

of the drug in the envelopes 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 (f) (1), the envelopes containing the drug bore no labeling containing directions for use; and, Section 502 (f) (2), they bore no labeling containing warnings against use of the drug in those pathological conditions, or by children, where its use may be dangerous to health, or against unsafe dosage and methods and duration of administration.

**DISPOSITION:** March 11, 1947. Pleas of guilty having been entered, the court imposed fines of \$500 and \$100, respectively, against defendants Blaine and Schwab.

**2202. Misbranding of Nanette Hormone Cream. U. S. v. 274 Jars, etc.** (F. D. C. No. 22989. Sample Nos. 61334-H to 61336-H, incl.)

**LABEL FILED:** April 25, 1947, Western District of Pennsylvania.

**ALLEGED SHIPMENT:** On or about March 8 and 21, 1947, by the Nix Cosmetics Co., Inc., from Memphis, Tenn.

**PRODUCT:** 274 2-ounce jars and 16 6-ounce jars of *Nanette Hormone Cream* at Pittsburgh, Pa. Analysis indicated that the product had essentially the composition stated on its label.

**LABEL, IN PART:** "Nanette Hormone Cream Each 2 Ozs. Contains 5 Mgs. Stilbestrol (Synthetic Estrogenic Substance)."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the name "Hormone Cream" and the label statement "Each 2 Ozs. Contain 5 Mgs. Stilbestrol (Synthetic Estrogenic Substance)" were false and misleading since they represented and suggested that the article contained a hormone and that it would exert a beneficial hormone-like effect, or beneficial estrogenic effect, upon the body when used as directed, whereas the article did not contain a hormone and would produce no beneficial hormone-like effect, or beneficial estrogenic effect, when used as directed.

Further misbranding, Section 502 (f) (1), the directions for use in the labeling "Apply gently one-half heaping teaspoonful at bedtime. Leave on overnight." were inadequate since they failed to indicate the conditions in which the article was to be used, the body area to which the article was to be applied, and the duration of its use.

**DISPOSITION:** May 20, 1947. Default decree of condemnation and destruction.

**2203. Misbranding of calcium polysulphide solution. U. S. v. 5 Drums \* \* \*** (F. D. C. No. 23499. Sample Nos. 68292-H, 68293-H, 86127-H.)

**LABEL FILED:** July 14, 1947, District of Kansas.

**ALLEGED SHIPMENT:** On or about February 26 and 27, 1947, by the Sulphur Products Co., Inc., from Greensburg, Pa.

**PRODUCT:** 5 drums of *calcium polysulphide solution* at Sabetha, Kans. The shipper supplied the consignee with a suggested form of label containing directions for use, but had not entered into any agreement with the consignee relative to the labeling of the article, as contemplated by Section 503 (a), to the effect that the article would not be adulterated or misbranded when relabeled.

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

**DISPOSITION:** September 24, 1947. Default decree of condemnation and destruction.

#### DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

**2204. Adulteration Bethiamin, Livitamin, and calcium gluconate. U. S. v. The S. E. Massengill Company. Plea of guilty. Fine, \$3,000.** (F. D. C. No. 20204. Sample Nos. 7678-H, 20850-H, 21738-H, 21757-H.)

**INFORMATION FILED:** February 3, 1947, Eastern District of Tennessee, against The S. E. Massengill Co., a corporation, Bristol, Tenn.

**ALLEGED SHIPMENT:** On or about December 15, 1944, and November 1 and December 8, 1945, from the State of Tennessee into the States of Missouri and New York.

**LABEL, IN PART:** "Bethiamin A Brand of Thiamine Hydrochloride (B<sub>1</sub>) \* \* \* For Intramuscular or Intravenous Administration," "Calcium Gluconate, 10%," or "Livitamin Represents in one Fluid Ounce \* \* \* Thiamine Hydrochloride (B<sub>1</sub>) 3 mg. in 100 cc. 10.14."

**NATURE OF CHARGE:** *Bethiamin.* Adulteration, Section 501 (a) (1), the article consisted in part of a filthy substance by reason of the presence of viable mold; and, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, in that it purported and was represented to be suitable and appropriate for intramuscular and intravenous administration, a use which requires a sterile product, whereas the article was unsuitable and inappropriate for intramuscular and intravenous administration since it was unsterile by reason of contamination with viable mold.

*Calcium gluconate.* Adulteration, Section 501 (d), boric acid had been substituted in part for "Calcium Gluconate Ampuls," in that the article purported to be and was represented as "Calcium Gluconate Ampuls," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and the article contained boric acid, whereas "Calcium Gluconate Ampuls," the specifications of which are set forth in the Pharmacopoeia, do not contain boric acid.

*Livitamin.* Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, in that it was represented to contain 3 milligrams of thiamine hydrochloride in 1 fluid ounce and 10.14 milligrams of thiamine hydrochloride in 100 cc., whereas it contained less thiamine hydrochloride than represented.

**DISPOSITION:** March 4, 1947. A plea of guilty having been entered, the court imposed a fine of \$1,000 on each of the 3 counts of the information.

#### DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS\*

**2205. Adulteration and misbranding of estrogenic hormones. U. S. v. Organics, Inc., and Lawrence Hicks. Plea of guilty on behalf of corporation; plea of not guilty by individual defendant. Fine of \$500 and costs against corporation; individual defendant found not guilty. (F. D. C. No. 22009. Sample Nos. 15452-H, 52460-H.)**

**INFORMATION FILED:** April 8, 1947, Northern District of Illinois, against Organics, Inc., Chicago, Ill., and Lawrence Hicks, president of the corporation.

**ALLEGED SHIPMENT:** On or about May 29 and July 8, 1946, from the State of Illinois into the States of Ohio and Michigan.

**PRODUCT:** Examination showed that the product contained 60 percent of the labeled claim for estrogenic activity, or 6,000 International Units per cubic centimeter.

**NATURE OF CHARGE:** Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, in that it purported and was represented to possess a physiological activity equivalent to 10,000 International Estrone Units per cubic centimeter, whereas it possessed a physiological activity equivalent to less than 10,000 International Estrone Units per cubic centimeter.

Misbranding, Section 502 (a), the label statement "Natural Estrogenic Hormones Isolated from Gravid Equine Urine consisting principally of Estrone \* \* \* 10,000 I. U. per cc." was false and misleading.

**DISPOSITION:** June 24, 1947. A plea of guilty having been entered on behalf of the corporation, and a plea of not guilty having been entered by the individual, the court imposed a fine of \$500 and costs against the corporation and found the individual defendant not guilty.

**2206. Adulteration and misbranding of P-Drine Sulfathiazole, Elixir Feotone, Sulfedol, isotonic solution ephedrine gluconate, and isotonic ephedrine solution. U. S. v. Benjamin Volk (Summit Pharmaceutical Co.). Plea of guilty. Fine, \$50. (F. D. C. No. 21469. Sample Nos. 3270-H, 15790-H, 43282-H to 43284-H, incl.)**

**INFORMATION FILED:** On or about May 20, 1947, District of New Jersey, against Benjamin Volk, trading as the Summit Pharmaceutical Co., at Morristown, N. J.

\*See also No. 2204; veterinary preparations, Nos. 2241, 2242.