tension and muscular aches and pains; reducing weight without diet; removing "inches and pounds off your waist, hips and thighs"; increasing circulation to carry away waste fat; and providing deep massage to relieve tension and muscular pains.

DISPOSITION: 6–4–59. Default—destruction.

5999. Electro-Warmth Bed Warmer. (F.D.C. No. 42840. S. No. 40–250 P.)

QUANTITY: 5 individually cartoned devices at Moss Beach, Calif.

SHIPPED: 11–24–58, from Danville, Ohio, by Patented Products Corp.

LABEL IN PART: (Ctn.) "Electro-Warmth Automatic Bed Warmer Patented Products Corporation, Danville, Ohio"; (tag on device) "Electro-Warmth * * * You Sleep On It Not Under It * * * Patented Products Corp., Danville, Ohio."

ACCOMPANYING LABELING: Leaflets entitled "Sleeping Comfort and Health," "New Electro-Warmth," and "Electro-Warmth—It's Warm"; pamphlets entitled "Which Bed Warmer Works Best"; and printed sheets entitled "Here's Why Users Prefer Electro-Warmth."

RESULTS OF INVESTIGATION: The article consisted of a mattress pad containing a variable controlled heating element.

LIBELED: 2–20–59, N. Dist. Calif.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment for relieving or curing arthritis, colds, chronic sinus and tonsil infections, organic pains, and neuritis; and that the article would provide better health and longer life.

DISPOSITION: 5–5–59. Default—destruction.

DRUG FOR VETERINARY USE

6000. Paladide (veterinary). (F.D.C. No. 42873. S. No. 51–481 P.)

QUANTITY: 26 25-lb. pails, 312 1-lb. jars, and 41 cases, each containing 12 1-lb. jars, at Chicago, Ill.

SHIPPED: Between 11–7–58 and 1–27–59, from Kansas City, Mo., by Jensen-Salsbery Laboratories, Inc.

LABEL IN PART: (Jar) "Jen-Sel * * * therapeutic iodide compound PALADIDE * * * Each ounce contains: Cuprous iodide* . . . . . 24.1 gr. Palatable, inert base * * * Supplies 1.04 Gm. of available iodine."

ACCOMPANYING LABELING: Circular entitled "Jen-Sal Product Guide and Price List."

LIBELED: 3–6–59, N. Dist. Ill.; amended libel 3–31–59.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for lumpy jaw and respiratory diseases of cattle and swine, mastitis, metritis, and as supportive therapy in such conditions as functional sterility and cervical abscesses in cattle and swine.

DISPOSITION: 5–20–59. Default—destruction.

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6001–6040

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered by default, or by consent, and in one case following reversal by the appellate court of the judgment of the trial court; (2) criminal proceedings terminated upon a plea of guilty; and (3) an injunction proceeding terminated by dismissal after compliance. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *October 11, 1960.*

CONTENTS*

* For drugs actionable because of deviation from official or own standards, see No. 6003; omission of, or unsatisfactory, ingredient statements, No. 6012; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 6025; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 6005, 6012.

563420—60——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. 6001–6040

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.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b)(1), the article was in package form and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502(c), a word, statement, or other information required by the Act to appear on the label or labeling was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502(e)(2), the article was a drug not designated solely by a name recognized in an official compendium, and it was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient and the proportion of alcohol contained therein; 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 its labeling; Section 503(b)(4), the article was 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.

DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

6001. Quik-Kap Capsules and Rem-Al Emetic. (F.D.C. No. 35122. S. Nos. 36–917 L, 38–356 L.)

INFORMATION FILED: 12–14–53, S. Dist. N.Y., against Leo Savitch, general manager of the Personal Drug Co., and the Rem-Al Drug Co., New York, N.Y.

ALLEGED VIOLATION: Between 9–27–51 and 10–16–51, while a number of capsules of drug were being held for sale at New York, N.Y., after shipment in interstate commerce, the defendant caused the capsules to be repacked into boxes labeled "*Quik-Kap Capsules*" and containing a leaflet entitled "Instruction Leaflet and Order Blank" which act of repacking resulted in such drug in the boxes being misbranded.

In addition, on 9–20–51, the defendant caused to be introduced into interstate commerce, at New York, N.Y., for delivery to Birmingham, Ala., a bottle of *Rem-Al Emetic* which was misbranded.

LABEL IN PART: "QUIK-KAP Capsules For * * * PERSONAL DRUG CO. 6 HESTER ST. NEW YORK 2, N.Y. AVERAGE DOSE * * * ACTIVE