the common or usual name of the drug, namely, "pentobarbital sodium"; and, Section 502 (f) (1), the labeling of the repackaged capsules failed to bear adequate directions for use since a portion of the repackaged capsules bore no labeling containing directions for use and since the directions for use on the labeling of the remainder of the repackaged capsules, namely, "One capsule at bedtime when needed," "One capsule at bedtime when necessary," and "one or two at bedtime," were not adequate directions for use.

DISPOSITION: October 5, 1949. Pleas of guilty having been entered, the court imposed a total fine of $600 against the defendants jointly.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

2959. Adulteration of ointment. U. S. v. 62,092 Tubes * * *. (F. D. C. No. 27942. Sample No. 32825–K.)

LIBEL FILED: October 28, 1949, Northern District of California.

ALLEGED SHIPMENT: Between June 6, 1947, and May 13, 1949, from Cleveland, Ohio.

PRODUCT: 62,092 1⅛-ounce tubes of *ointment* at Berkeley, Calif. Examination disclosed that a material proportion of the product was decomposed, as evidenced by the dry and granular condition of the *ointment*, discoloration of the *ointment*, and corrosion of the tubes.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a decomposed substance. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: December 20, 1949. Default decree of condemnation and destruction.

2960. Adulteration of orange peel. U. S. v. 37 Bags * * *. (F. D. C. No. 28247. Sample No. 10068–K.)

LIBEL FILED: November 3, 1949, Southern District of New York.

ALLEGED SHIPMENT: In May 1945, from Haiti.

PRODUCT: 37 41-pound bags of *orange peel* at New York, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: December 19, 1949. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

2961. Action to enjoin and restrain the interstate shipment of various drugs. U. S. v. Cowley Pharmaceuticals, Inc. Preliminary injunction denied. (Inj. No. 186.)

COMPLAINT FILED: February 26, 1948, District of Massachusetts, against Cowley Pharmaceuticals, Inc., Worcester, Mass.

NATURE OF CHARGE: The defendant had been, and at the time of filing the complaint was, shipping in interstate commerce certain drugs which were adulterated and misbranded in the following respects;

Niacinamide tablets, sulfathiazole tablets, vitamin B_1 tablets, quinine sulfate tablets, phenobarbital tablets, and *ferrous sulfate tablets,* drugs the names of which are recognized in the United States Pharmacopoeia. Adulteration, Section 501 (b), the strength of each of the drugs differed from the standard set forth in the United States Pharmacopoeia, in that the *ferrous sulfate tablets* contained more than the maximum quantity of ferrous sulfate permitted by that compendium, and the remaining tablets of the drugs contained less of the labeled drug than the minimum quantity prescribed by that compendium. Misbranding, Section 502 (a), the label statements declaring the quantity of each of the drugs contained in the various tablets were false and misleading.

A P C Compound Pink Tablets, ephedrine with phenobarbital tablets, and *calcium gluconate C T tablets,* drugs not recognized in an official compendium. Adulteration, Section 501 (c), their strength differed from that which they were represented to possess on their labels since the *A P C Compound Pink Tablets* contained more acetophenetidin than the labeled amount; the *ephedrine with phenobarbital tablets* contained less ephedrine and more phenobarbital than the labeled amount; and the *calcium gluconate C T tablets* contained less calcium gluconate than the labeled amount. Misbranding Section 502 (a), the statements, "Each tablet contains: * * * acetophenetidin 2 grs." on the label of the *A P C Compound Pink Tablets,* "Each tablet contains Calcium Gluconate 1 gm." on the label of the *calcium gluconate C T tablets,* and "Each tablet contains Ephedrine 3/8 gr. Phenobarbital ½ gr." on the label of the *ephedrine with phenobarbital tablets,* were false and misleading.

Thyroid tablets. Misbranding, Section 502 (a), the label statement "Tablets * * * Thyroid U. S. P." was false and miselading since the statement represented that the product consisted solely of desiccated thyroid, as required by the standard set forth in the United States Pharmacopoeia, whereas the article consisted of desiccated thyroid and diiodo hydroxyquinoline, or desiccated thyroid and phenacetin and salol.

