

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

4988. Aqueous extract of pituitary anterior and ovarian. (F. D. C. No. 37547. S. Nos. 5-695/6 M.)

QUANTITY: 82 cartons, 25 2-cc. ampuls each, and 362 30-cc. vials at Evanston, Ill.

SHIPPED: Between 10-15-54 and 12-10-54, from Rensselaer, N. Y., by Winthrop-Stearns, Inc.

LABEL IN PART: (Ampul) "2 cc size Sterile Aqueous extract of Pituitary Anterior and Ovarian With procaine hydrochloride 1% and chlorobutanol"; (vial) "Multidose Vials - Sterile Aqueous extract of Pituitary Anterior - Ovarian * * * Each cc contains water soluble extractives from 5 gr. of Anterior Pituitary and 20 gr. of Ovarian Tissue with procaine HCl 1% in isotonic salt solution with chlorobutanol - George A. Breon and Company, New York 18, NY."

ACCOMPANYING LABELING: Leaflets entitled "[For Physicians' Information] The Administration of Aqueous Anterior Ovarian Substances."

LIBELED: 1-10-55; amended 7-20-55, N. Dist. Ill.

CHARGE: 502 (a)—the accompanying labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for menopausal nervous instability, essential amenorrhea, and dysmenorrhea; and 502 (f) (1)—the labeling of the article, when shipped, failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

DISPOSITION: George A. Breon & Co., claimant, New York, N. Y., filed answers to the libel and to the amended libel, denying that the product was misbranded as alleged. On 8-11-55, interrogatories were served upon the claimant by the Government. The claimant withdrew its answer; and, on 10-5-55, the court entered a default decree of condemnation and destruction.

4989. Alberty products. (F. D. C. No. 36439. S. Nos. 83-633/7 L, 83-639/41 L.)

QUANTITY: 14 12-oz. btls., of *Alberty Phar-Oil*, 13 180-tablet pkgs. of *Alberty Special Formula tablets*, 9 200-tablet btls. and 57 475-tablet btls. of *Alberty Phloxo B tablets*, 6 200-pellet btls. and 21 475-pellet btls. of *Alberty's Lebara No. 2 pellets*, 29 3-lb cans and 54 12-oz. cans of *Instant Alberty Food*, 8 124-tablet btls. and 4 275-tablet btls. of *Ri-Co tablets*, 15 50-perle btls. and 3 350-perle btls. of *Alberty Garlic and Vegetable Oil Perles*, and 1 225-pellet btl. and 4 500-pellet btls. of *Alberty's Sabinol pellets* at Des Moines, Iowa.

SHIPPED: Between 7-2-53 and 1-25-54, from Hollywood, Calif., by Alberty Food Products.

LABEL IN PART: (Btl.) "Alberty Phar-Oil * * * A Dietary Food Supplement Ingredients: Cod Liver Oil, Wheat Germ Oil, Linseed Oil."

(Pkg.) "Alberty New Improved Special Formula Tablets A Dietary Supplement Ingredients: Kelp, DiCalcium Phosphate, Iron (ferrous) Gluconate, Copper Peptonate, Mixed Tocopheral Concentrate, Manganese Sulfate, Pantothenol, Para-Aminobenzoic Acid. In a base of Yeast, Liver Extract, Orchic

*See also No. 4986.

Substance, Nucleinic Acid, Spleen Substance, Pancreatin, and Excipients * * * Net Contents 180 App. 12-Grain Tablets."

(Btl.) "Alberty Phloxo B Tablets Vitamin B₁ with Homeopathic Amounts of Five Phosphates. Each Tablet Contains 40 Int. Units of Vitamin B₁ 1/1000 gr. each of Phosphates of Iron, Potassium, Sodium, Calcium and Magnesium"; "Alberty's Lebara No. 2 Pellets Homeopathic Principle Each Pellet Contains: Celandine, Fringe-tree Barberry, Cinchona Off."

(Can) "Instant Alberty Food Special Dietary Food Made with Regular Alberty Food and Milk Made with Dried Whole and Skim Milk and a Special Grind of Cereal (Wheat, Barley) and Dibasic Calcium Phosphate."

(Btl.) "Ri-Co Tablets Homeopathic Combination * * * Each Tablet Contains: Lithium Benzoicum 3X Ammonium Phos. 3X Lycopodium 6X"; "Alberty Garlic and Vegetable Oil Perles * * * 6 Min. Perles Fresh Garlic Concentrated 8 to one And Combined in Vegetable Oil (No established therapeutic or nutritional value.) * * * a Convenient Way of Including Garlic Oil in the Diet"; "Alberty's Sabinol Homeopathic * * * Each Pellet Contains: Berberis Vulgaris 1X Lycopodium 3X Uranium Nit 6X Equisetum 3X."

LIBELED: 3-11-54, S. Dist. Iowa; libel amended 8-9-54.

