The information alleged also that all of the defendants, on 4–30–58, caused to be shipped from Philadelphia, Pa., to Pleasantville, N.J., a number of tablets which were in violation of 505(a), and which were misbranded under 502(a).

CHARGE: 502(a)—The label statement "For Investigational and Export Use Only" was false and misleading in that the article was not for investigational and export use only; and 505(a)—the article was a new drug which may not be introduced into interstate commerce, since an application filed pursuant to 505(b) was not effective with respect to such drug.

PLEA: Nolo contendere.

DISPOSITION: 3–22–60. Partnership—probation for 5 years; Levin—$2,250 fine, 6 months jail sentence which was suspended, and probation for 5 years; Lavin—$1,250 fine, 4 months jail sentence which was suspended, and probation for 5 years.

DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

DRUGS FOR HUMAN USE

6043. Various drugs. (F.D.C. No. 41978. S. Nos. 31–201/2 P, 31–204/6 P.)

QUANTITY: 8,665 capsules of *Vi-Aquamin Therapeutic* in unlabeled ctns., 172 2-oz. btls. of *Pen-Vee suspension benzathine penicillin V*, 300 capsules of *chloramphenicol* in unlabeled btls., 143 boxes of *Chlorhidrate De Neohetramine*, and 2 unlabeled 500-tablet btls. of *Terramycin*, at Brooklyn, N.Y.

SHIPPED: On various dates during 1957 and 1958, from points outside the State of New York.

LABEL IN PART: (Btl.) "Pen Vee Suspension Benzathine Penicillin V Oral * * * Each 5 cc contains 180 mg. (300,000 units)" and (box) "Chlorhidrate De Neohetramine * * * 25 Mg."

RESULTS OF INVESTIGATION: The Pen-Vee penicillin V was analyzed and found to be penicillin having a potency of 273,600 units per 5 cc. The article had separated and had a lumpy consistency.

LIBELED: 8–14–59, E. Dist. N.Y.

CHARGE: *Vi-Aquamin Therapeutic capsules*, 502(b)—while held for sale, the label of the article failed to bear (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents; 502(e)—its label failed to bear (1) the common or usual name of the drug and (2) the common or usual name of each active ingredient; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use.

Pen-Vee suspension benzathine penicillin V, 501(c)—while held for sale, the strength of the article differed from, and its quality fell below, that which it purported and was represented to possess since the article contained less than 300,000 units of penicillin per 5 cubic centimeters and since it had separated and had a lumpy consistency; and 502(1)—the article contained penicillin, and was not from a batch with respect to which a certificate or release issued pursuant to 507 was effective.

Chloramphenicol capsules, 502(b)—while held for sale, the article 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; 502(e)(1)—it failed to bear a label containing the common or

usual name of the drug; 502(f)(1)—its labeling failed to bear adequate directions for use; 502(f)(2)—its labeling failed to bear the warning relating to blood dyscrasias which may be associated with its use; 502(1)—it contained chloramphenicol, and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507; and 503(b)(4)—it was a drug which was subject to the provisions of 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Chlorhidrate De Neohetramine, 502(c)—while held for sale, the information required to appear on the label did not appear in such terms as to render it likely to be understood by the ordinary individual under customary conditions of purchase and use since such information was not printed in the English language; 502(e)(1)—it failed to bear a label containing the common or usual name of the drug; and 502(f)—its labeling failed to bear (1) adequate directions for use and (2) a warning that the user should not drive a car or operate machinery since the product may cause drowsiness.

Terramycin, 502(b)—while held for sale, the article 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; 502(e)(1)—it failed to bear a label containing the common or usual name of the drug; 502(f)(1)—its labeling failed to bear adequate directions for use; and 503(b)(4)—it was a drug which was subject to the provisions of Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

The libel alleged also that an article labeled Homicebrin was misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

DISPOSITION: 1-8-60. Default—destruction.

DRUG FOR VETERINARY USE

6044. Medicated feed. (F.D.C. No. 43195. S. Nos. 52-634 P.)

QUANTITY: 18 50-lb. bags at Mankato, Minn.

SHIPPED: 4-10-59, from Muscatine, Iowa, by Grain Processing Corp.

LABEL IN PART: (Tag) "From Grain Processing Corp. Muscatine, Iowa. Antibiotic Bacitracin Feed Supplement 10 Grams Bacitracin/Lb."

LIBELED: 6-22-59, Dist. Minn.

CHARGE: 502(1)—when shipped, the article contained manganese bacitracin, and it was not from a batch with respect to which a certificate or release had been issued in accordance with regulations.

DISPOSITION: 8-6-59. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

6045. Dur-Den-Col. (F.D.C. No. 43037. S. No. 6-248 P.)

QUANTITY: 15 cases, 12 btls. each, at Johnson City, Tenn.

SHIPPED: 3-5-59, from Norton, Va., by Southwest Pharmaceutical Corp., Inc.

LABEL IN PART: (Btl.) "Dur-Den" Col * * * ingredients per fluid ounce—Tinc. Phytolacca 0.25 cc. Sodium Salicylate 0.43 gm. Potassium Iodide 43 mg. Methyl Salicylate * * * 12 fluid ounces."

*See also Nos. 6041, 6043.