defendants filed a motion for leave to withdraw their pleas of guilty and enter pleas of not guilty. This motion was denied on 7–13–54. On 8–11–54, the court fined each individual defendant $1,000 and sentenced each to imprisonment for 6 months. The court suspended this sentence and placed the defendants on probation for 2 years. The partnership was dismissed as a defendant upon the Government's motion at the time of sentencing.

On 8–20–54, the individual defendants filed a notice of appeal to the United State Court of Appeals for the Third Circuit; and, on 12–28–54, this court, after considering arguments and briefs of counsel, entered an order affirming the judgment of the lower court.

**4922. Lady Bountiful device.** (F. D. C. No. 38480. S. No. 36–961 M.)

QUANTITY: 179 individually cartoned devices at New York, N. Y.

SHIPPED: 9–3–55, from Hollywood, Calif., by Atlanta Corp.

ACCOMPANYING LABELING: A brochure entitled "The story of Lady Bountiful" and a circular designated "Lady Bountiful News November 22, 1951."

RESULTS OF INVESTIGATION: The device consisted of two rubber-edged plastic cups, one of which was slightly larger than the other, and a long rubber hose attached to a specially designed aspirator for attachment to the water faucet.

In use, the plastic cup would be pressed against the chest so that it enclosed one of the breasts and the rubber edge formed an air-tight seal against the chest. The small compact pump fitted over the cold water faucet; the cold water flowed through the specially designed pump and down the drain, never touching the breast but creating a controlled vacuum directed into the plastic cup. By applying and relaxing the thumb on the opening at the top of the rubber tube, the vacuum in the cup exercised the breast by contraction and relaxation.

LIBELED: 10–6–55, S. Dist. N. Y.

CHARGE: 502 (a)—the labeling accompanying the article, when shipped and while held for sale, contained false and misleading representations that the article was effective for increasing the size of the breasts, for providing shape, growth, and expansion for underdeveloped or sagging breasts so that they would become full, round, and firm; and for improving the tone of the breast tissues; and 502 (j)—the article was dangerous to health when used with the frequency and duration prescribed, recommended, and suggested in its labeling since the directions appearing therein recommended and suggested that the device be used from 10 to 25 minutes a day for a period of 2 or 3 months, whereas when used as recommended and suggested, the device may be dangerous where an unsuspected cancer is present or where other pathological conditions may be present.

DISPOSITION: 12–28–55. Default—portion delivered to Food and Drug Administration and remainder destroyed.

## NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

**4923. H–17 and physiological salt solution.** (F. D. C. No. 38421. S. Nos. 13–116/7 M.)

QUANTITY: 37 50-cc. vials of *H–17* and 37 50-cc. vials of *physiological salt solution* at Philadelphia, Pa.

SHIPPED: 5–10–55, from Los Angeles, Calif., by Rene Labhardt.

RESULTS OF INVESTIGATION: The *H–17* was represented by the shipper to contain alcoholic extract of *Radix gelsemii, Radix ononidis, Salix alba, Passiflora, Hydrastis*, formic acid, *Nerium* 0.00003 mgm., *Cannabis sativa* 0.00003 mgm., sodium gold chlorate 0.00003 mgm., and ergot 0.00003 mgm.

The vials of *physiological salt solution* were closed by a rubber stopper which could be readily penetrated by the ordinary hypodermic needle; thus, the contents of the vial could be withdrawn without removal or destruction of the closure. Such vials are classed as multiple dose containers under the definition set forth in the United States Pharmacopeia. Since the vials contained 50 cc. and the Pharmacopeia requires that no multiple dose container shall contain "a volume * * * more than sufficient to permit the withdrawal of 30 cc.," the article was not packaged in conformity with the pharmacopeial requirement.

LIBELED: 9–2–55, E. Dist. Pa.

CHARGE: 502 (b) (1) and (2)—when shipped, both articles failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; 502 (e) (2)—the label of the *H–17* failed to bear the common or usual name of each active ingredient; 502 (g)—the *physiological salt solution* purported to be a drug, the name of which is recognized in the United States Pharmacopeia, an official compendium, and it was not packaged as prescribed therein; and 505 (a)—the *H–17* was a new drug which could not lawfully be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 10–20–55. Default—destruction.

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

**4924. Nutrilite food supplement.** (F. D. C. No. 37268. S. No. 89–515 L.)

INFORMATION FILED: 7–27–55, W. Dist. Wis., against Reuben L. Oschman, Platteville, Wis.

ALLEGED VIOLATION: On 8–5–54, the defendant, in the course of a sales talk to an individual, made oral representations that the article was an effective treatment for the diseases, symptoms, and conditions set forth below, which act resulted in the article being misbranded while held for sale.

LABEL IN PART: (Pkg.) "Nutrilite (R) XX Food Supplement This package contains multiple vitamin capsules and mineral tablets for use as a dietary food supplement to fortify, or supplement, the diet."

CHARGE: 502 (f) (1)—the labeling of the article failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which the article was intended, namely, nervousness, rundown condition, arthritis, sinus trouble, asthma, high blood pressure, low blood pressure, heart trouble, back trouble, prostate gland trouble, headaches, rupture, lack of muscle tone, fatigue, diabetes, piles, stomach ulcers, and hardening of arteries.

PLEA: Guilty.

DISPOSITION: 9–23–55. $100 fine and probation for 1 year.

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*See also No. 4921.