

**Certified/Return Receipt Requested**

February 18, 1997

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
PO Box 15905
Lenexa, Kansas 66285-5905

Telephone (913) 752-2100

WARNING LETTER

Burdette L. Frew, President
MFA, Inc.
201 Ray Young Drive
Columbia, Missouri 65201-3599

Ref. # - KAN-97-08

Dear Mr. Frew:

An inspection of your medicated feed mill operation, MFA, Inc., 465 West Marion, Marshall, Missouri, conducted by FDA investigators from this office on January 21 to 23, 1997, 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 potency assays on at least three representative samples of feeds containing Carbadox, and CSP, both Category II drugs, at periodic intervals during the calendar year of 1996; 2) failure to document follow-up investigations on reports of out-of-tolerance drug assays.

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

We have received and reviewed a letter from Mr. Hunt dated January 30, which is a response to the Form FDA 483 observations. The letter was reviewed prior to the issuance of this letter. It appears from the letter that proper steps are being taken to correct the noted deviations.

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MFA, Inc.

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 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 January 21 to 23 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 if the January 30 letter will suffice as your response to this letter, or you may expand on that letter with additional information concerning corrections being made. 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: Ronald K. Hunt, General Manager
MFA, Inc.
465 West Marion
Marshall, MO 65340