

211. Tranquilease (cosmetic cream). (F.D.C. No. 41505. S. No. 4-382 P.)

QUANTITY: 48 individually cartoned jars at Washington, D.C.

SHIPPED: 1-29-58, from Philadelphia, Pa., by Denney & Denney, Inc.

LABEL IN PART: (Jar) "TRANQUILEASE . FRANCES DENNEY The Original Cosmetic Tranquilizer for the Skin * * * 1.8 Oz. Net."

ACCOMPANYING LABELING: Carton inserts entitled "Tranquilease The only cosmetic of its kind." and leaflets entitled "Bulletin from Frances Denney."

RESULTS OF INVESTIGATION: Analysis showed that the article was a white perfumed oil-in-water cream emulsion containing glycerol monostearate, waxes (including lanolin and/or sterols), inorganic pigments (mostly zinc oxide and titanium dioxide), mineral oil, glycerol, and a nitrogen compound (probably an amide).

LIBELED: 4-4-58, Dist. Columbia.

CHARGE: 602(a)—when shipped, the labeling and the name of the article contained false and misleading representations that the article would tranquilize the skin and correct all abnormal skin conditions resulting from emotional upsets, tension, and fatigue.

The libel alleged also that the article was misbranded under the provisions of the law applicable to drugs, as reported in notices of judgment on drugs and devices No. 6213.

DISPOSITION: On 5-15-58, Frances Denney and Denney & Denney, Inc., appeared as claimants and denied that the article was a drug or that it was misbranded. Thereafter, the Government and the claimants filed written interrogatories. The claimants objected in part to the Government's interrogatories for specific reasons, and a further general objection was made to all the interrogatories on the grounds of self-incrimination. On 11-14-58, the court entered a memorandum opinion, ruling against the claimants on their self-incrimination objection, and ruling in part for the claimants and in part for the Government on the other objections (23 F.R.D. 192). Such opinion is reported in notices of judgment on drugs and devices No. 6213, referred to above.

An order was entered in accordance with the opinion and the interrogatories were answered by the claimants. Thereafter, the Government filed a motion for summary judgment. On 10-20-59, the claimants filed a motion to withdraw their claim and answer. On 10-29-59, an order was entered by the court withdrawing claimants' claim and answer and directing that the article be condemned and destroyed. On 11-16-59, the article was destroyed.

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]

212-231

COSMETICS

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, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings.

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

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

WASHINGTON, D.C., *September 12, 1962.*

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*For inconspicuousness of required label information, see No. 231.

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