

the article was adequate and effective in the treatment and prevention of cancer and other diseases and conditions in man; 502(b)(1)—the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(e)(1)—the label of the article failed to bear the common or usual name of the article, namely, *distilled water*; 502(f)(1)—the label of the article failed to bear adequate directions for use in that the directions for use with respect to dosage and frequency and duration of administration of the article were not adequate for the treatment or prevention of the diseases and conditions for which the article was intended, including in particular, cancer; 502(f)(1)—the labeling of the article failed to bear adequate directions for use and it was not exempt from such requirement since it was in the possession of persons who were not regularly and lawfully engaged in the manufacture, transportation, storage, or distribution of prescription drugs, and since the article was not to be dispensed upon prescription; 502(f)(2)—the labeling of the article failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health and against unsafe methods of administration; and 502(j)—the article was dangerous to health when used with the frequency prescribed, recommended, and suggested in its label.

Hypodermic kits. 502(f)(1)—the labeling of the article failed to bear adequate directions for use; 502(f)(2)—the labeling of the article failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health and against unsafe methods of application; and 502(j)—the article was dangerous to health when used with the frequency prescribed, recommended, and suggested in its labeling.

DISPOSITION: 1-4-61. Default—delivered to the Food and Drug Administration.

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

6442. Bacitracin. (F.D.C. No. 45072. S. Nos. 32-340 R, 32-451 R, 33-362/4 R, 36-101/2 R.)

QUANTITY: 734 ctnd. vials at New York, N.Y.

SHIPPED: Between 8-11-60 and 8-16-60, from Philadelphia, Pa., by Philadelphia Ampoule Laboratories.

LABEL IN PART: (Ctn. and ampul) "No. 2005 Bacitracin U.S.P. Sterile 50,000 Units For Intramuscular or Topical Use * * * Philadelphia Ampoule Laboratories, Philadelphia 23, Pa. * * * Lot No. 8018 Exp. Date 9-62."

LIBELED: 11-16-60, S. Dist. N.Y.

CHARGE: 501(b)—when shipped, the strength of the article differed from the strength set forth in the United States Pharmacopoeia for *bacitracin*; 502(a)—the label statement "50,000 Units" was false and misleading as applied to a product containing less than 50,000 units of *bacitracin* per ampul; and 502(1)—the article purported to be, and was represented as, a drug composed wholly or in part of *bacitracin*, and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507.

DISPOSITION: 12-27-60. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6443. Dextro-amphetamine sulfate tablets, pentobarbital sodium capsules, and dextro-amphetamine sulfate with amobarbital tablets and capsules. (F.D.C. No. 45323. S. Nos. 29-662/4 R, 53-597 R, 53-600 R.)

QUANTITY: 5 1,000-tablet btl. of dextro-amphetamine sulfate with amobarbital, 3 1,000-tablet btl. and 7 200-tablet bags of dextro-amphetamine sulfate, 1 700-capsule btl. of pentobarbital sodium, and 1 btl., containing 541 capsules of dextro-amphetamine sulfate with amobarbital, at Minneapolis, Minn., in possession of Cedar Drug Co.

SHIPPED: On unknown dates, from outside the State of Minnesota.

LBELED: 1-4-61, Dist. Minn.

CHARGE: 502(b)—while held for sale, all of the articles failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e)(1)—the label of the 7-bag lot failed to bear the common or usual name of the drug; 502(f)(1)—the label of the 7-bag lot failed to bear adequate directions for use; and 503(b)(4)—the label of the 7-bag lot failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 2-16-61. Default—destruction.

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

6444. Food supplements. (F.D.C. No. 44330. S. Nos. 52-117/8 P.)

INFORMATION FILED: 7-20-60, Dist. Minn., against Arthur W. Stemper, t/a A. & N. Stemper Co., and Mrs. Arthur W. Stemper.

ALLEGED VIOLATION: On 7-16-59, in a sales talk at Minneapolis, Minn., the defendants orally represented the articles to persons there present to be an effective treatment for the diseases, symptoms, and conditions set forth below, which act resulted in the articles being misbranded while held for sale after shipment in interstate commerce.

LABEL IN PART: "A Complete Balanced Food Supplement NUTRITION-ALL Proteins—Minerals—Vitamins," and "NUTRITION-ALL High protein."

CHARGE: 502(f)(1)—the labeling of the articles failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which the articles were intended, namely, low and high blood pressure, bad nerves, bursitis, cancer, poor eyesight, rare blood condition, diabetes, and arthritis.

PLEA: Guilty.

DISPOSITION: 11-14-60. Each defendant was fined \$100 and placed on probation for 2 years.

6445. Nutrin vitamin and mineral capsules. (F.D.C. No. 44344. S. No. 66-601 P.)

INFORMATION FILED: 7-26-60, W. Dist. Pa., against Chester H. Nairne, t/a Chester H. Nairne Co., Niles, Ohio.

ALLEGED VIOLATION: Between 10-22-59 and 10-29-59, the defendant, in the course of sales talks at Pittsburgh, Pa., made oral representations holding

*See also Nos. 6441, 6443.