

prove the efficacy, etc., of HYROCAIN," which statement represented and suggested that the Food and Drug Administration considers the article effective in the conditions and for the purposes for which it was offered, and which was false and misleading since the Food and Drug Administration does not consider the article effective in all of the conditions and for all of the purposes for which the article was offered.

DISPOSITION: 11-24-54. Consent—claimed by American Pharmaceutical Co. and relabeled.

4760. Cacodyne. (F. D. C. No. 33297. S. No. 33-012 L.)

QUANTITY: 20,300 ampuls, 10 cc. each, of *Cacodyne* (Colloidal Isotonic Iodine Solution) and 20,300 ampuls, 1 cc. each, of *Cacodyne* (Sodium Cacodylate) at Chicago, Ill., in possession of Research Medications, Inc.

SHIPPED: Between 9-1-50 and 12-19-51, from Tuckahoe and New York, N. Y.

LABEL IN PART: "10 cc. Size *Cacodyne* Each 10 cc. contains 0.2 percent Colloidal Isotonic Iodine Solution" or "*Cacodyne* Each cc. contains 7 gr. of Sodium Cacodylate (Arsenic derivative)."

ACCOMPANYING LABELING: Brochures entitled "*Cacodyne* An Isotonic Colloidal * * * for all arterial diseases" and reprints entitled "A Regimen for Restoration of Cardiovascular Reserve," "A New Management for the Sustained Relief of Angina Pectoris and Coronary Disease," "Decisiveness Imperative in Cardiovascular Management," and "Cardiovascular Disease, Its Treatment Based on Control of Hypertension and Restoration of Coronary Efficiency."

RESULTS OF INVESTIGATION: The articles, after their receipt at Chicago, Ill., were in part repackaged by the consignee, Research Medications, Inc., into combination packages containing 1 ampul of each article; and, when shipments of the repackaged articles were made by the consignee, there would be enclosed in the shipping container a copy of the above-mentioned brochure containing the statement "Reprints and other information on request."

LIBELED: 6-20-52, N. Dist. Ill.

CHARGE: 502 (a)—the labeling accompanying the articles while held for sale contained false and misleading representations that the articles were an adequate and effective treatment for all arterial diseases and all forms of circulatory impairment.

DISPOSITION: Research Medications, Inc., claimant, consented to the entry of a decree, and on 6-26-52, an order was entered condemning the articles and providing for their release to the claimant for the purpose of bringing them into compliance with the law. Thereafter, a dispute arose between the claimant and the Government as to the disposition of certain of the literature accompanying the articles, and the claimant filed a petition requesting the court to vacate the consent decree and to set the matter down for a hearing on its merits.

On 12-18-52, the court entered an order which permitted the claimant to file an answer, but left the consent decree standing as security; the court further ordered that that portion of the article which bore labeling which had been approved by the Food and Drug Administration during its negotiations with the claimant be released to the claimant, but that the accompanying labeling be held intact. Thereafter, the claimant filed a motion for particulars, or for more definite allegations, which motion was granted by the court on 12-24-52. The information requested by such motion was furnished by the Government

on 1-26-53. The claimant, on 2-4-53, filed an answer denying that the articles were misbranded as alleged.

Subsequently, the Government served interrogatories upon the claimant. The claimant objected to certain of the interrogatories; however, the court, on 5-11-53, overruled the objections and ordered the claimant to answer all interrogatories. Interrogatories then were served upon the Government by the claimant and were answered. Thereafter, the Government filed a request for admissions. The claimant subsequently withdrew its answer, and the court, on 3-2-54, with the consent of the claimant and the Government vacated the order entered on 12-18-52, an act which left the consent decree operative. The drug was satisfactorily relabeled, and the accompanying literature was destroyed.

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¹ (4758) Seizure contested. Contains opinion of the court.

² (4756) Injunction issued.

³ (4757) Contempt of injunction.

⁴ (4747) Prosecution contested. Contains opinion of the court.

⁵ (4741) Injunction issued. Contains opinions of the court, findings of fact, and conclusions of law.

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]

4761-4780

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 which were terminated with the entry of default or consent decrees of condemnation or which were dismissed after trial; (2) criminal proceedings which were terminated upon pleas of guilty; (3) injunction proceedings terminated with the entry of injunctions; and (4) contempt proceedings for violation of an injunction which were dismissed. The seizure proceedings are civil actions taken against the goods alleged to be in violation, and the criminal, injunction, and contempt 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., September 14, 1956.

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*For presence of a habit-forming narcotic without warning statement, see No. 4761; omission of, or unsatisfactory, ingredients statements, No. 4761; sale under name of another drug, No. 4774; failure to bear a label containing an accurate statement of the quantity of the contents, No. 4761; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 4761.

**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS
REPORTED IN D. D. N. J. NOS. 4761-4780**

Adulteration, Section 501 (a) (1), the article consisted in part of a filthy substance; 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from that which it purported or was represented to possess; Section 501 (d) (2), the article was a drug, and a substance had been substituted wholly or in part therefor.

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 quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the drug; Section 502 (e) (2), the article was 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 (i) (3), the article was offered for sale under the name of another drug; Section 502 (1), the article purported to be and was represented as a drug composed wholly or partly of a kind of chlortetracycline or a derivative thereof, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; Section 503 (b) (4), the article was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

**DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE
HAD BEEN ISSUED**

4761. Steclin capsules, Altepose tablets, and Feosol tablets. (F. D. C. No. 37952. S. Nos. 21-814/5 M, 21-817 M.)

QUANTITY: 1 btl. containing 430 *Steclin capsules*, 1 btl. containing 300 *Altepose tablets*, and 1 btl. containing 1,900 *Feosol tablets* at Philadelphia, Pa.

SHIPPED: 11-12-54 and 2-5-55, from Long Island, N. Y., by Carl H. Kaplan, t/a Economy Buying Service, Inc.

LABEL IN PART: (Btl.) "500 Steclin," "1000 Altepose," and "Feosol Tab."

LIBELED: 4-28-55, E. Dist. Pa.

CHARGE: 502 (b) (1)—the three articles when shipped failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; 502 (b) (2)—the *Steclin capsules* and *Feosol tablets* failed to bear labels containing an accurate statement of the quantity of contents; 502 (d)—the *Altepose tablets* contained a quantity of vinbarbital, a habit forming derivative of barbituric acid, and its label failed to state the quantity or proportion of such derivative and in juxtaposition therewith the statement: "Warning: May Be Habit Forming"; 502 (e) (1)—the label of the *Steclin capsules* failed to bear the common or usual name of the drug; 502 (e) (2)—the label of the *Altepose tablets* and *Feosol tablets* failed to bear the common or usual name of each active ingredient; 502 (f) (1)—the labeling of the three