DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

6009. Wonda Foot Balm and Wonda Mineral Foot and Body Bath Tablets. (F.D.C. No. 39370. S. Nos. 38-108 M, 38-110 M.)

INFORMATION FILED: 9-19-57, S. Dist. N.Y., against Almo Products Corp., New York, N.Y., and William Newman, secretary-treasurer of the corporation.

SHIPPED: Between 1-10-56 and 2-15-56, from New York to Missouri.

RESULTS OF INVESTIGATION: The *Wonda Foot Balm* contained activated lanolin, menthol, eucalyptus and hexachlorophene G 11, and the *Wonda Mineral Foot and Body Bath Tablets* contained aluminum potassium-sulfate, pine oil compound, sodium bicarbonate, citric acid and eucalyptus oil.

Investigation showed that the labeling of *Wonda Foot Balm* contained false and misleading representations that it was adequate and effective for the treatment of burning sore feet and muscular soreness; that the labeling of the *Wonda Mineral Foot and Body Bath Tablets* contained false and misleading representations that the article was an adequate and effective treatment for relieving aches and pains; and that the labeling of both articles contained false and misleading representations that the articles were adequate and effective treatments for overcoming and preventing varicose veins, leg pains, pain in hips, nervousness, droop shoulder, backache, neuritis, sciatica, and pain in knees.

CHARGE: 502(a)—when shipped, the labeling of the articles bore false and misleading therapeutic claims and representations.

PLEA: Guilty.

DISPOSITION: 8-19-59. Corporation—$500 fine; individual—$400 fine.

6010. Slim-Drin tablets. (F.D.C. No. 43294. S. No. 56-799 P.)

QUANTITY: 12,000 tablets in bulk drum, and 204 25-tablet btls, and 36 100-tablet btls., at Hollywood, Fla., in possession of Vishy Drug Products.

SHIPPED: 3-31-59, from Philadelphia, Pa., by Richlyn Laboratories.

LABEL IN PART: (Drum) "Phenylpropanolamine HCL 25 Mg. * * * Richlyn Laboratories, Philadelphia 24, Pa."; (btl.) "Slim-Drin Appetite Depressant Vishy Drug Products Hollywood Florida Distributor Directions: * * * Each tablet contains Phenylpropanolamine Hydrochloride 25 mgm. Caution: * * * Control No. 604."

ACCOMPANYING LABELING: (Display ctn.) "Slim-Drin For Appetite Control Just released by the Federal Government for overcounter sale."

RESULTS OF INVESTIGATION: The display cartons were purchased as blank cartons by the dealer and printed as needed.

The article in the bottles was repackaged by the dealer from the tablets in the bulk drum which were shipped as described above.

LIBELED: 7-9-59, S. Dist. Fla.

CHARGE: 502(a)—(drum) when shipped, the drum label of the article contained false and misleading representations that the article was adequate and effective for controlling the appetite in the management of obesity, and that it was an adequate and effective treatment for relieving asthma and bronchial spasm of the allergic type; and, while held for sale, the name "Slim-Drin" and certain statements on the bottle label and on the display carton contained

*See also Nos. 6001, 6004-6006, 6008.

false and misleading representations that the article was an adequate and effective treatment in controlling appetite, and causing one to lose weight immediately without tough diets; and, in addition, the display cartons contained statements that the article had just been released by the Federal Government for over the counter sale and that the article contained no harmful drugs, which statements were false and misleading since it contained the drug phenylpropanolamine which is not a harmless drug; certain precautions must be observed in its use; and such drug had not been "just released" but has been available for sale without prescription for a number of years under labeling which contains appropriate restrictions on the dosage and with caution against use by individuals with high blood pressure, heart disease, diabetes, and thyroid disease, except as directed by a physician.

DISPOSITION: 11–10–59. Default—destruction.

6011. Alfex alfalfa tablets. (F.D.C. No. 43151. S. No. 54–869 P.)

QUANTITY: 7 drums, each containing between 22,000 and 32,000 tablets and several hundred 30-tablet, 100-tablet, and 200-tablet btls. at Philadelphia, Pa., in possession of Shane Laboratories, Inc.

SHIPPED: 3–23–59, from North Kansas City, Mo.

LABEL IN PART: (Drum) "Alfex Tablets Concentration 29,000 * * * Caution: For Repackaging Use Only"; (btl.) "Alfex Hi-Potency Alfalfa Extract 400 Mg. In Each Tablet * * * Distributed by Shane Laboratories, Philadelphia * * * Pa."

ACCOMPANYING LABELING: Leaflets entitled "A Message of Hope for Arthritic Sufferers"; a form letter headed "Dear Pharmacist"; a window display banner reading: "Pains? Stiffness? Why Suffer? Arthritis For Relief Take Alfex Tablets"; and a newspaper advertisement used as a counter display headed "Arthritis Sufferers At Last! Amazing Fast Relief from Arthritis-Sciatica-Rheumatism-Bursitis Alfex."

RESULTS OF INVESTIGATION: The tablets in the bottle were repackaged by Shane Laboratories, Inc., from bulk drums which were shipped as described above.

LIBELED: 5–21–59, E. Dist. Pa.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the article was adequate and effective in the treatment of arthritis, rheumatism, sciatica, and bursitis.

DISPOSITION: 8–19–59. Consent—claimed by Shane Laboratories, Inc., and reworked and relabeled.

6012. Kank-A solution. (F.D.C. No. 43277. S. No. 63–629 P.)

QUANTITY: 36 ctns., each containing one display card of 14 vials each, and 17 ctns., each containing one display card of 28 vials each, at Boston, Mass.

SHIPPED: 5–25–59 and 6–2–59, from Plymouth, N.H., by John Arthur Geyer Co.

LABEL IN PART: (Ctn.) "One Card Kank-A * * * Mr. Druggist: Recommend Kank-A," (display card) "Use Kank-A," and (vial) "Kank-A * * * Contents: Myrrh, Benzoin, S.D., Alcohol."

LIBELED: 6–23–59, Dist. Mass.; amended libel 6–24–59.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for canker sores and denture sores; 502(c)—the information required by the Act to appear on the labeling, namely, the common or usual names of the active