



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Certified/Return Receipt Requested

April 23, 1997

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

WARNING LETTER

Paul S. Davis, President &
General Manager
Interstate Marine Terminal
P.O. Box 43
Boonville, Missouri 65233

Ref. # - KAN-97-015

Dear Mr. Davis:

An inspection of the medicated feed mill operation known as PM AG Products, Inc., located at 103 County Road 463, New Franklin, Missouri, for which you are the contract operator, was conducted by an investigator from this office on March 17 and 18, 1997. This inspection found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (21 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 (Act).

Our investigation found: 1) failure to conduct the three required annual assays for liquid Type B feed containing the drug combination of monensin and tylosin; 2) failure to show documentation of mix time studies that would indicate medicated Type B liquid feeds were adequately mixed; 3) failure of the Master Record Files to contain mixing instructions, mixing steps and times.

The above is not intended to be an all-inclusive list of violations. As a manufacturer of medicated feeds, you are responsible for assuring that your overall operation and the products you manufacture are in compliance with the law. At the conclusion of the inspection Form FDA 483, Inspectional Observations, was issued to you. This form is a comprehensive listing of deviations observed by the investigator during the inspection. A copy of this form is enclosed for your information.

You should take prompt action to correct the noted violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may

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Page 2
April 23, 1997
Interstate Marine Terminal, Inc.

result in regulatory and/or administrative sanctions. These 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 facility 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 March 17 and 18 inspection, evaluated together with the evidence before FDA when the 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 fifteen (15) working days of receipt of this letter, to inform us of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. You may address your reply to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District

Enclosure - Form FDA 483

cc: Michael A. Reed, President
PM AG Products, Inc.
1055 W. 175th Street
Homewood, IL 60430