from any cause; loss of appetite; nervousness; neuritis; loss of muscle tone; digestive upsets; diarrhea; vague aches and pains; irritability; headache; constipation; reddening of the lips; dizziness; dryness of hair or skin; insomnia; indigestion; loss of weight; weakness; swelling and redness of the tongue or inflammation of the tongue or mouth; sores about the angle of the mouth; dental caries; anemia; defective teeth and gums; sponginess of gums; pyorrhea; gum infections; local hemorrhages of the nose, mouth, gums, and about the face; pale complexion; retarded development; lowered vitality; decreased red blood cells and hemoglobin; and night blindness; 502(f)(1)—while held for sale, the labeling failed to bear adequate directions for use for the purposes for which it was intended, namely, in the treatment for and prevention of cancer, impure blood, heart disease, ulcers, and for reducing, which were the purposes for which the article was offered in oral statements made during a sales presentation on 6–1–60, by the dealer, Andy S. Hansen, at Omaha, Nebr.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 12–6–60. Consent—destruction.

6486. Fresca powder. (F.D.C. No. 44577. S. No. 36–440 R.)

QUANTITY: 67 8-oz. jars at Philadelphia, Pa.

SHIPPED: 2–29–60, from Dinuba, Calif., by The House of Fresca.

LABEL IN PART: "Fresca Powder * * * a Medicinal Powder for Feminine Hygiene containing boric acid, alum, oil of peppermint and carbolic acid, especially prepared for use as a Douche."

LIBELED: 5–17–60, E. Dist. Pa.

CHARGE: 502(a)—when shipped, the jar label contained the false and misleading representations that the article was an adequate and effective treatment for vaginal irritations, cuts, skin abrasions, insect bites, prickly heat, chafing, "other irritations of the skin," and offensive, tender, and sore feet; and also the false and misleading statements "for use as a Douche for beneficial satisfying results" and "This powder is a high quality prescription and has fittingly proven its merits," which indicated that the article was offered for disease conditions for which it was not efficacious; and 502(f)(2)—when shipped, the labeling failed to bear the required warning statement for douche preparations, namely, "Warning: Do not use more often than twice weekly unless directed by a physician."

DISPOSITION: 12–7–60. Default—destruction.

DRUGS AND DEVICE ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

6487. Various drugs. (Inj. No. 376.)

COMPLAINT FOR INJUNCTION FILED: 3–21–60, N. Dist. N.Y., against Rand Pharmaceutical Co., Inc., Rensselaer, N.Y.

CHARGE: The complaint alleged that the defendant was in the business of preparing, selling, and introducing and causing to be introduced and delivering and causing to be delivered for introduction into interstate commerce, drugs which were adulterated and misbranded as follows: 501(b)—the articles purported to be drugs, the names of which were recognized in an official compendium, namely, the United States Pharmacopeia, and their strength

differed from the standards set forth in such compendium; 501(c)—they were not subject to the provisions of 501(b) and their strength differed from, and their quality feel below, that which they purported and were represented to possess; 502(a)—the labeling of the articles contained false and misleading statements with respect to the nature and quantity of the ingredients contained in the articles.

The complaint alleged also that the adulterated and misbranded condition of the drugs resulted from deficiencies in their ingredients which were due to inadequate manufacturing facilities, lack of identification control, lack of adequate analysis and formulas, or lack of other precautions essential to the preparation of drugs.

DISPOSITION: On 3–21–60, a consent decree of permanent injunction was filed. The injunction enjoined and restrained the defendants from directly or indirectly introducing or causing to be introduced, or delivering or causing to be delivered for introduction into interstate commerce, any articles of drug that are adulterated:

(a) In that their strength differs from, or their quality or purity falls below, the standard set forth in an official compendium; or

(b) In that their strength differs from, or their quality falls below, that which they purport and are represented to possess; and that are misbranded:

(a) Because of false and misleading statements in their labeling with respect to the nature and quantity of the ingredients contained therein.

