



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

June 3, 1998

Ref: 98-DAL-WL-37

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Mike Reed, President and CEO
PM Ag Products, Inc.
17475 Jovanna Drive
Homewood, IL 60430

Dear Mr. Reed:

An inspection of your medicated feed mill located at 7600 J.W. Peavy, Houston, Texas, conducted by a Food and Drug Administration (FDA) investigator on May 1; May 4 through 8; and May 12 through 14, 1998, 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).

The deviations include, but are not limited to the following:

1. Failure to perform drug potency assays for medicated feeds containing lasalocid, and labeled as ruminant free-choice liquid feeds. Our inspection revealed drug potency assays have not been performed since about November, 1997.
2. Failure to perform pH and viscosity testing for liquid medicated feeds containing lasalocid. Additionally, the pH meter used for determining pH was not properly maintained.
3. Failure to properly maintain a drug inventory record for the use of lasalocid.
4. Failure to perform daily comparisons of actual usage of lasalocid with theoretical usage of the drug after October 21, 1997. Additionally, six (6) noted discrepancies between actual and theoretical usage of the drug were not investigated.

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5. Failure to maintain adequate manufacturing instructions that include mixing times for the medicated feeds containing lasalocid and monensin.
6. Failure to test for accuracy the digital weight scale used to weigh drug ingredients.

The above is not intended to be an all-inclusive list of CGMP violations. As a 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.

At the conclusion of the inspection a Form FDA-483, Inspectional Observations, was issued to and discussed with Mr. Stephen A. Jannik, Manager for Bulk Liquid Storage. This form is a comprehensive listing of the investigator's observations of deviations found during the inspection. A copy is enclosed for your information.

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 this current 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 manufacturer, 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.

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Your reply should be addressed to Reynaldo R. Rodriguez, Jr., Compliance Officer, at the above letterhead address.

Sincerely,



Joseph R. Baca
Dallas District Director

Enclosure - FDA-483

JRB:RRR:jab

cc: Mr. Stephen A. Jannik
PM Ag Products, Inc.
7600 J.W. Peavy
Houston, Texas 77011