LIBELED: 5–26–61, Dist. P.R.; amended libel 8–22–61.

CHARGE: 502(a)—when shipped, the label of the article contained false and misleading representations that the article was adequate and effective as a treatment for stimulating and rejuvenating the male glands and restoring lost vitality and vigor; 502(a)—the listing on the label of the article of yohimbine HCl, vitamin E, extract damiana, and extract nux vomica as active ingredients in the article was false and misleading since such ingredients were not therapeutically active; and 503(b)(4)—the article was a drug subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 9–21–61. Default—destruction.

6791. Poly-Hemin capsules. (F.D.C. No. 45913. S. No. 17–358 R.)

QUANTITY: 106 100-capsule btls. at Salt Lake City, Utah, in possession of Brain-Kay-McQuarrie, Inc.

SHIPPED: 6–21–60, from Long Island City, N.Y., by Robin Pharmacal Corp.

LABEL IN PART: (Btl.) "Poly-Hemin * * * Brain-Kay-McQuarrie, Inc. Salt Lake City, Utah Each Tablet contains: * * * Folic Acid 1 mg. * * * Dosage, Average adult dose one or two capsules daily with meals."

ACCOMPANYING LABELING: 4,500 additional bottle labels.

RESULTS OF INVESTIGATION: The dealer had supplied the shipper with the labels for the article.

LIBELED: 6–9–61, Dist. Utah.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective for the treatment of anemias; and 503(b)(4)—the article was a drug subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 9–11–61. Default—destruction.

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

DRUGS FOR HUMAN USE*

6792. Amphetamine sulfate tablets and pentobarbital sodium capsules. (F.D.C. No. 45743. S. Nos 70–363/4 R.)

QUANTITY: Unknown quantities of tablets and capsules at Bangor, Maine, in possession of George H. Horton, M.D.

SHIPPED: Prior to 4–24–61, from outside the State of Maine.

LIBELED: 4–25–61, Dist. Maine.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use, and the articles were not exempt from that requirement since they were prescription drugs which were not used or dispensed by the practioner in the course of his professional practice.

DISPOSITION: 10–30–61. Default—destruction.

*See also Nos. 6781–6783, 6785, 6786.