



Food Safety and
Inspection Service

January 27, 2014

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

Phone: (510) 769-5712
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(b) (6)
Rancho Feeding Corporation
Establishment 527 M
1522 Petaluma Blvd. North
Petaluma, CA 94952

**CERTIFIED RETURN
RECEIPT REQUESTED**

E-mail: (b) (6)

NOTICE OF SUSPENSION HELD IN ABEYANCE

Dear (b) (6)

This letter confirms the verbal notification provided to you on January 24, 2014, that FSIS is placing the suspension in effect at Rancho Feeding Corporation, Establishment 527, in abeyance. This action is based on a determination that your corrective and preventive actions, as stated in your six submittals to the Alameda District Office and specified herein, have, at this time, addressed the statutory and regulatory concerns in the January 14, 2014, Notice of Suspension issued to your establishment.

This letter provides information on the basis for the suspension action, the establishment submittals and corrective and preventive actions, the basis for the Agency determination to place the suspension in abeyance, and your responsibilities and Agency verification activities relative to this matter, as well as other relevant information.

Suspension Action

On January 14, 2014, the Food Safety and Inspection Service (FSIS), Alameda District office, verbally notified you of the withholding of the marks of inspection and the suspension of the assignment of inspectors at your establishment for the Slaughter and Raw Intact (Raw Not Ground) processes. 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 product. Specifically, your establishment produced and shipped adulterated product 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 there under. This product is considered adulterated because it is unfit for human food as defined by 21 U.S.C. 601(m)(3) of the FMIA. 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. Your failure to prevent the production and shipment of adulterated product into commerce resulted in your establishment initiating,

in conjunction with FSIS, a voluntary Class I recall of these products on January 12, 2014.

Rancho's First Response

On January 15, 2014, your establishment provided your first response to the Notice of Suspension (NOS) dated January 14, 2014. Your submittal included some measures to correct the failures and provided some additional measures to prevent future occurrences.

After a thorough review and evaluation of your first response to the NOS, FSIS found your response inadequate to allow inspection service to resume at your establishment. On January 17, 2014, FSIS issued you a response letter identifying FSIS concerns with your first response. Specifically, your establishment failed to provide:

- Information about which areas/pens you would be placing the segregated animals in.
- Adequate clarification about the “*Unloading Observation Procedure*” that discusses the procedures during unloading only.
- Information on any written procedures for when your establishment segregates animals during moving or other activities.
- Documents demonstrating your employees have been trained on the new procedures.
- Adequate clarification on where your personnel will document the “*specific notation*” on what condition the animal is exhibiting.
- Your establishment’s procedure for communicating to FSIS the estimated time and date of arrival of animals.
- Information on 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.
- Adequate clarification about “*a red colored tag*” that will be applied to animals identified by FSIS as suspect. Your establishment failed to 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.
- Adequate information and documentation related to the “*Carcass ID*” number on your Suspect Post Mortem procedures. Your establishment failed to submit information on the Carcass ID number and how you will ensure the integrity of all animals.
- Information on your corrective actions referenced in your Suspect Post Mortem procedures.
- Information on your HACCP corrective action form,
- Your procedures and policy for saving market heads and also where you will be placing your head rack to ensure the rack is visible to inspection at all times.

In addition, your establishment proffered as part of your monitoring, you will depend on FSIS in-plant inspection activity to inform you of the adequacy of your program. However, FSIS stated to you that it is inappropriate, as a control measure for you to depend on FSIS inspection personnel activity within your establishment to verify the

accountability and integrity of the animals entering your establishment and further entering your slaughter facility.

Rancho's Second Response

On January 18, 2014, your establishment provided a second response to the NOS. Your response included the following revised documents: “*Daily Ante-Mortem and Cooler Inventory Procedure*”, “*Suspect Post Mortem Procedure*”, “*Unloading and Handling Observation Procedure*” and a training record. You revised your “*Unloading and Handling Observation Procedure*” to include the moving of animals as well as unloading of animals and clarified that the animals will be segregated into suspect pen ^{(b) (4)}. You indicated that Rancho employees will notate the condition of the animal on the lower portion of the pen card by checking the location of the abnormality. You indicated that your establishment will be instituting a two pen card system. You indicated that you will maintain records associated with the suppliers in accordance with 9 CFR 320. You provided a procedure for identifying animals that have received ante mortem from those that have not. You indicated that the purpose of the red colored tag is to visually inform your employees that the animal is suspect and to supplement the gang tag. You indicated that the “*Carcass ID*” number is the gang tag number. You indicated the HACCP form was inadvertently submitted and you provided your actual corrective action form for your Suspect Post Mortem procedures. You indicated that you may save market heads from animals under 30 months of age or the heads may be boned out. You indicated that the head rack is located on the wall located next to where FSIS personnel conduct post mortem inspection activities.

