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.)