

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS  
REPORTED IN D. D. N. J. NOS. 5401-5420

*Adulteration*, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from, or its purity or quality fell below, the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess; Section 501 (d) (2), the article was a drug, and a substance had been substituted wholly or in part therefor.

*Misbranding*, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form, and it 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; Section 502 (d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 503 (b) (4), the article was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

5401. Elixir Albephen, Merhistin expectorant, elixir Merbutal, and elixir Duophen. (F. D. C. No. 40337. S. Nos. 67-474 M, 67-476 M, 67-478/9 M.)

QUANTITY: 20 1-gal. btls. and 43 1-pt. btls. of *elixir Albephen*; 68 1-pt. btls. of *Merhistin expectorant*; 6 1-gal. btls. and 94 1-oz. btls. of *elixir Merbutal*; and 246 1-oz. btls. of *elixir Duophen*, at Silver Spring, Md., in possession of Meredyth Co.

SHIPPED: Between 5-5-54 and 1-30-57, from Philadelphia, Pa.

LABEL IN PART: (Btl.) "Elixir Albephen Each 5 cc \* \* \* contains Phenobarbital  $\frac{1}{4}$  gr., Hyoscyamine Sulfate 0.104 mg., Atropine Sulfate 0.0195 mg., Hyoscine Hydrobromide 0.0065 mg., Alcohol 23%," "Merhistin Expectorant Each 30 cc \* \* \* contains: Ephedrine Sulfate 40 mg., Citric Acid 3 gr., Merhistin Maleate 225 mg.," "Elixir Merbutal Each 5 cc \* \* \* contains: \* \* \* Sodium \* \* \* Butyl barbiturate 3 grs.," and "Physicians Sample \* \* \* Elixir Duophen Each 30 cc contains: Sodium pentobarbital 1 gr. \* \* \* Phenobarbital 1 gr."

ACCOMPANYING LABELING: A number of loose labels for use in repacking the *elixir Albephen*, some of which were the same as the Albephen label described above and some of which read, in part, as follows: "Elixir Albephen Each Ounce contains: D. Amphetamine Sulfate 15 mg., Thiamin HCL 30 mg., Riboflavin 2.7 mg., Niacin 40 mg., Alcohol 10%."

RESULTS OF INVESTIGATION: The articles in the 1-pt. and 1-oz. btls. were repacked by the consignee from bulk stock which had been shipped as described above. The *elixir Albephen* and *elixir Merbutal* in the 1-gal. btls. represented