

**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS
REPORTED IN D.D.N.J. NOS. 6301-6340**

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), and 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, and its purity and 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 in terms of numerical count; Section 502(e) (1), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the drug; 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 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 the labeling thereof; Section 503(b) (4), the article was a drug subject to Section 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.

**DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED
ACCORDING TO DIRECTIONS**

6301. Allure bust development device. (F.D.C. No. 43516. S. No. 71-808 P.)

QUANTITY: 4 devices at Tampa, Fla., in possession of Mrs. J. H. Burns.

SHIPPED: During 1957 or 1958, from Los Angeles, Calif., by Allure, Inc.

LIBELED: 8-31-59, S. Dist. Fla.

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

DISPOSITION: 10-17-60. Consent—claimed by Mrs. J. H. Burns. The devices were dismantled. Some of the parts were destroyed and the remainder of the parts were released to the claimant.

6302. Allure bust development device (4 seizure actions). (F.D.C. Nos. 43512, 43513, 43514, 43515. S. Nos. 71-806/7 P., 71-809/10 P.)

QUANTITY: 2 devices at Clearwater, Fla., and 5 devices at Tampa, Fla.

SHIPPED: Between the latter part of 1957 and January 1959, from Los Angeles and Hollywood, Calif., by Dimco Kitchen Equipment, and Allure, Inc.

LABEL IN PART: "Allure Mfd. by Allure Inc. Hollywood, Calif."

ACCOMPANYING LABELING: Claim (one device) for patent application and (one device) circulars entitled "Allure Salon Bust Developing and Firming."

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, 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 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: 8-31-59, S. Dist. Fla.

CHARGE: 502(a)—when shipped and while held for sale, the labeling, namely, the circular entitled "Allure Salon Bust Developing and Firming," which accompanied one device at Tampa, Fla., contained false and misleading representations that the device was a safe, adequate, and effective treatment for increasing the size of the female breast; for developing the breasts without surgery, hormones, creams, or exercise; that it was capable of bringing about complete bust correction and a beautiful bust line; that it would restore youth, beauty, and glamour; and that use of the device was healthful; and the labeling, namely, the claim for patent application, which accompanied another device at Tampa, Fla., contained false and misleading representations that the article was an adequate and effective treatment for development of the human female breast; 502(f)(1)—the labeling of the article (all lots) failed to bear adequate directions for use for the purposes for which it was intended; and 502(j)—the article (all lots) was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling.

DISPOSITION: 12-7-59. Default—delivered to the Food and Drug Administration.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

DRUGS FOR HUMAN USE

6303. Supplement to notice of judgment on drugs and devices, No. 6003. Vitamin B₁₂ injection. F.D.C. No. 40930, S. No. 67-040 M.

The notice of judgment in the above-identified case is incomplete in that it fails to report the order of dismissal with respect to the adulteration charge under Section 501(b) and the basis upon which the claimant of the article, Maizel Laboratories, Inc., consented to the entry of a decree of condemnation. In order that the notice of judgment may reflect these facts, the provisions of the decree of condemnation are set forth below in their entirety: