

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN
USED ACCORDING TO DIRECTIONS

3622. Adulteration and misbranding of ear wax drops and Alom Jel and misbranding of Vita-Malt, Eph-Thol nose drops, Pyrinimate, Pyrinimate tablets, hydrogen peroxide, milk of magnesia, and calamine lotion. U. S. v. 10,000 Bottles, etc. (F. D. C. No. 31639. Sample Nos. 18271-L to 18280-L, incl.)

LIBEL FILED: August 23, 1951, District of Arizona.

ALLEGED SHIPMENT: On or about May 7, 8, 14, 17, 18, 21, and 28, 1951, from Burbank and Los Angeles, Calif. The products were shipped to Phoenix, Ariz., and with the exception of the *Vita-Malt*, were either labeled or repacked and labeled while held for sale after such shipment.

PRODUCT: 10,000 bottles of *Vita-Malt*; 21 cases, each containing 48 bottles, of *Eph-Thol nose drops*; 11 cases, each containing 48 bottles, or *ear wax drops*; 53 cases, each containing 24 bottles, of *Alom Jel*; 98 bottles of *Pyrinimate*; 1 drum containing 25,000 25 mg. *Pyrinimate tablets* and 1 drum containing 25,000 50 mg. *Pyrinimate tablets*; 12 cases, each containing 24 bottles, of *hydrogen peroxide*; 17 cases, each containing 4 bottles, of *milk of magnesia*; and 8 bottles of *calamine lotion*.

Analysis showed that the *Eph-Thol nose drops* consisted of an aqueous solution containing 0.99 percent ephedrine sulfate, chlorobutanol (a chloral derivative), and a small proportion of menthol; that the *ear wax drops* contained approximately 4.8 percent phenol; that the *Alom Jel* contained 2.32 percent of aluminum oxide in the form of aluminum hydroxide and hydrated oxide (the United States Pharmacopeia provides that aluminum hydroxide gel shall contain not less than 3.6 percent of aluminum oxide in the form of aluminum hydroxide and hydrated oxide); that the *Pyrinimate* and the *Pyrinimate tablets* contained pyrilamine maleate, with the 50-milligram tablet containing approximately 41.5 milligrams of pyrilamine maleate per tablet; that the *hydrogen peroxide* was short volume; and that the *calamine lotion* contained glycerin and lime water, ingredients not specified in the formula for this article as set forth in the currently official United States Pharmacopeia, and did not contain polyethylene glycol 400 monostearate which is specified as an ingredient of the formula in the currently official United States Pharmacopeia.

LABEL, IN PART: "1 Lb. Size RC Vita-Malt Standardized," "RC Eph-Thol (Ephedrine Menthol) Nose Drops One Ounce," "RC Ear Wax Drops One Ounce Phenol 1% and Glycerine," "One Pint RC Alom Jel Aluminum Hydroxide Gel," "One Pt. RC Hydrogen Peroxide," "One Gal. RC Milk of Magnesia U. S. P.," and "One Gal. RC Calamine Lotion U. S. P. Packaged By Contract For R & C Co., Nutley, N. J.," and "R & C Pyrinimate Anti-Histamine Pyrinilamine Maleate 2.5 mg. Suerose - Glycerine [or "R & C Pyrinimate Tablets Anti-Histamine Pyrinilamine Maleate 25 mg. [or 50 mg.]] Packed by Contract For R & C Co., Nutley, N. J."

NATURE OF CHARGE: Adulteration, Section 501 (b), the *Alom Jel* purported to be and was represented as "Aluminum Hydroxide Gel," a drug, the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from that set forth in such compendium; and, Section 501 (c), the strength of the *ear wax drops* differed from that which it was represented to possess, namely, phenol 1 percent.