



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

93757d

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

December 18, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L #13-03

William Cramer
Owner
Diamond Pacific
P.O. Box 758
Perris, CA 92572

Dear Mr. Cramer:

An inspection of your licensed medicated feed mill located at 17971 Highway I-215, Perris, CA, conducted May 16 through June 7, 2002, found significant deviations from the current Good Manufacturing Practice (cGMP) regulations for licensed medicated feed manufacturers (Title 21, Code of Federal Regulations, Part 225). Such deviations cause feeds being manufactured at your facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

Section 501(a)(2)(B) of the Act states that a drug shall be deemed adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with cGMP, to assure that such feed meets the requirements of the Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

Our investigators documented that there is no assurance that the methods used in and the controls used for the manufacture of your medicated and non-medicated feeds are in conformity with cGMPs. These deviations from the regulations were reported to you in the Inspectional Observations, FDA-483, which was issued at the conclusion of the inspection and included the following:

- Failure to test on periodic basis feeds manufactured using a category II Type-A medicated article. Specifically, you did not conduct the required number of assays of all medicated feeds containing [REDACTED] (carbadox), [REDACTED] (tilmicosin), [REDACTED] (chlortetracycline, sulfathiazole, & penicillin), [REDACTED] (neomycin & oxytetracycline) or other drugs during calendar 2001 or 2002. [21 CFR § 225.58 (b)(1)]
- Your firm has an inadequate procedure identifying which feeds may be sequenced. Specifically, your procedure allows the manufacture of a finished swine feed after the producing a feed containing tilmicosin which has a seven day slaughter withdrawal time; the manufacture of turkey and broiler finish feeds after the manufacture of a feed containing amprolium which has a 24 hour slaughter withdrawal time; and the manufacture of a horse ration after a feed containing monensin which is toxic to equines. [21 CFR § 225.65 (b)(3)]
- Failure to maintain production records for the required length of time. Specifically, your production manager stated that batch production records were not being maintained for a one year period. [21 CFR § 225.102 (b)(2)]
- Failure to comply with Veterinary Feed Directive (VFD) requirements. Specifically, you did not have the original of the VFD and there was no ready means to determine which batch of medicated feeds was manufactured and distributed for each VFD to verify that only the prescribed amount of feed was distributed. [21 CFR § 558.6 (e)(1)]
- It was further determined that you are using drugs in a manner contrary to their approved labeling--specifically your use of [REDACTED] a drug approved for oral administration in the drinking water of animals. Such extra-label use is not permitted, except by or on the lawful written or oral order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship, and otherwise in compliance with the limitations set forth for specific extra-label uses. [21 CFR §§ 530.10 - 11] Your use of any drugs except those specifically approved for use in animal feeds is strictly forbidden. Use of such drugs in an animal feed causes those drugs to be adulterated under Section 501 (a)(5) of the Act because there is no approval for such use as required by Section 512 (a)(1)(B) of the Act.

These violations are not intended to be an all-inclusive list of deficiencies at your milling facility. As a producer of medicated and non-medicated feeds, you are responsible for assuring that your establishment is in compliance with all requirements of the federal regulations. Several of the violations noted during this inspection are similar to those cited during previous inspections.

We are also concerned about your firm's lack of required assays. While your firm investigated out-of-specification assay results, the extent of that investigation was insufficient to identify the root cause. Out-of-specification assays may be the result of any number of circumstances. It is critical that you evaluate all possible causes and determine as objectively as possible the likely basis for the unexpected or out-of-specification result. Possible causes to consider include, but are not limited to: age and storage of the medication, mixing time, age and quality of equipment used, scale accuracy, sampling technique, physical characteristics of the equipment and commodities, or human error. Each contributing factor should be considered when corrective action is implemented. There are numerous resources available for additional guidance in this area. These include university outreach services, industry associations, private consultants and government agencies.

We acknowledge your promise during the inspection to discontinue the use of prohibited materials, however, the degree of carry-over of medicated feeds remains a concern. We are concerned about the lack of consistent cleaning of the manufacturing system between feeds containing prohibited materials and ruminant feeds. Our investigators documented at least five occasions within the past year when you failed to sequence and/or flush the appropriate portions of the production system between the time of receipt of prohibited materials or their use in the manufacture of feeds and the subsequent receipt of ingredients used in the manufacture of ruminant feeds. You should perform a complete and detailed evaluation of your production equipment and processes to ensure you minimize or eliminate carry-over of medicated feeds. [21 CFR § 225.65] Enclosed with this letter is a copy of the current GMP requirements for medicated feeds and regulations for firms handling prohibited materials.

You should take prompt action to correct and prevent recurrence of the deviations listed in the FDA-483. Failure to promptly correct these deviations may result in regulatory action including, but not limited to, seizure, injunction and/or notice of opportunity for a hearing on a proposal to withdraw approval of your license. This letter constitutes official notification under the law and provides you an opportunity to correct the cited deviations.

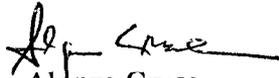
Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific actions taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the cGMP violations and prevent their recurrence. Please include copies of any available documentation showing that corrections have been made. If corrective actions cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed. If you have any questions or clarifications regarding this letter prior to your written response, you may contact Barbara Rincon, Compliance Officer at (949) 798-7739.

Letter to Mr. Cramer
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Please direct your written response to the attention of:

Thomas L. Sawyer
Director, Compliance Branch
United States Food and Drug Administration
19900 MacArthur Blvd., Ste. 300
Irvine, CA 92612

Sincerely,


Alonza Cruse
District Director

Enclosure 21 CFR 225 & 21 CFR 589.2000