

**CHARGE:** 501 (d) (2)—while held for sale, sulfamethazine had been substituted for sodium sulfamethazine, which the article was represented to be; 502 (a)—the label on the boxes of the article contained false and misleading representations that the article consisted of sulfamethazine and that it was an adequate and effective treatment for retained afterbirth, congested lungs, and acute mastitis in cattle, and distemper and colds in horses.

502 (f) (2)—the labeling of the article failed to warn that the article may cause severe toxic reactions and irreparable damage if the blood levels become too high; that constant supervision of the animals was essential during treatment; and that use of the article should be discontinued if toxic symptoms appeared.

**DISPOSITION:** 12-1-55. Consent—claimed by Stockton Veterinary Supply Co. and relabeled.

**5007. Solu-Stilbestrol.** (F. D. C. No. 38980. S. No. 26-201 M.)

**QUANTITY:** 23 1-gal. cans at Coon Rapids, Iowa.

**SHIPPED:** 12-28-54 and 4-1-55, from Chicago, Ill., by Vitamins, Inc.

**LABEL IN PART:** (Can) "Vit Inc 1 Gal. Solu-Stilbestrol-50 Containing 50 gm. diethylstilbestrol with a solubilizing agent dissolved in 1 gal. molasses.

**CAUTION:** For manufacturing, processing or repackaging of the preparation of a new drug limited by federal law to investigational use. Control #15530 Manufactured by Vitamins, Inc. 809 W. 58th St. Chicago 21, Ill., U. S. A. For Manufacturing Use."

**RESULTS OF INVESTIGATION:** Diethylstilbestrol intended for feeding to cattle for increasing their weight is regarded as a "new drug" ingredient.

Vitamins, Inc., filed a new-drug application for the article on 6-10-55 and submitted data concerning the use made of the article by the consignee, Garst Co., Coon Rapids, Iowa. These data were verified by information obtained by Food and Drug inspectors and showed that Garst Co. mixed the diethylstilbestrol preparation with cattle feed and fed the resultant mixture to its animals for fattening purposes, and showed further that no scientific tests of any real nature were conducted in connection with the feeding. In such circumstances, the new-drug application was not made effective.

**LIBELED:** On or about 3-8-56, N. Dist. Iowa.

**CHARGE:** 502 (f) (1)—the label of the article, when shipped and while held for sale, did not bear adequate directions for use, and the article was not entitled to any exemption from that requirement since the article had not been used and was not being used only in the manufacture of a new drug limited to investigational use as provided in the regulations.

**DISPOSITION:** 4-24-56. Default—destruction.

#### DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS\*

**5008. Various drugs.** (F. D. C. No. 37994. S. Nos. 19-261/71 M.)

**QUANTITY:** 161 btl. of *Asmax* tablets, 151 btl. of *Lipolin*, 108 btl. of *Aratex* tablets, 6 btl. of *amino acid wafers*, 35 btl. of *Rectone* tablets, 50 btl. of *herbal diuretic tablets*, 56 14-oz. btl. and 13 8-oz. btl. of *Detoxo*, and 54 btl. of *Glutamins* tablets at Akron, Ohio.

\*See also No. 5006.

**SHIPPED:** Between 10-20-54 and 3-31-55, from Los Angeles, Calif., by Pacific Mineral Industries.

**LABEL IN PART:** (Btl.) "Pacific Mineral Industries P. M. I. \* \* \* ASMAX An Organic Formula Containing Elocampane Root Yerba Santa Dragon Turnip Cubeb Berries Ipecac Root Horehound Herb White Pine Compound Irish Moss \* \* \* 120 Tablets \* \* \* A Dietary Supplement," "Lipolin A Dietary Supplement To aid in the utilization of fats and to aid in the prevention of fatty infiltration of the liver. \* \* \* 80 Caplets Each 3 Caplets Contain Methionine 50 Mg. Inositol 50 Mg. Choline (Dihydrogen Citrate) 123 Mg. Rutin 5 Mg. Plus excipients added as filler and coloring," "Lipolin To aid in the Utilization of Fats and the Prevention of Fatty Infiltration of the Liver \* \* \* 90 tablets Each 2 tablets contain: Methionine, 150 mg. Choline, 300 mg. Betaine, 150 mg. Inositol, 150 mg. Rutin, 20 mg. in a base of the wonder herb *Serpentaria Root*," "Aratex Calcium Phosphorus Thiamine Vitamin D Compounded with A Special Herbal Base \* \* \* Gentian Root Black Cohosh Buckbean Leaves Bitter Root Genseng Root Cinchona Bark Colombo Root Tamarac Bark The above herbs are blended in special base of tablet 120 Tablets," "New Improved Protamins B<sub>1</sub> B<sub>2</sub> B<sub>6</sub> in Amino Acid Wafers \* \* \* 150 Wafers \* \* \* 2 Wafers with each of three meals (6 wafers) daily will supply:—Vitamin B-1 6 Mg. \* \* \* Vitamin B-2 6 Mg. Vitamin B-12 6 Mcg. \* \* \* Plus 45 gr. of protein hydrolysate and 40 gr. of whey. The base material supplies the following essential and non-essential amino acids in varying amounts: Arginine Methionine Tyrosine Histidine Threonine Cystine Lysine Leucine Asparatic Acid Tryptophane Isoleucine Glutamic Acid Phenylalanine Valine," "Rectone \* \* \* An adjuvant for the relief of symptoms of rectal discomfort and body tonic. \* \* \* 120 Tablets Each tablet contains a pure blend of the following herbs in a molasses base: Poke Root Mandrake Root Violet Leaves Flax Seed Figwort Herbs Comfrey Root Culvers Root Mullein Leaves Myrrh Gum Foenugreek Seed White Oak Bark Lobelia Herb Golden Seal Root Pilewort Herb Cascara Sagrada Bark Slippery Elm Bark Witch Hazel Bark Cranesbill Root," "120 Tablets \* \* \* Formula S. B. K. A Herbal Diuretic Gravel Root Queen of Meadow Herb Althea Root Wild Carrot Leaves Pichi Tops Uva Ursi Leaves Hydrangea Root Celery Seed Shave Grass Couch Grass Root With Oil of Juniper Berries Formulated and Distributed by Pacific Mineral Industries Hollywood, California," "S. B. K. A Herbal Diuretic Gravel Root Queen of Meadow Herb Althea Root Wild Carrot Leaves Pichi Tops Uva Ursi Leaves Hydrangea Root Celery Seed Shave Grass Couch Grass Root With Oil of Juniper Berries Distributed by Ralph Brennan 195 Melbourne Ave. Akron, Ohio \* \* \* 120 Tablets," "Formula Detoxo To eliminate noxious toxins, putrefaction, and mucus from the gastro-intestinal tract. To increase Lactobacillus in the gastro-intestinal tract. Contents Acidophilus Lactobacillus (Placed in preparation) Blond Plantago Ovata Organic Pectin Magnesium Trisilicate Flavor Added," and "120 Glutamins A Food Supplement. Each 10 gn. sodium glutamate tablet contains 8.69 gns. Glutamic Acid, 1 mgm. Thiamine HCL-B<sub>1</sub> Excipients as binder and coloring added."

