

LIBELED: 2-26-59, Dist. Columbia.

CHARGE: 502(j)—when shipped, the article was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in its labeling.

DISPOSITION: 5-21-59. Default—destruction.

5862. Barnes-Hind Wetting Solution. (F.D.C. No. 43134. S. No. 62-351 P.)

QUANTITY: 21 doz., 2-oz. plastic btls. at Chicago, Ill.

SHIPPED: 2-19-59, from Sunnyvale, Calif., by Barnes-Hind Ophthalmic Products, Inc.

LABEL IN PART: (Plastic btl.) "Barnes-Hind Wetting Solution. An anti-septic wetting-out cleansing and sanitizing solution to be used with plastic contact lenses. * * * Active Ingredients: Benzalkonium chloride 0.002% * * * Barnes-Hind Ophthalmic Products, Inc., 895 Kifer Road, Sunnyvale, Calif."

RESULTS OF INVESTIGATION: Examination of the article showed that it was not sterile but was contaminated with viable micro-organisms of the *Pseudomonas* group.

LIBELED: 5-1-59, N. Dist. Ill.; amended 5-5-59.

CHARGE: 501(c)—when shipped, the purity or quality of the article fell below that which it purported or was represented to possess, since it was represented as suitable for use in the eye, whereas it was not suitable for such use by reason of contamination with *Pseudomonas*; and 502(j)—the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Directions: Gently rub 2 or 3 drops of Barnes-Hind Wetting Solution over the entire inner and outer surfaces of the lenses. Do not dry lenses before inserting."

DISPOSITION: 7-27-59. Default—destruction.

DRUG FOR VETERINARY USE

5863. Crisp Tonic Pills (veterinary). (F.D.C. No. 43170. S. No. 56-425 P.)

QUANTITY: 1 drum containing 4,500 tablets and 17 30-tablet boxes at Blacksburg, S.C., in possession of S. A. Crisp Canine Co.

SHIPPED: 8-30-47, from Passaic, N.J., by Purity Drug Co.

LABEL IN PART: (Drum) "Special Formula * * * pills S. C. Brown Each Pill Contains: Strychnine Sulfate $\frac{1}{120}$ gr. Arsenic Trioxide $\frac{1}{60}$ gr. Reduced Iron 1 gr. Extract Gentian 1 gr. Caution * * * Purity Drug Co. Inc., New York, N.Y. Passaic, N.J. 6603"; (box) "Crisp's Tonic Pills for Dogs * * * Each Containing Reduced Iron 1 gr. Strychnine Sulphate $\frac{1}{120}$ gr. Arsenic Trioxide $\frac{1}{16}$ gr. Extract Gentian Q.S. Directions * * * S. A. Crisp Canine Co., Blacksburg, S.C."

ACCOMPANYING LABELING: Pamphlets entitled "Crisp Canine Remedies."

RESULTS OF INVESTIGATION: The tablets in the boxes were shipped in bulk as described above and then were repacked and relabeled by the S. A. Crisp Canine Co. Analysis showed that the article contained about four times the declared amount of strychnine sulfate per tablet.

The pamphlets were prepared locally for the dealer.

LIBELED: 6-22-59, W. Dist. S.C.

CHARGE: 501(c)—the strength of the article, when shipped and while held for sale, differed from that which it purported to possess, namely, 1/120 grain strychnine sulfate per tablet; 502(a)—the label statements (drum and box) "Strychnine Sulphate 1/120 Gr." were false and misleading; 502(j)—the article was dangerous to health when used in the dosage, or with the frequency or duration recommended in the labeling; and 502(a)—the labeling of the repacked article, while held for sale, contained false and misleading representations and suggestions that the article was an adequate and effective treatment for overcoming "sluggish" symptoms in dogs and conditioning dogs after recovering from any disease; and the name "Tonic Pills" created the misleading impression that the article had unusual and general systemic conditioning and stimulating property.

DISPOSITION: 7-8-59. Consent—destruction.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

5864. Antiseptic nasal spray. (F.D.C. No. 43159. S. No. 51-364 P.)

QUANTITY: 28,800 individually cartoned 15-cc btls. at Chicago, Ill.

SHIPPED: 8-13-57 and 8-19-57, from Cleveland, Ohio, by Strong, Cobb & Co., Inc.

LABEL IN PART: (Btl.) "F & F Antiseptic Nasal Spray * * * Ingredients: Phenylephrine Hydrochloride 0.25% Pyrillamine Maleate 1.0% Tyrothricin 0.01% Cetyl Dimethyl Benzyl Ammonium Chloride 1:10,000 F & F Laboratories, Inc., Chicago 32, Illinois."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 1 percent pyrillamine maleate as stated on the label.

LIBELED: 5-25-59, N. Dist. Ill.

CHARGE: 502(a)—when shipped and while held for sale, the labels of the article contained false and misleading representations that it was an adequate and effective treatment for sinusitis; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 6-22-59. Default—destruction.

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

5865. Various drugs. (F.D.C. No. 42315. S. Nos. 32-161/2 P, 32-165/6 P, 32-168/75 P.)

QUANTITY: 1 186-capsule btl. of *Compazine Spansules*, 1 180-tablet btl. of *Nilivar Salud*, 1 370-tablet btl. of *Premarin with methyltestosterone*, 1 62-capsule box of *Panalba*, 1 180-capsule btl. of *Vascutum*, 1 185-tablet btl. of *penicillin*, 1 100-tablet btl. of *Neopenzine 300*, 1 1-oz. btl. of *Cathomyacin Calcium Syrup*, 1 1-pt. btl. of *Tetrabon V Tetracycline Syrup*, 24 cartoned vials of *Remanden-100*, 6 cartoned vials of *Remanden-250*, and 4 24-tablet btls. of *Dramcillin-250* (penicillin with sulfonamides), at New York, N.Y., in possession of Theresa Pharmacy.

SHIPPED: The articles were shipped at various times in the past 5 years, prior to the filing of the libel from outside the State of New York.

RESULTS OF INVESTIGATION: The *Compazine Spansule capsules*, *Nilivar Salud tablets*, *Premarin tablets with methyltestosterone*, *Panalba capsules*, *Vascutum*