SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6081–6120

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 Pharmacopoeia or National Formulary), and its strength differed from, or its quality and purity fell below, the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality and purity 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), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2) the drug 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 or by children where its use may be dangerous to health, or against unsafe dosage or methods of 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 the labeling thereof; Section 502(l), the article consisted in part of penicillin and dihydrostreptomycin, and the article was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

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 DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

6081. Arthritis remedy. (F.D.C. No. 43531. S. No. 5–699 P.)

QUANTITY: 20 2-oz. btls. at Martinsville, Va.

SHIPPED: 8–20–59, from Price, N.C., by Myrtle Chemical Co.

LABEL IN PART: "Arthritis Remedy * * * Manufactured by Myrtle Chemical Co., 802 Princeton Street, Martinsville, Va. * * * Ingredients: Mono Butyl Ether, Synthetic Joint Fluid, Bichromatic Potash, Antimony, Trichloride and Tergitol."

RESULTS OF INVESTIGATION: Examination showed that the article contained antimony chloride, diethylene glycol monobutyl ether, and Tergitol (a wetting agent). No potassium bichromate was present.

LIBELED: 9–18–59, W. Dist. Va.

CHARGE: 502(a)—when shipped, the name "Arthritis Remedy," and the label statement "Ingredients: * * * Bichromatic Potash" were false and misleading

as applied to an article which was not an adequate and effective treatement for arthritis, and which contained no potassium bichromate; 502(b)(2)—the article failed to bear a label containing an accurate statement of the quantity of contents; 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; and 505(a)—the article was a new drug within the meaning of the law, and an application filed pursuant to law was not effective with respect to the article.

DISPOSITION: 11-3-59. Default—destruction.

6082. Allure bust development device. (F.D.C. No. 43795. S. No. 23-186 P.)

QUANTITY: 4 crated devices at Los Angeles, Calif.

SHIPPED: 10-6-59, from Tulsa, Okla., by Mrs. Mabel Ward.

LABEL IN PART: (Device) "Allure Mfd. by Allure Incorporated, Hollywood, California, Model 1097, Serial No. 7959 [or other numbers]."

RESULTS OF INVESTIGATION: The article consisted of rubber-ringed plastic cups of various sizes which had small openings for connection to rubber hoses attached to an air compressor or electrically operated pump. Attached to the compressor was a pressure regulator, vacuum gauge, and a valve to regulate the amount of vacuum produced in each of the two breast cups while in use. The plastic cups were pressed over the breasts against the chest and the rubber-ringed edge formed an airtight seal. The air compressor was then operated to form a vacuum inside the cups to exercise the breasts by contraction and relaxation. The air compressor and accessory equipment were contained in a metal cabinet 36" x 22" x 18".

LIBELED: 11-6-59, S. Dist. Calif.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use for the purpose for which it was intended, namely, for developing the human breasts; and 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.

DISPOSITION: 12-3-59. Default—destruction.

6083. Allure bust development device. (F.D.C. No. 43331. S. No. 53-228 P.)

QUANTITY: 2 devices at Phoenix, Ariz., in possession of Allure Salon.

SHIPPED: During December 1958, from Hollywood, Calif., by Allure, Inc.

LABEL IN PART: "Allure Mfd. Allure Incorporated, Hollywood, Calif. Model 1053 [or "1052"] Serial No. 9358 [or "82058"]" and "Allure Inc. Switzer Machines."

ACCOMPANYING LABELING: White cards containing the words "I the undersigned do hereby request 'Allure Salon' to administer to me that certain treatment known as 'Switzer Method for Bust Development'."; pink colored folders headed "Free Consultation and Demonstration."; and leaflet entitled "Be Proud of Your Bust."

RESULTS OF INVESTIGATION: The article consisted of rubber-ringed plastic cups of various sizes which have small openings for connection to rubber hoses attached to an air compressor or electrically operated pump. Attached to the compressor is a pressure regulator and a vacuum gauge, and a valve to regulate the amount of vacuum produced in each of the two breast cups while in use. The plastic cups are pressed over the breasts against the chest and the