After a thorough review and evaluation of your second response to the NOS, FSIS found your responses thus far inadequate to resume and allow inspection service at the establishment. On January 19, 2014, FSIS held a conference call with your establishment representative and requested further information. Specifically, you failed to provide:

- Clarification on whether additional establishment personnel were trained on your new programs and procedures as the Training Log you provided attested to only one (1) individual having participated in the session.
- Information what your procedures will be to track all animals from the time they enter the property to the time that they reach finished product shipment.
- Adequate clarification 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. You failed to provide an example of the red colored tag your establishment will be using. During the call, your establishment representatives indicated that the red colored tag is used as a visual identifier for employees so that they are clear the carcass is suspect.

In addition, your establishment proffered as part of your monitoring, you will depend on FSIS in-plant inspection activity to inform you of the adequacy of your program. However, FSIS stated to you that it is inappropriate as a control measure for you to

depend on FSIS inspection personnel activity within your establishment to verify the accountability and integrity of the carcasses leaving your establishment.

Rancho's Third Response

On January 20, 2014, your establishment provided a third response to the NOS dated January 14, 2014. You submitted the following revised documents: "*Suspect Post Mortem Procedure*", and "*Unloading and Animal Handling Procedure*". In addition, you also provide an "*Individual Animal Tracking Procedure*" (IATP) and additional training records. You also indicated that the "*Daily Ante Mortem and Cooler Inventory Procedure*" had been replaced with IATP. The IATP disclosed unloading date, Rancho Feeding back tag number, any other IDs accompanying the animal, date animal presented for antemortem, lot number, cooler tag number, and final postmortem disposition. You provided a response letter that indicates that the tracking procedures will identify each animal upon receipt through the process. You revised the language in your "*Suspect Post-Mortem Procedure*" regarding verification of FSIS inspection activities.

After a thorough review and evaluation of your third response to the NOS, FSIS, again, found your response inadequate to allow and resume inspection service at your establishment. On January 21, 2014, FSIS held a conference call with you and your establishment representatives and requested additional documentation, information and clarification on your corrective actions. Specifically, you failed to provide:

- Adequate clarification for your "*Individual Animal Tracking Procedure*" form and the "*Suspect Post-Mortem Procedure*".
- Procedures for handling animals identified as Dead on Arrival (DOA), Dead in Pens (DIP) and condemned at ante mortem.

You indicated during the conference call that the Red Tag and Back Tags would be incorporated in the revised programs and that programs are dated to keep track of revisions.

Rancho's Fourth Response

On January 21, 2014, your establishment provided a fourth response to the NOS. You submitted the following revised documents: "*Suspect Post Mortem Procedure*", "*Unloading and Animal Handling Procedure*" and "*Individual Animal Tracking Procedure*".

After a thorough review and evaluation of your fourth response to the NOS, FSIS, again, found your response inadequate to allow and resume inspection service at your establishment. On January 22, 2014, FSIS issued you a response letter identifying the concerns with your fourth response. FSIS also held a conference call with your establishment representative to discuss that your response required additional information. Specifically, your establishment failed to provide:

- Information on how you planned to maintain proper identification for the carcass, head, viscera, and other parts once the back tags, ear tags and other identifiable information have been placed into the “*plastic bag*” and before the Cooler Tag is applied.
- Adequate clarification on whether your establishment still maintains pens which are considered off premises.
- Information if your establishment engages in collecting dead animals from the farm.
- Information regarding DOAs, DIPs and animals condemned during Ante-Mortem and procedures for how your establishment will ensure that the animals or parts thereof do not enter the food chain.
- Information on how your establishment will maintain the buyer and seller information for each animal received so inspection personnel can verify this information.
- Identification of who is responsible for ensuring that the corrective actions and proffered programs you provided will be adequately implemented.
- Clarification on your intention of future purchasing of diseased animals

In addition, FSIS also requested information on the two carcasses identified as having cancer eye hanging in your cooler with other carcasses and are ready to be shipped into commerce.

Rancho’s Fifth Response

On January 22, 2014, you provided your fifth response, which included a response letter that indicated your normal receiving hours for animals are 6AM to 6PM, Monday through Friday. You specified that on rare occasions when animals are unexpectedly delayed for any reason and arrive after 6 PM, they will be received in a humane manner. You indicated that the back tag and other identification will be maintained in a plastic bag affixed to the carcass. You indicated that DOAs and DIPs may be in the off premise pens and will be moved on premise for inspection. You indicated that the dead on arrival, dead in pen, and ante-mortem condemned animals will be denatured and placed in the inedible bin for pick up by the rendering company. You further stated that you will receive and off-load any Dead on Arrival (DOA) animals from trucks bringing animals for slaughter at Rancho Feeding and that you do not intend to be a dead animal collection center. You indicated that you will maintain traceback records in accordance with the regulations and that you would be the individual responsible for ensuring the new programs and procedures are adequately implemented.

