



Food Safety and
Inspection Service

January 17, 2014

Alameda District
620 Central Avenue,
Bldg. 2C
Alameda, CA 94501

Phone: (510) 769-5712
Fax: (510) 337-5081

(b) (6)
Rancho Feeding Corporation
Establishment 527 M
1522 Petaluma Blvd. North
Petaluma, California 94952

**CERTIFIED RETURN
RECEIPT REQUESTED**

e-mail: (b) (6)

Dear (b) (6):

We are in receipt of your response provided electronically to the Alameda District Office on January 15, 2014, responding to the Notice of Suspension initiated at your facility on January 14, 2014. This action was taken in accordance with Title 9 Code of Federal Regulations, Rules of Practice, Part 500.3(a)(1), because your establishment produced and shipped adulterated and misbranded products. Specifically, your establishment produced and shipped adulterated products into commerce due to your failure to present the products for ante mortem and post mortem inspection, as required by 21 U.S.C. 603(a) and 21 U.S.C. 604 of the Federal Meat Inspection Act (FMIA), and the regulations promulgated thereunder. As such, these products cannot enter commerce because they have not been inspected and found to be not adulterated and capable for use as human food as required under 21 U.S.C. 604 of the FMIA. In addition, the products were misbranded pursuant to 21 U.S.C. 601 (n)(1) in that the labels represented that the products had been inspected and passed, when, in fact, they had not been inspected and passed.

After a thorough review and evaluation of your written response submitted on January 15, 2014, to the Notice of Suspension (NOS), we have found your response to be inadequate to address the noncompliance identified in the NOS and cannot allow inspection service to resume at this time. There are several concerns that require further information and/or clarification.

1. In Item #1 of your response, you indicated that your establishment "*will segregate any animals observed by company personnel during unloading, moving or other activities related to the live animals, which are observed to have any obvious pathology or injury...*" Please clarify which areas/pens you will be placing the segregated animals in.

You provided "*Unloading Observation Procedure*" that discusses the procedures during unloading only. In Item #1 of your response, you indicate that animals will be segregated "*...during unloading, moving or other activities...*" Please clarify if you have written procedures for when your establishment segregates animals during moving or other activities.

Please clarify how you will ensure that employees who are responsible for observing for “*obvious pathology or injury*” and segregating the animals at receiving will conduct procedures as written, such as any training that will be conducted for these employees.

2. Furthermore, in Item #1, you indicated that “*when such identification of animals is done and they are segregated for ante-mortem inspection, the pen card will have a specific notation made on it regarding which animal was seen to exhibit what specific condition or pathology identified by Rancho personnel.*” You provided an example of the pen cards your establishment will be completing when conducting segregation of animals at receiving. Please clarify where on the pen card your personnel will document the “*specific notation*” on what condition the animal is exhibiting.
3. FSIS requests the establishment institute a procedure for communicating estimated time and date of arrival of animals.
4. Please clarify what your procedures are for separating and identifying animals that have received ante mortem inspection, from animals who have not yet received ante mortem inspection.
5. In Item #2, you indicate that “*a red colored tag*” will be applied to animals identified by FSIS as suspect. Please clarify if the red colored tag will have an identifier, such as a number designation, in order for your establishment to track the red colored tags. Please provide an example of the red colored tag your establishment will be using.

Furthermore, you provided a “*Suspect Post-Mortem Procedure*” form in which you will document the “*Carcass ID*”. Please clarify what carcass identification number you will be recording for the “*Carcass ID*” on the form.

You also provided a “*Suspect Post-Mortem Procedure*” program in which you indicate that if these procedures have not been completed, you will “*apply corrective actions and document to the corrective actions log.*” Your “*Suspect Post-Mortem Procedure*” form does not include an area for documenting corrective actions. Please clarify where you will be documenting corrective actions if your “*Suspect Post-Mortem Procedure*” is not being implemented.

6. In your “*Suspect Post-Mortem Procedure*” program you indicate that you will “*visually observe FSIS employee applying full inspection to the head, viscera and carcass*” and “*visually observe P.H.V. performing re-inspection*”

of carcass and viscera." FSIS objects to entries that confirm that USDA has completed adequate post mortem procedures.

7. In your submittal, you provided a HACCP Corrective Action form. Please clarify how this form relates to your corrective actions submitted and response to the NOS.
8. Please describe your procedures and policy for saving market heads, including your criteria on how you will determine if market heads are saved. Please clarify how you will be maintaining unique identification of each head and viscera so that they correspond to its specific carcass. Please explain how your establishment will document inventory control of your market heads.
9. Additionally, we request that the head rack be situated in a location visible to the inspector at all times.

The Alameda District personnel are available to review your submittal(s) and respond to all questions. If you have any questions, please call the Alameda District Office at (510) 769- 5712.

