



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Food and Drug Administration  
New Orleans District  
Southeast Region  
6600 Plaza Drive, Suite 400  
New Orleans, Louisiana 70127

Telephone: 504-253-4519  
Facsimile: 504-253-4520

December 13, 2001

**WARNING LETTER NO. 2002-NOL-16**

**FEDERAL EXPRESS  
OVERNIGHT DELIVERY**

Mr. Fred Rogers Adams, Jr., President  
Cal-Maine Foods, Inc.  
3320 W. Woodrow Wilson Avenue  
Jackson, Mississippi 39209-3409

Dear Mr. Adams:

An investigation of your medicated feed mill, located at 17521 Old Highway 80 West, Edwards, Mississippi, conducted on November 6 – 9, 2001, by a U.S. Food and Drug Administration (FDA) investigator found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds, Title 21, *Code of Federal Regulations*, Part 225 (21 CFR 225). Such deviations cause 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).

Our investigation found failure to maintain correct documentation of actual drug usage during production; failure to conduct required potency assays on at least three representative samples of each feed at periodic intervals during the calendar year; failure to manufacture medicated feeds in accordance with the master file formula; failure to maintain a daily inventory for each drug used; failure to maintain a drug inventory for each lot of drug on hand; and, failure to maintain complete master record files and production records.

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 operation 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. 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 515.22(c)(2). (This letter constitutes official notification under the law).

Based on the results of the November 6 – 9, 2001, 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, 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 thirty (30) working days of the 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 actions cannot be completed within thirty (30) 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 addressed to the U.S. Food and Drug Administration, Attention: Ms. Nicole F. Hardin, Compliance Officer, at the above address. If you have questions regarding any issue in this letter, you may direct them to Ms. Hardin at the above address or at 504-253-4519.

Sincerely,

  
Carl E. Draper  
District Director  
New Orleans District

Enclosure: FDA Form 483

cc: Mr. Joe Markus Wyatt, Sr.  
Vice President of Feeds Division  
Cal-Maine Foods, Inc.  
Post Office Box 2960  
Jackson, Mississippi 39209

Mr. Jimmy N. Kendrick  
Feed Mill Manager  
Cal-Maine Foods, Inc.  
Post Office Box 2960  
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