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

name of each active ingredient; and, 502 (d)—the *Mebaral tablets* contained a chemical derivative of barbituric acid, and the label of the tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

PLEA: Nolo contendere, by partnership to counts 1, 2, 3, 4, and 5; by Gates to counts 1, 2, 3, and 4; by Hanna to counts 1, 3, 4, 6, and 7; and by Sewell to counts 2 and 5.

DISPOSITION: 6-23-53—court fined partnership $175, Gates $100, and Sewell $50, and assessed costs against each defendant. 10-12-54—Hanna fined $50.

4566. Sulfanilamide. (F. D. C. No. 37360. S. No. 8-506 L.)

QUANTITY: 1 12-lb. drum and 12 1-lb. bags at Herkimer, N. Y., in possession of Kean's Cut Rate Drugs.

SHIPPED: 3-9-54, from Rahway, N. J.

RESULTS OF INVESTIGATION: The article was shipped in a bulk drum, and, upon receipt by the consignee, a portion of the article was repackaged into 1-lb. bags and relabeled.

LIBELED: 11-13-54, N. Dist. N. Y.

CHARGE: 502 (f) (1)—the labeling of the article (bulk and repackaged material) while held for sale failed to bear adequate directions for use, and the article was not entitled to any exemption from such requirement; and, 502 (b) (2)—the article in the bags failed to bear a label containing an accurate statement of the quantity of contents.

DISPOSITION: 1-11-55. Default—destruction.

4567. Pruvo tablets. (F. D. C. No. 35265. S. Nos. 55-127 L, 55-137 L.)

QUANTITY: 1 drum containing 20,000 tablets, and 432 btls., 75 tablets each, at Milwaukee, Wis., in possession of Pruvo Pharmacal Co.

SHIPPED: 5-13-53, from Cleveland, Ohio.

RESULTS OF INVESTIGATION: The tablets were shipped in interstate commerce in bulk, and, upon receipt by the consignee, a number of the tablets were repacked into bottles. Advertisements recommending *Pruvo tablets* for the treatment of arthritis and rheumatism were printed in local newspapers on the instructions of, and from mats furnished by, the Pruvo Pharmacal Co.

LIBELED: 5-20-53; amended 9-30-53, E. Dist. Wis.

CHARGE: 502 (f) (1)—the labeling of the article (in bulk and as repackaged) while held for sale to bear adequate directions for use by reason of the failure to list arthritis and rheumatism, which were the diseases for which the drug was intended and for which it was offered; and, the labeling failed also to bear adequate directions for use for the purposes for which it was intended, namely, as an effective treatment for all forms or arthritis and rheumatism, red, swollen, inflamed joints due to arthritis, and the crippling effect resulting therefrom.

DISPOSITION: 3-18-55. The Pruvo Pharmacal Co., claimant, having filed an answer and later having consented to the entry of a decree, the court ordered that the product be condemned and destroyed.