SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6201–6240

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia) and its strength differed from the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents; Section 502(d), the article contained a chemical derivative of barbituric acid, and its label 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(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug; and (2) the drug was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; 502(f)(1), the labeling of the article failed to bear adequate directions for use; Section 502(l), the article was composed in part of penicillin and streptomycin sulfate, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

6201. Andriol and Andriol E. (F.D.C. No. 44550. S. Nos. 99–842/3 P.)

QUANTITY: 54 1-oz. btls. of *Andriol* and 60 1-oz. btls. of *Andriol E* at Minneapolis, Minn., in possession of Frommes Method, Inc.

SHIPPED: The chemical substances contained in the articles, namely, "Delta 5-Androstene-3 beta, 17 beta Diol" and "Delta 5-Androstene-3 beta, 17 beta Diol Dipropionate," were shipped from Chicago, Ill., prior to the filing of the libel.

LABEL IN PART: (Btl.) "The Frommes Formula Andriol [or "Andriol E"] by Frommes Scalp Specialists, Minneapolis."

RESULTS OF INVESTIGATION: McDonald Laboratories, St. Paul, Minn., manufactured the *Andriol* from the chemical substances shipped in interstate commerce as described above. In addition, isopropyl alcohol was added to the article. Thereafter, the article labeled "*Andriol*" was sold to Frommes Method, Inc., who repacked a portion of the article into 1-oz. bottles. The Frommes Method, Inc., manufactured the *Andriol E* by adding tyrosine, l-lysine, and powdered pine odor to the *Andriol*, and packing such article into 1-oz. bottles.

The above-quoted chemical substances of the articles were new drug substances. The article of *Andriol* was sold and shipped to Frommes Method, Inc.,

by McDonald Laboratories without an effective new drug application and Frommes Method, Inc., did not have a new drug application for the repacked articles.

LIBELED: 5–2–60, Dist. Minn.

CHARGE: 505(a)—the articles were new drugs within the meaning of the law, and applications filed pursuant to the law were not effective with respect to the drugs.

DISPOSITION: 6–14–60. Default—destruction.

6202. Pega Palo. (F.D.C. No. 42518. S. No. 14–916 P.)

QUANTITY: 68 ½-lb. paper bags at Canton, Ohio.

SHIPPED: On an unknown date from the Dominican Republic.

LABEL IN PART: "PEGA PALO Bring to a boil one gallon of water, add one teaspoon of powder, cook for one hour in stainless pot with lid, take one ounce with each meal."

RESULTS OF INVESTIGATION: The article was being distributed by Durwood Drew Roberts during the course of lectures given by him at Canton, Ohio.

LIBELED: 12–2–58, N. Dist. Ohio.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use as a gland aid, which was the condition for which it was offered orally by Durwood Drew Roberts; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application pursuant to law was not effective with respect to such drug.

DISPOSITION: On 1–3–59, Durwood Drew Roberts, claimant, filed an answer denying that the article was misbranded or a new drug. In addition, the claimant filed a motion to quash service on the grounds that the "Summons on Libel of Information and Forfeiture" and unsigned "Libel of Information" was served in the M. Dist. Pa., by the United States Marshal of that district and was therefore without force and effect. The court overruled the motion to quash on 3–6–59.

Thereafter, the Government filed requests for admissions, which were not answered, and on 6–13–60, a default decree was entered ordering the destruction of the article.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

DRUG FOR VETERINARY USE

6203. Trace's Poultry and Animal Booster. (F.D.C. No. 44410. S. No. 69–006 P.)

QUANTITY: 37 3½-lb. tins at Slayton, Minn., in possession of the Slayton Drug Store.

SHIPPED: 1–23–60, from Madison, S. Dak.

LABEL IN PART: (Tin) "Trace's Hi-Potency Water Soluble Poultry and Animal Booster * * * Guaranteed Analysis Penicillin 3.25 gm. per lb. Streptomycin Sulphate 2 gm. per lb. Terramycin Oxytetracycline Hydrochloride 1.25 gm. per lb. Vitamin B_{12} 1 mg. per lb. Vitamin A 500,000 USP Units per lb. Vitamin D_3 400,000 ICU per lb. Niacin 2,000 mg. per lb. Riboflavin 500 mg. per lb. Pantothenic Acid 500 mg. per lb. Menadione (Vitamin K) 100 mg. per lb. Pyridoxine Hydrochloride 100 mg. per lb. Thiamine Hydrochloride B_1 2,000