

"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.

ALLEGED SHIPMENT: Between the approximate dates of December 8, 1944, and March 6, 1945, from the State of New York into the States of Pennsylvania, Connecticut, and Oklahoma.

LABEL, IN PART: "A Pro-Medico Product 3,500 cc Estrogenic Substance in Oil Each cc contains Estrogenic Substance derived from equine urine," "Estrogenic Hormones Multiple Dose Vial A sterile solution in ampul oil of estrogenic substances derived from equine urine * * * Manufactured for The Vale Chemical Co., Inc. Allentown, Penna.," "Gynestrin Estrogenic Hormones An oil solution of estrogenic hormones, derived from equine urine," and "Obenoids - Pink Each Tablet Contains—Phenobarbital $\frac{1}{4}$ grain."

NATURE OF CHARGE: *Estrogenic substance.* Adulteration, Section 501 (d), estrogenic substance other than as it naturally occurs in and is extracted from equine urine and containing little or no estrone, had been substituted for estrogenic substance as it naturally occurs in and is extracted from equine urine, which the product purported and was represented to be. Misbranding, Section 502 (a), the label statement "Estrogenic Substance derived from equine urine" was false and misleading.

Gynestrin estrogenic hormones. Adulteration, Section 501 (d), estrogenic hormones other than as they naturally occur in and are extracted from equine urine, had been substituted for estrogenic hormones as they naturally occur in and are extracted from equine urine, which the product purported and was represented to be. Misbranding, Section 502 (a), the label statement "Estrogenic Hormones derived from equine urine" was false and misleading.

Obenoids. Misbranding, Section 502 (a), the label statement "Contains—Phenobarbital" was false and misleading since the product contained no phenobarbital; and, Section 502 (e) (2), the product was not sold under a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the name and quantity and proportion of atropine that it contained.

DISPOSITION: On March 1, 1949, a motion by the defendant for a bill of particulars was granted to the extent of requiring the Government to state how many International Estrone Units per cubic centimeter were contained in the estrogenic substance in oil referred to in counts 1 and 3 of the indictment. On December 12, 1949, pleas of nolo contendere were entered and the corporation was fined \$900, and the individual defendant was fined \$9 and placed on probation for 6 months.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

✓ 2963. Misbranding of Nue-Ovo. U. S. v. 24 Units * * * (and 12 other seizure actions). Cases consolidated and tried to the court. Government's motion for summary judgment granted. Decree of condemnation and destruction. (F. D. C. Nos. 24649, 24709, 24728, 24840, 24850, 24859, 24874, 24891, 24894, 24895, 24908, 24909, 25101. Sample Nos. 14542-K, 27743-K, 28167-K, 28524-K, 28564-K, 28983-K, 29337-K, 31354-K, 36794-K, 37343-K, 37615-K, 40523-K, 40622-K, 40624-K.)

*See also Nos. 2951, 2961, 2962.