

3133. Adulteration of Testramone. U. S. v. 87 Vials * * *. (F. D. C. No. 29085. Sample No. 73927-K.)

LIBEL FILED: April 27, 1950, Southern District of New York.

ALLEGED SHIPMENT: On or about March 21, 1950, by Harvey Laboratories, Inc., from Philadelphia, Pa.

PRODUCT: 87 10-cc. vials of *Testramone* at New York, N. Y.

LABEL, IN PART: "Testramone Intramuscular Injection of Vitamin B Complex."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess since it was for parenteral administration and was contaminated with living micro-organisms, whereas a drug for parenteral administration is sterile.

DISPOSITION: June 30, 1950. Default decree of condemnation. The court ordered that the product be delivered to the Food and Drug Administration.

3134. Adulteration and misbranding of adhesive bandages. U. S. v. 1,978 Cartons, etc. (F. D. C. No. 28975. Sample Nos. 77209-K, 77210-K.)

LIBEL FILED: April 19, 1950, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about March 16, 1950, by the Seamless Rubber Co., New Haven, Conn.

PRODUCT: 4,856 cartons, each carton containing 12 tins, and each tin containing 36 *adhesive bandages*, at St. Louis, Mo.

LABEL, IN PART: (Tin) "Quik-Bands Assorted With Mercurochrome Sterilized [or "Assorted Sterilized Plain"] * * * Adhesive Bandages"; (individual bandage) "Sterile."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]", a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was not sterile.

Misbranding, Section 502 (a), the label statements "Sterile" and "Sterilized" were false and misleading as applied to an article which was not sterile.

DISPOSITION: April 28, 1950. The Seamless Rubber Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond to be brought into compliance with the law, under the supervision of the Federal Security Agency. The product was subsequently sterilized.

3135. Adulteration and misbranding of clinical thermometers. U. S. v. 22 Cartons * * *. (F. D. C. No. 29096. Sample No. 80968-K.)

LIBEL FILED: May 3, 1950, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about March 29, 1950, by the Hygrade Thermometer Co., from Brooklyn, N. Y.

PRODUCT: 22 cartons, each carton containing 12 boxes, and each box containing 1 *clinical thermometer*, at Philadelphia, Pa.

Examination of 24 samples showed that 6 failed to meet the hard shaker test prescribed by C. S. 1-32, i. e., failed to shake down to 96° F. or lower, and that 2 had engraved markings wider than the intervening space. C. S. 1-32 provides that the width of the marking shall not be more than one-half the length of the graduation interval.

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported or was represented to possess.

Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading as applied to the article, which failed to comply with the specifications as stated: (Leaflet in box) "Certificate of Accuracy for Clinical Thermometer * * * This test is governed by a Standard Thermometer which has been tested and approved by the Bureau of Standards, Washington, D. C. All our thermometers are manufactured in accord with their specifications. (C. S. 1-32 Department of Commerce.) * * *."

DISPOSITION: June 20, 1950. Default decree of condemnation and destruction.

3136. Adulteration and misbranding of clinical thermometers. U. S. v. 12 Dozen * * *. (F. D. C. No. 29036. Sample No. 7397-K.)

LABEL FILED: March 31, 1950, Western District of Pennsylvania.

ALLEGED SHIPMENTS On or about November 8, 1949, by the Guardian Thermometer Co., from New York, N. Y.

PRODUCT: 12 dozen *clinical thermometers* at Erie, Pa.

Examination of 24 thermometers showed that 1 thermometer failed to meet the C. S. 1-32 test for entrapped gas; that 3 thermometers failed to meet the test for hard shakers; and that 1 thermometer out of 5 failed to meet the test for loss of pigment.

LABEL, IN PART: "Clinical Fever Thermometers Oral" and "Globe Fever Thermometer Oral."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the following statements in the labeling were false and misleading as applied to the article, which failed to comply with the specifications stated: (On 1-dozen container and individual carton) "This thermometer has been tested, found to comply with the requirements of the Department of Commerce Commercial Standard C. S. 1-32" and (on leaflet packaged with thermometer) "This Is To Certify That Self-registering Clinical Thermometer 'GT' has been examined, tested and found to meet all requirements and tests specified in the 'Commercial Standard C. S. 1-32 for Clinical Thermometers' used by the United States Department of Commerce."

DISPOSITION: June 2, 1950. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3137. Misbranding of W. E. & M. E. Herb Laxative. U. S. v. 94 Bottles * * *. (F. D. C. No. 29031. Sample No. 80909-K.)

LABEL FILED: On or about April 6, 1950, District of New Jersey.

ALLEGED SHIPMENT: On or about February 27, 1950, by the W. E. & M. E. Herb Laxative Co., from Philadelphia, Pa.

PRODUCT: 94 4-ounce bottles of *W. E. & M. E. Herb Laxative* at Camden, N. J.

*See also Nos. 3121, 3129, 3130, 3132, 3134-3136.