



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

g1052d

March 23, 2001

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

Ref: 2001-DAL-WL- 14

**WARNING LETTER**

**VIA CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Brad Kerbs, President/CEO  
Purina Mills, Inc.  
1401 South Hanley Rd.  
St. Louis, Missouri 63144

Dear Mr. Kerbs:

An inspection of Purina Mills, Inc., 1108 N.W. 3<sup>rd</sup>, Oklahoma City, Oklahoma, conducted by a Food and Drug Administration investigator on February 2/6 and 13/14, 2001, 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 the 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).

A List of Inspectional Observations, Form FDA-483, describing the deviations was presented to Mr. Ron Duvel, Plant Manager, at the completion of the inspection. I have attached a copy of the FDA-483 for your information.

The inspection showed the failure of your firm to follow Purina's established SOP for Drug Sequencing Requirements, and that those established procedures provide for production of animal feed for a species for which a drug component of the medicated feed is not approved. Your firm failed to conduct the required assays of medicated feeds for drug components, and failed to properly identify bulk drug components in a manner that will assure their identity, strength, quality, and purity. Training of employees responsible for CGMPs and the quality and purity of medicated feeds is not being documented.

The inspection also showed a continuing failure by your firm to ensure quality control over labeling operations for bagged medicated feeds since June 2000. Distribution of medicated feeds lacking feeding directions and required withdrawal information may result in violative drug residues in the edible tissue of food producing animals, and create public health concerns.

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Such distribution may also create conditions of over use of medication, ineffectiveness in medical treatment, or unsafe use in an animal species for which a drug has not been approved. Drug products distributed without complete labeling are misbranded pursuant to Sections 502(e)(1)(A) and 502(f)(1) of the Act.

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 distribute are in compliance with the law.

This office has reviewed your firm's written response, dated February 20, 2001, addressed to Mr. Michael Chappell, District Director. The response is unsatisfactory for the following reasons:

Observations 1 and 2 – Because of the distribution of feeds from your facility without complete labeling since June 2000, no assurance has been provided verifying that the two “Cornerstone MIP” products containing Chlortetracycline and Sulfamethazine, may not have been fed to lactating dairy animals. In the instance where Amprolium is sequenced into “Equine Junior” feed, the response indicates there are no human or animal safety concerns. For your information, drug residue concerns may exist when drugs, not approved for use in equine, are present in horses slaughtered and exported for human consumption.

Observation 8 – The procedure described, for maintaining lot number and expiration date in a log book, does not identify the bulk drug and its container (other than original container) with the lot number and expiration date. Therefore, the procedure does not meet the requirement that the drug components be stored in a manner such that their identity, strength, quality, and purity will be maintained.

Observation 13 – The response does not include documentation of the actual medicated feed CGMP and/or quality control training the Quality Program Supervisor has received, verifying that person's qualifications to perform required job functions.

Observations 15 and 16 – The response does not include documentation demonstrating CGMP compliance. No assurance has been provided demonstrating that medicated feed production records, showing a check of the daily drug component inventory records, have been reviewed for discrepancies and initialed by a responsible individual at the end of the day, and prior to distribution. Questioning of QC and Production Supervisors during the inspection indicates this review and documentation in not conducted.

Observation 19 – The response does not provide documentation demonstrating CGMP compliance with the regulation requiring complete Master Record Files. Additionally, when questioned, the Production Supervisor was unable to provide the investigator information

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documenting established mixing times for the various medicated feeds being produced.

You should take prompt action to correct these 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. 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 Medicated Feed Mill 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 current inspection, evaluated together with the evidence before FDA when the Medicated Feed Mill 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, strengths, 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 the receipt of this letter of the steps you have taken to further correct the continuing areas of non-compliance identified above, and to bring your firm into full compliance with the law. Documentation responding to the issues should be provided to this office. 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 response should be directed to James R. Lahar, Compliance Officer at the above address.

Sincerely,



*for*

Michael A. Chappell  
Dallas District Director

MAC:jrl

Enclosure: FDA-483

cc: Ron Duvel, Plant Manager  
1108 N.W. 3<sup>rd</sup>  
Oklahoma City, Oklahoma 73106