The complaint alleged that the device was shipped in a folder entitled "Here are your HEEL-INS"; that the folder contained instructions to place the plates on the inner soles of a pair of shoes, one in each shoe, and bore the statement "Designed for the relief of arthritis"; and that such statement was false and misleading since the device was not effective for the relief of arthritis.

DISPOSITION: On 11–2–53, the court, after hearing the arguments of counsel, refused to issue a temporary injunction. Thereafter, an answer to the complaint was filed by the defendants, and a set of interrogatories was filed by the government and was answered by the defendants.

On 6–23–54, with the consent of the defendants, a decree was entered enjoining the defendants, during the pendency of the action and until its final determination, from introducing the device into interstate commerce so long as it was misbranded. The prohibited misbranding was that which involved labeling which represented the device to be beneficial, effective, or have value in the cure, mitigation, treatment, or prevention of arthritis, or which was false and misleading in any particular. In addition, the decree specifically prohibited the use of the above-mentioned folder as labeling.

DRUGS FOR VETERINARY USE

4560. Lions stock remedy. (F. D. C. No. 36831. S. No. 88–875 L.)

QUANTITY: 6 33⅓-lb. drums and 12 125-lb. drums at Centreville, Mich.

SHIPPED: 3–30–54, from St. Louis, Mo., by Live Stock Remedy Co.

LABEL IN PART: (Drum) "Lions Stock Remedy * * * Directions Inside Worm Seed Mandrake Iron Magnesium & Sodium Sulfate Gentian Ginger Anise Seed Sassafras Blood Root Sulphur Sodium Bi Carb Licorice Senna Asafoetide Potassium Iodide."

ACCOMPANYING LABELING: Circular designated "Lions Stock Remedy Made Since 1888 Directions."

LIBELED: 6–9–54, W. Dist. Mich.

CHARGE: 502 (a)—the accompanying labeling of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment for white scours of pigs and calves and for restoring shoats to a normal, healthy condition; and, 502 (f) (1)—the labeling failed to bear adequate directions for use since the labeling recommended use of the article for hogs, cows, cattle, horses, sheep, dogs, cats, poultry, turkeys, and chicks, but failed to state the conditions or purposes for which the article was intended to be given to such animals.

DISPOSITION: 7–15–54. Consent—claimed by Live Stock Remedy Co. and relabeled.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 4541 TO 4560

PRODUCTS

[1] (4541) Prosecution 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]

4561–4580

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 were adulterated or misbranded within the meaning of the Act while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings which were terminated with the entry of default or consent decrees of condemnation and (2) criminal proceedings which were terminated with pleas of guilty or nolo contendere. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firms or individuals* charged to be responsible for violations.

Similar actions with respect to products alleged to be in violation at the time of shipment are reported in other supplements.

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

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

WASHINGTON, D. C., *January 19, 1956.*

CONTENTS*

*For presence of a habit-forming narcotic without warning statement, see No. 4565; omission of, or unsatisfactory, ingredients statements, Nos. 4564, 4565; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 4564–4566; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 4564.

369875—56

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 4561–4580

Adulteration, Section 501 (a) (1), the article consisted in part of a filthy substance; and, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502 (d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502 (l), the article purported to be and was represented as a drug composed wholly or partly of a kind of penicillin and it was from a batch with respect to which a certificate issued pursuant to Section 507 was not effective; and, Section 503 (b) (4), the article was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New drug violation, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

4561. Sodium ascorbate injection. (F. D. C. No. 37011. S. Nos. 90–433/4 L.)

QUANTITY: 299 25-ampul cartons, 10 6-ampul cartons, and 497 individual ampuls at Kansas City, Mo., in possession of B. F. Ascher & Co., Inc.

SHIPPED: Between 11–28–52 and 6–1–54, a number of unlabeled ampuls in bulk were shipped from Decatur, Ill., and Seymour, Ind.

LABEL IN PART: (Carton) "10 cc. Sodium Ascorbate Injection * * * 10 cc. contain: Sodium Ascorbate equivalent to Ascorbic Acid 1 Gram [or "2 Grams"] * * * For Intramuscular or Intravenous Injection Manufactured for B. F. Ascher & Company, Inc."

ACCOMPANYING LABELING: Pamphlets designated "physician's report."

RESULTS OF INVESTIGATION: After receipt of the article at Kansas City, it was labeled as described above by the consignee, B. F. Ascher & Co., Inc. The above-mentioned pamphlets were printed locally for the consignee.

LIBELED: 7–16–54, W. Dist. Mo.

CHARGE: 502 (a)—the labeling of the article, while held for sale, contained false and misleading representations that the article was effective for the treatment of poliomyelitis, mumps, herpes Zoster, chickenpox, influenza, virus pneumonia, and virus encephalitis; for the prevention and treatment of