4412. Misbranding of phenylbutazone tablets, chloramphenicol capsules, and conjugated estrogens tablets. U. S. v. Donahoe Pharmacy, Inc., and Victor Goldman. Pleas of guilty. Fine of $150 against corporation and $50 against individual. (F. D. C. No. 35763. Sample Nos. 45150–L, 45531–L, 45532–L, 45557–L to 45559–L, incl.)

INFORMATION FILED: February 2, 1954, District of Massachusetts, against Donahoe Pharmacy, Inc., Natick, Mass., and Victor Goldman, president of the corporation.

NATURE OF CHARGE: On or about June 24 and July 1, 6, and 13, 1953, while a number of *phenylbutazone tablets, chloramphenicol capsules,* and *conjugated estrogens tablets* were being held for sale at Donahoe Pharmacy, Inc., after shipment in interstate commerce, the defendants caused a number of the *phenylbutazone tablets* and *chloramphenicol capsules* to be dispensed upon requests for refills of written prescriptions without obtaining authorization by the prescribers and caused a number of *conjugated estrogens tablets* to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: March 26, 1954. The defendants having entered pleas of guilty, the court fined the corporation $150 and the individual $50.

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

4413. Misbranding of Special Formula tablets. U. S. v. 1 Drum, etc. (F. D. C. No. 36491. Sample No. 51025–L.)

LIBEL FILED: April 20, 1954, Eastern District of New York.

ALLEGED SHIPMENT: On or about December 24, 1953, by Faraday Laboratories, from Newark, N. J.

PRODUCT: *Special Formula tablets.* 1 drum containing 25,000 red-coated tablets and 1 drum containing 25,000 green-coated tablets at Long Island City, N. Y., in possession of Edward J. Moore Sons, together with a number of loose labels intended for use in repackaging the tablets.

LABEL, IN PART: (Drum) "Spec. Formula S. C. Red (or Green) Each tablet contains: Quinine HCL. 2½ gr. Dried Ferrous Sulfate 1 gr. Ext. Black Haw Bk. Tree 1 gr. Ext. Wild Yam Root 1 gr. Jamaica Ginger ½ gr. Aloin 1/11 gr. Caution: Federal law prohibits dispensing without prescription. * * * Bulk Shipment For Repackaging and Relabeling Only."; (loose labels) "Red Sanger Number 5 (or Green Corbin No. 10) Contains: Dried Ferrous Sulfate (Iron 20 mgs.), Quinine Hydrochloride, Aloin, P. E. Wild Yam, P. E. Black Haw, and Ginger. For the relief of pains not due to organic disease ordinarily associated with the menstrual period. Dose: Adults only, 2 capsules before each meal (6 capsules per day) during menstruation. * * * Contains 24 Capsules Distributed by Sanger & Company (or Corbin Capsule Company) 10–93 Jackson Ave., Long Island City 1, N. Y."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the tablets failed to bear adequate directions for use since their labeling did not bear a statement of the recommended or usual dose, nor information as to the use of the drug by practitioners licensed by law to administer such drug; and such information was not contained in scientific literature. The tablets were misbranded in such respect when introduced into and while in interstate commerce.