measles; and for the prevention of recurrence of herpes simplex; and, 505 (a)—the article was a new drug since it was not generally recognized among qualified experts as safe for use in the treatment and prevention of the above-mentioned conditions, and that as a new drug it could not be lawfully introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 8–19–54. Consent—destruction.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

4562. Procaine penicillin G in aqueous suspension. (F. D. C. No. 36894. S. No. 76–703 L.)

QUANTITY: 108 100-carton boxes and 90 loose cartons at Canton, Mass.

SHIPPED: 10–2–53 and 10–5–53, from Terre Haute, Ind.

LIBELED: 7–13–54, Dist. Mass.

CHARGE: 502 (l)—while held for sale, the article purported to be and was represented as a drug composed wholly or partly of a kind of penicillin, and it was from a batch with respect to which a certificate issued pursuant to the law was not effective since the effective date of the original certificate had expired and an application for an extension of the effective date of the original certificate was denied.

DISPOSITION: 11–26–54. Default—destruction.

DRUG IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

4563. Monkey Brand Gland Compound. (F. D. C. No. 36868. S. Nos. 79–316/7 L.)

QUANTITY: 2 drums containing a total of 199,750 tablets in bulk, together with a number of 30-tablet bottles in retail cartons at Columbus, Ohio, in possession of Gold's, Inc.

SHIPPED: The tablets had been shipped in bulk drums on 5–6–52 and 5–17–54, from Baltimore, Md.

LABEL IN PART: (Retail carton) "Now in Tablet Form Original Monkey Brand Gland Compound The Original Gland Tonic * * * Sole Distributors Gold's, Inc. Columbus, O."; (btl.) "Monkey Brand Compound Tablets * * * Contains Vitamin B_1, Iron Carbonate, Nux Vomica, Zinc Phosphide, Cascarin and Damiana."

ACCOMPANYING LABELING: Circulars entitled "Monkey Brand Compound Tablets."

RESULTS OF INVESTIGATION: Upon receipt of the bulk shipments of the tablets, the consignee, Gold's, Inc., repackaged the tablets into bottles and cartons labeled as described above. The bottle labels and cartons, together with the above-mentioned circulars, were obtained by the consignee from local printers.

LIBELED: 6–30–54, S. Dist. Ohio; libel amended on or about 7–21–54.

CHARGE: 502 (a)—the labeling of the article, while it was held for sale, namely, the carton and bottle labels and the above-mentioned circulars, contained false and misleading representations that the article was effective for enriching the blood, toning up the nervous force, revitalizing persons with a tired, worn-out, old age feeling and lack of ambition, and those who suffer from loss of sleep, impaired appetite, and nervousness; restoring sufferers to health,

strength, and happiness; assisting the vital organs in performing their function of providing health and youthful vigor; increasing strength and endurance; causing a general feeling of renewed life; overcoming general weakness, backache, pains in the joints, and invigorating vital organs; bringing the flush of health to the face of weak and rundown men and women; assisting the organs of the body in performing their functions; providing abundant power, life force, and the needed health and energy to aid nature in warding off disease; overcoming the effects of weakened kidneys; preventing rheumatism, lumbago, weak back, pimples, and headaches; treating gastric and intestinal disturbances, indigestion, and nervous stomach; rejuvenating one who is rundown and has a completely worn-out system; building vitality, enabling one to feel years younger; and restoring youthful vigor, pep, and strength; and, 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."

DISPOSITION: 9–7–54. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

4564. (F. D. C. No. 33722. S. Nos. 23–551 L, 23–554 L.)

INFORMATION FILED: 5–14–53, S. Dist. N. Y., against Henry H. Schumann, t/a Schumann's Drug Store, Hunter, N. Y.

CHARGE: Between 8–1–51 and 8–4–51, *tablets containing a mixture of sulfadiazine and sulfamerazine* and *tablets containing a mixture of crystalline penicillin potassium G, sulfamerazine, sulfadiazine, and sulfacetamide* were each dispensed once without a prescription. Such act of dispensing resulted in the drugs being misbranded as follows: 502 (b) (2)—the drugs failed to bear labels containing an accurate statement of the quantity of contents; 502 (e) (2)—the labels of the drugs failed to bear the common or usual name of each active ingredient; and, 502 (f) (1) and (2)—the labeling of the drugs failed to bear adequate directions for use and adequate warnings against use. The *tablets containing a mixture of sulfadiazine and sulfamerazine* were also misbranded under 502 (b) (1) because they failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

PLEA: Guilty.

DISPOSITION: 10–4–54. Fine, $50; $25 remitted.

4565. (F. D. C. No. 34322. S. Nos. 14–804/7 L, 14–809/11 L.)

INFORMATION FILED: 4–13–53, Dist. Kans., against Self Service Drugs, a partnership, Hutchinson, Kans., Marvin W. Gates, manager of the partnership, and Earl R. Hanna and Frank Sewell, pharmacists.

CHARGE: Between 3–26–52 and 4–10–52, *dextro-amphetamine sulfate tablets* were dispensed 4 times (counts 1, 2, 3, and 4) and *Mebaral tablets* were dispensed 3 times (counts 5, 6, and 7) without a prescription. Such dispensing resulted in the drugs being misbranded as follows: 502 (b) (2)—the drugs failed to bear labels containing an accurate statement of the quantity of contents; and, 502 (f) (1)—the labeling of the drugs failed to bear adequate directions for use.

The drugs were further misbranded as follows: 502 (e) (2)—the label of the *dextro-amphetamine sulfate tablets* failed to bear the common or usual