



DEPARTMENT OF HEALTH AND HUMAN SERVICE

93799d
Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
FAX: 504-253-4520

November 5, 2002

WARNING LETTER NO. 2003-NOL-02

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Robert J. Whana, IV, President
G.H. Leidenheimer Baking, Ltd.
1501 Simon Bolivar
New Orleans, Louisiana 70113-2329

Dear Mr. Whana:

On June 25, 2002, an investigator of the U.S. Food and Drug Administration (FDA) collected a sample of Leidenheimer Muffuletta Enriched Bread from your facility, located at 1501 Simon Bolivar Avenue, New Orleans, Louisiana. This sample was analyzed by the FDA Southeast Regional Laboratory. The level of sodium per 64 gram serving was determined to be 418 mg per serving (check analysis 481 mg). This is 174% (check analysis 200%) of the label declaration of 240 mg sodium per serving. Also, the serving size, which is expressed as "½ Muffuletta (64g)" is inconsistent with the declaration of 4 servings per 255 gram package. The serving size should be ¼ Muffuletta, because there is only one muffuletta per package. Therefore, your Muffuletta bread product is misbranded within the meaning of Section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act).

This product is also misbranded within the meaning of section 403(r)(1)(B) of the Act. The statement "FRENCH BREAD IS A LOW FAT CHOLESTEROL FREE FOOD.", enclosed in a heart symbol, is an implied health claim for dietary saturated fat, cholesterol and risk of coronary heart disease. However, the claim fails to include all of the elements required by the authorizing regulation [Title 21 of the *Code of Federal Regulations* (CFR), 101.75(c)(2)]. In addition, the claim does not include a statement referring to the location on the label that contains all of the elements required by the claim [21 CFR 101.14(d)(2)(iv)].

We also note that the second paragraph on the information panel, under the heading "Healthy Food Choices," includes the statement "French Bread is a good source of carbohydrates..." Section 403(r)(2)(A)(i) of the Act allows nutrient content claims to be made only if the terms used in the claim have been defined by regulation. The term "good source" is defined in 21 CFR 101.54 and may be used on the label of a bread product that contains 10 to 19 percent of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) of a nutrient per reference amount customarily consumed. However, because no RDI or DRV has been established for

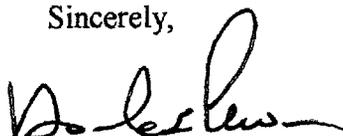
carbohydrates, claims relating to the level of carbohydrates in a food have not been defined and are therefore not authorized by regulation.

The above violations are not meant to be an all-inclusive listing of deficiencies on your labels. Other label violations can also subject your food products to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes and regulations enforced by FDA. It is also your responsibility to assure that the current objectionable conditions are corrected and that appropriate policies and procedures are implemented to prevent recurrence of the problems. Failure to make corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction. You can find the Act through links in FDA's home page at <http://www.fda.gov>.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, along with a copy of the revised label. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to the U.S. Food and Drug Administration, Attention: Nicole F. Hardin, Compliance Officer, at the above address. If you have questions concerning the contents of this letter, you may contact Ms. Hardin at (504) 253-4519.

Sincerely,



Howard E. Lewis
Acting District Director
New Orleans District

Enclosures:

21 CFR Part 101
A Food Labeling Guide