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 Ml 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.