RESULTS OF INVESTIGATION: Each vial was closed by a rubber stopper which could be readily penetrated by the ordinary hypodermic needle; thus the contents of the vial could be withdrawn without removal or destruction of the closure.

LIBELED: 9–16–54, E. Dist. N. Y.

CHARGE: 502 (g)—the article purported to be a drug, namely, "Sterile Isotonic Sodium Chloride Solution for Parenteral Use," the name of which is recognized in the United States Pharmacopeia, an official compendium, and it was not packaged as prescribed therein (1) in that the article was packaged in a multiple-dose container containing a volume of the article more than sufficient to permit the withdrawal of 30 cc., whereas the United States Pharmacopeia prescribes that no multiple-dose container in which "Sterile Isotonic Sodium Chloride Solution for Parenteral Use" is packaged shall contain a volume more than sufficient to permit the withdrawal of 30 cc., and (2) in that the article was packaged in a multiple-dose container without the addition of a suitable substance or mixture of substances to prevent the growth of micro-organisms, whereas the United States Pharmacopeia prescribes that a suitable substance or mixture of substances to prevent the growth of micro-organisms must be added to "Sterile Isotonic Sodium Chloride Solution for Parenteral Use" packaged in multiple-dose containers.

DISPOSITION: Bio-Ramo Drug Co., Inc., claimant, filed an answer on 11–17–54, denying that the article was misbranded. Thereafter, the Government served interrogatories upon the claimant which were answered. On 8–31–55, with the consent of the claimant, judgment of condemnation was entered and the product was ordered destroyed.

4960. Water for injection. (F. D. C. No. 37080. S. No. 77–171 L.)

QUANTITY: 700 vials at Philadelphia, Pa.

SHIPPED: 7–15–54, from Baltimore, Md., by Bio-Ramo Drug Co., Inc.

LABEL IN PART: (Vial) "100 cc. Single Dose Vial Water For Injection U. S. P. * * * Manufactured by Bio-Ramo Drug Co., Inc. Baltimore 1, Md. Caution Contains no preservative."

RESULTS OF INVESTIGATION: Each vial was closed by a rubber stopper which could be readily penetrated by the ordinary hypodermic needle; thus the contents of the vial could be withdrawn without removal or destruction of the closure.

LIBELED: 10–1–54, E. Dist. Pa.

CHARGE: 502 (g)—the article purported to be a drug, namely, "Water for Injection," the name of which is recognized in the United States Pharmacopeia, an official compendium, and it was not packaged as prescribed therein (1) in that the article was packaged in a multiple-dose container containing a volume of the article more than sufficient to permit the withdrawal of 30 cc., whereas the United States Pharmacopeia prescribes that no multiple-dose container in which "Water for Injection" is packaged shall contain a volume more than sufficient to permit the withdrawal of 30 cc., and (2) in that the article was packaged in a multiple-dose container without the addition of a suitable substance or mixture of substances to prevent the growth of micro-organisms, whereas the United States Pharmacopeia prescribes that a suitable substance or mixture of substances to prevent the growth of micro-organisms must be added to "Water for Injection" packaged in multiple-dose containers.

DISPOSITION: On 11–3–54, pursuant to agreement of the claimant, Bio-Ramo Drug Co., Inc., and the Government, an order was entered for the removal of the case to the Eastern District of New York. On 8–31–55, with the consent of the claimant, judgment of condemnation was entered and the product was ordered destroyed.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 4921 TO 4960

PRODUCTS

[1] (4957) Seizure contested. Contains findings of fact and conclusions of law.
[2] (4921) Prosecution contested.
[3] (4959) Seizure contested.

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4961–4980

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement, "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503 (b) (1) and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *March 1, 1957.*

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