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DEPARTMENT OF HEALTH & HUMAN SERVICES

**Public Health Service
Food and Drug Administration**

**San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94102-7070
Telephone: 510-337-6700**

**CERTIFIED MAIL
RETURNED RECEIPT REQUESTED**

April 14, 1997

Wesley J. Allen, President
Leprino Foods
1830 W. 38th Avenue
P.O. Box 173400
Denver, Colorado 80217-3400

WARNING LETTER

Dear Mr. Allen:

An inspection of your dairy plant located at 2401 MacArthur Drive, Tracy, California was conducted by FDA Investigator Kathryn D. Macropol and Regional Dairy Specialist Barbara Cassens on February 25, 26, and 28, 1997. This inspection included a check-rating of your Grade "A" dairy products included on the Interstate Milk Shippers List and an inspection of your non-grade "A" products, namely cheese, whey protein concentrate and lactose. At the conclusion of the inspection you were presented with Form FDA-483 listing serious deviations from Title 21, Code of Federal Regulations (21 CFR), Parts 110 and 1240.61, and the Pasteurized and Dried Milk Ordinances (PMO/DMO, 1995 Revision) as they pertain to the manufacture of the aforementioned non-grade "A" products. The products are adulterated within the meaning of Section 402 (a) (4) of the Food, Drug, and Cosmetic Act and in violation of the Public Health Service Act, Section 361. A copy of form FDA-483 is enclosed for your reference.

Most significantly, the observations included time-temperature abuse of the raw whey held in tanks #81 and 83 prior to pasteurization and salt whey stored in tank number seventy-eight. Raw whey stored in these tanks was not rotated every four hours, and in one case (on 2/25/97) was held in one of these tanks for over nine hours. Salt whey was held for as long as fourteen hours between the temperatures of 110 and 120 °F.

Other objectionable conditions noted during this inspection were:

Pasteurizer deficiencies include: improper leak detection grooves on vat pasteurizers #46 and #47; vat pasteurizer temperature recording charts varying as much as seven degrees difference from the

mercury in glass indicating (official) thermometer; and an air space thermometer with excessive condensate making it illegible.

- Cross connections discrepancies include: raw foam in HTST balance tank number two rising up the flow diverter and leak detection lines toward the flow diversion valves; potable water to nonpotable sources, including a submerged water inlet at the HPLV tank located outside the plant; and an insufficient air gap between potable water line and starter room CIP make up tank overflow.
- Improper equipment construction and repair deviations include: an in-use collapsed raw whey "flip-flop" tank (number eighty-one); a reducing line used to connect the raw pressure sensor to the regenerator line of HTST number one which created a dead end; duct tape is used to hold dried lactose transfer lines together; a leaking centrifugal pump at the lactose wash station; a leaking positive displacement pump at HTST number one; and cracks and holes in the air boots which join the primary and main chambers of the lactose powder line.
- Lack of product protection includes: no lid on the cheese brine tank located outside the plant; improper drip deflector shields located on agitator shafts of the double "O" vats; an open vent on the feed tank to the ultrafiltration unit, which exposes the product inside this tank to potential contamination; an unfiltered fan blowing air through an elevated walkway directly on product at the whey/curd separator; leaking water coming from the ceiling of the curd room next to curd-whey separator which was in operation at the time; clean milk transfer hoses located outside in the raw receiving area stored with hose ends uncapped; and vat pasteurizers (numbers forty-two and forty-eight) contained product and had uncapped outlet valves.
- Equipment cleaning/housekeeping deficiencies include: old product residue trapped inside the vent of tank number eighty-three, which contains product; a build-up of dust, dirt, and debris on the unused string cheese equipment located next to the cheese and whey processing equipment, which was in operation during the inspection; there is no hot water at the raw milk silo hand wash sink, and a strong sour odor is coming from the drain located next to the freezer in the cheese cutting and packaging room.

These conditions present the likely possibility that foods processed at your plant could become adulterated with filth or pathogenic bacteria.

A food is considered adulterated within the meaning of Section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act if it bears or contains any poisonous or deleterious substance which may render it injurious to health, and under Section 402 (a) (3) of the Act if it consists in whole or in part of any filthy substance, or if it is otherwise unfit for food. In addition, 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.

Wesley J. Allen
Denver, Colorado

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The adulteration of food after shipment into interstate commerce is prohibited by Section 301(k) of the Act. The introduction of adulterated food in interstate commerce is prohibited by Section 301(a) of the Act. The Act provides for seizure of adulterated foods and for injunction against the manufacturer of adulterated foods.

At the conclusion of the inspection, Mr. Stephen Secrest, Plant Manager, promised to correct the violations listed on form FDA-483. This list is not meant to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act, and regulations promulgated thereunder, are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) working days of receipt of this letter, please notify FDA in writing concerning the extent to which those corrections have been implemented. Your response should include an explanation of any delays encountered, and a date by which you expect to attain full correction. Please direct your response to : Barbara Cassens, Regional Dairy Specialist, FDA Pacific Region, 1301 Clay Street, Suite 1180N, Oakland, CA 94612.

Sincerely,



Patricia C. Ziobro
District Director
San Francisco District/Pacific
Region

Enclosures:
Form FDA-483