On 11–5–56, upon the consent of the parties that a condemnation decree might be entered without any adjudication as to any issue of fact or law, judgment of condemnation was entered and the court ordered that the device and accompanying labeling be turned over to the Department of Health, Education, and Welfare.

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

5314. Elixir Sonidel, triple sulfa suspension, and elixir butabarbital sodium. (F. D. C. No. 39844. S. Nos. 30–398 M, 43–265 M, 43–305 M.)

INFORMATION FILED: 7–24–57, E. Dist. Mo., against Halitosine Co., t/a Allan & Co., St. Louis, Mo.

SHIPPED: Between 1–30–56 and 10–30–56, from Missouri to Tennessee.

LABEL IN PART: (Btl.) "One Pint Elixir Sonidel [or "Contents I Pint Triple Sulfa Suspension" or "One Gallon Elixir Butabarbital Sodium"] * * * Allan & Co., St. Louis, Mo."

CHARGE: *Elixir Sonidel.* 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess since the article contained more phenobarbital than declared on its label; and 502 (a)—the label statement "Each 5 cc contains: Phenobarbital * * * 16.20 mg." was false and misleading.

Triple sulfa suspension. 501 (b)—the article, when shipped, purported to be a drug, the name of which "sulfacetamide, sulfadiazine, and sulfamerazine suspension" is recognized in the National Formulary, an official compendium, and its strength differed from the official standard since it contained less than 90 percent of the labeled amounts of sulfacetamide, sulfadiazine, and sulfamerazine, the minimum permitted by the standard; and 502 (a)—the label statement "Each 5 cc Contains: Sulfadiazine .167 gms. Sulfamerazine .167 gms. Sulfacetamide .167 gms." was false and misleading.

Elixir butabarbital sodium. 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess since the article contained more butabarbital sodium than declared on its label; and 502 (a)—the label statement "Each 30 cc Contains * * * 0.2 gms. Sodium Butabarbital" was false and misleading.

PLEA: Guilty.

DISPOSITION: 9–20–57. $150 fine.

5315. First aid kits containing halazone tablets. (F. D. C. No. 39426. S. No. 51–900 M.)

QUANTITY: 818 *first aid kits*, each containing 1 bottle of *halazone tablets* at Denver, Colo.

SHIPPED: Between 1–26–56 and 5–10–56, from Tulsa, Okla.

LABEL IN PART: (Btl.) "100 Water Purification Tablets For Purifying Drinking Water In Canteens Halazone N. N. R. (P-sulfonedichloramidobenzoic acid) Each tablet contains 0.004 Gm. (1/16 grain) of Halazone with sodium carbonate, sodium chloride and boric acid."

RESULTS OF INVESTIGATION: Analysis showed that the tablets contained from 75 percent to 98 percent of the declared amount of halazone. The National

*See also Nos. 5301, 5320 (veterinary preparation).

Formulary provides that halazone tablets contain not less than 90 percent of the labeled amount of halazone.

LIBELED: 8–23–56, Dist. Colo.

CHARGE: 501 (b)—while held for sale, the tablets purported to be and were represented as "Halazone Tablets," a drug the name of which is recognized in the National Formulary, an official compendium, and their strength differed from the official standard.

DISPOSITION: 2–8–57. Consent—claimed by Associated Traders, Inc., Denver, Colo. The bottles of *halazone tablets* were removed from the *first aid kits* and were destroyed.

5316. Clinical thermometers. (F. D. C. No. 39280. S. Nos. 51–556/7 M.)

QUANTITY: 1,469 *oral thermometers* and 358 *rectal thermometers* at Denver, Colo.

SHIPPED: Between 2–27–56 and 4–23–56, from Bronx, N. Y., by Dependable Thermometer Co.

LABEL IN PART: (Envelope) "Tested Clinical Thermometer Oral [or "Rectal"] Centigrade."

ACCOMPANYING LABELING: Leaflets designated "Certificate of Examination Fever Thermometer."

RESULTS OF INVESTIGATION: Examination revealed that 7 out of 24 oral thermometers and 3 out of 24 rectal thermometers failed to meet the labeled standard of accuracy and were not suitable for use as clinical thermometers because of faulty construction in that the gradation range was inadequate; there were too wide spaces between gradations; some had more than 5° C. per inch of scale; and some failed to retain pigment in markings when tested by recognized procedures.

LIBELED: 6–21–56, Dist. Colo.

CHARGE: 501 (c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess; and 502 (a)—the following statements in the labeling were false and misleading: "Tested" and "This Certifies that this registering clinical thermometer has been tested on the above date at 98°, 102°, and 106° F. or its equivalent in centigrade scale, and is correct within plus or minus .20° F. or .11° C. at any of these test points. The accuracy of this thermometer has been determined by testing and checking same with instruments tested by the National Bureau of Standards of the United States Dep't of Commerce, Washington, D. C."

DISPOSITION: 3–13–57. Default—24 thermometers of each type were turned over to the Food and Drug Administration and the remainder was destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

5317. Cellaids. (F. D. C. No. 38958. S. Nos. 21–943/49 M, 21–951 M, 21–953 M.)

QUANTITY: 73 pkgs. at Seattle, Wash.

SHIPPED: Between 7–8–55 and 11–25–55, from Denver, Colo., by George Collingwood.

LABEL IN PART: (Pkgs.) "Cellaids * * * Calcium Fluoride [or "Calcium Phosphate," "Calcium Sulphate," "Iron Phosphate," "Potassium Chlorid," "Sodium

*See also Nos. 5301, 5308, 5312–5314, 5316.