

tion 502 (j), the article was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling.

DISPOSITION: April 9, 1948. Default decree of condemnation and destruction.

**DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED**

**2304. Misbranding of penicillin sodium. U. S. v. 998 Cartons \* \* \*. (F. D. C. No. 23192. Sample No. 64200-H.)**

**LABEL FILED:** June 18, 1947, Southern District of New York.

**ALLEGED SHIPMENT:** On or about March 28, 1947, by Barich, Inc., from Rutherford, N. J.

**PRODUCT:** 998 cartons, each containing 5 vials, of *penicillin sodium* at New York, N. Y.

**LABEL, IN PART:** (Cartons) "5 vials 100,000 Units Each Penicillin Sodium (Crystalline) \* \* \* Eto Pharmacal Company, New York 17, New York."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the labeling of the article was misleading, since it failed to reveal the fact that Eto Pharmacal Company was not the manufacturer of the article, which fact was material in the light of the unmodified words "Eto Pharmacal Company" appearing on the label; and the label statement "Lot No. B 5 \* \* \* Nov. 1, 49" was misleading, in that it represented and suggested that the article had been certified under such identifying mark in accordance with regulations promulgated by the Federal Security Administrator, whereas such was not the case.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; and, Section 502 (1), the article was represented as a drug composed wholly of penicillin sodium, a derivative of a kind of penicillin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to law.

DISPOSITION: December 17, 1947. Ekstrand & Tholand, Inc., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration.

**2305. Misbranding of penicillin sodium. U. S. v. 36 Cartons, etc. (F. D. C. No. 23178. Sample Nos. 54399-H, 54400-H.)**

**LABEL FILED:** June 6, 1947, Middle District of North Carolina.

**ALLEGED SHIPMENT:** On or about May 15, 1947, by the Institutional Products Co., from New York, N. Y.

**PRODUCT:** 36 cartons, each containing 5 500,000-unit vials, and 87 cartons, each containing 5 200,000-unit vials, of penicillin sodium at Winston-Salem, N. C.

**LABEL, IN PART:** "Penicillin Sodium Proctor \* \* \* Proctor Laboratories 475 Fifth Avenue, New York \* \* \* Lot No. 90 [or "Lot No. 77"]."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the labeling was misleading, since it failed to reveal the fact that Proctor Laboratories was not the manufacturer of the article, which fact was material in the light of the unmodified words "Proctor Laboratories" appearing thereon; and the label statements "Lot No. 90," appearing on the 36-carton lot, and "Lot No. 77, appearing on the 87-carton lot, were misleading, since they represented and suggested that the article had been certified under such identifying marks in accordance with the regulations, when such was not the case.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; and, Section 502 (1), the article was represented as a drug composed wholly of penicillin sodium, a derivative of a kind of penicillin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to the provisions of the Act.

DISPOSITION: March 24, 1948. Default decree of condemnation. The product was ordered delivered to a Federal institution.