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), and its strength differed from 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.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(e)(2), the article was a drug 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), the labeling of the article failed to bear (1) adequate directions for use and (2) adequate warnings against use in those pathological conditions 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 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling; Section 502(l), the article was, or purported to be, or was represented as, a drug composed partly of penicillin, streptomycin, or a derivative thereof; and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507, and it was not exempt from such requirement by regulations promulgated under Section 507 (c) or (d).

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUG AND DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

5441. Laubach's No. 7 tablets. (F.D.C. No. 40553. S. No. 62–447 M.)

QUANTITY: 2 bulk drums containing a total of 52,100 tablets at Jersey City, N.J., in possession of Laubach Proprietary Medicines, Inc.

SHIPPED: 3–15–57, from Philadelphia, Pa., by Hance Bros. & White Co.

LABEL IN PART: (Drum) "Private Formula * * * P.F. 3687 * * * Laubach * * * Each Tablet Contains: Boric Acid 2 gr."

ACCOMPANYING LABELING: Placards headed "WHEN REST IS BROKEN" and "KEEP FIT."

RESULTS OF INVESTIGATION: The above-mentioned placards, which were on display in the dealer's store window, had been printed locally.

LIBELED: 8–12–57, Dist. N.J.

CHARGE: 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for all bladder and kidney irregularities; and 502(j)—when shipped and while held for sale, the article was dangerous to health

when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, (drum) "Dose: One or two tablets daily."

DISPOSITION: 9–18–57. Default—destruction.

5442. Form-Allure bust developers. (F.D.C. No. 40528. S. No. 74–321 M.)

QUANTITY: 9 devices at Portland, Oreg.

SHIPPED: 4–13–57 and 4–18–57, from Los Angeles, Calif., by Marbrook Co., Ltd.

LABEL IN PART: "The Marbrook Co. Ltd. form-allure of Hollywood."

ACCOMPANYING LABELING: Leaflets designated "Form-Allure" and printed sheets designated "Instructions and Suggestions."

RESULTS OF INVESTIGATION: The article consisted of two hemispherical plastic cups, approximately 4 inches in diameter at the open end, which were connected by means of rubber tubing to a treadle-operated vacuum pump. In use, the plastic cups were pressed against the chest wall so that each enclosed one of the breasts and the edge of the cup formed an airtight seal against the chest. Operation of the foot treadle caused a vacuum to be formed inside the plastic cups.

LIBELED: 8–28–57, Dist. Oreg.

CHARGE: 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the device was effective for developing the breasts, increasing the size of the breasts, and improving the appearance of the breasts; and 502(j)—the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "One application daily should suffice but when convenient to do so, use twice daily—morning and evening. The time required for each user is determined by the length of time necessary to produce a flush over the area. When the breasts are pink—that is sufficient. In use, count ten to twenty strokes—remove cups (break vacuum) and wait for a few seconds—then repeat the operation. In the majority of cases three or four such applications is sufficient to produce the desired flush. Do not assume that if a short period is good, a longer period will be better. And, always control the length and number of strokes to your comfort. Regular, daily use for several months is suggested, then taper off and use only occasionally, as required."

DISPOSITION: 10–10–57. Default—delivered to the Food and Drug Administration.

DRUG FOR VETERINARY USE

5443. Hog fattener. (F.D.C. No. 40369. S. No. 227 M.)

QUANTITY: 76 75-lb. bags and 1 ton in bulk in Decatur, Nebr.

SHIPPED: 4–25–57, from Des Moines, Iowa, by Swift & Co.

LABEL IN PART: (Bag) "Swift's Hog Fattener."

RESULTS OF INVESTIGATION: Examination showed that the article was a pelleted medicated feed containing about 0.32 percent arsanilic acid.

LIBELED: 7–10–57, Dist. Nebr.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it was represented to possess, namely, .01 percent arsanilic acid; 502(e)(2)—the label of the article failed to bear the common or usual name