DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	11/18/2025-12/2/2025* FEI NUMBER 1000522918

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Darlene O. Lopes, Co-Owner

FIRM NAME	STREET ADDRESS
Tony L. Lopes Dairy L.P.	27500 Bunker Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Gustine, CA 95322	Dairy

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

Your extralabel use of an approved human or animal drug caused a residue above an established safe level, safe concentration, or tolerance.

Specifically, your extralabel use of (b) (4) brand (b) (4) labeled sulfadimethoxine (b) (4) grams each) caused illegal drug residues to occur in two dairy cattle. These two dairy cows were offered for sale by your dairy to be slaughtered for human food consumption. Your employee (b) (6), (b) (7)(C)) stated he administers three (3) (b) (4) of (b) (4) per day, and your medication treatment records show these treatments can last for up to six (6) days for the treatment of (b) (4). Neither your veterinarian's prescription nor the product labeling of (b) (4) permits such dosage or length of treatment.

USDA tests found illegal sulfadimethoxine levels in the liver of a cow identified with your ear tag (b) (4). USDA reported a test result of 0.167 parts per million (ppm) of sulfadimethoxine in this cow in a letter dated December 16, 2024, referencing Form No. 103460347.

Additionally, USDA tests found illegal sulfadimethoxine levels in the liver of a cow identified with your ear tag (b) (4). USDA reported a test result of 0.256 parts per million (ppm) of sulfadimethoxine in this cow in a letter dated August 26, 2025, referencing Form No. 103651149.

A tolerance for sulfadimethoxine in the edible tissues of cattle has been established at 0.1 ppm.

OBSERVATION 2

You administered a prohibited drug in an extralabel manner to food-producing animal(s).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Thomas W Gordon, Investigator	X Thomas W Gordon Investigator Signed By: Thomas W. Gordon -S Date Signed: 12-02-2025 10:34:04	12/2/2025

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Specifically, you used a prohibited drug ((b) (4) brand (b) (4) labeled sulfadimethoxine (b) (4) grams each (b) (4)) in an extralabel manner. Your employee (b) (6), (b) (7)(C) stated he is administering three (3) boluses per day to your lactating dairy cattle weighing up to (b) (4) pounds for the treatment of pneumonia, and your medication treatment records show these treatments can last for six (6) days. Your veterinarian's prescription states, "GIVE (b) (4) PER 600 LBS (b) (4) AS AN INITIAL DOSE, FOLLOWED BY ½ (b) (4) PER 600 LB (b) (4) ONCE A DAY FOR 2–4 DAYS DO NOT TREAT BEYOND 5 DAYS."

For example, your medication treatment records for the cow identified with your ear tag (b) (4) show she was treated with (b) (4) on 8-15/16/17/18/19/20-2024. The administration of (b) (4) is recorded as the numeral four (4) in your treatment records. You stated your employees administered three (3) (b) (4) for each day of treatment. This treatment of three (3) (b) (4) s each day exceeds the dosage, and a treatment time of six (6) days exceeds the length of time allowed by your veterinarian's prescription.

Also, your medication treatment records for the cow identified with your ear tag (b) (4) show she was treated with (b) (4) on 7-24/25/26/27-2025. The administration of (b) (4) is recorded as the numeral four (4) in your treatment records. You stated your employees administered three (3) (b) (4) for each day of treatment. This treatment of three (3) (b) (4) each day exceeds the dosage allowed by your veterinarian's prescription.

OBSERVATION 3
You did not keep and maintain complete treatment records.

Specifically, your medication treatment records document the date of treatment, the ear tag of the treated cow, the condition being treated, the drug being administered, and sometimes the dose of the medication being administered. However, your records do not always document the dose administered, the route of

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administration, the individual administering the medication, the milk and slaughter withdrawal times for each animal drug administered, or the dates when those withdrawal times will be observed.

Additionally, you stated that your employees initially document their medication treatments on yellow paper pads and then transfer the information to your treatment records. You indicated that these yellow pads are discarded after a specified time. This was also confirmed with your employee (b) (6), (b) (7)(C) When asked to provide the yellow pads for the medication treatments for cows (b) (4) (August 2024) and (b) (4) (July 2025), you were unable to do so.

***DATES OF INSPECTION**

11/18/2025(Tue), 11/20/2025(Thu), 12/02/2025(Tue)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."