On January 23, 2014, FSIS held a conference call with you and your establishment representatives to discuss your latest submittal and the remaining items that require additional information and clarification. Specifically, you failed to provide:

- Adequate clarification on whether you would be purchasing diseased animals.
- Information on your off premise pens and the supplier records you are maintaining.

We reviewed the diagram, in your response, of the establishment's designated official premises and it includes pens that are referred to as "*off premises*". We asked in light of this information if you would consider these areas as part of the official premises, and you stated yes.

Rancho's Sixth Response

On January 23, 2014, you provided your sixth response. In your response letter, you indicated that in addition to your procedures and programs for tracking animals through the process to ensure animals are presented for inspection, your establishment will take all reasonable measures to avoid the purchase of any animal showing any observable form of disease, including but not limited to cancer eye. You clarified that you will request, from FSIS, condemn certificates for animals which are DOA, DIP or condemned on Ante Mortem inspection. In addition, these animals are controlled by FSIS via a red condemn tag. Your establishment also clarified that the Bill of Sale will be used for the purpose of tracing carcasses to the live animal purchases and that those records would be made available to FSIS upon request.

Abeyance of Suspension Action

After a thorough review and evaluation of your proffered corrective and preventive actions, FSIS determined that your combined six submittals addressed the concerns in the Notice of Suspension. FSIS has decided to hold in Abeyance the NOS to afford you the opportunity to implement your proposed action plan. This letter confirms the verbal notification provided to you on January 24, 2014.

During this Abeyance period, FSIS will continue to verify, assess, and evaluate the efficacy of the corrective and preventive actions you have implemented to assure that all procedures are followed, and, as necessary, corrective actions are taken. FSIS has designed a Verification Plan to confirm that your establishment fully implements all corrective and preventive actions proffered by your establishment. This verification plan identifies your corrective and preventive actions, inspection task codes and the regulatory requirement under which FSIS inspection personnel will verify implementation and effectiveness of your corrective and preventive actions. FSIS will provide a copy of the FSIS Verification Plan to assist you in understanding the nature and importance of the agency's verification activities.

Conditions and Responsibilities

We expect that upon resuming operations under Federal inspection, your establishment will implement the commitments you provided in your six submittals in response to the NOS. Please be advised that only FSIS can amend the verification plan.

Please be reminded that as an operator of a federally inspected facility, you are expected to comply with the FSIS regulations and to take appropriate action to prevent the production or shipment of adulterated or misbranded product. The regulations require establishments to take appropriate action(s) when either the establishment or FSIS identifies regulatory noncompliance or that the establishment's SSOP, HACCP or other systems may be ineffective.

It is also important for you to understand that FSIS has the responsibility to initiate actions, if your establishment fails to operate, in accordance with the regulations, or conditions occur that may render products unwholesome or adulterated. In these situations, FSIS personnel will continue to take action to control regulated product and may also take other administrative enforcement action. FSIS may initiate further administrative enforcement actions, including the withdrawal of the grant of inspection in accordance with 9 CFR Part 500.6 and the Uniform Rules of Practice, 7 CFR sub-title A, Part 1, Subpart H.

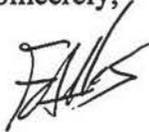
Please be aware that your failure to comply with regulatory requirements and to present animals for ante mortem and postmortem inspection may result in immediate reinstatement of the suspension of inspection at your establishment or other appropriate action. In addition, your failure to effectively implement the commitments, proposed actions, and agreements that you made with FSIS, that were the basis for holding the Suspension in Abeyance, may result in the immediate reinstatement of the suspension of inspection at your establishment or other appropriate action.

In accordance with Title 9 CFR 500.5(a)(5), you may appeal this action by contacting:

Dr. Hany Sidrak
Executive Associate for Regulatory Operations
1400 Independence Avenue, SW
Room 3157-S
Washington, DC 20250
Phone: 202-205-4208

If you have any questions, please call the Alameda District Office at (510) 769-5712.

Sincerely,



Frank Gillis
Deputy District Manager

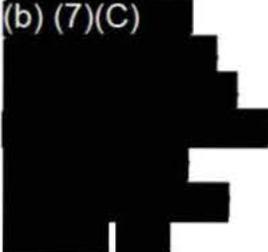
cc:

Y. Sharma, DM

A. Amin, DDM

V. Felix, DDM

(b) (7)(C)

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A. Khroustalev, IEA, RD

USDA IIC, Est. 527 M

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