



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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FB 11/2/00

Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

November 1, 2000

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

Ref. KAN-2001-007

Mr. Charles Crumbaker, Feedmill Manager
Crumbaker Pork, LLC
4337 W. Smolon Road
Salina, Kansas 67401

Dear Mr. Crumbaker:

On August 14, 2000, we conducted an inspection of your feed mill in Salina, Kansas. The investigator documented deviations from the Good Manufacturing Practices (cGMP) Regulations for medicated feeds Title 21, Code of Federal Regulations, Part 225 (21 CFR 225). These deviations cause medicated feeds manufactured by your firm to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food Drug and Cosmetic Act (the Act).

Deviations noted include the following:

1. Five master formulas do not match the actual rations being produced. [21 CFR 225.102 (b)(1)(iv)]
2. The drug inventory record does not accurately show drug lot number used on days when lot number changes and is used in more than one type of feed. [21 CFR 225.42 (b)(6)(ii)]
3. Production record does not include name and quantity of drug component use in each batch/run. [21 CFR 225.102 (b)(2)(ii)]
4. Drug levels in the feed do not comply with legal levels allowed on drug label for CTC 50 (chlortetracycline) for three rations; Grower 1, Starter 3, and Starter 2. [21 CFR 225.42 (a)]
5. There is no documentation available to indicate an accuracy test was performed on the fat meter. [21 CFR 225.30 (b)(3)]
6. The tube that conveys the drug to the mixer had residual buildup of rust and micro ingredients. [21 CFR 225.65 (b)]

MRM:

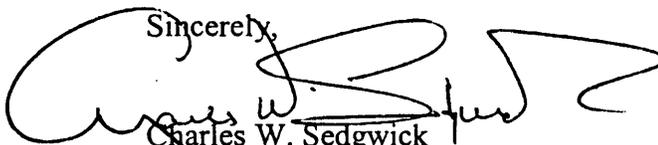
Mr. Charles Crumbaker
Crumbaker Pork, LLC
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The above observations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all medicated feeds manufactured by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt action to correct these violations and establish appropriate procedures that will prevent their recurrence. Failure to promptly correct these cGMP violations may result in regulatory action and/or administrative sanctions without further notice. These sanctions include but, are not limited to, seizure or injunction.

You should notify this office in writing within fifteen (15) working days of receipt of this letter. Include in your response any corrective actions you have taken or plan to take and have yet to complete. Include copies of any available documentation demonstrating the corrections made. All the items stated in your response will be verified during our next inspection. If you have further questions or concerns, you should reply directly to Monica R. Maxwell, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles W. Sedgwick", written over a horizontal line.

Charles W. Sedgwick
District Director
Kansas City District