

SHIPPED: 8-1-55 and 9-6-55, from Dunedin, Fla., by L & H Drug Co., Inc.

LABEL IN PART: (Ctn. & btl.) "Lane's Diuretic Compound For Kidneys Alcohol 12.5% * * * Active Ingredients: Fluidextracts of Uva Ursi, Zea, Buchu,—Glycerol and pure lemon juice. * * * 4 fluid ounces" and "Lane's Formula No. 2 * * * Active Ingredients: Magnesium Sulfate Thiamin HCL (B₁), Fluid Extract Cascara Sagrada, Aromatic U. S. P. * * * 8 Fluid Ounces."

ACCOMPANYING LABELING: (Leaflet enclosed in each carton) "Lane's Famous Products."

LIBELED: 4-18-56, W. Dist. Tenn.

CHARGE: 502 (a)—the accompanying labeling of the articles, when shipped, contained false and misleading representations that *Lane's diuretic compound* was an adequate and effective treatment for kidney stones and that *Lane's Formula No. 2* was an adequate and effective treatment for gallstones.

DISPOSITION: 6-15-56. Default—destruction.

5159. Electronic devices. (F. D. C. No. 39275. S. Nos. 40-064/5 M.)

QUANTITY: 2 devices at Chicago, Ill.

SHIPPED: Between 7-13-55 and 10-16-55, from Detroit, Mich., by Colo Products, Inc.

LABEL IN PART: "Neu-Clear Therapy Electronic 'Condensator' Generating 'Fluid' Electricity" and "'Holder's' Electronic-Oscillating 'Condensator' Generating 'Fluid' Electricity."

ACCOMPANYING LABELING: Booklet entitled "Holder's Electronic High-Frequency Condensator Operating Instructions" and leaflets entitled "Doctors Report On Holder's Electronic Condensator" and "'Holder's' Electronic Oscillating Condensator."

RESULTS OF INVESTIGATION: The devices consisted of an electronic, high-voltage oscillator and a group of glass electrode applicators. The electrodes were gas-filled and produced a glow discharge during application. Radio frequencies emanating from the devices were of such low power and low frequency as to have negligible absorption in the body.

LIBELED: 6-12-56, N. Dist. Ill.

CHARGE: 502 (a)—the labeling accompanying the devices, when shipped, contained false and misleading representations that the devices were effective for locating trouble areas and toxic conditions and for determining the seriousness of the condition; for treating all body ailments, including ailments of the eyes, ears, throat, tonsils, teeth, face, heart, lungs, liver, gallbladder, kidneys, pancreas, spleen, stomach, bowels, anus, rectum, breasts, ovaries, uterus, vagina, cervix, brain, and frontal sinus; and for treating abscesses, anemia, arthritis, rheumatism, paralysis, hay fever, hemorrhoids, varicose veins, leg ulcers, multiple sclerosis, mucous colitis, malnutrition, pain, influenza, indigestion, head noises, and allergic conditions due to a large variety of products.

DISPOSITION: 7-11-56. Default—delivered to Food and Drug Administration.

DRUG FOR VETERINARY USE

5160. Beebe Water Wormer. (F. D. C. No. 38975. S. No. 21-158 M.)

QUANTITY: 96 4-oz. btls., 123 8-oz. btls., and 51 32-oz. btls. at Fremont, Nebr.

SHIPPED: Between 11-21-55 and 1-18-56, from St. Paul, Minn., by Beebe Laboratories, Inc.

LABEL IN PART: (Btl.) "Beebe Water Wormer * * * Active Ingredients: Piperazine Citrate 32% Inert Ingredients: Water and Coloring 68% Directions: For Chickens: Remove all sources of drinking water the night before treatment. Mix thoroughly two ounces (four tablespoonfuls) in five gallons of drinking water and allow birds to drink freely. Provide only the treated drinking water for one day when treating for round worms. Treats 800 birds of any age. For Pigs: Remove all sources of drinking water the night before treatment. Mix thoroughly two ounces (four tablespoonfuls) in five gallons of drinking water and allow pigs to drink freely. One day treatment is sufficient for eliminating round worms. Treats 100-125 pigs weighing 25-40 pounds each."

LIBELED: 3-9-56, Dist. Nebr.

CHARGE: 502 (a)—the labeling of the article, when shipped and while held for sale, contained false and misleading representations that the article, when fed as directed, was an adequate and effective treatment for large round-worm infestation in chickens and pigs.

DISPOSITION: 4-18-56. Consent—claimed by Beebe Laboratories, Inc., St. Paul, Minn., and relabeled.

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PRODUCTS

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Androgenic substance-----	5149	Elixir Cena-B-----	5151
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Beebe Water Wormer-----	5160	Gassup -----	5146
Bursitis, remedies for. <i>See</i>		Gel, Acthone (veterinary)-----	5142
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Ce-Kelp tablets-----	5156	matism, remedies for.	
Cena-B, Elixir-----	5151	Gracital tablets. <i>See</i> Dexatal	
Citru-Mix -----	5153	tablets.	
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Condensator, Electronic, Hold-		Herbal drugs-----	¹ 5143, ² 5155
er's -----	5159	Holder's Electronic Condensator	5159
Cortisone acetate tablets-----	5141	Kidney stones, remedy for-----	5158
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Desoxycorticosterone acetate---	5149	Lane's diuretic compound and	
Devices-----	² 5147, 5148, 5159	Lane's Formula No. 2-----	5158
Dexatal tablets (Gracital)-----	5150	Laxative without required warn-	
Dextro-amphetamine sulfate tab-		ing statement-----	5146
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Diabetes, remedy for-----	¹ 5143	Rheumatism, remedies for.	
Diuretic -----	5158	Meticortelone tablets-----	5141

¹ (5143) Prosecution contested.

² (5147, 5155) Injunction issued.

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]

5161-5200

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 relate to drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default, consent, or trial; (2) criminal proceedings which were terminated with a plea of guilty or nolo contendere; (3) injunction proceedings terminated with the entry of an injunction. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

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

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

WASHINGTON, D. C., June 12, 1958.

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*For omission of, or unsatisfactory, ingredients statements, see Nos. 5188, 5190; failure to bear a label containing an accurate statement of the quantity of the contents, No. 5190; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 5190; cosmetic, actionable under the drug provisions of the Act, No. 5161.

**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS
REPORTED IN D. D. N. J. NOS. 5161-5200**

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its strength differed from, or its quality and purity fell below, the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess; Section 501 (d), the article was a drug, and a substance had been substituted wholly or in part therefor.

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 (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 (l), the article purported to be and was represented as a drug composed wholly or partly of penicillin or a derivative thereof, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507.

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

5161. Extar (liquid dentifrice). (F. D. C. No. 39412. S. No. 46-689 M.)

QUANTITY: 72 ctns., 6 btls. each, at Trenton, N. J.

SHIPPED: 6-14-56, from Philadelphia, Pa., by Extar Division, A. J. Parker Co.

LABEL IN PART: (Ctn.) "Extar"; (btl.) "Contents: 67 Gm. * * * Liquid Dentifrice."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 12 percent ethylenediaminetetra acetic acid, together with inorganic sodium phosphates.

LIBELED: 8-7-56, Dist. N. J.

CHARGE: 505 (a)—the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: 9-7-56. Default—destruction.

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

5162. Anchor Anti-Blote. (F. D. C. No. 39153. S. No. 25-958 M.)

QUANTITY: 40 2-lb. cans at Des Moines, Iowa.

SHIPPED: 6-1-56, from St. Joseph, Mo., by Anchor Serum Co.