SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 4661–4680

Adulteration, Section 501 (a) (2), the article had been held under insanitary conditions; 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 quality and purity 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, and its quality fell below, that which it purported or was represented to possess; and, Section 501 (d), the article was a drug, and a substance had been (1) mixed with the article so as to reduce its quality or (2) 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 (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 including the quantity, kind, and proportion of any alcohol contained therein; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; and, Section 502 (i) (3), the article was offered for sale under the name of another drug.

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

DRUGS FOR HUMAN USE

4661. Drug for treatment of stomach disorders, hyperacidity, and ulcers. (Inj. No. 166.)

COMPLAINT FOR INJUNCTION FILED: Between 2–5–48 and 3–25–48, Dist. Minn., against Joseph E. McCoy, Thief River Falls, Minn., to enjoin the interstate shipment of a misbranded drug consisting of a suspension of bismuth subnitrate in a solution of water, sugar, alcohol, pepsin, and orange flavoring material.

CHARGE: The complaint alleged that the defendant had been and still was introducing into interstate commerce the above-described drug, which was misbranded as follows:

502 (a)—the labeling represented that the drug was efficacious in the cure, mitigation, and treatment of stomach disorders, hyperacidity, and gastric ulcers, whereas it was not effective for such purposes;

502 (e)—the label of the drug failed to bear the common or usual name of each active ingredient, including the quantity, kind, and proportion of the alcohol contained therein; and,

502 (f) (1)—the labeling of the drug failed to bear adequate directions for use since the labeling contained no reference to the disease conditions for which the drug was intended.

The complaint alleged also that the defendant had been repeatedly warned that the drug shipped by him in interstate commerce was misbranded within the meaning of the law; that the only effect of such warnings had been to cause the defendant to change the labeling so as to avoid one type of misbranding; and that in so doing, the defendant misbranded the drug in a different way, namely, by eliminating the false and misleading statements in the labeling, the defendant omitted all reference to the disease conditions for which the drug was intended and thereby misbranded the drug by failing to include in the labeling adequate directions for use.

DISPOSITION: 6–2–49. The defendant having filed an answer denying that the drug was misbranded and later having failed to pursue the matter further, an order of default was entered, together with an order permanently enjoining the defendant from shipping in interstate commerce the drug described in the complaint with or under the following labeling:

Joseph E. McCoy, M. D.
Thief River Falls, Minnesota
Specializing in Stomach Disorders
Hyperacidity and Gastric Ulcers
Take One Teaspoonful After Each Meal.
Shake Well Before Using

J. E. McCoy, M. D.
Thief River Falls, Minnesota
Take one Teaspoonful after each
meal. Shake well

J. E. McCoy, M. D.
Thief River Falls, Minnesota
(SHAKE WELL)
Take one teaspoonful after
each meal.

J. E. McCoy, M. D.
Thief River Falls, Minnesota
For Stomach Disorders, Hyper-
acidity and Gastric Ulcers
Directions: Take one teaspoonful
after each meal. Shake well be-
fore using.
Contains: Pepsin, Bismuth, Sub-
nitrate.
Alcohol–10 Per Cent–Net Contents–
8 Fluid Ounces

4662. Amphetamine sulfate tablets. (F. D. C. No. 35600. S. Nos. 72–608 L, 86–517 L, 86–524 L.)

INFORMATION FILED: 2–3–55, S. Dist. Fla., against Ledyard H. DeWees, Coral Gables, Fla.

SHIPPED: Between 4–10–54 and 6–9–54, from Florida to Maryland and Ohio.

RESULTS OF INVESTIGATION: The drug was shipped in unlabeled bottles.

CHARGE: 502 (b) (1) and (2)—the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; 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 it failed to bear a label con-