



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

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

VIA FEDERAL EXPRESS

Our Reference: 2955472

June 27, 2000

James J. Chen, Owner  
Delicious Foods Co.  
1655 Whipple Road, #18  
Hayward, CA 94544

**WARNING LETTER**

Dear Mr. Chen:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 1655 Whipple Road, #18, Hayward, California on April 11, 13, and 19, 2000. The inspection revealed significant insanitary conditions which cause products in your facility to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) because they have been prepared, packed or held under insanitary conditions whereby they may have been contaminated with filth.

Furthermore, the inspection revealed that products manufactured by your firm, Green Onion Bread, Onion Roll, Whole Wheat Steam Bun, and Sweet Steam Bun, are misbranded in that they fail to bear nutritional labeling as required under Section 403(q)(1) of the Act, and Title 21, Code of Federal Regulations, Part 101.9 (21 CFR 101.9), and are not exempt under section 403(q)(5) from this requirement.

The following is a list of the insanitary conditions observed by FDA Investigator Larkin R. Buckalew during the inspection, some of which were confirmed by FDA laboratory analyses:

1. Rodent Activity

- a. 22/50-lb bags of [REDACTED] All-Purpose Flour, stacked on the floor, revealed evidence of rodent activity: a live rodent observed running from the bags, 15 bags found to bear adhering rodent excreta pellets, 21 bags bearing rodent urine stains, and three (3) bags bearing rodent gnaws.

- b. 14/50-lb bags of [REDACTED] Flour, stacked on the floor, revealed evidence of rodent activity: 13 bags found to bear adhering rodent excreta pellets, six (6) bags bearing rodent urine stains, and four (4) bags bearing rodent gnaws.
  - c. Twelve (12) rodent excreta pellets were found on the mixer head of the small [REDACTED] mixer in the dough preparation room.
  - d. Ten (10) rodent excreta pellets were found on the table surface and frame of the [REDACTED] Dough Roller. Three (3) rodent excreta pellets were found on the bottom shelf of the L-shaped table holding the dough roller. Containers of corn oil were stored on the bottom shelf.
  - e. Six (6) rodent excreta pellets were found at the bottom of the [REDACTED] proofer equipment where the [REDACTED] frames rest on the floor.
  - f. Eighty (80) rodent excreta pellets were found on a 1' x 6' area of the floor near the flour storage area.
  - g. The floor area along both walls after entering through the roll-up door was observed to have numerous rodent excreta pellets.
2. Plant
- a. A hole in the ceiling that is approximately two (2) inches in diameter was observed in the dough preparation room. An electrical cord was observed to pass through the hole which hung within 1-1 ½ inches of the [REDACTED] mixer where 12 rodent excreta pellets were observed.
  - b. The fan vents in the ceiling of the dough preparation room were observed to have a build-up of debris.
3. Equipment and Utensils
- a. Old product was observed adhering to the inside and outside of the mixing bowls for both the large and small [REDACTED] mixers. The frames on the [REDACTED] mixers were observed to have old product build-up. Old product build-up was also observed on the inside and outside of the [REDACTED] Dough Roller.
  - b. The exhaust hood above the gas stove in the dough preparation room was observed to have a build-up of debris.
  - c. The portable fans used to cool steamed rolls were observed to have a build-up of debris on the fan blades and fan guards.

4. Personnel

- a. Employees in the dough preparation room did not wear hair restraints. One woman employee was observed to wear unsecured jewelry, and three employees were wearing soiled aprons.

5. Sanitary Facilities and Controls

- a. The roll-up door allowing access to the facility was observed to be left open for approximately six hours on April 11, 2000, and again on April 13, 2000 during FDA inspection.
- b. The food-contact surfaces in the dough preparation room were observed to be wet-cleaned but not thoroughly dried and sanitized before subsequent use.
- c. There were no paper towels in the paper towel dispenser next to the sink in the dough preparation room.
- d. Empty discarded bags were found laying on the floor in the dough preparation room.

The following is a list of adulterated products found during the inspection, all of which were voluntarily destroyed:

1. Fifteen (15) bags of 50-lb [REDACTED] All-Purpose Flour, coded "OAK 03 16700."
2. Thirty-six (36) bags of 50-lb [REDACTED] Enriched Flour Bleached, code "07 MAR 0 V 06 39," "07 MAR 0 V 06 40," and "07 MAR 0 V 06 41."
3. Three (3) bags of 50-lb [REDACTED] Flour Bleached, coded "19 APR 9V 23 01."

Your firm's product labels fail to bear nutritional labeling. You indicated during FDA inspection that you distribute approximately [REDACTED] total units of each food product. Your firm, therefore, qualifies for the small business exemption from nutritional labeling. Please forward the form to the Office of Food Labeling, Center for Food Safety and Applied Nutrition, with a copy to our office.

At the conclusion of the inspection, the insanitary conditions were listed on Form FDA 483 (Inspectional Observations) and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. It is your responsibility to have an effective, ongoing sanitation program which eliminates the serious insanitary conditions which we have observed to exist in your facility.

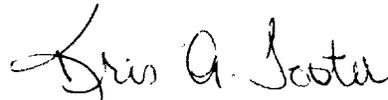
Please note that, per 21 CFR 101.15(c)(2), if a label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label shall appear thereon in the foreign language. Therefore, if the product identity appears in the Chinese language, then the net contents, ingredient statement, and name and address of the manufacturer must also be represented in the Chinese language.

You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. These include seizure and/or injunction.

Please advise FDA in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070.

Sincerely,



Kris A. Foster  
Acting District Director

Enclosure: Form FDA 483