The injunction further enjoined the defendant from directly or indirectly introducing or causing to be introduced or delivering or causing to be delivered for introduction into interstate commerce, any drug manufactured, prepared, relabeled or repacked by them unless and until:

(a) Sufficient qualified and experienced personnel, including supervisory personnel are employed in the defendant's plant to properly operate it;

(b) A properly qualified pharmaceutical chemist is employed to make sufficient analyses of each batch of finished drug to insure that it conforms to the labeling under which it is to be shipped and to the requirements of the National Formulary or United States Pharmacopeia or other standard which may be applicable. Lacking this, a representative sample of each finished batch of drugs is submitted to a reliable established outside laboratory for examination and the results of such examination are received prior to shipment;

(c) A system of properly identifying and storing raw materials as they are received at the plant is instituted;

(d) Batches of drugs in preparation are not manipulated in an improper manner resulting in unwarranted shortages or averages in the final yield;

(e) Sampling of finished tablets, and all other finished products is done in a representative manner to insure the taking of a representative, adequate sample;

(f) Capsules are assayed in finished form rather than in earlier stages of manufacture;

(g) Finished batches of drugs are analyzed prior to shipment;

(h) Effective new drug applications are obtained for new drugs prior to their distribution;

(i) At least one qualified person in the plant has sufficient information concerning the new drugs shipped from the plant to eliminate confusion and violations;

(j) Adequate samples of incoming raw materials are taken and appropriate analyses of these samples made;

(k) Preparation of manufacturing records and forms is done with such clarity, care and completeness so that each lot or batch of drugs manufactured, prepared, relabeled, or repacked is so identified that the complete manufacturing, packing, and labeling history and control examination reports are readily available and so as to eliminate mistakes and confusion;

(l) Each batch or lot of drugs manufactured, prepared, relabeled or repacked is properly identified at all times and during all stages of said manufacturing, preparation, relabeling or repacking;

(m) Operations involving the weighing out of raw materials and the preparation of formulas and application of labeling are checked by another qualified party in addition to the employee originally performing such duties;

(n) Returned goods are recorded, handled, stored, and again disposed of in a manner which will eliminate uncertainty, confusion and the possibility of mistakes;

(o) Samples of each lot of raw materials and each batch or lot of drugs manufactured, prepared, relabeled or repacked by them are taken and retained for the time reasonably necessary for the distribution and use of drugs distributed;

(p) Representatives of the Food and Drug Administration of the Department of Health, Education, and Welfare are given free access to all records and controls pertaining to (1) the receipt of all raw materials or lots of drugs for manufacturing, preparing, repacking or relabeling; (2) the manufacturing, preparing, repacking or relabeling of all lots or batches of drugs; and (3) the distribution of all batches or lots of drugs whether interstate or intrastate, including, but not limited to, the records necessary to establish that adequate control systems have been installed embodying all of the herein listed safeguards for interstate commerce considered necessary to good pharmaceutical manufacturing practice.

6488. Procaine penicillin G in streptomycin sulfate in aqueous suspension. (F.D.C. No. 44851. S. No. 34–825 R.)

QUANTITY: 2,942 vials at New York, N.Y.

SHIPPED: On 3–31–60, from New York, N.Y., to Phoenix, Ariz., and returned to New York on 6–9–60.

LABEL IN PART: "10 cc. size 5 doses Procaine Penicillin G in Streptomycin Sulfate in Aqueous Suspension."

RESULTS OF INVESTIGATION: Examination showed that the article was badly discolored and lumpy; that it could not with certainty be uniformly resuspended; that withdrawal with a 22-gauge needle was nearly impossible; and that the article contained substantially less than its labeled content of penicillin and streptomycin.

LIBELED: On or about 8–19–60, S. Dist. N.Y.

CHARGE: 501(c)—while held for sale, the strength of the article differed from and its purity and quality fell below that which it purported and was represented to possess, since *procaine penicillin G in streptomycin sulfate in aqueous suspension* is recognized in the Antibiotic Regulations (21 CFR 146a.67) and it failed to conform to the standard set forth in such regulations since it did not contain the potency represented and it was not in an aqueous