

93941d



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Minneapolis District Office  
Central Region  
212 Third Avenue South  
Minneapolis, MN 55401  
Telephone: (612) 334-4100  
FAX: (612) 334-4134

April 8, 2003

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**Refer to MIN 03 - 15**

Paul A. Stitt  
Chief Executive Officer  
Natural Ovens of Manitowoc, Inc.  
4300 County Highway CR  
Manitowoc, Wisconsin 54221

Dear Mr. Stitt:

The Food and Drug Administration (FDA) collected samples of five of your products on February 19, 2002, via your Internet site *www.naturalovens.com*. The samples were collected to determine your firm's compliance with the Federal Food, Drug, and Cosmetic Act (the Act), the Nutrition Labeling and Education Act (NLEA), and their implementing regulations, specifically, the regulations contained in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101). A limited, follow-up inspection was conducted at your Manitowoc, Wisconsin, facility on December 17, 2002, during which FDA collected more recent labels and verified that there had not been any formula or labeling changes made to your products in 2002. This inspection confirmed FDA's findings from its September 2001 and February 2002 inspections.

We reviewed product labels and analyzed samples of your 7 Grain Herb Bread, Multi-Grain Stay Trim Bread, Right Wheat Whole Grain Bread, and 100% Whole Grain Bread for nutrient content. We also reviewed the label from a sample of your Ultra Omega Balance™ Flax Based Supplement with Added Soy and product labels for your Sunny Millet Bread and Health Max Whole Wheat Bread. The results of the referenced reviews and the analyses of the sampled products show that your products are misbranded within the meaning of Section 403 of the Act (21 U.S.C. 343). We also reviewed your firm's Internet labeling for several of your products. Your product labels direct the consumer to your internet website address, from which your products may be purchased directly, via the statement "Connect to *www.naturalovens.com* for information about nutrition and health. . . ." We have concluded that the labeling found on your Internet website also causes your products to be misbranded under Section 403 of the Act.

Page Two

Paul A. Stitt  
April 8, 2003

The specifics of each deviation and the applicable sections of the Act and regulations follow:

7-Grain Herb Bread, 24 ounce loaf

Promotional labeling contained on your Internet site advises consumers that this product is "Rich in fiber, it also contains over 300 anti-carcinogenic compounds." The claim "rich in fiber" misbrands the product under Section 403(r)(1)(A) of the Act because the term "rich in" is defined by regulation to mean that the product contains 20% or more of the Recommended Daily Intake (RDI) or Daily Reference Value (DRV) for that nutrient [21 CFR 101.54(b)]. According to the label, the product only contains 16% of the Daily Value (DV) for fiber; therefore, "rich in fiber" is an unauthorized nutrient content claim on this product. The claim "Rich in fiber, it also contains over 300 anti-carcinogenic compounds" also misbrands the product under Section 403(r)(1)(B) of the Act because the claim does not meet the requirements of the regulation authorizing a health claim for fiber-containing grain products and cancer (21 CFR 101.76).

The labeling contained on the immediate packaging includes a statement that antioxidants "help prevent...degenerative diseases of all types." This statement is an unauthorized health claim and causes your product to be misbranded within the meaning of Section 403(r)(1)(B) of the Act.

FDA analyzed a sample of this bread for nutrient content and Omega-3 fatty acid content. This analysis reveals your product is misbranded within the meaning of Section 403(a)(1) of the Act in that:

- Analysis reveals the calorie content is 154% (original analysis) and 146% (check analysis) of the value declared in the nutrition information.
- Analysis reveals the total fat content is 246% (original) and 240% (check) of the value declared in the nutrition information.
- Analysis reveals the fiber content is 42.3% (original) and 57.3% (check) of the value declared in the nutrition information.
- The label states 225 mg of Omega-3 and no Omega-3 was detected in the analysis.

Multi-Grain Stay Trim Bread, 24 ounce loaf

The labeling contained on the immediate packaging includes a statement that antioxidants "help prevent...degenerative diseases of all types." This statement is an unauthorized health claim and causes your product to be misbranded within the meaning of Section 403(r)(1)(B) of the Act.

Page Three

Paul A. Stitt  
April 8, 2003

FDA analyzed a sample of this bread for nutrient content and Omega-3 fatty acid content. This analysis reveals your product is misbranded within the meaning of Section 403(a)(1) of the Act in that:

- Analysis reveals the calorie content is 133% (original analysis) and 126% (check analysis) of the value declared in the nutrition information.
- Analysis reveals the fiber content is 36.6% (original) and 38.4% (check) of the value declared in the nutrition information.
- The label states 200 mg of Omega-3 and no Omega-3 was detected in the analysis.

