



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive SE  
Bothell, WA 98021-4421

Telephone: 425-486-8788  
FAX: 425-483-4996

November 15, 2001

**VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 02-12

Mr. Nicholas Kazan, Owner  
Europa Bakery  
601 West 36<sup>th</sup> Street  
Anchorage, Alaska 99503

**WARNING LETTER**

Dear Mr. Kazan:

The Food and Drug Administration (FDA) has reviewed your labels for your "Europa Bakery" bread products which were collected by James I. Vik, Investigator, during an inspection of your plant located at 601 West 36<sup>th</sup> Street, Anchorage, Alaska, on September 27, 2001. Our review reveals these labels cause the above products to be in violation of section 403 of the Federal, Food, Drug, and Cosmetic Act (the Act), and Title 21, Code of Federal Regulations (21 CFR), Part 101-Food Labeling, as follows:

The labels for your "Europa Bakery" bread products are misbranded in that they fail to bear nutritional labeling as required under section 403(q)(1) of the Act, and 21 CFR 101.9, and they are not exempt under section 403(q)(5) from this requirement, and they were labeled after August 8, 1994. The FDA maintains a list of small businesses requesting exemptions from the nutritional labeling requirements of conventional foods. As of October 15, 2001, we observed that your firm is not on that list. I have enclosed a copy of the regulations (21 CFR 101.9) and the Small Business Food Labeling Exemption form. If your firm plans to use a single generic label with various kinds of breads, you must file an exemption, provided you meet the requirements, for each kind of bread you will be selling. You must reapply annually if you qualify for the exemption.

The above violation concerns certain labeling requirements and is not meant to be an all-inclusive list of deficiencies on your label. Other label violations can subject the food to legal

Nicholas Kazan, Owner  
Europa Bakery, Anchorage, Alaska  
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action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

Please 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 violation. If corrective action cannot be completed within 15 working days, state the reason and the time within which the corrections will be completed.

Please send your reply to the Food and Drug Administration, Attention: Connie P. Rezendes, Acting Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, Washington 98021-4421. If you have any question regarding any issue in this letter, please contact Connie P. Rezendes at (425) 402-3178.

Sincerely,

A handwritten signature in black ink, appearing to read 'Charles M. Breen', written over a horizontal line.

Charles M. Breen  
District Director

Enclosures:

21 CFR Part 101  
Section 403 of the Federal Food, Drug, and Cosmetic Act  
Small Business Food Labeling Exemption Information

cc: ADEC with disclosure statement