

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 Bisuthsubsalicylate 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."