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May 20, 1999

WARNING LETTER NO. 99-NOL-30**FEDERAL EXPRESS**
OVERNIGHT DELIVERY

Paul V. Sella, Jr., General Manager and CEO
Producers Feed Company
Highway 49 West
Isola, Mississippi 38754

Dear Mr. Sella:

An inspection of your medicated feed mill, located at Highway 49 West, Isola, Mississippi 38754, conducted on April 7 and 9, 1999, found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title 21, *Code of Federal Regulations* (CFR), Part 225). Such deviations cause medicated feeds being manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act). Observations include, but are not limited to, the following:

1. Failure to conduct an adequate investigation and corrective action for out-of-limit assay results for medicated feeds containing Ormetoprim and Sulfadimethoxine;
2. Failure to modify the production room formula to comply with actual amounts of ingredients listed in the #74/A Master Formula for catfish feed;
3. Failure to modify the production records to comply with the Master Formula for the sinking catfish feed formulation;
4. Failure to maintain calibration records for the scale used to weigh drug ingredients;
5. Failure to maintain a completed Master Formula that describes the current labeling that accompanies PFC 35% Catfish Food Medicated (2); and
6. Failure to sign and date the daily drug inventory record upon review.

In addition, your firm is manufacturing feeds containing animal protein concentrates that were produced from ruminants. All feeds containing a protein derived from ruminants must comply with 21 CFR 589.2000. Enclosed is a copy of the regulation and a paper entitled *FDA Guidance for Industry 68*.

The above is not intended to be an all-inclusive list of CGMP violations. As the manufacturer of medicated and non-medicated feeds, you are responsible for assuring that your overall operations and the products you manufacture and distribute are in compliance with the law.

You should take prompt action to correct these CGMP violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these CGMP violations may result in regulatory and/or administrative sanctions. The sanctions include, but are not limited to, seizure, injunction, and/or notice of opportunity for a hearing on a proposal to withdraw approval of your license, under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 514.115(c)(2). This letter constitutes official notification under the law.

Based on the results of the April 7 and 9, 1999 inspection, evaluated together with the evidence before FDA when your license was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

You should notify this office in writing, within 15 working days of 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 CGMP violations and prevent their recurrence. If corrective action cannot be completed within 15 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 addressed to the U.S. Food and Drug Administration, Attention: Patricia K. Schafer, Compliance Officer, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896. If you have any questions or desire a meeting with Agency staff, you may contact Ms. Schafer at (504) 589-7166.

Sincerely,



 James E. Gamet
District Director
New Orleans District

Enclosure FDA-483