

and particulars set out in the information, and, therefore, constituted a misbranding, first, without reference to the newspaper advertising related to the respective shipments. That conclusion alone warrants the conviction of both defendants upon each of the three counts. For it is sufficient to support conviction on the ground of the shipment of a misbranded drug, that the labeling be 'false or misleading in any particular.' Title 21 U. S. C. A., Section 352 (a), in relation to Title 21 U. S. C. A., Sections 321 (a) and 331 (a). *United States v. One Device*, supra; *United States v. Dr. David Roberts Veterinary Co., Inc.* (7 cir) 104 F (2) 785.

"But the court, secondly, finds and concludes that misbranding of the drugs thus shipped existed in each instance also because of the failure of the labeling to bear 'adequate directions for use,' within the meaning of Title 21 U. S. C. A., Section 352 (b), regard being had to the varied conditions for which the 'drug' was 'prescribed, recommended, or suggested in its labeling' and 'in its advertising . . . . . sponsored by or in its behalf by its manufacturer, packer or distributor,' i. e. the defendants, within the meaning of Title 21 C. F. R. Section 1.106 (a) (1). In the final phase of this conclusion rooted in 'advertising' the court has in view the newspaper advertising received in evidence. That advertising is not itself an offense against the Act denounced in the present information. But it is the defendants' own 'recommendation and suggestion' respecting the use of the drug, by which in part the adequacy of the labeling's 'direction for use' is to be appraised.

"It may be stated very briefly that the court does not regard the proceedings in Civil Action No. 79-52, supra, as a defense to the charges against the defendants. Their offense, if any, antedated the prosecution of the civil suit, and was complete long before Case No. 79-52 was commenced. And nothing which occurred in the civil action even assumes to affect the defendants' criminal liability for the earlier shipment of drugs comparable in character to those proceeded against in the civil case.

"The court, therefore, finds and adjudges the defendants, and each of them, to be guilty as charged, and convicts the defendants, and each of them, of the charges against them, in each of the three counts of the information.

"Concerning the sentence to be pronounced, it is considered that only the opening portion of Title 21 U. S. C. A., Section 333 (a), has present application. No situation drawn to the court's attention would warrant resort to the more severe provision of subsection (a) or to subsection (b) of the same section. The maximum allowable sentence for each defendant under each count is, therefore, imprisonment for not more than one year (applicable, of course, only to an individual defendant) or a fine of not more than \$1,000.00 or both such imprisonment and fine. Maximum sentences ought rarely to be resorted to unless the circumstances of the offense are aggravated. Whatever the facts may be, no aggravating features of the offenses under prosecution have been established.

"The court has resolved to, and does, sentence the defendant, Vitamin Industries, Inc., to pay a fine of \$150.00 upon each of the three counts of the information (in all \$450.00) and, in addition thereto, the costs of this action, and the defendant Joseph L. Zweiback to pay a fine of \$50.00 upon each of the three counts of the information (in all \$150.00). No sentence to imprisonment is imposed or considered to be warranted."

**4585. Anterior pituitary aqueous extract.** (F. D. C. No. 37041. S. No. 83-979 L.)

**QUANTITY:** 36 cartoned vials at Minneapolis, Minn.

**SHIPPED:** Between 2-25-54 and 4-9-54, from Indianapolis, Ind., by Pitman-Moore Co.

**LABEL IN PART:** (Vial) "10 cc. Size Parenteral Solution Extract of Anterior Pituitary Aqueous Each cc. contains the water soluble extractive from 18½ grs. of fresh anterior pituitary. Chlorobutanol (chloral deriv.) 0.5% (Preserv.). Caution: To be dispensed only by or on the prescription of a veterinarian. Warning: Contains no known therapeutically active principle derived from anterior pituitary for which recognized methods of assay exist."

**LIBELED:** 8-11-54, Dist. Minn.

**CHARGE:** 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

**DISPOSITION:** 11-3-54. Default—destruction.

**4586. Ovarian tissue extract.** (F. D. C. No. 37030. S. No. 40-257 L.)

**QUANTITY:** 137 8-cc. vials at Phoenix, Ariz.

**SHIPPED:** 6-3-54, from Los Angeles, Calif., by American Bio-Chemical Corp.

**LIBELED:** 8-18-54, Dist. Ariz.

**CHARGE:** 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

**DISPOSITION:** 11-24-54. Default—destruction.

**4587. Glanosol.** (F. D. C. No. 36833. S. No. 80-545 L.)

**QUANTITY:** 135 unlabeled 30-cc. vials in bulk containers at Philadelphia, Pa.

**SHIPPED:** 5-20-54, from Inwood, Long Island, N. Y., by Bel-Mar Laboratories, Inc.

**LABEL IN PART:** (Bulk container) "No. 419V30 Multiple Dose \* \* \* Glanosol Each 2 cc. contains the water soluble extractives of dried glands derived from fresh glands equivalent to: Adrenal Cortex . . . 1½ gr. Ovarian . . . 16 gr. Anterior Pituitary. . . . 5 gr. Thyroid (dried) . . . . 1 gr. Thymus . . . . 3 gr. Lymphatic . . . . 2 gr. Chlorobutanol (chloral deriv.) . . . . 0.5% Water . . . . q. s. \* \* \* For intramuscular Use \* \* \* There is no scientific evidence for the presence of therapeutically active principles in the aqueous glands listed, with the exception of thyroid. \* \* \* Caution: Federal law prohibits dispensing without prescription."

**LIBELED:** 6-16-54, E. Dist. Pa.

**CHARGE:** 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use.

**DISPOSITION:** 9-28-54. Default—destruction.

**4588. Urasal.** (F. D. C. No. 36236. S. Nos. 45-946/7 L.)

**QUANTITY:** 19 cartons, 1 3½-oz. btl. each, and 26 cartons, 1 10-oz. btl. each, at Manchester, N. H.

**SHIPPED:** 7-27-53, from San Juan, P. R., by Horner Laboratories, Inc.

**LABEL IN PART:** (Btl.) "Urasal \* \* \* Granular Effervescent Contains: Methenamine, Piperazine, and Benzoic Acid in Proportionate Combination."

**RESULTS OF INVESTIGATION:** Examination indicated that the article consisted essentially of methenamine in an effervescent base.

**LIBELED:** 1-15-54, Dist. N. H.

**CHARGE:** 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use since its labeling failed to state the condition or conditions for which the article was intended.

**DISPOSITION:** 12-13-54. Claimed by Horner Laboratories, Inc., and subsequently destroyed.