

ACCOMPANYING LABELING: Placard reading, in part, "Laubach's Medicines * * * Laubach's No. 15 Tablets," leaflet entitled "Laubach's Medicines for Stomach Disorders," and booklets entitled "Are You Suffering From Acid Stomach—Gastric Ulcers."

RESULTS OF INVESTIGATION: The tablets in the 30-box lot were repacked from the 2-drum and 9-bottle lots, and the tablets in the 5-box lot were repacked from the 3-drum lot. The accompanying labeling was printed locally for the consignee.

LIBELED: 6-21-57, Dist. N.J.

CHARGE: 502(a)—the labeling accompanying the articles, while held for sale, contained false and misleading representations that *Laubach's No. 25 Duplex tablets* were an adequate and effective treatment for acute rheumatic fever, muscular aches, pains, gout, and muscular lumbago, and that *Laubach's No. 15 tablets* were an adequate and effective treatment for stomach disorders, including stomach ulcers.

DISPOSITION: 9-3-57. Consent—claimed by Laubach Proprietary Medicines, Inc., Jersey City, N.J., and relabeled.

5580. Listerine. (F.D.C. No. 40843. S. Nos. 60-746 M, 61-355 M, 75-869 M, 76-153 M, 76-289 M, 76-625 M.)

QUANTITY: 89 14-oz. btls., 88 7-oz. btls., and 114 3-oz. btls., and 23 cases, 12 14-oz. btls. each, 135 cases, 12 7-oz. btls. each, and 87 cases, 48 3-oz. btls. each, at Boston, Mass.

SHIPPED: At various times, including 8-14-57, from Lititz, Pa., by Lambert-Hudnut.

LABEL IN PART: (Btl. wrapper) "Listerine Antiseptic * * * Alcohol 25% Active Ingredients: Thymol, eucalyptol, methyl salicylate, menthol, benzoic acid and boric acid Lambert Pharmacal Company * * * St. Louis, Mo."

ACCOMPANYING LABELING: Placard headed: "A Timely Warning."

LIBELED: 10-14-57, Dist. Mass.

CHARGE: 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was effective for preventing Asian influenza.

DISPOSITION: 3-10-58. Default—delivered to charitable institutions for their use and not for sale.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 5561 TO 5580

PRODUCTS

	N.J. No.		N.J. No.
Amphetamine, d e x t r o-, sulfate		Chorionic gonadotropin.....	5568, 5569
timed disintegration capsules	5562, 5570	Colonoid capsules	5574
Antiseptic, Listerine.....	5580	Cortisone acetate tablets.....	5561
Arthritis, remedy for. See Rheumatism, remedy for.		Del-Caps timed disintegration capsules	5562, 5570
Asian influenza, remedy for.....	5580	Devices	5575-5578
Bicarbonate, sodium tablets.....	5579	Dextro-amphetamine sulfate	
Bursitis, remedy for. See Rheumatism, remedy for.		timed disintegration capsules.....	5562, 5570
		Digitoxin tablets.....	5564-5566

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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]

5581-5620

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 seizure proceedings in which decrees of condemnation were entered after default or consent. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation.

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

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

WASHINGTON, D.C., *October 15, 1959.*

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*For presence of a habit-forming substance without warning statement, see No. 5584; omission of, or unsatisfactory, ingredients statements, Nos. 5584, 5594, 5607; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 5584, 5607; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 5584.

**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.