Sincerely,



Frank Gillis
Deputy District Manager

cc:
Y. Sharma, DM
A. Amin, DDM
V. Felix, DDM

(b) (7)(C)

USDA IIC, Est. 527 M



Food Safety and
Inspection Service

January 22, 2014

Alameda District
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AMENDED

Dear (b) (6) :

We are in receipt of your response provided electronically to the Alameda District Office on January 15, 2014, January 18, 2014, January 20, 2014, and January 21, 2014, responding to the Notice of Suspension initiated at your facility on January 14, 2014. This action was taken in accordance with Title 9 Code of Federal Regulations, Rules of Practice, Part 500.3(a)(1), because your establishment produced and shipped adulterated and misbranded products. Specifically, your establishment produced and shipped adulterated products into commerce due to your failure to present the products for ante mortem and post mortem inspection, as required by 21 U.S.C. 603(a) and 21 U.S.C. 604 of the Federal Meat Inspection Act (FMIA), and the regulations promulgated thereunder. As such, these products cannot enter commerce because they have not been inspected and found to be not adulterated and capable for use as human food as required under 21 U.S.C. 604 of the FMIA. In addition, the products were misbranded pursuant to 21 U.S.C. 601 (n)(1) in that the labels represented that the products had been inspected and passed, when, in fact, they had not been inspected and passed.

After a thorough review and evaluation of your written responses submitted to the Notice of Suspension (NOS), we have found your response to be inadequate to address the noncompliance identified in the NOS and cannot allow inspection service to resume at this time. There are several concerns that require further information and/or clarification.

1. On January 15, 2014, FSIS personnel observed two bovine carcasses in the carcass cooler with cooler tag #437 and #438. During records review, FSIS also observed on your establishment's kill sheet for cattle slaughtered on January 9, 2014, you had identified, the same two carcasses with cooler tag #437 and #438 were marked with the letter "e" indicating cancer eye cattle. Please explain why these two carcasses identified as having cancer eye are hanging in the cooler with other carcasses and are ready to be shipped into commerce.

2. FSIS determined that your establishment failed to present cattle produced on January 8, 2014, which were likely affected with epithelioma of the eye (cancer eye), a condemnable condition pursuant to Title 9 CFR 311.12, for required ante-mortem inspection and post-mortem inspection. These failures to present are evidenced by the fact that two cattle heads, which were found in commerce, were still intact, had skin still attached, and had no incisions for the four pairs of lymph nodes on the head, which normally are incised for inspection by FSIS personnel. In addition, there was no denaturant or USDA mark of condemnation on the heads. In light of these findings, please explain your intention for future purchasing of diseased animals particularly cancer eye animals.
3. Your establishment has not provided a mechanism to communicate the estimated time and date of arrival of animals to allow inspection personnel the opportunity to observe the unloading of animals in order to verify your *“Unloading and Animal Handling procedure”* and *“Individual Animal Tracking Procedure”*.
4. It is still unclear how your establishment plans to maintain proper identification for the carcass, head, viscera, and other parts such as feet of animals, once the back tags, ear tags and other identifiable information have been placed into the “plastic bag” and before the Cooler Tag is applied. Please clarify how you will maintain identification of these animals throughout the process. Also, please indicate where you will keep the plastic bag that contains the tag and if it will be affixed to the carcass, head, etc.
5. Please clarify if your establishment still maintains pens which are considered off premises. If so, please clarify where the off premise pens are located. Please clarify if your establishment will be unloading live animals in off premise pens and if these animals will be identified on the Individual Animal Tracking Procedure log. Please clarify what procedures you have in place to allow for inspection personnel to verify the animals that are unloaded into off premise pens.
6. Your establishment has requested that for Dead on Arrivals (DOAs), FSIS issue a Condemnation Certificate:
 - a) Please clarify if DOAs will be unloaded from the trucks to off premise pens. If they are unloaded into the off premise pens, please provide your procedures for presenting the DOAs to inspection personnel.
 - b) Please clarify when and how you will notify FSIS of DOAs which occur outside of operating hours.

- c) If DOA or Dead in the Pens (DIP) are in off premises pens, please clarify if your establishment will be requesting a Condemn Certificate from FSIS.
 - d) Please clarify if your establishment engages in collecting dead animals from the farm. If so, please provide procedures on how your establishment will dispose of those animals.
7. For DOAs, DIPs and animals condemned during Ante-Mortem, please provide additional information on how your establishment will ensure that the animals or parts thereof do not enter the food chain. Please provide the procedures including the chemicals your establishment is using to ensure adequate denaturing and proper disposal of DOAs, DIPs and animals condemned during Ante-Mortem.
8. Please clarify how your establishment will maintain the buyer and seller information for each animal received for inspection personnel to verify this information per Title 9 CFR 320.1(b)(1)(iv). This information is not captured on your establishment's new "*Individual Animal Tracking Procedure*" or the pen cards provided. FSIS is requesting clarification on where you will be documenting the buyer and seller information for each animal received.
9. Please identify who is responsible for ensuring that the corrective actions and proffered programs you provided will be adequately implemented. Please clarify who will be the plant contact person for FSIS for ensuring implementation of these procedures.

The Alameda District personnel are available to review your submittal(s) and respond to all questions. If you have any questions, please call the Alameda District Office at (510) 769- 5712.

Sincerely,
/S/ Abdalla Amin
For

Frank Gillis
Deputy District Manager

cc:
Y. Sharma, DM
A. Amin, DDM

V. Felix, DDM

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