

**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS  
REPORTED IN D.D.N.J. NOS. 5581-5620**

*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 Pharmacopeia and National Formulary), and its strength differed from, and its quality and purity fell below, the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength and quality differed from that which it purported or was represented to possess.

*Misbranding*, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502(e) (2), the article was a drug not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502(f) (1), the labeling of the article failed to bear adequate directions for use; Section 502(f) (2), the labeling of the article failed to bear 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; and Section 503(b) (4), the article was a drug 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.

**NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION**

**5581. Clarimycin.** (F.D.C. No. 41325. S. No. 83-423 M.)

**QUANTITY:** 35 display cartons, each containing 6 btl., at Columbus, Ohio.

**SHIPPED:** 11-22-57, from Jersey City, N.J., by Merritt Corp.

**LABEL IN PART:** (Btl.) "5 drams Clarimycin Anti-Biotic Acne Lotion \* \* \*

Active ingredients: Neomycin Sulphate, Allantoin."

**LIBELED:** 1-7-58, S. Dist. Ohio.

**CHARGE:** 505(a)—The article, when shipped, was a new drug which may not be shipped in interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

**DISPOSITION:** 8-20-58. Consent—destruction.

**5582. Clarimycin.** (F.D.C. No. 41372. S. No. 60-378 M.)

**QUANTITY:** 366 display cards, each containing 1 btl., at Detroit, Mich.

**SHIPPED:** 11-25-57, from Jersey City, N.J., by Merritt Corp.

**LABEL IN PART:** (Btl.) "Contents: 5 drams Clarimycin Anti-Biotic Acne Lotion \* \* \* Active Ingredients: Neomycin Sulphate, Allantoin."

**LIBELED:** 1-22-58, E. Dist. Mich.

**CHARGE:** 505(a)—the article, when shipped, was a new drug which may not be shipped in interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

**DISPOSITION:** Merritt Corp., claimant, having filed a motion for consolidation and removal, the court, on 5-16-58, after consideration of the briefs of the parties, handed down the following opinion in denial of the motion:

O'SULLIVAN, *District Judge*: "This cause is before the Court upon motion of Merritt Corporation to consolidate this cause with cause No. 17780, also pending in this court, Civil Action 5184 pending in the United States District Court for the District of Ohio, Eastern Division, and cause No. 16750, pending in the United States District Court for the Western District of Pennsylvania, and to remove the cases so consolidated for trial in the Southern District of New York. After due consideration thereof, the Court does find and order as follows:

"1) The claimant, Merritt Corporation, claims that its motion has validity by reason of the provisions of 21 USC 334(a) and 21 USC 334(b), or if not entitled to have its motion granted under those two statutes, then under 28 USC 1404(a) or 28 USC 1404(b).

"2) The Government's libel is bottomed upon its claim that the articles subject to the libel constitute a new drug and that there is no statutory authority for this Court in such case to remove or consolidate the causes mentioned, by virtue of the above-mentioned statutes. The Court so finds.

"3) Claimant asserts that the cause pending in the District Court of Pennsylvania is, in effect, a misbranding case which would authorize the removal sought. If such is true, then a motion might well be addressed to the Pennsylvania District Court to remove that cause to the Southern District of New York, and the other causes pending in Michigan and Ohio might well be held in abeyance pending disposition of the Pennsylvania cause so removed to New York.

"NOW, THEREFORE, it is hereby Ordered that the motion of Merritt Corporation to consolidate and remove the mentioned causes may be, and it is, denied."

On 8-27-58, the claimant having consented, the court entered a decree of condemnation and ordered that the product be destroyed.

**5583. Royal jelly capsules.** (F.D.C. No. 40945. S. No. 69-118 M.)

**QUANTITY:** 500 capsules, each containing 50 mg., of *royal jelly* at New York, N.Y., in possession of Reid & Cubit, Inc.

**SHIPPED:** 9-10-57, from Linden, N.J.

**LABEL IN PART:** "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:** Printed matter designated "Reprints of Scientific News Reports on Royal Jelly."

**RESULTS OF INVESTIGATION:** The article was shipped as described above in bulk containers and, upon receipt at New York, N.Y., it was repackaged into small vials and relabeled by the dealer as above described.

**LIBELED:** 12-10-57, S. Dist. N.Y.

**CHARGE:** 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article would sexually rejuvenate, increase the life span, and give a lift to the aged and infants; and 505(a)—the article was a new drug within the meaning of the law, and an application filed pursuant to law was not effective with respect to the article.

**DISPOSITION:** 1-6-58. Default—destruction.