session of persons not regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs and since the article was not to be dispensed as required by 503(b); and 503(b)(4)—the article was subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 11–24–59. Default—delivered to the Food and Drug Administration.

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

**6386. Amphetamine sulfate tablets.** (F.D.C. No. 44199. S. Nos. 46–609/12 P.)

QUANTITY: 11 drums, each containing 50,000 tablets, 261 1,000-tablet btls., and 9 100-tablet btls., at Birmingham, Ala., in possession of Medical Specialties Corp.

SHIPPED: Between 7–21–58 and 11–25–59, from Houston, Tex., and Philadelphia, Pa.

LIBELED: 1–22–60, N. Dist. Ala.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use, and the article was not exempt from such requirement since, although it was a prescription drug in possession of a wholesale distributor of prescription drugs, the exemption from bearing adequate directions for use had expired with respect to the article as provided in Regulation 1.106(b) because deliveries were, or would be, made contrary to 503(b).

DISPOSITION: 6–13–60. Default—destruction.

**6387. Dainty-Maid Service.** (Inj. No. 372.)

COMPLAINT FOR INJUNCTION FILED: 12–18–59, E. Dist. Mich., against Mrs. Wilma Becker, Detroit, Mich.

CHARGE: The complaint alleged that the defendant was engaged in selling and distributing an article designated by the name of *"Dainty-Maid Service,"* consisting of a douche bag, a chrome-plated clamp, a box of "Dainty-Maid Personal Powder," a "Dainty-Maid Colonator," and a "Dainty-Maid 'Return-Flow' Earigator"; that the article was shipped to the defendant, from time to time, from Middlefield, Conn.; that while the article was being held for sale by the defendant after shipment in interstate commerce, the defendant, in the course of sales talks to prospective customers, caused oral representations to be made regarding the diseases, symptoms, and conditions for which the article was intended; and that defendant's act of making such oral representations resulted in the article being misbranded under 502(f)(1), in that the labeling failed to bear adequate directions for use in the treatment and prevention of the diseases, symptoms, and conditions for which the article was intended, namely, for preventing "female troubles," operations, including hysterectomies, cancer of the female parts, rot and decay in the vaginal tract, toxic poisons from entering the blood stream, and bladder trouble; for preventing and overcoming leukorrhea and painful or delayed menstruation; for overcoming Trichomonas infection and other conditions manifested by the presence of pus and inflammation, leukorrhea, sinus con-

*See also Nos. 6384, 6385.

ditions, hay fever and head colds; and for providing benefits to the bladder, kidneys, and related parts.

DISPOSITION: 12–18–59. The defendant having consented, the court entered a decree of permanent injunction enjoining and restraining the defendant from making or causing to be made any oral or written representations for the use of the article in the prevention or cure of any disease, condition, or infection of any kind which was not stated in the labeling of the article, while such article was held for sale after shipment in interstate commerce.

## DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

**6388. Sulfapyridine sodium powder (2 seizure actions).** (F.D.C. Nos. 44699, 44700. S. Nos. 41–268/70 R.)

QUANTITY: 1 100-lb. drum, 8 1-lb. btls., and 1 25-lb. drum, at San Francisco, Calif.

SHIPPED: The article was shipped in bulk, on 10–8–58, from New York, N.Y., by Fine Chemical Co.

LABEL IN PART: (Drum) "Sodium Sulfapyridine N.F.X. For Manufacturing Use Only Fine Chemical Company, New York, N.Y."; (btl.) "Sulfapyridine Sodium N.F. Powder (Not Sterile) Trico Pharmaceutical Co. Oregon City–San Francisco–Los Angeles"; and (drum) "Sulfapyridine Sodium N.F. Powder Not Sterile Trico Pharmaceutical Co."

RESULTS OF INVESTIGATION: A portion of the bulk drug was repacked into 8 1-lb. bottles and 1 25-lb. drum after shipment. Analysis showed that the drug contained less than 99 percent sulfapyridine sodium.

LIBELED: 7–5–60, N. Dist. Calif.

CHARGE: 501(b)—when shipped, the strength of the article differed from the standard set forth in the National Formulary.

DISPOSITION: 8–24–60. Default—destruction.

**6389. Tweltone solution.** (F.D.C. No. 44756. S. No. 22–273 R.)

QUANTITY: 48 cartoned vials at Kansas City, Mo.

SHIPPED: 4–4–60, from Indianapolis, Ind., by Pitman-Moore Co.

LABEL IN PART: "10 cc. size Sterile Solution Tweltone Liver Folic Acid $B_{12}$ * * * Pitman-Moore Company Div. of Allied Labs., Inc., Indianapolis. Sterility Test: 19464 Serial Lot No. 22159070."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 50 percent of the declared amount of vitamin $B_{12}$.

LIBELED: On or about 7–26–60, W. Dist. Mo.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported to possess; 502(a)—the label statement "Each cc. Represents: Vitamin $B_{12}$ Activity * * * Equivalent to 10 Micrograms Cyanocobalamin, Fortified With Folic Acid, 10 mg. and Crystalline Vitamin $B_{12}$ 50 Micrograms." was false and misleading.

DISPOSITION: 9–23–60. Default—destruction.

**6390. Estrophen-B Regular Strength tablets.** (F.D.C. No. 44732. S. No. 4–504 R.)

QUANTITY: 1 drum containing 18,000 tablets in bulk, 96 100-tablet btls., and 1 1,000-tablet btl., at Petersburg, Va.