

muscular. 1 Gram daily or on alternate days; for children, intravenous 0.02 to 0.5 Gram," was dangerous to health because of its pyrogenic effect.

DISPOSITION: 12-16-55. Default—destruction.

4982. E-Z thumb guard. (F. D. C. No. 38970. S. No. 27-203 M.)

QUANTITY: 11 display cards, each containing 6 *E-Z thumb guards*, at Phenix City, Ala.

SHIPPED: 12-5-55, from New York, N. Y., by E-Z Products Co.

ACCOMPANYING LABELING: (Display card and card attached to each thumb guard) "E-Z Thumb Guard."

RESULTS OF INVESTIGATION: The device consisted of a piece of metal measuring approximately  $1\frac{3}{4}$  inches in length and  $1\frac{1}{8}$  inches in width, containing a double row of rectangular perforations and folded so as to form a cylinder and pliable enough to be pressed snugly around the thumb or finger of a baby. Attached to the cylinder was a string long enough to be looped between the fingers and tied around the wrist for securing the thumb guard in place.

LIBELED: 2-27-56, M. Dist. Ala.

CHARGE: 502 (a)—the labeling accompanying the device, when shipped, contained false and misleading representations that it would prevent thumb or finger sucking; that it would protect the baby's health, teeth, gums, and facial features; that it would guard the baby's teeth; and that it would easily and effectively stop the habit of thumb sucking; and 502 (j)—the article, when used as a baby's thumb guard as suggested in the labeling, would be dangerous to health.

DISPOSITION: 4-2-56. Default—destruction.

#### NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

4983. Au-Bi-Ol. (F. D. C. No. 38873. S. No. 29-944 M.)

QUANTITY: 104 10-cc. vials and 2 100-cc. vials at Brooklyn, N. Y.

SHIPPED: Sometime after 3-29-51, from Hamburg, Germany, by E. Tosse & Co.

LABEL IN PART: (Vial) "Au-Bi-Ol 'Tosse-Germany' 1 cc. contains 0.09 g Bismuthsubsalicylate and 0.005 g Aurothiosalicylate, suspended in vegetable oil \* \* \* Intragluteal \* \* \* E. Tosse & Co., Hamburg."

LIBELED: 12-27-55, E. Dist. N. Y.

CHARGE: 503 (b) (4)—the article, when shipped, was a drug subject to 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and 505 (a)—the article was a new drug which could not lawfully be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 2-27-56. Default—destruction.

4984. Dental hemostat. (F. D. C. No. 38695. S. No. 22-472 M.)

QUANTITY: 1,386  $\frac{1}{4}$ -oz. btls. at Chicago, Ill.

SHIPPED: 8-3-55, from Portland, Oreg., by Ruson Laboratories, Inc.

LABEL IN PART: (Btl.) "Orylstat For Topical Use Only \* \* \* Active Ingredients: Racemic Epinephrine (dimethylaminoethanolcatechol Hydrochloride) 8%, with chlorobutanol, a chloroform derivative, as a preservative 0.5%, N-(caprylcolaminoformylmethyl)-Pyridinium Chloride\* 1:2000. Inert Ingredients: Distilled water, sodium chloride, 90% \*Ruson Chloride."

RESULTS OF INVESTIGATION: Analysis showed that the article contained no N-(caprylaminoformylmethyl)-Pyridinium Chloride.

LIBELED: 11-17-55, N. Dist. Ill.

CHARGE: 502 (a)—the label statement "Active Ingredients \* \* \* N-(caprylaminoformylmethyl)-Pyridinium Chloride\* 1:2000" was false and misleading; and 505 (a)—the article, when shipped, was a new drug which could not lawfully be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 2-8-56. Default—destruction.

4985. B & H inhalant powder. (F. D. C. No. 38747. S. No. 25-796 M.)

QUANTITY: 8 display placards, 21 vials each, and 2 cartons, 3 vials each, at Minneapolis, Minn.

SHIPPED: 5-23-55, from Billings, Mont., by B & H Laboratories.

LABEL IN PART: (Vial) "B & H Inhalant Powder Contains borate soda, silver nitrate, menthol."

ACCOMPANYING LABELING: Cards designated "Colds Asthma Hay Fever Headaches Sinus B & H Inhalant Powder 'Amazing Discovery'" and leaflets entitled "Sinus And Hay Fever Sufferers B & H Inhalant Powder."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 98.1 percent borax, 1.86 percent silver nitrate, and a small amount of menthol.

LIBELED: 12-16-55, Dist. Minn

CHARGE: 502 (a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for colds, asthma, hay fever, and all kinds of headaches and sinus trouble; and 505 (a)—the article was a new drug which could not lawfully be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 2-3-56. Default—destruction.

## DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

### DRUGS FOR HUMAN USE

4986. Various drugs. (F. D. C. No. 38907. S. Nos. 37-041/2 M, 37-045 M 37-048 M, 37-056/9 M, 37-061 M, 37-063 M, 37-067/9 M, 37-073/83 M 37-085 M, 37-087/8 M.)

QUANTITY: 2 btl. containing a total of 1,650 *Roncovite tablets*; 4 btl. containing a total of 5,000 *Zilatone tablets*; 3 btl. and 1 drum containing a total of 28,000 *Creamalin tablets*; 1 btl. containing 800 *Pheno-Bepadol tablets*; 9 100-capsule btl. of *Fer-Dona capsules*; 2 btl. containing a total of 1,000 *Kiophyllin tablets*; 2 btl. containing a total of 650 *Pavatrine tablets*; 2 btl. containing a total of 4,000 *Amodrine tablets*; 1 1,100-capsule btl. of *Sulphocol capsules*; 6 btl. of *Hemosule capsules*; 2 btl. containing a total of 1,360 *Butisol Sodium capsules (Mol-Iron tablets)*; 1 1,100-capsule btl. of *Propadrine capsules*, 92 vials of *Dibenzylethylenediamine dipenicillin G oral suspension*; 2 btl. containing a total of 200 *Bicillin-Sulfas tablets*; 1 btl. containing 109 *Sulfabiotic tablets*; 1 btl. of *Pansulfa with penicillin tablets*; 1 btl. of *Aureomycin Spersoids*; 8 envelopes containing a total of 700 *Diamox tablets*; 2 btl. of *Erythrocin*; 3 btl. of *Thorazine*; 3 boxes of *Aureomycin capsules*; 2 btl.