



Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

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April 7, 2004

Warning Letter No. 2004-NOL-21

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Joseph F. Sanderson, Jr., President/CEO
Sanderson Farms, Inc.
225 North 13th Avenue
Laurel, Mississippi 39440

Dear Mr. Sanderson:

An inspection of your medicated and non-medicated animal feed operations, located at Copiah County Industrial Park, Gallman, Mississippi, conducted by a U.S. Food and Drug Administration (FDA) investigator during January 13 - 15, 2004, found significant deviations from the Current Good Manufacturing Practice (CGMP) requirements for Medicated Feeds, Title 21, *Code of Federal Regulations*, Part 225 (21 CFR 225). Such deviations cause the medicated feeds 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).

Our investigation found the following:

1. You failed to investigate and take corrective action for significant discrepancies between actual drug usage and theoretical drug usage [21 CFR 225.42(b)(7)]. For example:
 - On January 6, 2004, you used [] of [] above the theoretical quantity to manufacture [] batches of bulk chicken feed;
 - On January 2, 2004, you were [] of [] below the theoretical quantity to manufacture [] batches of bulk chicken feed;
 - On January 1, 2004, you used [] of [] above the theoretical quantity to manufacture [] batches of bulk chicken feed;
 - On January 2, 2004, your records indicate that you did not use any [] and [] to manufacture [] batches of bulk medicated chicken feed labeled as containing these ingredients; and,

- On December 31, 2004, you used [] of [] above the theoretical quantity to manufacture [] batches of bulk chicken feed.
 - You failed to compare the actual amount of drug used and the theoretical amount of drug used on January 7, 8, and 12, 2004 [21 CFR 225.42(b)(7)]. During this period, you manufactured [] batches of Broiler Starter Feed, containing [] [] and [] batches of Broiler Grower Feed, containing [] []
- 2) You failed to have an approved master formula to manufacture [] batches Broiler Starter Feed #2173 on January 8, 2004, and [] batches of the same feed on January 4, 2004 [21 CFR 225.102(b)(1)].
 - 3) Labels were not initialed and dated by a responsible individual [21 CFR 225.80(b)(2)].
 - 4) Your firm fails to have a Master Record file for manufacturing specific products, which provides the complete procedure for manufacturing specific products [21 CFR 225.102(a)].
 - 5) Your firm also fails to maintain a receipt record for each lot of drug received [21 CFR 225.42(b)(5)].

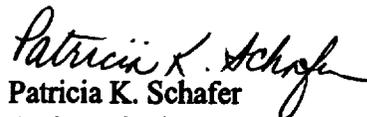
The above is not intended to be an all-inclusive list of deviations from the regulations or CGMP requirements. As a manufacturer of medicated and non-medicated animal feeds, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

You should take prompt action to correct these violations, and you should establish a system whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action, such as seizure and/or injunction, and/or administrative sanctions. The sanctions may include notice of opportunity for a hearing on a proposal to withdraw approval of your Medicated Feed Mill License, under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 514.115(c)(2). This letter notifies you of our findings and provides you an opportunity to correct the cited deficiencies.

We are aware that [] Feed Mill Manager, promised to correct the deviations noted during the inspection. We are in receipt of your firm's response written by [] [] Ph.D., Corporate Nutritionist, received in our office on January 26, 2004. Although you begin to address our concerns, you have not provided any documents demonstrating corrections have been made nor did you explain how you will prevent their recurrence. You should notify this office in writing, within thirty (30) working days of the receipt of this letter, of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within thirty (30) working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Mark W. Rivero, Compliance Officer, at the above address.

Sincerely,


Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: FDA Form 483

cc: Mr. Steve M. Hefner, Feed Mill Manager
Sanderson Farms, Inc.
Post Office Box 506
Hazlehurst, MS 39083