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	12/7/2021-12/9/2021* FEI NUMBER 3008325389

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Derek R. Veneman, Managing Partner

FIRM NAME	STREET ADDRESS
Temple Creek Dairy, Inc.	26250 Carter Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Escalon, CA 95320-9528	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, during the inspection on 12/07/21, you affirmed receiving a (b) (4) letter, dated (b) (4) with (b) (4) notifying that on or about (b) (4), you sold a cow to be slaughtered into food for human consumption which contained desfuroylceftiofur drug in the edible tissues. On (b) (4), the (b) (4) collected Sample No. (b) (4) of a cow identified with Back Tag (b) (6), (b) (7)(C) which was slaughtered for human food at (b) (4), located at (b) (4). (b) (4) identified this cow with a retain tag number (b) (6), (b) (7)(C) and tested its edible tissues which revealed the presence of violative levels of desfuroylceftiofur in the kidney tissues at (b) (4). The FDA has established the tolerance level of desfuroylceftiofur in the kidney tissues of cattle at 0.400 ppm.

OBSERVATION 2

You did not maintain complete treatment records.

Specifically, on 12/07/21, you provided for my review with copies of the handwritten medication treatment records and electronic records kept in (b) (4) program for the lactating cows. I observed that the medication treatment records for the suspect cow identified with Ear Tag (b) (6), (b) (7)(C) documented only the name of the drug administered in handwritten medication treatment records, and the name of the drug administered, the milk and meat withdrawal dates in electronic records. However, these medication treatment records are

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Gulshan R Anand, Investigator	X Gulshan R Anand Investigator Signed By: Gulshan R. Anand -S Date Signed: 12-09-2021 08:19:08	12/9/2021

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incomplete as they lacked the condition treated, route and dosage of the drug administered, and identity of the person administering the drug.

OBSERVATION 3

You did not use an approved drug according to directions specified in your veterinarian's prescription for frequency or duration of treatment.

Specifically, on 12/07/21, you stated that as a routine treatment practice to control pneumonia in the lactating cows, you administer at the (b) (4) (b) (4) of (b) (4) brand (b) (4) ((b) (4) (b) (4)). My review of the medication treatment records for the suspect cow identified with Ear Tag (b) (6), (b) (7)(C) revealed that on (b) (4) , this cow was administered with (b) (4) of (b) (4) brand (b) (4) ((b) (4) (b) (4)) at the (b) (4) . However, on (b) (4) that cow identified with Ear Tag (b) (6), (b) (7)(C) was again administered with (b) (4) of (b) (4) brand (b) (4) ((b) (4) (b) (4)) at the (b) (4) to treat its non-specific illness, which was later sold for beef on (b) (4) . This was an oversight by management, as this animal should not have been treated with Zoetis brand (b) (4) ((b) (4)). You stated the average weight of your dairy cows is approximately (b) (4) .

Your veterinarian's written prescription label pasted on the bottle of (b) (4) brand (b) (4) ((b) (4) (b) (4)) states in parts, "(b) (4) "

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Temple Creek Dairy, Inc.	26250 Carter Rd
CITY, STATE, ZIP CODE, COUNTRY Escalon, CA 95320-9528	TYPE ESTABLISHMENT INSPECTED Dairy

Therefore, you failed to follow your veterinarian's written prescription for the use of (b) (4) brand (b) (4) ((b) (4) (b) (4)) drug on your cows.

***DATES OF INSPECTION**
12/07/2021(Tue), 12/09/2021(Thu)

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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."