CHARGE: 502 (f) (1)—while held for sale, the labeling of the above-mentioned articles failed to bear adequate directions for use for the purposes and conditions for which they were intended, namely, the following purposes and conditions for which the articles were offered orally by Mr. and Mrs. Kenneth Hackworth on 2-5-54, 2-9-54, and 2-11-54: *Alberty Phar-Oil*—in the treatment of nervousness, irritableness, menopausal distress, thyroid trouble, kidney disturbances, anemia, paralysis, muscular atrophy, coronary thrombosis, hypertensive heart disorders, rheumatic heart, Parkinson's disease, painful menstruation, cerebral palsy, multiple sclerosis, sterility, loss of sex interests, skin eruptions, burns, brittle nails, nephritis, catarrh, diseases of women, leg pains, bursitis, impaired functioning of the sex glands, prostate trouble, swelling of the prostate, and lack of libido and potency in men; *Alberty Special Formula tablets*—in improving libido and sexual strength, providing sex drive, increasing muscular and sexual activity, improving general health, providing better circulation and functioning of the blood making organs, and providing increased sexual desire; *Alberty Phloxo B tablets*—in providing good health and normal sex power and in treating hypertension and menopausal difficulties; *Alberty's Lebara No. 2 pellets*—in treating menopausal distress and nervousness and in restoring sex desire; *Instant Alberty Food*—in the treatment of rheumatism, arthritis, lumbago, and bursitis, and in restoring sexual vigor; *Ri-Co tablets*—in the treatment of sciatica, lumbago, and bursitis; *Alberty Garlic and Vegetable Oil Perles*—in the treatment of infertility, impotency, skin infections, colds, and influenza; and *Alberty's Sabinol pellets*—in the treatment of kidney sores, bladder sores, and pus in the kidneys.

502 (a)—when shipped, the label of *Alberty Phloxo B tablets*, *Alberty's Lebara No. 2 pellets*, *Ri-Co tablets*, and *Alberty's Sabinol pellets* contained the following false and misleading representations: that *Alberty Phloxo B tablets* were an adequate and effective treatment for sleeplessness, insomnia, irritability, and nervousness; that *Alberty's Lebara No. 2 pellets* were an adequate and effective treatment for liver conditions; that *Ri-Co tablets* were an adequate and effective treatment for pain and stiffness due to arthritis and rheumatism; and that *Alberty's Sabinol pellets* were an adequate and effective treatment for symptoms due to gravel or stone in the kidney and spasms of the ureters.

DISPOSITION: Alberty Food Products, claimant, filed an answer to the libel on or about 6-25-54, together with a set of interrogatories to be answered by the Government. Thereafter, the Government filed objections to the interrogatories and submitted a request for admissions. The claimant failed to reply to the request for admissions and to file any brief or argument to the objections to the interrogatories.

On 6-30-55, an application for default judgment was filed by the Government, and an order was entered setting the matter down for hearing. The claimant failed to appear at the hearing, and on 7-13-55, the court entered a decree condemning the goods and ordering their destruction.

4990. Various drugs. (F. D. C. No. 38189. S. Nos. 18-390/6 M, 18-398 M.)

QUANTITY: 135 1¼-oz. cartoned tubes of *Petty's pile ointment*, 21 1¼-oz. cartoned tubes of *Petty's analgesic balm*, 42 1¼-oz. cartoned tubes of *Petty's Heal-Aid ointment*, 59 1-oz. cartoned tubes of *Petty's In-A-Min-It*, 8 10-lb. bags and 8 3-lb. bags of *Petty's bathing salt*, 20 8-oz. jars of *Petty's Aroseptic Pulvis Antisepticus*, 50 ½-oz. cartoned vials of *Petty's toothache drops*, and 345 ⅔-oz. cartoned tubes of *Petty's zinc ointment*.

SHIPPED: Between 3-22-55 and 5-3-55, from Freeport, N. Y., by Pharmak, Inc.

LABEL IN PART: (Carton) "Petty's Pile Ointment * * * Contains Tannic Acid, Zinc Oxide, Boric Acid, Benzocaine, Cresol, Oils of Lavender, Thyme, Camphor and Eucalyptus"; "Petty's Analgesic Balm Counter-Irritant and Local Anesthetic * * * Contains Menthol, Methyl Salicylate, Lanolin."

(Tube) "Petty's Heal-Aid Ointment Antiseptic, Astringent, Soothing * * * Contains Calamine, Phenol, Oils of Sassafras and Eucalyptus, Ichthammol, Benzocaine"; "In-A-Min-It * * * Active Ingredients: Tragacanth U. S. P. Glycerin U. S. P. * * * Petty's."

(Bag) "Petty's Bathing Salt."

(Jar) "Petty's * * * Aroseptic Pulvis Antisepticus N. F."

(Vial) "Petty's Toothache Drops Alcohol 52% Chloroform 2% Oil Of Cloves Cinnamon Creosote Phenol Benzocaine."

(Tube) "Petty's Zinc Ointment Zinc Oxide Ointment."

LIBELED: 6-22-55, Dist. N. J.

CHARGE: 502 (a)—the labeling of the articles, when shipped, contained false and misleading representations that *Petty's pile ointment* was an adequate and effective treatment for blind, bleeding, and itching piles, both internal and external or protruding; that *Petty's analgesic balm* was an adequate and effective treatment for neuralgia, chilblains, sore throat, stiff muscles and joints, earache, pleurisy, sprains, bruises, and colds on the chest; that *Petty's Heal-Aid ointment* was an adequate and effective treatment for corns, bunions, callouses, chilblains, warts, bruises, boils, earache, piles, rectal irritations, eczema, and all burning or itching skin affections; that *Petty's In-A-Min-It* was effective in the prevention of appendicitis, convulsions in infants, and headaches; that *Petty's bathing salt* was an adequate and effective treatment for weak and impaired circulation; that *Petty's Aroseptic Pulvis Antisepticus* was an adequate and effective treatment for all types of wounds, sores, ulcers, burns, scalds, eczema, itching, skin eruptions, piles, foot itch, corns, and callouses; and that *Petty's zinc ointment* was an adequate and effective treatment for skin eruptions, sore nipples, weeping sores, and drying up excessive nasal secretions during colds in the head. 502 (e) (2)—the label of *Petty's*