

PLEA: Guilty.

DISPOSITION: 11-16-53. \$900 fine.

4543. B-amino-complex tablets. (F. D. C. No. 35676. S. No. 45-682 L.)

QUANTITY: 98 100-tablet btls. at Cambridge, Mass.

SHIPPED: 9-15-53 and 9-24-53, from New York, N. Y., by Unitone Corp.

LABEL IN PART: The label borne upon the above-mentioned bottles was the same as the label described in notice of judgment No. 4549.

LIBELED: 10-1-53, Dist. Mass.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use for the purpose for which it was intended, namely, in the treatment of deafness.

DISPOSITION: Pursuant to agreement of the parties, an order was entered on 10-29-53 directing the removal of the libel action to the Eastern District of New York. On 2-1-55, with the consent of the claimant, Unitone Corp., a decree of condemnation and destruction was entered.

4544. Polyzone device. (F. D. C. No. 36465. S. No. 69-747 L.)

QUANTITY: 1 device at Pueblo, Colo.

SHIPPED: 6-16-53, from Los Angeles, Calif., by the Polyzone Co.

ACCOMPANYING LABELING: Leaflet entitled "For Doctors Only Polyzone."

RESULTS OF INVESTIGATION: The article was assumed to consist of a device for transforming ordinary diatomic oxygen into ozone (triatomic oxygen) for administration to the human body.

LIBELED: 3-26-54, Dist. Colo.

CHARGE: 502 (a)—the accompanying labeling of the device when shipped contained false and misleading representations that ozone produced by the device was nontoxic and that the device provided, through the agency of the ozone generated by it, an adequate and effective treatment for rheumatism, sciatica, heel spurs, arthritis, male and female pelvic infections, vaginal infections, rectal inflammations, infected rectal crypts, rectal tumors, rectal fissures, colitis, hemorrhoids, fistulas, pruritus ani, spastic sphincters, inflammations of the eye, ear, nose, and throat, sinus infections, internal and external ulcerations, and all acute and chronic conditions; and, 502 (f) (1)—the labeling of the device failed to bear adequate directions for use.

DISPOSITION: 11-4-54. Default—delivered to Food and Drug Administration.

4545. Polyzone device. (Inj. No. 284.)

COMPLAINT FOR INJUNCTION FILED: 10-22-54, S. Dist. Calif., against Roy G. Collison, t/a Polyzone Co., Los Angeles, Calif.

ACCOMPANYING LABELING: A leaflet entitled "For Doctors Only Polyzone" and a booklet entitled "Polyzone Therapy Manual."

RESULTS OF INVESTIGATION: The device was designed to produce ozone by the passage of oxygen through an electrical field.

CHARGE: That the defendant was causing the introduction into interstate commerce of the *Polyzone device*, which was misbranded under 502 (a) by reason of false and misleading representations, namely:

(1) That the ozone produced by the device was beneficial and useful for all acute and chronic conditions, arthritis, catarrhal deafness, fistulas,