

and pep \* \* \* poor general health Savory produces remarkable results for those suffering with the above disorders."

Further misbranding, Section 502 (b) (2), the article was a drug in package form, and it failed to bear a label containing an accurate statement of the quantity of the contents.

The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: October 24, 1951. Default decree of condemnation and destruction.

3619. Misbranding of Golden Rub. U. S. v. 10 Cases \* \* \*. (F. D. C. No. 31345. Sample No. 18251-L.)

LIBEL FILED: July 17, 1951, District of Arizona.

ALLEGED SHIPMENT: On or about May 15, 1951, by Dr. A. Zaugg, from Los Angeles, Calif.

PRODUCT: 10 cases, each containing 12 1-pint bottles, of *Golden Rub* at Tucson, Ariz. Analysis showed that the product contained ammonia and ammonium salts of organic acids, including salicylic acid.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label and in a leaflet entitled "Golden Rub" attached to each bottle were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for arthritis, neuritis, bursitis, rheumatism, and psoriasis, whereas the article was not an adequate and effective treatment for such conditions.

DISPOSITION: October 2, 1951. Default decree of condemnation and destruction.

#### DRUG FOR VETERINARY USE

✓ 3620. Misbranding of Campbell's Chemical Mix. U. S. v. 46 Cartons \* \* \*. (F. D. C. No. 31384. Sample No. 13115-L.)

LIBEL FILED: August 3, 1951, District of Montana.

ALLEGED SHIPMENT: On or about July 3, 1951, by the S. & L. Campbell Co., from Dupont, Colo.

PRODUCT: 46 3-pound cartons of *Campbell's Chemical Mix* at Martinsdale, Mont. Examination showed that the product consisted of ammonium chloride, potassium chlorate, and sodium chlorate.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the label of the article were false and misleading: "Campbell's Chemical Mix for Cattle and Sheep" and (instructions for feeding sheep and cattle on alfalfa or clover) "\* \* \* put one 3-lb. package of Campbell's Chemical Mix to 100 lbs. No. 4 salt and mix thoroughly. Put in troughs where they can have access to it at all times. When feeding dairy cows chop or bran, put ¼ teaspoonful in the chop or bran twice daily out of the 3-lb. package. For drench, mix one teaspoonful in ¾ quart of water and drench \* \* \* We recommend force feeding when grain is fed—feed about 2 or 3 days before turning on clover or alfalfa." (The product would not be effective for the purposes suggested and implied.)

DISPOSITION: October 18, 1951. Default decree of condemnation and destruction.

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# FEDERAL SECURITY AGENCY

## FOOD AND DRUG ADMINISTRATION

### NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3621-3640

### DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations by the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *May 1, 1952.*

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\*For presence of a habit-forming narcotic without warning statement, see Nos. 3621-3623; omission of, or unsatisfactory, ingredients statements, Nos. 3621-3622, 3634; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3621-3623; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 3621.

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**DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN  
USED ACCORDING TO DIRECTIONS**

5622. 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.)

**LABEL 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.

Misbranding, Section 502 (b) (1), the labels of each of the articles failed to bear the name and place of business of the manufacturer, packer, or distributor. (There was no R & C Co. of Nutley, N. J., as declared upon the labels of the articles.)

Further misbranding, Section 502 (a), the label statement "Pyrinilamine Maleate 50 mg." on the label of a portion of the *Pyrinimate tablets* was false and misleading as applied to an article containing less than 50 mg. of pyrilamine maleate, and the label designation "U. S. P." on the label of the *calamine lotion* was false and misleading as applied to an article, the identity of which differed from that listed in the current revision of the United States Pharmacopeia; and, Section 502 (b) (2), the *hydrogen peroxide* failed to bear a label containing an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the *Eph-Thol nose drops* contained a chemical derivative of chloral, namely, chlorobutanol, which derivative has been found to be and by regulations designated as, habit forming; and the label of the article failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the label of the *Eph-Thol nose drops* failed to bear the common or usual name of each active ingredient since ephedrine sulfate was not declared, and the label of the *Pyrinimate* and the *Pyrinimate tablets* failed to bear the common or usual name of each active ingredient since pyrilamine maleate was not declared; and, Section 502 (j), the *ear wax drops* were dangerous to health when used in the dosage prescribed in the labeling.

The articles were adulterated and misbranded as described above while held for sale after shipment in interstate commerce.

DISPOSITION: On or about November 29, 1951, the Kimball Drug Co., Phoenix, Ariz., having appeared as claimant, judgment of condemnation was entered and the court ordered that the products be released under bond for reprocessing and relabeling to comply with the law, under the supervision of the Federal Security Agency.

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

3622. Misbranding of Dexedrine Sulfate tablets, Gantrisin tablets, and Seconal Sodium capsules. U. S. v. Gary Drug Co., Inc., Jacob H. Raverby, and Tobias Levine. Pleas of guilty. Fine of \$200 against corporation and \$50 against each individual. (F. D. C. No. 31244. Sample Nos. 79826-K, 79832-K, 79982-K, 79983-K, 79985-K to 79987-K, incl., 79991-K to 79995-K, incl.)

INFORMATION FILED: November 8, 1951, District of Massachusetts, against the Gary Drug Co., Inc., Boston, Mass., Jacob H. Raverby, president and treasurer of the corporation, and Tobias Levine, a pharmacist employed by the corporation.

INTERSTATE SHIPMENT: From the States of Pennsylvania, New Jersey, and Indiana, into the State of Massachusetts, of quantities of *Dexedrine Sulfate tablets*, *Gantrisin tablets*, and *Seconal Sodium capsules*.

\*See also No. 3640 (veterinary preparations).