**ACCOMPANYING LABELING:** Leaflets entitled "Asthma And Allied Bronchial Conditions \* \* \* Asmax," "Lipolin," "Arthritis Rheumatism Aratex," "Hemorrhoids \* \* \* Rectone," "Kidney And Bladder Conditions \* \* \* S. B. K. A Herbal Diuretic," "Detoxo," and "Doctor's Order Form."

Libe  
ct.

**LIBELED:** 6-1-55, N. Dist. Ohio.

CHARGE: 501 (c)—When shipped, the strength of the *Detoxo* differed from, and its quality fell below, that which it purported and was represented to possess since its labeling represented that the article contained a significant number of viable *Lactobacillus acidophilus* micro-organisms when such was not the case and 502 (a)—the labeling of the articles, when shipped, contained the following false and misleading representations:

(a) That the *Asmar tablets* were an adequate and effective treatment for asthma and allied bronchial conditions, affections of the throat and lungs due to phlegm accumulations in the air passages, spasms of the respiratory system, and conditions requiring respiratory stimulation;

(b) That the *Lipolin* was an adequate and effective treatment for prevention of fatty infiltration of the liver, high blood pressure, hardening of the arteries, liver conditions, capillary fragility, liver damage, cirrhosis of the liver, necrosis of the liver, infective hepatitis, diabetes, multiple sclerosis, alcoholism, psoriasis, gallbladder conditions, and affections of the spleen;

(c) That the *Aratex tablets* were an adequate and effective treatment for arthritis, rheumatism, impaired glandular function, overacid conditions of the body, weakened veins, impure blood, inflammation, fever, nausea, and bursitis;

(d) That the *amino acid wafers* were an adequate and effective treatment for gastrointestinal conditions;

(e) That the *Rectone tablets* were an adequate and effective treatment for piles, impaired glandular function, sluggish liver, inflammation, irritability, bleeding, impaired body functions, and spasms;

(f) That the *herbal diuretic tablets* were an adequate and effective treatment for kidney conditions, bladder conditions, gravel and sediment in the bladder, and pus in the urinary system;

(g) That the *Detoxo* was an adequate and effective treatment for toxemia and affections of the gastrointestinal tract;

(h) That the *Glutamins tablets* were an adequate and effective treatment for epilepsy, nerve exhaustion, melancholy, and mental slowness, and for providing regeneration of nerve tissue, mental uplift, and change of personality.

DISPOSITION: 7-21-55. Default—destruction.

5009. *Rauwolfia serpentina*. (F. D. C. No. 37558. S. No. 6-621 M.)

QUANTITY: 2 100-lb. drums and 1 37-lb. drum of "Pow. *Rauwolfia Serpentina*"; 5 drums containing 750,000 tablets, 22 btl., 1,000 tablets each, 7 btl. 500 tablets each, and 32 btl., 100 tablets each, of "Powdered Whole Root *Rauwolfia Serpentina*" 100-mg. size; and 7 btl., 5,000 tablets each, 16 btl. 1,000 tablets each, 17 btl., 500 tablets each, and 64 btl., 100 tablets each, "Powdered Whole Root *Rauwolfia Serpentina*" 50-mg. size, at Cincinnati, Ohio.

SHIPPED: The powdered *Rauwolfia* was shipped in bulk drums on 9-13-55 from New York, N. Y., by Prentiss Drug and Chemical Co.

LABEL IN PART: (Powder) "Pow. *Rauwolfia Serpentina*"; (tablets) "*Rauwolfia* Brand of Powdered Whole Root *Rauwolfia Serpentina*."

RESULTS OF INVESTIGATION: Upon receipt of the shipment of powdered *Rauwolfia*, the consignee manufactured a portion into tablets. An examination showed that the article contained large amounts of the ground root of a species of *Rauwolfia* other than *Rauwolfia serpentina*.

LIBELED: 1-11-55, S. Dist. Ohio.