Soda mint tablets. Misbranding, Section 502 (a), the label statements "Soda Mint Tablets" and "Each tablet contains Sodium Bicarbonate * * * flavored with mint" were false and misleading since the product contained aspirin, and the label failed to declare the presence of aspirin.

The complaint alleged further that the defendant had shipped in interstate commerce certain foods which were adulterated and misbranded, as set forth in notices of judgment on foods.

PRAYER OF COMPLAINT: That the defendant be perpetually enjoined from commission of the acts complained of, and that a preliminary injunction be granted during the pendency of the action.

DISPOSITION: On March 30, 1948, at the conclusion of the hearing on the Government's motion for a preliminary injunction, the court handed down findings of fact and a conclusion of law, and on April 2, 1948, entered an order denying the Government's prayer for a preliminary injunction. The findings of fact, conclusion of law, and discussion follow:

HEALEY, *District Judge:*

FINDINGS OF FACT

"1. The respondent, Cowley Pharmaceuticals, Inc., is a Massachusetts Corporation having its principal place of business in Worcester, Massachusetts.

"2. The respondent is and has been engaged in the manufacture and sale of various articles of drug and articles of food, a large quantity of which are sold and shipped in interstate commerce.

"3. The government has submitted evidence that on various dates during the period from June 4, 1946, to November 2, 1947, the respondent, in violation of 21 USCA Sec 331 (a), shipped in interstate commerce certain articles of drug as defined by 21 USCA 321 (g) (1), (2), and (3), and certain articles of food as defined by 21 USCA Sec 321 (f) (1) which were allegedly adulterated and misbranded, in the particulars stated in Exhibit A appended to the complaint.

"4. In all cases but one, the product is allegedly adulterated and misbranded because it allegedly contained a different quantity of some constituent part than was stated on the label. In the case of the soda mint tablets, it is alleged that they contained aspirin, the presence of which was not disclosed on the label.

"5. There is no evidence that any inspection of respondent's factory has been made by any agent of the Food and Drug Administration since October 1, 1947.

"6. There is no evidence that any adulterated or misbranded articles of drug or food have been shipped in interstate commerce by the respondent since the shipment made on November 2, 1947.

"7. By his affidavits, Benjamin C. Cowley, president and treasurer of the respondent, states that he has adopted the recommendations made by the government agents and inspectors regarding improvements in respondent's factory, facilities and methods of manufacture so as to eliminate the probability of any future violations of the Act.

DISCUSSION

"The purpose of the Federal Food, Drug, and Cosmetic Act is to protect the consuming public, *United States* v. *Lord-Mott Company*, 57 F Supp 128; *United States* v. *Crown Rubber Sundries Company*, 67 F Supp 92; *Federal Security Administrator* v. *Quaker Oats Company*, 318 US 218, and the Act is sufficiently broad to allow the issuance of an injunction even though no wilfulness or knowledge on the part of the respondent or its agents is shown. *United States* v. *Greenbaum*, 138 F (2d) 437.

"However, in my opinion, a preliminary injunction should not issue unless the government makes out a case where there is a strong probability that the respondent's allegedly illegal acts will continue in the future.

"In the instant case, the complaint was filed on February 26, 1948, more than three months after the last alleged violation of the Act, and almost five months after the last inspection of respondent's premises by the government agents. In the light of the affidavits presented by the respondent containing statements that the causes for any possible violations have been eliminated, and in the absence of any evidence of recent violations, there is not sufficient evidence of the probability of any future violations to warrant the issuance of a preliminary injunction as prayed for.

CONCLUSION OF LAW

"The complainant has not produced sufficient evidence of the probability of future violations of the Act by the respondent to warrant the issuance of a preliminary injunction."

2962. Adulteration and misbranding of estrogenic substance in oil and Gynestrin estrogenic hormones, and misbranding of Obenoids. U. S. v. Pro-Medico Laboratories, Inc., and Samuel Heller. Pleas of nolo contendere. Corporation fined $900; individual defendant fined $9 and placed on 6 months' probation. (F. D. C. No. 17879. Sample Nos. 3826–H, 3905–H, 6708–H, 6709–H, 20195–H.)

INDICTMENT RETURNED: December 9, 1947, Eastern District of New York, against Pro-Medico Laboratories, Inc., Brooklyn, N. Y., and Samuel Heller, director.