and nerves damaged by heart and neuromuscular diseases; that the *Vi-Arthra-M capsules* were offered for energy restoration in detoxification and for the relief of pain associated with rheumatism and arthritis; that the *Pre-Creatine capsules* contained betaine anhydrous and glycocyamine; that the *Neo-Creatine capsules* and the *Neo-Creatine granules* contained betaine anhydrous and glycine; and that the *Vi-Arthra-M capsules* contained betaine, glycocyamine, glucuronolactone, para-aminobenzoic acid, sodium gentisate, and vitamin C. It was alleged further that all of these drugs were new drugs within the meaning of the law and that they may not be introduced into interstate commerce in the absence of an effective new drug application.

The complaint alleged also, with respect to the *Pre-Creatine capsules*, that the defendant submitted a new drug application in the name of Mercury Pharmaceuticals, Inc.; that, in November 1958, this new drug application became effective; and that, on November 27, 1959, this new drug application was suspended on the ground that it contained a number of untrue statements of material facts.

The complaint alleged further that, with respect to the other drugs, no new drug application was filed or ever became effective; that subsequent to November 27, 1959, the defendant continued to introduce all of these new drugs into interstate commerce without having an effective new drug application with respect to any of them; and that the defendant violated the law by causing the introduction and delivery for introduction into interstate commerce of such new drugs since there was no effective new drug application with respect to any of them.

DISPOSITION: On 10–16–61, a consent decree of permanent injunction was entered, enjoining the defendant from causing to be introduced or delivered for introduction into interstate commerce *Pre-Creatine capsules, Neo-Creatine capsules, Neo-Creatine granules, Vi-Arthra-M capsules* or any similar drug, or any other drug containing betaine anhydrous, glycocyamine, glycine, betaine, glucuronolactone, para-aminobenzoic acid, or sodium gentisate, without having an effective new drug application for such drug.

7002. Pre-Creatine capsules. (F.D.C. No. 45212. S. No. 23–401 R.)

INFORMATION FILED: 6–12–61, N. Dist. Calif., against Andrew Doty, t/a Creatine Laboratories, Inc., San Francisco, Calif.

SHIPPED: 1–19–60, from San Francisco, Calif., to Kansas City, Mo.

LABEL IN PART: (Btl.) "100 Capsules, PRE-CREATINE, Contains Precursors of Creatine Caution Federal Law Prohibits Dispensing without Prescription Manufactured for Creatine Laboratories, Inc., San Francisco."

CHARGE: 505(a)—when shipped, the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

PLEA: Guilty.

DISPOSITION: 11–6–61. $300 fine and probation for 2 years.

7003. Li-Bex with iron and succinylcholine chloride injection. (F.D.C. No. 47155. S. Nos. 23–357/8 T.)

QUANTITY: 357 vials, each in a plastic case, of *Li-Bex with iron* and 755 vials, each in a plastic case, of *succinylcholine chloride injection*, at Denver, Colo., in possession of Lyle A. Wittney & Co., Inc.

SHIPPED: Between 9–19–61 and 12–14–61, from Decatur and Chicago, Ill.

LABEL IN PART: (Vial and case) "30 cc. * * * Li-Bex With Iron Each 2 cc. Represents Vit. B–12 Activity (From Liver Inj. U.S.P. Beef) Equivalent to: Cyanocobalamin 1.0 mcgm. * * * Caution:" and "10 cc. Vial Succinylcholine Chloride Injection 20 mg. per cc. * * * Warning: For use only by skilled anesthetists with facilities for immediate artificial respiration. Manufactured for Wittney & Co., Inc. Denver, Colorado."

ACCOMPANYING LABELING: Leaflet entitled "Succinylcholine Chloride Injection."

RESULTS OF INVESTIGATION: The leaflets were prepared by the dealer and the labels of *succinylcholine chloride injection* were supplied to the manufacturer by the dealer. The *Li-Bex with iron* was shipped by Medical Chemicals Corp., Chicago, Ill.

LIBELED: 2–21–62, Dist. Colo.

CHARGE: (*Li-Bex with iron*) 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to the law was not effective with rspect to the drug; (*succinylcholine chloride injection*) and 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use and it was not exempt from such requirement since it was a drug intended for veterinary use which, because of its toxicity or other potentiality for harmful effect, or the method for its use, was not safe for animal use except under the supervision of a licensed veterinarian, and its label failed to bear the statement "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian," and its label also failed to bear the recommended or usual dosage for each animal species for which the article was intended.

DISPOSITION: 4–9–62. Consent—claimed by Lyle A. Wittney & Co., Inc. The *Li-Bex with iron* was destroyed and the *succinylcholine chloride injection* was released under bond for relabeling.

7004. Tain oral suspension and Tain Inlay-Tab tablets. (F.D.C. No. 46967. S. Nos. 27–395/6 T, 28–879/80 T, 29–401/2 T.)

QUANTITY: 131 8-oz. ctnd. btls. and 183 50-tablet ctnd. btls.; 9 cases, 12 50-tablet ctnd. btls. each, and 5 cases, 12 8-oz. ctnd. btls. each; and 14 8-oz. ctnd. btls. and 33 50-tablet ctnd. btls., at Kansas City, Mo.

SHIPPED. Between 12–29–61 and 1–29–62, from Lincoln, Nebr., by Dorsey Laboratories.

LABEL IN PART: (Btl. and ctn.) "8 Fl. Oz. List No. 6050 Dorsey Tain Oral Suspension Caution * * * Dorsey Laboratories a division of the Wander Company, Lincoln, Nebraska * * * Each Teaspoonful (5 ml.) contains: Triacetyloleandomycin 125 mg. Triaminic[R] 25 mg. (phenylpropanolamine hydrochloride) 12.5 mg. pheniramine maleate 6.25 mg. pyrilamine maleate 6.25 mg. Acetaminophen 150 mg. * * * Expiration Date May '63"; (ctn. only) "Triacetyloleandomycin is effective against most gram positive organisms involved in respiratory infections. * * * Has analgesic and antipyretic action * * * is an effective oral nasal decongestant and has antihistaminic action"; and (50-tablet btl. and ctn.) "50 Tablets List No. 1339 Dorsey Tain Antibiotic Decongestant Analgesic Each Tain Inlay-Tab contains: Triacetyloleandomycin equivalent to 125 mg. oleandomycin Triaminic[R] 25 mg. phenylpropanolamine hydrochloride 12.5 mg. pheniramine maleate 6.25 mg. pyrilamine maleate 6.25 mg. Calurin[R] (calcium acetylsalicylate carbamide) (equivalent to aspirin 300 mg.) Caution: * * * Dorsey Laboratories a division of The Wander Company Lincoln, Nebraska Expiration Date Dec. '63."