

**5323. Epsom salt.** (F. D. C. No. 40172. S. No. 60-638 M.)

**QUANTITY:** 36 cases, 12 7-oz. ctns. each, and 24 cases, 12 1-lb. ctns. each, at Hermon, Maine, in possession of Byron H. Smith & Co.

**SHIPPED:** From Midland, Mich.

**LABEL IN PART:** "Three Crow Brand Epsom Salts U. S. P. \* \* \* Packed by The Atlantic Spice Co., Bangor, Maine."

**RESULTS OF INVESTIGATION:** The product was shipped from Michigan in 100-lb. bags, and upon receipt by Byron H. Smith & Co., it was repacked by that firm into the cartons and cases described above.

**LIBELED:** 4-23-57, Dist. Maine.

**CHARGE:** 501 (f) (1)—the labeling of the article, while held for sale, failed to bear adequate directions for use since no directions for use or dosage directions were given; and 502 (f) (2)—the article was essentially a laxative, and its labeling failed to warn that frequent or continued use of the article may result in dependence upon laxatives to move the bowels and that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present.

**DISPOSITION:** 6-2-57. Default—delivered to a charitable institution.

**5324. First aid kits.** (F. D. C. No. 39428. S. Nos. 47-912/3 M.)

**QUANTITY:** 637 *first aid kits* at New York, N. Y.

**SHIPPED:** 6-26-56 and 7-3-56, from Tulsa, Okla., and St. Louis, Mo.

**RESULTS OF INVESTIGATION:** Examination showed that a portion of the *first aid kits* consisted of a canvas pouch containing, among other items, a bottle of 100 *halazone tablets*. Examination showed further that another portion of the first aid kits consisted of a leather pouch holding, among other items, a tube of *boric acid ointment* and a bottle of 100 *halazone tablets*.

Analysis showed that the *halazone tablets* contained from 18 to 80 percent of the declared amount of halazone, whereas the National Formulary provides that halazone tablets contain not less than 90 percent of the labeled amount of halazone. The label of the *boric acid ointment* bore no directions for use.

**LIBELED:** 9-6-56, S. Dist. N. Y.

**CHARGE:** 501 (b)—the strength of the *halazone tablets*, while held for sale, differed from the standard for halazone tablets set forth in the National Formulary; and 502 (f) (1)—the labeling of the *boric acid ointment* failed to bear adequate directions for use.

**DISPOSITION:** 12-18-56. Default—destruction.

**5325. Niagara devices.** (F. D. C. No. 39678. S. No. 56-387 M.)

**QUANTITY:** 5 *Niagara Hand Units*, 2 *Niagara Thermo-Cyclopads*, 1 *Deluxe Niagara Thermo-Cyclopad* with *Niagara Hand Unit*, and 1 *Deluxe Niagara Thermo-Cyclopad* without *Niagara Hand Unit*, at Minneapolis, Minn., in possession of Ralph E. Dixon.

**SHIPPED:** 9-19-56, from Adamsville, Pa., by Niagara Midwestern Corp.

**LABEL IN PART:** (Metal box attached to *Niagara Hand Unit*) "Niagara \* \* \* Hand Unit Model No. 1 \* \* \* Niagara Manufacturing and Distributing Corp. Adamsville, Penn. U. S. A."; (carton containing *Niagara Thermo-Cyclopad*) "The New Niagara Thermo-Cyclopad \* \* \* This carton contains 1-Niagara Thermo-Cyclopad \* \* \* Manufactured and distributed by the Niagara Manufacturing and Distributing Corp. Adamsville,

Pa.”; (metal box attached to the *Niagara Thermo-Cyclopad*) “Thermo-Cyclopad Model 10.”

**ACCOMPANYING LABELING:** Copies of a brochure designated “General Directions For Use” and leaflets designated “Miracle of Science . . . At Last . . . Two of mankind’s greatest healers” and “Miracle Science . . . Niagara Cyclo-Massage.”

**RESULTS OF INVESTIGATION:** The *Niagara Thermo-Cyclopad* consisted of a rectangular pad with an electrical attachment at one end. The pad was approximately 23½ inches long, 15½ inches wide, and 1¾ inches deep. The electrical attachment had a control box connected to it by means of electrical wiring, and the control box had a connection for plugging into household current. In operation, the pad could be heated by means of electric current, and it also could be made to vibrate by means of its built-in electrical mechanism.

The *Niagara Hand Unit* consisted of a rounded metallic object approximately 10 inches long and 3½ inches in diameter at the largest part. It had an electrical wire connector and control box which, when plugged into the household current, caused the unit to vibrate. The slender end of the *Niagara Hand Unit* had a rubber cup attachment.

**LIBELED:** 11-15-56, Dist. Minn.

**CHARGE:** 502 (a)—the labeling accompanying the devices, when shipped, contained false and misleading representations that the devices provided an adequate and effective treatment for impaired circulation, arthritis, bursitis, rheumatism, lumbago, numbness of the extremities, fibrositis, nervous tension, muscle spasm, impaired muscle and joint mobility, insomnia, and renewing one’s life; and 502 (f) (1)—while held for sale, the labeling of the devices failed to bear adequate directions for use in preventing and overcoming calcium deposits; in overcoming “locked joints” and sinus congestion; in enabling diabetics to stop taking insulin; in overcoming prostate trouble, asthma, hay fever, respiratory conditions, and baldness, which were the conditions for which the devices were intended and for which they were recommended orally by Ralph E. Dixon in promoting the sale of the devices.

**DISPOSITION:** 1-2-57. Default—delivered to the Food and Drug Administration.

**5326. Schlessing Ultrasoniseur devices.** (F. D. C. No. 33565. S. No. 18-735 L.)

**QUANTITY:** 75 devices at Los Angeles and Santa Monica, Calif.

**SHIPPED:** Between 7-1-51 and 9-4-52, from St. Louis, Mo., by A. Schlessing & Co., Inc.

**ACCOMPANYING LABELING:** Pamphlets entitled “Therapeutics by Ultrasonics”; leaflets entitled “Please Read Carefully. The Schlessing Ultrasoniseur . . .” and “that they may WALK again . . .”; sheets entitled “Reports on Ultrasonic Physical Medicine from American Users”; form letters headed “Dear Doctor:”; and guarantees and order blanks regarding Schlessing Ultrasoniseur.

**LIBELED:** 9-5-52, S. Dist. Calif.

**CHARGE:** 501 (c)—the strength of the devices, when shipped and while held for sale, differed from, and their quality fell below, that which they purported and were represented to possess since their ability to produce total sound output (ultrasonic) differed materially from the ability which they were represented to possess and the output meter (dosimeter) did not accurately gauge the energy density output of the devices; 502 (a)—the labeling of