

**LABEL IN PART:** (Some labels) "Physician's Professional Package," "Physician's Trial Package," "Physician's Sample," "Professional Sample," "Sample-Not To Be Sold," and "Professional Specimen."

**RESULTS OF INVESTIGATION:** The articles consisted of quantities of prescription drugs repacked by the dealer into containers having labels bearing brand names indicative of manufacture outside the State of Colorado, and quantities of nonrepacked physicians' samples of prescription drugs.

**LIBELED:** 7-27-61, Dist. Colo.; amended libel 8-25-61.

**CHARGE:** 502(a)—while held for sale, the statements "Physician's Trial Package," "Physician's Sample," "Professional Sample," "Sample-Not To Be Sold," "Professional Specimen" and similar wording on the labels of a number of the articles of drug were false and misleading as applied to the articles in the possession of a repacker and intended for sale and not then intended for use as "complimentary-not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)—the repacked articles of drug 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(f) (1)—the labeling of the repacked articles of drug failed to bear adequate directions for use and they were not exempt from that requirement since they were subject to the provisions of 503(b) (1) and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history as required by regulations; and 503(b) (4)—the repacked articles of drug were subject to the provisions of 503(b) (1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

**DISPOSITION:** 10-6-61. Default—destruction.

**6864. Elixir phenobarbital.** (F.D.C. No. 46471. S. Nos. 45-523/4 R.)

**QUANTITY:** 100 cases, 4 1-gal. btls. each, at Atlanta, Ga.

**SHIPPED:** Between 2-8-61 and 4-3-61, from Greenville, S.C., by Cambridge Pharmaceuticals.

**LABEL IN PART:** (Some btls.) "Elixir Phenobarbital Hyoscyamine and Hyoscyne Hydrobromide and Atropine \* \* \* Each 5 cc contains: Hyoscyamine Hydrobromide 0.1037 mg. Hyoscyne Hydrobromide 0.0065 mg. Atropine Sulfate 0.0194 mg. Phenobarbital 16 mg. Alcohol 20% Mfg. for Grady Hospital, Atlanta, Georgia Mfg. by Cambridge Pharmaceuticals, 117 Cleveland Street, Greenville, S.C." and (some btls.) "Elixir Phenobarbital and Belladonna Alkaloids (NF) Each 5 cc contains: 16.2 mg. Phenobarbital (Warning: May be habit forming) 0.1037 mg. Hyoscyamine Sulfate 0.0194 mg. Atropine Sulfate 0.0865 mg. Hyoscyne Hydrobromide 20% Alcohol Caution: \* \* \* Mfg. for Grady Memorial Hospital \* \* \* Atlanta, Georgia Mfg. by Cambridge Pharmaceuticals, 117 Cleveland Street Greenville, S.C."

**RESULTS OF INVESTIGATION:** Analysis showed that all bottles of the article contained less than 10 percent of the labeled amount of the belladonna alkaloids (calculated as atropine sulfate). The label of some bottles bore the notation NF, however, this article was not a drug the name of which was recognized in the National Formulary.

**LIBELED:** 10-2-61, N. Dist. Ga.

**CHARGE:** 501(c)—when shipped, the strength of the article differed from that which it purported to possess; 502(a)—the declaration of the quantity of belladonna alkaloids (hyoscyamine sulfate, atropine sulfate, and hyoscyne hydrobromide) was false and misleading as applied to a product containing less than the declared amount of belladonna alkaloids, and the label declaration "NF" on some bottles, representing that the article was a drug, the name of which was recognized in the National Formulary, an official compendium, was false and misleading; 502(d)—the article in some bottles contained phenobarbital, a derivative of barbituric acid, and its label failed to bear the statement "Warning—May be habit forming"; 502(f) (1)—the labeling failed to bear adequate directions for use in that it was in dosage form in which it may be dispensed, and the label did not bear the common or usual dosage; and 503(b) (4)—the article in some bottles 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:** 11-1-61. Consent—claimed by Cambridge Pharmaceuticals and released under bond for reprocessing.

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

#### **DRUGS FOR HUMAN USE\***

**6865. Various prescription drugs.** (F.D.C. No. 46639. S. Nos. 13-148/55 T.)

**QUANTITY:** Approximately 300 boxes, btls., vials, etc., at Chicago, Ill., in possession of Jack's Drugs.

**SHIPPED:** On unknown dates, by various drug handlers.

**LABEL IN PART:** (Some labels) "Physician's Sample," "Physician's Professional Package," "Professional Sample Not To Be Sold," "Professional Sample," or similar wording.

**RESULTS OF INVESTIGATION:** Some of the articles were prescription drugs which had been repacked by the dealer, Jack's Drugs, from physicians' samples into bottles to which had been affixed labels bearing the brand names of the drugs, a "complimentary—not for sale" professional sample legend, and the names and addresses of manufacturers, packers, or distributors located outside the State of Illinois; some of the articles were prescription drugs originally intended for use as samples for physicians and others lawfully engaged in dispensing prescription drugs, and bearing labels containing a "complimentary—not for sale" professional sample legend, and the names and addresses of manufacturers, packers, or distributors located outside the State of Illinois; some of the articles had been on the premises when the drug store had been purchased by the dealer; and some of the articles had been obtained by the dealer from a local physician.

**LIBELED:** 11-13-61, N. Dist. Ill.

**CHARGE:** 502(a)—while held for sale, the words "Physician's Sample Not To Be Sold," "Physician's Sample," "Sample-Not To Be Sold," "Physician's Professional Package," "Professional Sample Not To Be Sold," "Professional Sample," and similar wording on the labels of the articles, were false and misleading as applied to the articles in the possession of a repacker and intended for sale, and not intended for use as "complimentary—not for sale"

\*See also Nos. 6861, 6863, 6864.