

**CHARGE:** 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess, namely, 10 mg. of vitamin B<sub>1</sub> per tablet; and 502 (a)—the bottle label contained false and misleading representations that the article was effective in the treatment of chronic diarrhea and celiac disease.

**DISPOSITION:** 5-21-57. Default—destruction.

5336. Halazone tablets. (F. D. C. No. 40168. S. No. 63-029 M.)

**QUANTITY:** 9 cases containing a total of 892 btl. at New York, N. Y.

**SHIPPED:** 1-22-54, from Philadelphia, Pa.

**LABEL IN PART:** (Btl.) "100 Water Purification Tablets for Purifying Drinking Water in Canteens \* \* \* Halazone N. N. R. \* \* \* Each tablet contains 0.004 Gm. ( $\frac{1}{16}$  grain) of Halazone with sodium borate and chloride."

**RESULTS OF INVESTIGATION:** Examination showed that the article contained from 0.5 percent to 91.5 percent of the labeled amount of halazone.

**LIBELED:** 4-23-57, S. Dist. N. Y.

**CHARGE:** 501 (b)—the strength of the article, while held for sale, differed from the standard for halazone tablets set forth in the National Formulary.

**DISPOSITION:** 5-22-57. Default—destruction.

## DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

### DRUGS FOR HUMAN USE\*

5337. Fenugreek seed, yerba maté, and toasted yerba maté. (F. D. C. No. 39004. S. Nos. 40-035 M, 40-038/9 M, 40-053/8 M.)

**QUANTITY:** 1 170-lb. drum, 1 154-lb. drum, 8 10-oz. pkgs., and 48 2½-oz. pkgs. of *fenugreek seed*; 27 50-lb. boxes, 1 25-lb. drum, 53 1-oz. pkgs., and 49 6½-oz. pkgs. of *yerba maté*; 41 78-lb. boxes, 1 35-lb. drum, 25 1-oz. pkgs., and 19 6½-oz. pkgs. of *toasted yerba maté*, at Hammond, Ind., in possession of Indiana Botanic Gardens.

**SHIPPED:** Between 4-5-55 and 2-29-56, from North Bergen, N. J., Jersey City, N. J., Chicago, Ill., and Curitiba, Brazil.

**LABEL IN PART:** (Pkg.) "Fenugreek (*Trigonella Foenum Graecum*) Part used—The seeds"; "Yerba Mate (*Dex Paraguensis*) Other Common Names: Jesuit's Tea, Brazil Tea, Jerusalem Tea or Mate, Paraguay Tea Part used—The leaves"; "T-Mate (Toasted Yerba Mate) (*Llex Paraguensis*) Other Common Names: Jesuit's Tea, Brazil Tea, Jerusalem Tea or Mate, Paraguay Tea Part used—The leaves."

**ACCOMPANYING LABELING:** Booklets entitled "Herbal Catalog" and the 1948, 1951, 1952, 1955, and 1956 editions of a booklet entitled "The Herbalist Almanac."

**RESULTS OF INVESTIGATION:** The articles were shipped in interstate commerce in bulk; and, upon their receipt, the consignee repacked portions of the articles into packages labeled as described above. The booklets were printed locally for the consignee and were distributed to former and prospective customers to promote the sale of the various products advertised in them.

**LIBELED:** 3-29-56, N. Dist. Ind.

\*See also Nos. 5322, 5325, 5326, 5333-5335.

**CHARGE:** 502 (a)—the labeling accompanying the articles, while held for sale, contained the following false and misleading representations:

1. That the *fenugreek seed* had the same composition and properties as cod liver oil; that it served as an adequate substitute for cod liver oil in nutritive value and for medicinal use; and that it was effective in the treatment of scrofula, rickets, anemia, and debility following infectious diseases; and

2. That the *yerba maté* and *toasted yerba maté* were a "miracle herb"; that their use would give one strength and endurance, produce mental exhilaration, bodily comfort, and refreshment without subsequent depression; that their use would facilitate digestion without disturbing sleep; that they were soothing to the nerves; that they would relieve physical or mental strain; that they would reduce the appetite; that they were an effective treatment for "dizzy spells," asthma, sciatic rheumatism, and nervousness; that they would give the user strength and pep; and that they would enable one to do a great deal of work with little food.

**DISPOSITION:** 9-7-56. Default—portion of booklets delivered to Food and Drug Administration and remainder, together with the drugs, destroyed.

**5338. D.A.G. antiseptic and Dikkers veterinary antiseptic.** (F. D. C. No. 39733. S. Nos. 24-025/6 M.)

**QUANTITY:** 18 1-pt. btl. of *D.A.G. antiseptic* and 90 4-oz. and 24 1-pt. btl. of *Dikkers veterinary antiseptic* at Phoenix, Ariz.

**SHIPPED:** 11-13-56, from Los Angeles, Calif., by Dikkers Biochemical Laboratory.

**LABEL IN PART:** (Btl.) "D.A.G. \* \* \* Antiseptic \* \* \* For minor irritations, cuts, bruises, burns. Contains: Iodophenol in a natural seaweed base. Directions: Apply to affected surface or use wet dressing. As a gargle use full strength. Do not dilute. Sold to Doctors only. Manufactured by Dikkers Biochemical Laboratory, Los Angeles, California" and "Dikkers Veterinary Antiseptic. Non Toxic. Non irritant. Contains: Iodophenol in a natural chondrus base. Caution: To be dispensed only by or on the prescription of a veterinary. Manufactured by Dikkers Biochemical Laboratory, Los Angeles, California."

**ACCOMPANYING LABELING:** Leaflets entitled "D.A.G. Dikkers Antiseptic and Germicide" and "D.A.G. A Therapeutic Seaweed Extract with Tri-Iodophenols. An Ethical Product for the Dental Profession."

**RESULTS OF INVESTIGATION:** Analysis showed that the articles were contaminated with viable organisms and were not antiseptic.

**LABELED:** 1-10-57, Dist. Ariz.

**CHARGE:** 501 (c)—when shipped, the strength of the articles differed from, and their purity and quality fell below, that which they purported and were represented to possess; and 502 (a)—the statement on the labels of the articles, when shipped, namely, "Antiseptic," was false and misleading, and the labeling accompanying the articles, when shipped, contained the following false and misleading representations:

(1) That the *D.A.G. antiseptic* was effective as an antiseptic in oral hygiene, periodontal diseases, Vincent's infection, pyorrhea, gingivitis, dermatology, eye, ear, nose, and throat conditions, proctology, genitourinary conditions, gynecology, internal medicine, and surgery; and