

**CHARGE:** Prenatal vitamin and mineral capsules, Polyvitamin Drops, Geriatric capsules and Multi-Vitamin Therapeutic capsules; 402(b)(1)—while held for sale, the valuable constituent of the article, namely, vitamin B<sub>1</sub>, had been in part omitted, or abstracted from the article; 403(a)—the label statements "Each capsule contains \* \* \* Vitamin B<sub>1</sub> 1 Mg.," "A daily dose of 0.6 cc. \* \* \* provides \* \* \* Thiamine (B<sub>1</sub>) 1 Mg.," "Each capsule contains \* \* \* Vitamin B<sub>1</sub> 5 Mg." and "Each capsule contains \* \* \* Vitamin B<sub>1</sub> 10 Mg.," were false and misleading;

Vitamin and mineral capsules: 402(a)(2)(C)—while held for sale, the article contained a food additive, namely, folic acid, which was unsafe within the meaning of 409 since it and its use and intended use were not in conformity with a regulation or exemption in effect pursuant to law;

Prenatal vitamin and mineral capsules: 403(j)—when shipped, the article purported to be and was represented as a food for special dietary use, by reason of its mineral content and its label failed to bear as required by regulations a statement of the proportion of the minimum daily requirements for pregnant or lactating women for calcium, phosphorous, and iron supplied by such food when consumed in a specified quantity during a period of one day; and

Geriatric capsules: 403(a)—when shipped, the labeling of the article contained false and misleading representations that the article was of unusual value for special dietary supplementation because the nutritional requirements of the elderly were different from those of adults generally.

**DISPOSITION:** 8-26-63. Default—destruction.

**29300. Ellis Vivo-Tone.** (F.D.C. No. 47740. S. Nos. 14-231/3 T.)

**QUANTITY:** 271 100-capsule btls. of a dietary supplement, 43 100-capsule btls. of lecithin, and 266 100-tablet btls. of alfalfa, at Chicago, Ill., in possession of Ellis Research Laboratories, Inc.

**SHIPPED:** 6-19-59 and 7-27-59, from Oak Park, Mich.

**LABEL IN PART:** (Btl.) "9 Ellis Vivo-Tone A Dietary Supplement \* \* \* Essential Unsaturated Fatty Acids As Present in Safflower Oil Plus Vitamin B-6 \* \* \* Control No. 45924; ["10 Vivo-Tone \* \* \* Lecithin With Safflower Oil \* \* \* Control No. 2421"; or "11 Ellis Vivo-Tone \* \* \* Alfalfa 10 gr. Tablets \* \* \* Control No. 3960"] Available only through doctors who provide Micro-Dynameter Analysis \* \* \* Distributed by Ellis Research Labs., Inc., Chicago 11, Illinois."

**ACCOMPANYING LABELING:** Booklets entitled "An Introduction To Vivo-Tone, A research paper submitted for the exclusive use of Micro-Dynameter users."

**RESULTS OF INVESTIGATION:** The articles were shipped in bulk lots which were subsequently repacked by the dealer into bottles described above.

**LIBELED:** 7-26-62, N. Dist. Ill.

**CHARGE:** 403(j)—the articles purported to be and were represented as special dietary foods and their labels failed to bear, as required by regulations, a statement of the dietary properties upon which such use was based.

The libel alleged also that the articles were misbranded under the provisions of the Act relating to drugs as reported in notices of judgment on drugs and devices, No. 7437.

**DISPOSITION:** 9-10-62. Default—destruction.

# 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]

29301-29400

#### FOODS

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 foods which were alleged to be adulterated or misbranded within the meaning of the Act, when introduced into and while in interstate commerce, when shipped to a holder of a guaranty, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered upon default, consent, or, in one case, motion for summary judgment, and in which, in one case, a decree of partial discharge and partial relabeling was entered; (2) criminal proceedings which were terminated upon pleas of guilty and nolo contendere, and, in one case, upon a judgment of guilty; and (3) injunction proceedings dismissed subsequent to the granting in one case, and the denial in one case, of temporary restraining orders. 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., August 18, 1964.

