4979. (F. D. C. No. 38545. S. Nos. 4–777 M, 5–734 M, 5–737 M, 5–739 M.)

INFORMATION FILED: 11–29–55, N. Dist. Ill., against **Althafer's Drugstore (a partnership), Crystal Lake, Ill., and Richard W. Copeland (a partner in the partnership) and Gertrude M. H. Copeland (apprentice pharmacist).**

CHARGE: Between 12–10–54 and 2–5–55, *Pentids tablets* (counts 1, 2, and 3) were dispensed 3 times and *Pondets troches* (penicillin-bacitracin troches) (count 4) were dispensed once without a prescription.

PLEA: Nolo contendere—by partnership to each of 4 counts of information, by Richard W. Copeland to counts 1, 2, and 4, and by Gertrude M. H. Copeland to count 3.

DISPOSITION: 12–9–55. Partnership—$100 fine, plus costs; Richard W. Copeland—$200 fine; and Gertrude M. H. Copeland—$100 fine.

4980. (F. D. C. No. 38130. S. Nos. 4–952 M, 5–045/8 M.)

INFORMATION FILED: 8–4–55, N. Dist. Ill., against **Sidney Brown and Frank Davis (partners in, and pharmacists for, Brown's Pharmacy), Chicago, Ill., and Grant V. McCain (an employee).**

CHARGE: Between 1–7–55 and 1–18–55, *Pondets troches* and *Pentids tablets* were each dispensed twice and *Metandren Linguets* were dispensed once without a prescription.

PLEA: Nolo contendere—by McCain to dispensing *Pondets troches*, by Brown to dispensing *Pentids tablets*, and by Davis to dispensing *Pentids tablets* and *Metandren Linguets*.

DISPOSITION: 10–14–55. McCain fined $100; Davis, $200, plus costs; and Brown, $150.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 4961 TO 4980

PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

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]

4981–5000

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 which were terminated with the entry of default decrees of condemnation. 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., *March 29, 1957.*

CONTENTS*

*For drugs in violation of prescription labeling requirements, see Nos. 4983, 4986; presence of a habit-forming narcotic without warning statement, No. 4986; omission of, or unsatisfactory, ingredients statements, Nos. 4986, 4990; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 4986.

418265—57——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 4981–5000

Adulteration, Section 501 (a) (1), the article consisted in part of a filthy or decomposed substance; Section 501 (a) (2), the article had been held under insanitary conditions; Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (National Formulary), and its strength differed from the standard set forth in such compendium; 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) (1), the article was in package form, and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 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 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; 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 its labeling; Section 502 (l), the article purported to be and was represented as a drug composed partly of a kind of penicillin, chlortetracycline, or Chloromycetin, 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."

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.

DRUG AND DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

4981. Calcium gluconate. (F. D. C. No. 38639. S. No. 30–305 M.)

QUANTITY: 272 10-cc. ampuls at Chicago, Ill.

SHIPPED: 10–7–55, from Memphis, Tenn. (a return shipment).

LABEL IN PART: (Ampul) "A–50 10 cc. Calcium Gluconate U. S. P. 10% Solution W/V in ampul water no preservative Intramuscular and Intravenous * * * 954."

LIBELED: 10–17–55, N. Dist. Ill.

CHARGE: 502 (j)—the article, when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling of the article, when shipped, namely, "Usual Dose: Adults, intravenous or intra-