

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 arsenic 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 arsenic acid; 502 (e) (2)—the label of the article failed to bear the common or usual name

of each active ingredient since arsanic acid was not declared; and 502(j)—the article was dangerous to health when used in the dosage and with the frequency or duration prescribed, recommended, or suggested in its labeling, namely, "It may be hand fed two or three times a day, or self fed by keeping it in a hopper at all times."

DISPOSITION: 8-12-57. Default—destruction.

#### NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

5444. Royal jelly capsules. (F.D.C. No. 40545. S. No. 74-956 M.)

QUANTITY: 51 boxes at San Marino, Calif., in possession of Eugene E. Thomas, t/a Ault Bee Farms.

SHIPPED: 7-9-57, from Weslaco, Tex., by Ault Bee Farms.

LABEL IN PART: "Royal Jelly 30 Capsules \* \* \* Each capsule contains  
Net Weight: 25 Milligrams ---- Royal Jelly 60 Milligrams ---- Pure Honey  
60 Milligrams ---- Organic Alfalfa 60 Mg. Organic Calcium & Phosphorous  
60 Milligrams ---- Organic Wheat Germ This is a food, not a medicine.  
Ault Bee Farms, Box 1144, Pasadena, Calif."

ACCOMPANYING LABELING: Brochure entitled "Dr. Lisi prescribes Royal Jelly For His Holiness Pope Pius XII," a printed sheet headed "Ault Bee Farms \* \* \* Dear Friend:" and a printed sheet headed "Ault Bee Farms \* \* \* Here is an Excerpt From 'Here's Health' Magazine."

RESULTS OF INVESTIGATION: The brochure was received by the consignee from the Ault Bee Farms, Weslaco, Tex., and the printed sheets were printed locally for the consignee.

LIBELED: 8-6-57, S. Dist. Calif.

CHARGE: 502(a)—the designation "Royal Jelly" borne on the label of the article, when shipped, was misleading since the article contained 2 or more ingredients and was designated by the name of one but not all of such ingredients, even though the names of all such ingredients were stated elsewhere on the label; 502(a)—the labeling accompanying the article, when shipped and while held for sale, contained false and misleading representations that the article was capable of producing a state of well being and mental alertness; that the product contained all the vitamins and minerals needed by the body; and that it would prolong life, increase and sharpen appetite and sense of taste, lessen digestive difficulty, improve nervous balance, increase virility and sexual energy, increase ability to train and work harder, give one an increased feeling of youthfulness, prevent illness and debility, normalize the human mechanism, cure a wide variety of illnesses, reactivate body functions and check a tendency toward obesity, repair wastage, and rejuvenate body cells; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 8-27-57. Default—destruction.

5445. Royal jelly capsules. (F.D.C. Nos. 40345, 40346. S. No. 66-025 M.)

QUANTITY: 13 dozen 15-capsule bottles, 4 dozen 100-capsule bottles, and 4 additional 100-capsule bottles at San Francisco, Calif.

SHIPPED: Between 3-26-57 and 4-29-57, from New York, N.Y., by Tamara (a business organization).