



Department of Health and Human Services

Public Health Service

Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510-337-6700

VIA FEDERAL EXPRESS

Our Reference: 2938822

August 29, 2002

Phuong My Luong, Owner
Egourmet, Inc. dba Eastern Gourmet
1950 Innes Avenue #5
San Francisco, CA 94124

WARNING LETTER

Dear Ms. Luong:

On April 24, 25, 29, and May 30, 2002, the U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 1950 Innes Avenue #5, San Francisco, CA.

Our inspection found that you did not follow the Good Manufacturing Practice regulations found in Title 21, Code of Federal Regulations, Part 110 (21 CFR 110). A copy of 21 CFR 110 is enclosed for your ready reference. The following is a list of conditions observed by FDA during the inspection. These conditions cause products manufactured in your facility to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), as food is "prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, of whereby it may have been rendered injurious to health."

The following is a list of the deviations observed by FDA during the inspection:

1. Failure to clean non-food contact surfaces as frequently as necessary to protect against contamination of food, 21 CFR 110.40(c). Specifically, batter mixing machines, overhead hoods, dough processing machines and processing-area walls bore accumulated ingredient residues.
2. Failure to locate and operate fans and other air-blowing equipment in manner that minimizes the potential for contaminating food and food-contact surfaces, 21 CFR

110.40(a). Specifically, a fan used to cool hot baked items bore accumulated dust anti dirt on its blades and screens.

3. Failure to provide sufficient space for placement of equipment and storage of materials as necessary for the maintenance of sanitary operations and production of safe food, 21 CFR 110.20(b)(1). Specifically, ingredients and equipment are stored up against walls and adjacent to one another without sufficient room for cleaning and/or inspection.

4. Failure to have employees confine eating to areas other than where contamination of processed food can occur, 21 CFR 110.11(b)(8). Specifically, several employees were observed eating meals on a production table where food was being processed.

5. Failure to wear, where appropriate, hair nets or other effective hair restraints, 21 CFR 110.10(b)(6). Specifically, several employees were observed without hair nets or effective hair restraints in the facility and in the production area.

6. Failure to conform to hygienic practices to the extent necessary to protect against the contamination of food, 21 CFR 110.10(b). Specifically, oven mitts, used to handle hot baking pans and racks, were covered with accumulated dirt and residue.

7. Failure to wear outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials, 21 CFR 110.10(b)(1). Specifically, the aprons worn by the employees were dirty.

During the inspection, FDA collected labels of your Mini Cupcake product. Review of the label reveals that the product is misbranded within the meaning of section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) because the label fails to list whey in the ingredient statement. Whey is a listed ingredient in the "For Muffins Only" batter mix used to make your Mini Cupcake product.

The declaration of whey is of particular concern because it is an allergenic substance. FDA has received an increasing number of reports concerning consumers who have experienced adverse reactions following exposure to an allergenic substance in foods. For sensitive individuals the presence of allergens in food is potentially life-threatening. Ingredients that are among the most commonly known to cause serious allergic responses are milk, eggs, fish, crustacea, tree nuts, wheat, peanuts, soybeans and derivatives of these products. Whey is a derivative of milk.

Your Mini Cupcake is also misbranded within the meaning of 403(q)(1) of the Act because the label fails to bear nutrition information. Your firm is not exempt from providing nutrition information labeling under section 403(q)(5) of the Act.

At the conclusion of the inspection, the inspectional deviations were listed on form FDA-483 and discussed with Micheal K. Do, General Manager. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You are responsible for ensuring that your processing facility operates in

compliance with applicable statutes and regulations including the Good Manufacturing Practice regulations (21 CFR 110). You are also responsible for ensuring that your labels are in compliance with applicable statutes and regulations.

Almost three months have elapsed since the FDA inspection. You have had sufficient time to correct the violations that FDA conveyed to you at the close of the inspection. We may take further action if you have not corrected these violations. For Instance, we may move to seize your products and/or enjoin your firm from operating.

Please advise us in writing within fifteen (15) working days of receipt of this letter of the specific actions you have taken to correct these violations include copies of your revised labels.

If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which corrections will be completed Your written reply to this letter should be sent to MS Harum Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,

/s/

Dennis K. Linsley
District Director
San Francisco District