The product is further misbranded under Section 403(r)(1)(A) of the Act because the end panel of the label bears the nutrient content claim "high fiber." However, the product does not meet the requirements for this claim [21 CFR 101.54(b)]. The claim "high fiber" is defined by regulation to mean that the product contains 20% or more of the DV for fiber. The nutrition facts panel indicates that the product contains 5 g of fiber or 20% of the DV. However, FDA sample analysis reveals that the product contains only 1.83 g (original analysis) or 1.92 g (check analysis) of fiber, or approximately 7% of the DV for fiber, which does not meet the regulatory definition of "high fiber."

Right Wheat Whole Grain Bread, 24 ounce loaf

FDA analyzed a sample of this bread for nutrient content and Omega-3 fatty acid content. This analysis reveals that your product is misbranded within the meaning of Section 403(a)(1) of the Act in that:

- Analysis reveals the calorie content is 148% (original analysis) and 140% (check analysis) of the value declared in the nutrition information.
- Analysis reveals the total fat content is 197% (original) and 195% (check) of the value declared in the nutrition information.
- Analysis reveals the fiber content is 36.2% (original) and 51.4% (check) of the value declared in the nutrition information.
- Analysis reveals the protein content is 208% (original) and 203% (check) of the value declared in the nutrition information.
- The label states 175 mg of Omega-3 and no Omega-3 was detected in the analysis.

Page Four

Paul A. Stitt  
April 8, 2003

100% Whole Grain Bread, 24 ounce loaf

FDA analyzed a sample of this bread for nutrient content and Omega-3 fatty acid content. This analysis reveals that your product is misbranded within the meaning of Section 403(a)(1) of the Act in that:

- Analysis reveals the calorie content is 150% (original analysis) and 140% (check analysis) of the value declared in the nutrition information.
- Analysis reveals the total fat content is 194% (original) and 190% (check) of the value declared in the nutrition information.
- Analysis reveals the fiber content is 38.6% (original) and 41% (check) of the value declared in the nutrition information.
- The label states 300 mg of Omega-3 and no Omega-3 was detected in the analysis.

Sunny Millet Bread

The labeling contained on the immediate packaging includes a statement that antioxidants “help prevent...degenerative diseases of all types.” This statement is an unauthorized health claim and causes your product to be misbranded within the meaning of Section 403(r)(1)(B) of the Act.

Health Max Whole Wheat Bread

The labeling contained on the immediate packaging includes a statement that antioxidants “help prevent...degenerative diseases of all types.” This statement is an unauthorized health claim and causes your product to be misbranded within the meaning of Section 403(r)(1)(B) of the Act.

Ultra Omega Balance Flax Based Supplement with Added Soy

The Ultra Omega Balance product is misbranded under Section 403(r)(1)(A) of the Act because the label bears the nutrient content claims “...rich source of Omega-3...,” “...high levels of polyphenols...,” and “...rich in isoflavones and phosphatidyl serine...” on the information panel. The terms “rich” and “high,” when used to describe the level of a nutrient in a product, are nutrient content claims, which are defined by regulation to mean that the product contains 20% or more of the RDI or DRV of the nutrient. There is no RDI or DRV for Omega-3, polyphenols, isoflavones, or phosphatidyl serine. Therefore, “rich” and “high,” when used to describe the levels of the above nutrients, are unauthorized nutrient content claims [21 CFR 101.54(b)].

Page Five

Paul A. Stitt  
April 8, 2003

The product is further misbranded under Section 403(q)(5)(F) of the Act because the label bears a "Nutrition Facts" panel instead of a "Supplement Facts" panel. The product's statement of identity is "ULTRA OMEGA BALANCE...Flax Based Supplement With Added Soy." Use of the term "supplement" in the statement of identity indicates the product is a dietary supplement [21 CFR 101.3(g)], and dietary supplements must bear a "Supplement Facts" panel [21 CFR 101.36].

We request that you notify this office in writing within 15 working days of receipt of this letter stating the actions you will take to correct the violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and a reasonable time within which the corrections will be completed.

Failure to make prompt corrections may result in further enforcement action, including injunction, being initiated by the FDA.

This letter does not represent a comprehensive review of all of the products distributed by your firm, nor does it represent a complete review of all product labeling and nutrient analysis. As CEO, it is your responsibility to ensure that all products distributed by your firm are in compliance with the Act and its implementing regulations.

Your reply should be directed to Compliance Officer Tyra S. Wisecup at the address indicated in the letterhead. Ms. Wisecup may be reached at (612) 758-7114.

Sincerely,

  
W. Charles Becoat  
Director  
Minneapolis District

TSW/ccl  
