

An order in accordance with the foregoing opinion was entered on 1-25-60, following which the claimant submitted further answers to the interrogatories. On 10-20-60, the claimant having consented to the entry of a decree, judgment of condemnation was entered, and the article was ordered released under bond for relabeling under the supervision of a representative of the Department of Health, Education, and Welfare. The claimant failed to file the bond as provided in the above decree and, accordingly, an order was entered on 1-20-61 directing that the article be turned over to the Food and Drug Administration.

DRUG AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

6447. Sodium dehydrocholate injection. (F.D.C. No. 45087. S. Nos. 26-251 R, 26-421 R.)

QUANTITY: 1,184 ampuls at Los Angeles and Downey, Calif.

SHIPPED: On 7-5-60 and 7-27-60, and subsequent thereto, from Philadelphia, Pa.

LABEL IN PART: "3 MI Ampul Sodium Dehydrocholate N.F. 20%."

RESULTS OF INVESTIGATION: Analysis showed that the contents of the ampuls had a pH of 7.0 to 7.1, whereas, the National Formulary requires a pH between 8.5 and 9.5. Examination showed also that some of the ampuls contained varying amounts of suspended matter which, upon separation and analysis, proved to be dehydrocholic acid.

LIBELED: 11-10-60, S. Dist. Calif.

CHARGE: 501(b)—while held for sale, the quality of the article fell below the standard for *sodium dehydrocholate injection* set forth in the National Formulary; and 502(a)—the labeling of the article was false and misleading as applied to an article that purported to be of a quality represented in the standard established in the National Formulary for *sodium dehydrocholate injection*, but was not of such quality.

DISPOSITION: 12-5-60. Default—destruction.

6448. Rubber prophylactics. (F.D.C. No. 44836. S. No. 42-007 R.)

QUANTITY: 72 gross ctns., in pkgs. of 2 each, at Reno, Nev.

SHIPPED: 8-26-60, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Pkg.) "Package of Two Spartans Prophylactics."

RESULTS OF INVESTIGATION: Examination showed that 2.6 percent of the units examined were defective in that they contained holes.

LIBELED: 10-25-60, Dist. Nev.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "For the Prevention of Disease" was false and misleading as applied to an article containing holes.

DISPOSITION: 12-15-60. Default—destruction.

6449. Rubber prophylactics. (F.D.C. No. 44713. S. Nos. 32-774/5 R.)

QUANTITY: 3 ctns., each containing 72 boxes of 2 cellophane-wrapped units each, and 3 ctns., each containing 48 3-unit boxes, at Middle Village, N.Y.

*See also No. 6442.

SHIPPED: 5-11-59 and 12-16-59, from Hanover, Germany, by Blausiegel Richter, Käufer & Co., G.M.B.H.

LABEL IN PART: "Blausiegel BF 2 Spezial" and "Blausiegel Edel * * * B 3."

ACCOMPANYING LABELING: Leaflets printed in whole or in part in the German language.

RESULTS OF INVESTIGATION: Examination showed that the article (both lots) contained holes.

LIBELED: 7-15-60, E. Dist. N.Y.

CHARGE: 501(c)—the quality of the article fell below that which it was represented to possess; 502(a)—the label statement "For Protection Against Disease" was false and misleading; and 502(c)—the article failed to bear a label containing all words, statements, and other information required by, or under the authority of, the Act to appear on the label or labeling in the English language.

DISPOSITION: 9-12-60. Default—destruction.

6450. Rubber prophylactics. (F.D.C. No. 44887. S. Nos. 22-752/4 R, 31-084 R, 31-097/9 R.)

QUANTITY: 106 gross ctns., each containing 48 3-unit pkgs.; 106 gross ctns., each containing 48 3-unit plastic boxes; 83 gross ctns., each containing 144 single-unit plastic boxes; 53 gross ctns., each containing 48 foil-wrapped 3-unit plastic boxes; and 53 gross ctns., each containing 48 foil-wrapped 3-unit pkgs., at Akron, Ohio.

SHIPPED: 8-26-60, from Oklahoma City, Okla., and 8-16-60 and 8-23-60, from Dallas, Tex. These were return shipments.

LABEL IN PART: (Ctn.) "Checks Deluxe Thin Prophylactics [or "Three's Gladiator Prophylactics Transparent Thins Reservoir End" or "Three's Poket-Pak Silver Coin Package Deluxe Thin Prophylactics"] * * * March Rubber and Plastics Co., Inc., Akron 6, Ohio."

RESULTS OF INVESTIGATION: Examination showed that the article was defective in that it contained holes.

LIBELED: 9-15-60, N. Dist. Ohio.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess.

DISPOSITION: 10-11-60. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

6451. Miracle Special Tonic. (Inj. No. 394.)

COMPLAINT FOR INJUNCTION FILED: 12-5-60, E. Dist. Mich., against Lee Anna Robinson, t/a Lee Anna Robinson Co., Detroit, Mich.

CHARGE: The complaint alleged that the defendant was engaged in the business of manufacturing, preparing, packing, labeling, selling, and distributing in interstate commerce, an article of drug designated as "Lee Anna Robinson's Miracle Special Tonic"; that investigation had disclosed that the article was

*See also Nos. 6441, 6442, 6445-6449.