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San Francisco District
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DEPARTMENT OF HEALTH & HUMAN SERVICES



VIA FEDERAL EXPRESS 4165 0457 1290

October 15, 1999

Our Reference No. 2953300

Farr Hariri, President
Farmo Corporation
dba Belfiore Cheese Company
2031-A 2nd Street
Berkeley, CA 94709

WARNING LETTER

Dear Mr. Hariri:

On August 23-25, 1999, FDA Investigators Barbara Cassens and Jennifer S. King conducted an inspection of your cheese processing facility located at 2031-A 2nd Street, Berkeley, CA. The inspection was conducted to determine compliance with FDA's good manufacturing practice regulations for foods as defined in Title 21, *Code of Federal Regulations*, Part 110 (21 CFR 110). This inspection covered the manufacturing of Mozzarella Ovaline Balls, Mozzarella Cherry Size Balls, and Ricotta Cheese. At the conclusion of the inspection, you were presented with Form FDA-483, which listed gross insanitary conditions and practices in your facility. These deficiencies cause products made in your facility to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). A copy of Form FDA-483 is enclosed for your reference. The violations are summarized below.

During the inspection, the investigators observed numerous poor employee practices relating to the manufacture of the cheese. Specifically, the employees allowed cheese curd to come in contact with their hands, arms, and gloves that had not been properly washed or sanitized. Employees were observed placing food contact equipment fittings directly on the floor and then connecting them to a vessel containing in-process cheese curd without cleaning the fittings. Such practices allow for the introduction of foreign material (skin, arm hair, dirt) and pathogenic and spoilage microorganisms into the cheese curd prior to packaging.

Mozzarella cheese balls in [REDACTED] were held at temperatures greater than 45° F and less than 145° F for a prolonged period with no subsequent re-pasteurization of the [REDACTED]. During a two-hour period, a FDA Investigator took the temperature of the [REDACTED] and found it was 79° F - 83° F. These temperatures could cause the growth of spoilage microorganisms in the [REDACTED] which may render the product unfit for food. In addition, these conditions provide an environment for the survival and/or growth of pathogenic microorganisms that can cause illness in humans.

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The equipment and utensils used to manufacture cheese were in poor condition. The investigators observed equipment and utensils that had pitted surfaces, peeling paint, dented surfaces, and cracked seams, which cannot be adequately cleaned and sanitized.

Severe structural defects were noted, which included numerous cracks, missing tile grout, and cracked coving. These defects allow moisture to pool on the floor and provide an environment for microbiological growth. Peeling wall paint, ceiling mold, and unshielded lighting were noted, which could provide opportunities for foreign material to be introduced into the cheese curd.

Other conditions that could lead to product contamination include the following:

Condensation from an overhead steam line was dripping into the [REDACTED] catch tank. The agitator carriage on the mozzarella cheese vat had a buildup of greasy material that was hanging from the carriage directly above unprotected cheese curd. There was a screened air vent with dirt build-up located directly above the mozzarella and ricotta cheese vats.

A food is adulterated under Section 402(a)(4) of the Act if it is prepared, packed, or held under insanitary conditions whereby it may be contaminated with filth, or whereby it may be rendered injurious to health. The introduction of adulterated food into interstate commerce is prohibited by Section 301(a) of the Act.

Our latest inspection found that many of the insanitary conditions throughout your facility had also been noted in the previous inspection of August 1997. It is your responsibility as the president and owner to insure that your facility is operating in compliance with the applicable laws and regulations. It is your responsibility to insure not only that the current objectionable conditions are corrected, but that adequate policies and procedures are implemented to prevent a recurrence of these violations. Failure to promptly correct the violations may result in enforcement actions, such as seizure and/or injunction, without further notice.

During the inspection, it was noted that the products labeled "Mozzarella in Water Cherry Size Balls" and "Mozzarella in Water Ovaline Balls" were not packaged in water, but instead, in [REDACTED], [REDACTED]. Furthermore, on August 25, 1999, you told Investigator Cassens that when making the mozzarella cheese balls, you use [REDACTED] not starter, as the label declares. The identity of the product should be factual and not misleading, e.g., "Mozzarella Cheese Balls in [REDACTED]" and should comply with 21 CFR 101.3 and 133.155. In addition, the ingredients should be declared by the common or usual name in descending order of predominance as described in 21 CFR 101.4 and 133.155. Please be aware that this is not a comprehensive review of your firm's

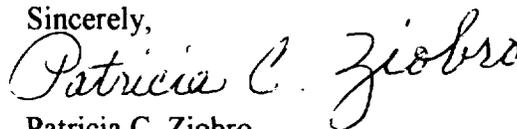
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product labels. It is your responsibility to insure that all of your firm's labels are in compliance with the labeling regulations.

Within fifteen (15) working days of receipt of this letter, please notify FDA in writing concerning the steps you have taken to correct the noted violations. Your response should include an explanation of any delays encountered, and a date by which you expect to complete all of the corrections. Your response should be directed to:

Barbara Cassens, Regional Dairy Specialist
Food and Drug Administration
1301 Clay Street, Suite 1180-N
Oakland, CA 94612
Phone (510) 637-3960, Extension 125
FAX (510) 637-3976

Sincerely,



Patricia C. Ziobro
Director
San Francisco District

Enclosure: Form FDA-483