

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 22201 23rd Drive SE Bothell, WA 98021-4421 (425) 486-8788 Fax: (425) 483-4996 Industry Information: www.fda.gov/oc/industry	<small>DATE(S) OF INSPECTION</small> 09/01/2010 - 09/10/2010
	<small>FEI NUMBER</small> 3004392984

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Kelli M. Estrella, Co-owner

<small>FIRM NAME</small> Estrella Family Creamery, LLC	<small>STREET ADDRESS</small> 659 Wynoochee Valley Rd
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Montesano, WA 98563-9313	<small>TYPE ESTABLISHMENT INSPECTED</small> Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Failure to manufacture and store foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination.

Specifically, on 9/1/10 cheese wheels were observed being stored in cheese storage Cave 1, in direct contact with rough-cut, undressed lumber shelving that showed a buildup of product residue.
 On 9/1/10 a leaking cooler water line in Cave 1 was observed dripping onto the top wood shelf within several inches of exposed cheese product.

OBSERVATION 2

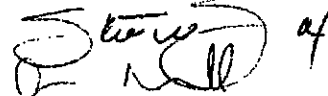
Failure to take necessary precautions to protect against contamination of food and food contact surfaces with microorganisms and foreign substances.

Specifically, the owner was observed on 9/1/10 removing a core of cheese from a wheel with a trier, placed a portion of cheese into her mouth, and replaced the cheese plug in the wheel, before loading it for transport to market. The trier was wiped with a rag after each use without apparent washing or sanitizing and no hand washing was observed before a repeat of this process.

OBSERVATION 3

Employees did not wash hands thoroughly in an adequate hand-washing facility after each absence from the work station and at any time their hands may have become soiled or contaminated.

Specifically, the owner was observed on 9/1/10 making multiple trips to transfer unwrapped ready-to-eat cheese from the processing area to the retail area and transport vehicle without washing her hands before handling other ready-to-eat cheeses.

SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> Scott W. Fox, Investigator JASON W. CURNELL, CSO		<small>DATE ISSUED</small> 09/10/2010
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OBSERVATION 4

Suitable outer garments are not worn that protect against contamination of food and food packaging materials. Specifically, the owner was observed on 9/1/10 carrying cheese wheels held against her street clothing from the storage and processing area to the retail packaging room.

OBSERVATION 5

Failure to take effective measures to protect against the inclusion of metal and extraneous material in food. Specifically, on 9/1/10 cheese wheels were observed stored directly on rough-cut wood shelving in Cave 1 that showed extensive splintering and loose wood particles. Loose nuts, bolts, tacks, and other metal parts were observed on several shelves next to product. A hand wrench was observed lying on one shelf in direct contact with a wheel of cheese.

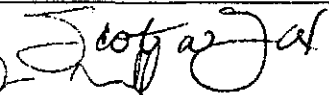
OBSERVATION 6

The materials and workmanship of equipment does not allow proper cleaning. Specifically, on 9/1/10 several of the cheese press pipes were observed with peeling paint and all had taped handles. The weights used to hang on the press handles were observed with a heavy buildup of rust on either end. Two employees were observed to alternately handle the pipes and weights and cheese molds and cloth containing curds. On 9/1/10 rough-cut, undressed lumber shelving and support structures used to store and age exposed cheese were observed in Cave 1.

OBSERVATION 7

Failure to maintain buildings, fixtures, or other physical facilities in a sanitary condition. Specifically, on 9/1/10 the following areas were observed to be soiled with hand prints, dark smudges, or splash residue:

- 1) The exterior of the plastic drawer/storage cabinet, next to a clean utensil storage rack, in the processing room.
- 2) The exterior and interior surfaces of the entrance door to cheese storage Cave 1.
- 3) The exterior and interior surfaces of the entrance door to cheese storage Cave 2.
- 4) The exterior and interior surfaces of the entrance door to cheese storage Cave 3.
- 5) The exterior and interior surfaces of the door between the main processing room and the hallway leading to cheese storage Caves 2 and 3.
- 6) The bare plywood panel above the window air conditioner unit in the main processing room.

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OBSERVATION 8

Failure to store cleaned and sanitized portable equipment in a manner which protects food-contact surfaces from contamination.

Specifically, on 9/1/10 several ounces of water were observed in each of four cleaned stainless steel milk buckets stored upright and lidded on a utensil drying/storage rack.

OBSERVATION 9

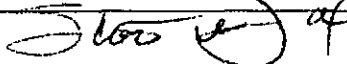
Effective measures are not being taken to exclude pests from the processing areas and protect against the contamination of food on the premises by pests.

Specifically, on 9/1/10 ten or more live, small flying insects were observed on the ceiling and walls of the milk room vestibule. At three of these insects were observed on the outside of the cheese cloth and molds of cheese draining on a work table in the processing room.

OBSERVATION 10

Failure to wear hair restraints where appropriate.

Specifically, the owner was observed on 9/1/10 not wearing hair restraint while carrying cheese wheels from the three storage caves and staging them on a work table in the main processing room.

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