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**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN ALLEGED VIOLATIONS REPORTED IN F.N.J. NOS. 29301-29400**

*Adulteration.* Section 402(a) (2) (A), the article bore or contained an added poisonous or added deleterious substance, which was unsafe within the meaning of Section 406; Section 402(a) (2) (B), the article was a raw agricultural commodity and contained a pesticide chemical which was unsafe within the meaning of Section 408(a); Section 402(a) (2) (C), the article contained a food additive which was unsafe within the meaning of Section 409; Section 402(a) (3), the article consisted in whole or in part of a filthy, putrid, or decomposed substance, or it was otherwise unfit for food; Section 402(a) (4), the article had been prepared, packed, or held under insanitary conditions whereby it might have become contaminated with filth or might have been rendered injurious to health; Section 402(b) (1), a valuable constituent had been in whole or in part omitted or abstracted from the article; Section 402(b) (2), a substance had been substituted in whole or in part for the article; Section 402(b) (4), a substance had been added to the article or mixed or packed therewith so as to increase its bulk or weight; Section 402(c), the article contained a color additive which was unsafe within the meaning of Section 706(a); Section 406, a poisonous or deleterious substance was unsafe since such substance was not required in the production of food and could have been avoided by good manufacturing practice; Section 408(a), a poisonous or deleterious pesticide chemical, or a pesticide chemical not generally recognized, among qualified experts, as safe for use, added to a raw agricultural commodity, was deemed to be unsafe because no tolerance or exemption from the requirement of a tolerance for such pesticide chemical in or on the raw agricultural commodity had been prescribed by the Secretary of Health, Education, and Welfare; Section 409, a food additive was deemed to be unsafe because the food additive and its use or intended use failed to conform to the terms of an effective exemption or because there was not in effect, or the food additive and its use or intended use failed to be in conformity with, a regulation prescribing conditions for safe use; and Section 706(a), a color additive was deemed to be unsafe because such additive and its use were not in conformity with a regulation listing such additive for a particular use, and such additive was neither from a batch certified for such use, nor had, with respect to such use, been exempted from certification.

*Misbranding.* Section 403(a), the labeling of the article was false and misleading; Section 403(c), the article was an imitation of another food and its label failed to bear in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated; Section 403(e), 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 the contents in terms of weight, measure, or numerical count; Section 403(f), a word, statement, or other information required by or under authority of the Act to appear on the label or labeling was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 403(g) (1), the article purported to be or was represented as a food for which a definition and standard of identity had been prescribed by regulations and it failed to conform to such definition and standard; Section 403(h) (1), the article purported to be or was represented as a food for which a standard of quality had been prescribed by regulations, and its quality fell below such standard; Section 403(i) (2), the

article was not subject to the provisions of Section 403(g) and the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each such ingredient; Section 403(j), the article purported to be and was represented for special dietary uses, and its label failed to bear such information concerning its vitamin, mineral, and other dietary properties as the Secretary had determined to be, and by regulation prescribed as, necessary in order fully to inform purchasers as to its value for such uses; and Section 403(k), the article contained a chemical preservative and failed to bear labeling stating that fact.

## CEREALS AND CEREAL PRODUCTS

### CORNMEAL\*

29301. Cornmeal and cooking oil. (F.D.C. No. 49094. S. Nos. 67-500 V, 2-561 X.)

QUANTITY: 1,500 1-lb. 8-oz. bags of cornmeal; and 895 cases each containing 12 1-pt. btls., 1,218 cases each containing 12 1-qt. btls., and 1,114 cases each containing 6 44-oz. btls. of cooking oil, at Jacksonville, Fla.; in possession of Dixie Lily Milling Co. of North Florida.

SHIPPED: Between 2-12-63 and 6-8-63, from Tifton, Ga., and Chattanooga, Tenn.

LABELS IN PART: (Bag) "Dixie Lily Fine Foods Superlative Sifted Water Ground Meal \* \* \* Manufactured and Distributed by Dixie Lily Milling Co. \* \* \* Tampa, Fla.," and (btl.) "Dixie Lily Golden Heart Cooking and Salad Oil Prepared from Pure Vegetable, Citrus Seed and Corn Oils \* \* \* A Blend of Unsaturated Oils \* \* \* Packed and Distributed by Dixie Lily Milling Co., Jacksonville, Florida."

ACCOMPANYING LABELING: Additional repack cornmeal bags, and additional repack cooking oil bottle labels.

RESULTS OF INVESTIGATION: Both the cooking oil and the cornmeal had been shipped in bulk and had been repacked by the dealer.

LIBELED: 7-8-63, M. Dist. Fla.

CHARGE: 403(a)—while held for sale, the labeling of the articles including the name of the cooking oil "Golden Heart Cooking and Salad Oil" contained false and misleading representations that the articles were adequate and effective to prevent premature aging, heart disease, hardening of the arteries, and to lower blood cholesterol levels.

DISPOSITION: On 7-15-63, Dixie Lily Milling Co. of North Florida filed an appearance as owner of the articles, filed a motion to dismiss the libel, and filed a motion to strike that portion of the libel which concerned itself with the vegetable oil and its labels. On 7-17-63, the court granted the claimant's motion to strike that portion of the libel which concerned itself with the vegetable oil and its labels and discharged and released the vegetable oil and its labels, provided the claimant met the further requirements of the court's order. The court required:

(a) That the cornmeal, including all parts thereof, not be repacked in any containers of any size which bore the following language in legible form:

\*See also No. 29312.