



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Received 5/24/99 pm

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Public Health Service

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Food and Drug Administration
New Orleans District
Southeast Region
4298 Elysian Fields Ave.
New Orleans, LA 70122

Telephone: 504-589-6341
FAX: 504-589-6360

May 21, 1999

WARNING LETTER NO. 99-NOL-28

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Ralph T. Oldham, President
Oak Grove Pork Farm, Inc.
12789 Hwy 17
Oak Grove, Louisiana 71263

Dear Mr. Oldham:

An inspection of your medicated feed mill, located at 12789 Hwy 17, Oak Grove, Louisiana, conducted on April 1, 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 maintain daily drug inventory records;
2. Failure to maintain records for the assays of medicated feeds from the period December 12, 1996 to the present date; and,
3. Failure to maintain records for the calibration of the scales.

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.

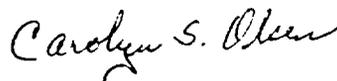
Based on the results of the April 1, 1999 inspection, evaluated together with the evidence before FDA when your license was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds are inadequate to assure and preserve the

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,



for James E. Gamet
District Director
New Orleans District

Enclosure: FDA-483