DISPOSITION: 5-10-60. Fine of \$500 on each of the 2 counts of the information, plus costs. Fine on count 2 was suspended.

6158. (F.D.C. No. 44280. S. Nos. 5-831/2 P, 5-834/7 P.)

INFORMATION FILED: 3-21-60, E. Dist. N.C., against Alexander L. Hogan, t/a Hogan's Pharmacy, Kinston, N.C.

CHARGE: Between 3-17-59 and 6-9-59, Pro-Banthine tablets were dispensed 4 times and Dartal tablets and Equanil tablets were each dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: On 4-18-60, the case came on for trial before the court without a jury. The defendant was found guilty, fined \$500, and placed on probation for 2 years.

6159. (F.D.C. No. 43700. S. Nos. 59–661/7 P.)

INFORMATION FILED: 12-31-59, E. Dist. N.C., against Arthur D. Wall, t/a Grifton Pharmacy, Grifton, N.C.

CHARGE: Between 4-30-59 and 6-8-59, Ergoapiol with savin capsules, Aphrodex capsules, Testacoids tablets, and capsules containing amytal were each dispensed once, and Meticorten tablets were dispensed 3 times without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 5-9-60. \$300 fine and probation for 2 years.

6160. (F.D.C. No. 43726. S. Nos. 5-901/7 P.)

INFORMATION FILED: 2-16-60, E. Dist. N.C., against George David Grimes, t/a David Grimes Drug Store, Robersonville, N.C.

CHARGE: Between 3-11-59 and 5-13-59, Benzedrine Sulfate tablets, Equanil tablets, and pentobarbital sodium capsules were each dispensed twice, and Pen-Tabs (penicillin G potassium tablets) were dispensed once without a prescription.

PLEA: Guilty.

Disposition: 4-26-60. \$200 fine and probation for 2 years.

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Allylisobutylbarbituric acid, tab-	Chloramphenicol capsules 6147
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Amobarbital and amphetamine	Cyclogesterin tablets6147
sulfate, tablets containing a	
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mixture of 6141	Desoxyephedrine hydrochloride
Amphetamine sulfate tablets 16121-	tablets 6156, 6157
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Benzedrine Sulfate tablets 6160	lets 6137-6139, 6147

<sup>&</sup>lt;sup>1</sup> (6126, 6151, 6158) Prosecution contested.

## 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]

#### 6161-6200

#### 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 (1) seizure proceedings in which decrees of condemnation were entered after default or consent; (2) a criminal proceeding terminated upon a plea of guilty; and (3) an injunction proceeding terminated upon the entry of a consent decree of temporary injunction. The seizure proceedings are civil actions taken against the goods alleged to be in violation, and the criminal and injunction proceedings are against the firms or individuals charged to be responsible for violations.

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

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

WASHINGTON, D.C., December 13, 1960.

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<sup>\*</sup>For drugs in violation of prescription labeling requirements, see No. 6163; omission of, or unsatisfactory, ingredient statements, Nos. 6172, 6175; failure to comply with the packaging requirements of an official compendium, No. 6175; failure to bear a label containing an accurate statement of the quantity of the contents, No. 6172; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 6172; cosmetic, actionable under the drug provisions of the Act, No. 6165.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6161-6200

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 its strength differed from, and its quality 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 differed from, or its purity or quality fell below, 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(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), the labeling of the article failed to bear (1) adequate directions for use; and (2) 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; Section 502(g), the article purported to be a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and it was not labeled as prescribed therein; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; and Section 503(b)(4), the article was a drug subject to 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.

## DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

6161. Allure bust development device. (F.D.C. No. 44114. S. No. 26-112 R.) QUANTITY: 1 device at Lompoc, Calif.

SHIPPED: 1-17-60, from Alamogordo, N. Mex., by Mrs. Patra Roland.

LABEL IN PART: (Metal plate on device) "Allure Mfd. by Allure Incorporated, Hollywood, Calif., Model 31358, Serial No. 1032."

RESULTS OF INVESTIGATION: The article consisted of rubber-ringed plastic cups of various sizes which had small openings for connection to rubber hoses attached to an air compressor or pump operated by an electric motor. Attached to the compressor was a pressure regulator, a vacuum gauge, and a valve to regulate the amount of vacuum produced in each of the two breast cups.

While in use, the plastic cups were pressed over the breasts against the chest and the rubber-ringed edge formed an airtight seal. The air compressor was then operated to form a vacuum inside the cups to exercise the breasts by contraction and relaxation.

The air compressor and accessory equipment were contained in a metal cabinet 36" x 22" x 18".