

LABEL IN PART: (Ctn.) "Royal Jelly * * * 50 mg. each * * * The Royal Jelly is guaranteed to be a natural product from the bee hive. This Royal Jelly from selected queen cells is not more than two days old after introducing the larvae, which gives the most active concentration."

ACCOMPANYING LABELING: Leaflets entitled "Theft From Queen Bee—Honey Jelly Keeps Child Ruler Young," reprints entitled "Reprints of Scientific New Reports on Royal Jelly," and books entitled "The Miracle of Royal Jelly."

LIBELED: 7-5-57, N. Dist. Calif.

CHARGE: 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was an adequate and effective preventive and treatment for cancer, "what ails you," rejuvenation of the aged, keeping one young, adding years to one's life, healing ulcers, seborrhea, infectious hepatitis, stomatitis, eczema, acne, diabetes, and cirrhosis of the liver; that the article aids growth, fertility in women past the menopause, rejuvenation of sexual activity, stimulation of appetite, and elimination of nervous and vascular disorders; that the article would be effective for heart disease, liver ailments, hemorrhoids, increasing mental activity, pimples, blackheads, other skin blemishes, rejuvenating the tissues of the skin, and for other purposes.

505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 7-24-57. Default—destruction.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

DRUG FOR VETERINARY USE

5446. Strep Pen spray (2 seizure actions). (F.D.C. Nos. 39696, 39697. S. Nos. 45-741/2 M.)

QUANTITY: 21 pints at Harmony, Md., and 57 pints at Laurel, Del.

SHIPPED: 7-5-56 and 9-10-56, from Vineland, N.J., by Eastern Laboratories, Inc.

LABEL IN PART: (Btl.) "Strep Pen Spray For Inhalation Therapy of Poultry * * * Contains 25 gm. Dihydrostreptomycin Base * * * and 5 million units of Penicillin G Potassium Contents—1 Pint * * * Manufactured for M & D Sales Co. Snow Hill, Md. [or "Twin Supply Service Co., Baltimore, Md.]."

RESULTS OF INVESTIGATION: Examination showed that the article had a potency of 2,000 units of penicillin G potassium per pint.

LIBELED: On or about 11-28-56, Dist. Md., and 11-21-56, Dist. Del.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess; 502(a)—the label statement "Contains * * * 5 million units of Penicillin G Potassium [in] 1 Pint" was false and misleading; and 502(1)—the article was represented as a drug composed in part of penicillin and a streptomycin derivative; it was not from a batch with respect to which a certificate had been issued pursuant to law; and it was not exempt from such requirement.

DISPOSITION: 1-28-57 and 1-30-57. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

5447. **Elip tablets.** (F.D.C. No. 34887. S. Nos. 37-389/90 L.)

QUANTITY: 39 bags, 1,200 tablets each, at Baldwin, N.Y., in possession of Baldwin Laboratories, and 94 12-tablet vials at Baldwin, N.Y., in possession of Elip Distributing Co.

SHIPPED: 6-6-52, from East Newark, N.J.

LABEL IN PART: (Bag) "Elip Tablet"; (vial) "Elip Tablets * * * Active Ingredients: Potassium Bitartrate, Sulfur, Rhubarb."

ACCOMPANYING LABELING: Window sign bearing the words "Elip For Piles" and counter display placards bearing the words "An Internal Preparation For The Relief of Piles."

RESULTS OF INVESTIGATION: The tablets in the bags represented the remainder of a bulk shipment which had been made to Baldwin Laboratories at Baldwin, N.Y., from East Newark, N.J.; and the tablets in the vials represented a portion of such bulk shipment which had been sold by Baldwin Laboratories to Elip Distributing Co. and repackaged into vials by that company.

The above-described window sign was on display in the window of Baldwin Laboratories, and the counter display placard was used by the Elip Distributing Co. in preparing the vials of tablets for sale. The vials were attached to the placards in units of six.

LIBELED: 3-20-53, E. Dist. N.Y.; amended libel 1-10-55.

CHARGE: 502(a)—while held for sale, the labeling of the article in the bags and vials contained false and misleading representations that the article was an adequate and effective treatment for piles and the discomfort and itching of rectal irritation caused by piles; and 502(f) (2)—the labeling of the article failed to bear a warning against its use for bleeding piles.

DISPOSITION: The Elip Distributing Co. and Ira Lichtenstein, t/a Baldwin Laboratories, claimants, filed an answer to the original libel, denying that the article was misbranded as alleged. Interrogatories were served by the Government upon the claimants on 10-20-53; and the claimants, without answering the interrogatories, made a motion for summary judgment. The matter was argued before the court on 1-13-54, and on 2-11-54 the court handed down the following decision in denial of the motion:

BYERS, District Judge: "This is a claimant's motion in a condemnation proceeding under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301, et seq.) for summary judgment.

"The basis of the motion is a holding by the U.S. Post Office Department that the subject matter of the libel was not falsely and fraudulently labeled.

"Fraud is not alleged in the libel, nor was such an allegation requisite under the law. *U.S. v. 5 cases, etc.*, 156 Fed (2) 493 Cf. *U.S. v. Dotterweich*, 320 U.S. 277.

"It is clear that such a departmental holding is not *res judicata*.

"Motion denied. Settle order."

Following the decision, the claimants filed answers to the interrogatories. The amended libel was filed, to which the claimants filed an answer, denying that the article was misbranded; they again advanced the defense of *res judicata* based upon the prior Post Office proceedings. The Government moved to strike the allegations in the answer relating to the *res judicata* defense; and on 9-6-55, the court granted the Government's motion to strike.