5644. Thorazine hydrochloride tablets, Butazolidin tablets, Ansolysen Tartrate tablets, Serpasil Apresoline tablets, Doriden tablets, Meticortelone tablets, and Meticorten tablets. (F.D.C. No. 39504. S. Nos. 61–941/43 M, 61–946/9 M.)

QUANTITY: 41 50-tablet vials of *Thorazine hydrochloride tablets;* 14 100-tablet vials and 5 1000-tablet vials of *Butazolidin tablets;* 19 100-tablet vials of *Ansolysen Tartrate tablets;* 12 100-tablet vials of *Serpasil Apresoline tablets;* 14 100-tablet btls. of *Doriden tablets;* 37 100-tablet vials of *Meticortelone tablets;* and 19 100-tablet vials of *Meticorten tablets* at Woodside, N.Y., in possession of Henry Schein.

SHIPPED: At various times, including July or August, 1956, from Philadelphia, Pa.; Cleveland, Ohio; Summit, N.J.; and Bloomfield, N.J.

RESULTS OF INVESTIGATION: The articles were all new drugs which had been repackaged by the dealer, Henry Schein, under his own labels.

LIBELED: 10–8–56, E. Dist. N.Y.

CHARGE: 505(a)—the articles were new drugs which may not be lawfully introduced into interstate commerce since applications filed pursuant to law were not effective with respect to such drugs.

DISPOSITION: Henry Schein appeared as claimant and filed an answer to the libel on 11–21–56. The Government served written interrogatories upon the claimant. Subsequently, answers were filed to the interrogatories after which the Government filed a motion for summary judgment. On 2–6–59, the court handed down the following decision in denial of the motion:

RAYFIEL, J., *District Judge:* "The plaintiff moves for summary judgment under Rule 56 of the Federal Rules of Civil Procedure.

"The Government commenced this action by filing a libel in rem for the seizure and condemnation of certain vials and bottles containing various kinds of drugs which had been shipped in interstate commerce by their respective manufacturers to one Henry Schein, the claimant herein, a pharmacist of Woodside, Queens County, New York, in this District, and repacked and relabeled by him.

"The basis for the libel was the claim, made by the Government, that the said claimant had not filed 'New Drug' applications with the Secretary of Health, Education and Welfare for the repacked articles, as required by the Federal Food, Drug and Cosmetic Act, Title 21, U.S. Code, Sections 301 et seq.

"Section 355(a) of said title provides that no person shall introduce a new drug in interstate commerce unless an application, filed pursuant to subsection (b) thereof, is effective with respect thereto. Subsection (b) sets forth the requirements of the application, such as reports of investigations as to the safety thereof, its components, specimens of labels, etc.

"The claimant contends, and the Government does not deny, that the manufacturers of *all* of the drugs seized have filed the applications required by Section 355(a), and that they are effective. The Government argues, however, that because the drugs have been *repacked* by the claimant, and in some instances *relabeled*, he, too, is required to file effective 'New Drug' applications therefor.

"The claimant admits that he did not file such applications, but contends that he was not required to do so, since he did nothing more with the drugs in question than repack them in smaller containers and quantities for sale *only* to physicians and institutions such as hospitals, etc.

"It is apparent, therefore, that there are triable issues presented which can be disposed of only by a trial.

"Accordingly, the motion for summary judgment is denied."

On 3–26–59, with the consent of the claimant and the Government, a decree was entered dismissing the libel against the *Ansolysen Tartrate, Serpasil Apresoline, Doriden, Meticortelone,* and *Meticorten tablets,* and ordering that

such articles be returned to the claimant. In addition, on the same day, a consent decree of condemnation and destruction was entered against the *Thorazine hydrochloride tablets* and the *Butazolidin tablets.*

5645. Beauty for Life Capsules. (F.D.C. No. 41312. S. Nos. 24–644 M, 75–231 M.)

QUANTITY: 205 75-capsule btls. at El Segundo, Calif.

SHIPPED: 10–16–57, from Roslyn, N.Y., by Helena Rubenstein, Inc.

LABEL IN PART: "Beauty For Life Three Capsules Contain * * * Vitamin A 4000 U.S.P. Units Vitamin D 400 U.S.P. Units Vitamin B_1 * * * 1 mg. Vitamin C * * * 30 mg. Riboflavin * * * 2 mg. Niacin 10 mg. Vitamin B_6 * * * 3 mg. Vitamin B_{12} 9 micrograms Folic Acid 0.6 mg. Calcium Pantothenate 6.6 mg. Gelatin 1800 mg. Royal Jelly 30 mg. * * * Recommended Dosage: Three (3) a day."

LIBELED: 1–6–58, S. Dist. Calif.

CHARGE: 502(a)—when shipped, the name "Beauty For Life Capsules" and the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for restoring abnormal skin, hair, and nails to normal, that it would aid looks and physical well-being, make one look younger, prevent dryness, brittleness, and splitting of nails indefinitely, and would have beneficial effects in treating nervous tension; and 505(a)—the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the drug.

DISPOSITION: 2–7–58. Default—destruction.

5646. Royal jelly capsules. (F.D.C. No. 40974. S. No. 55–060 M.)

QUANTITY: 585 capsules in btls. at Louisville, Ky., in possession of Royal Drugs of Kentucky.

SHIPPED: 10–11–57, from Cambridge, Mass.

LABEL IN PART: "15 Capsules Queen Bee Brand Royal Jelly * * * Distributed by Royal Drugs of Ky. * * * Each capsule contains 50 mg. Royal Jelly * * * Dietary Supplement."

ACCOMPANYING LABELING: Reprints entitled "Royal Jelly, by R. B. Willson."

RESULTS OF INVESTIGATION: The capsules in the bottles were repackaged and relabeled by the consignee from bulk stock which had been shipped as described above. The above-mentioned accompanying labeling had been produced locally from a reprint of an article in the "American Bee Journal."

LIBELED: 12–4–57, W. Dist. Ky.

CHARGE: 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that *royal jelly* would prolong life, produce sexual rejuvenation, cure cerebral neuritis (pains in the head and down the arm), arthritis, diabetes, asthma, failing eyesight, sterility in women, impotency in men, and increase lactation in women; and 505(a)—the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: 3–14–58. Default—destruction.