

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

2552. Misbranding of penicillin-G sodium crystalline. U. S. v. 88 Vials * * * .
(F. D. C. No. 25508. Sample No. 9439-K.)

LIBEL FILED: September 1, 1948, Southern District of New York.

ALLEGED SHIPMENT: On or about March 8, 1948, from Newark, N. J., by the Vitamin Corporation of America.

PRODUCT: 88 100,000-unit vials of *penicillin-G sodium crystalline* at New York, N. Y.

LABEL, IN PART: "Penicillin-G Sodium Crystalline * * * Manufactured for Solvecillin, Inc. * * * Newark, New Jersey."

NATURE OF CHARGE: Misbranding, Section 502 (1), the article was represented as a drug composed wholly of penicillin-G sodium crystalline, 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 as provided for by Section 507; and, Section 502 (a), the label statement "Lot No. 3127C Exp. Date Nov. 1950" was false and misleading since the statement represented and suggested that the article had been certified by the Federal Security Administrator under such identifying terms, whereas, it had not been so certified.

DISPOSITION: September 23, 1948. Default decree of condemnation. The product was ordered delivered to a charitable organization.

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAIL-
URE TO BEAR ADEQUATE DIRECTIONS OR WARNING
STATEMENTS***

2553. Action to enjoin and restrain the interstate shipment of Paracelsus. U. S. v. American Biochemical Corporation. Injunction granted. (Inj. No. 203.)

COMPLAINT FILED: On or about November 18, 1948, Northern District of Ohio, against the American Biochemical Corp., Cleveland, Ohio.

ALLEGED VIOLATION: The complaint alleged that the defendant had been and was continuing to ship in interstate commerce a product known as *Paracelsus*, which consisted essentially of a mixture of chemical salts and which was distributed for use both as a dietary food supplement and for therapeutic purposes.

That accompanying the product there was and had been theretofore printed and graphic matter relating to the product entitled "Malnutrition, Disease, Due to Mineral Lack," which described the product and related to it; that the printed and graphic matter had been shipped by the defendant into interstate commerce and had been used with the product by the consignees and had been associated together with the product.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying labeling were false and misleading. These statements represented and suggested that the article was effective to prevent and cure malnutrition and disease, to provide pep, to stimulate hormone production, and to prevent and cure arthritis; and that all individuals suffer from mineral deficiency and would benefit by use of the article. The article was not effective for such purposes and was not capable of fulfilling the promises of benefit

*See also No. 2596.

stated and implied. Further misbranding, Section 502 (a), the following label statements were false and misleading since if taken as directed, the article would supply materially less calcium and iron than stated:

When Taken According to Directions Will Supply Percentage of Daily Requirements as Listed

	<i>Calcium</i>	<i>Iron</i>
Man-----	13.50%	16.00%
Woman-----	13.50%	16.00%
Pregnancy latter half-----	7.00%	12.75%
Lactation-----	5.25%	12.75%
Children 1 to 9 years-----	10.75%	19.20%
Children 10 to 12 years-----	9.00%	16.00%
Girls 13 to 15 years-----	8.00%	13.00%
Boys 12 to 15 years-----	7.50%	13.00%
Girls 16 to 20 years-----	10.50%	13.00%
Boys 16 to 20 years-----	7.50%	13.00%

Further misbranding, Section 502 (f) (1), the article failed to bear adequate directions for use since at times it failed to bear labeling which set forth the purposes for which the article was intended to be used as a drug.

The article was alleged also to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

PRAYER OF COMPLAINT: That the defendant be restrained and enjoined during the pendency of the action and permanently, from shipping in interstate commerce an article known as *Paracelsus*, or under any other name, which was adulterated or misbranded as alleged.

DISPOSITION: December 10, 1948. The defendant having consented to the entry of a decree, a permanent injunction was granted enjoining and restraining the defendant from shipping in interstate commerce an article under the trade name *Paracelsus*, or under any other name, which was adulterated or misbranded as alleged in the complaint.

2554. Misbranding of Mel-O-Eze, Mount Clemens Mineral Salts, Mount Clemens Cleme-Tone Concentrated Mineral Water, and Pile-Dume. U. S. v. 42 Jars, etc. (F. D. C. No. 24919. Sample Nos. 14868-K to 14871-K.)

LIBEL FILED: July 6, 1948, Northern District of Illinois.

ALLEGED SHIPMENT: On or about May 10, 1948, from Mount Clemens, Mich., by the Mount Clemens Mineral Water Co., Inc.

PRODUCT: 42 1-ounce jars of *Mel-O-Eze*, 24 75-pound drums of *Mount Clemens Mineral Salts*, 36 6-ounce bottles of *Mount Clemens Cleme-Tone Concentrated Mineral Water*, and 42 1-ounce jars of *Pile-Dume* at Chicago, Ill. Examination showed that the *Mel-O-Eze* consisted essentially of chloride and carbonates of potassium, sodium, calcium, and magnesium in a fatty ointment base; that the *Mount Clemens Mineral Salts* consisted essentially of water and chlorides of calcium, magnesium, sodium, and a small proportion of iron; that the *Mount Clemens Cleme-Tone Concentrated Mineral Water* consisted essentially of water and calcium and magnesium and sodium chlorides; and that