



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Food and Drug Administration  
Atlanta District Office

94785d

60 8th Street, N.E.  
Atlanta, Georgia 30309

April 28, 2004

**VIA FEDERAL EXPRESS**

Lonnie Pilgrim  
Chairman of the Board  
Pilgrim's Pride Corporation  
110 South Texas Street  
Pittsburg, Texas 75686-0093

**WARNING LETTER**  
**(04-ATL-07)**

Dear Mr. Pilgrim:

An inspection of your medicated feed mill located at 654 Univeter Road in Canton, Georgia, was conducted by a Food and Drug Administration investigator between January 28 and February 3, 2004. That inspection found significant deviations from the Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title 21, Code of Federal Regulations (21\_CFR), Part 225). Such deviations cause the poultry 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).

You have failed to establish adequate cleanout procedures for all equipment used in the production and distribution of feed, to avoid unsafe contamination of medicated and non-medicated feeds, as required by 21 CFR 225.65. No written procedures or records were available describing the method or frequency of cleanout procedures used on the weigh lorry and [REDACTED] delivery trucks. You have failed to establish the suitability of the limited flush currently performed on your delivery trucks. The flush involves only one of the [REDACTED] compartments in the delivery vehicles. These procedures should address the method(s) of cleanout used between medicated and non-medicated feeds and after feeds containing pesticides.

Drug inventory records maintained could not be established as an accurate daily comparison of the actual amount of drug used with the theoretical drug usage, as required by 21 CFR 225.42(b)(7). The beginning inventory listed in the records is

assumed to be the same as the previous days' closing inventory. Your firm lacked documentation to verify that the beginning amount had been verified to be correct, as required by 21 CFR 225.42(b)(6)(i). One of the critical determinations is a physical measurement (LBS. IN BIN/CAN) which can vary significantly depending upon the person taking the measurement. Another factor (the "lbs ABOVE FUNNEL") is calculated by computer using a formula which no one could provide. No investigation is to be initiated until a discrepancy of [REDACTED] pounds in the inventory is obtained. No explanation could be provided as to how the [REDACTED] pound figure was determined to be the cut off for significant discrepancies. The figure appeared to be excessive.

A Master Record File was not available which provided the complete procedure for manufacturing all medicated feeds at the facility, as required by 21 CFR 225.102. The file should include complete procedures for manufacturing feed containing Type A medicated articles which include mixing steps and times. The batch production records generated are not checked at the end of the working day to determine whether all required production steps have been performed, as required by 21 CFR 225.102(b)(4). The production record generated is not sufficient to allow for this review. The batch record review currently performed is to determine only if a production note has been generated. A production note is to be generated when formula deviations, production errors, or equipment malfunctions occur during manufacture of a batch. Production records which do not contain a production note were not reviewed by a responsible individual at the end of the day.

Incoming labels are not proofread upon receipt from the printer against the Master Record File to verify suitability and accuracy, as required by 21 CFR 225.80(b)(2). This could explain why the labels applied to bulk shipments of feeds containing Cyromazine are inaccurate. The labels state that the feeds contain 1 lb/ton but the feeds are formulated to contain .01 lb/ton.

The above is not intended as an all-inclusive list of CGMP violations. At the conclusion of the inspection, the Inspectional Observations (FDA 483) was issued to and discussed with George S. Bass, General Manager. An amended copy of the FDA 483 is provided for your review. Further review indicates that the observations (#3 and #4) dealing with assays were a misinterpretation of the requirements. These observations should be disregarded. 21 CFR 225.58 does not require three drug assays for each feed formula, rather it requires three drug assays for each drug or drug combination for which a feed mill license is needed. Further, a drug assay is required for the first batch of feed ever made with the drug or drug combination which requires a feed mill license, not the first batch of feed made each year with that drug. However, on a related matter, our review found that the assay limits you are using for Roxarsone are incorrect. The limits should be 85 – 120%. Had these limits been utilized, assay #197167 would have been subpotent. 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). Based on the results of our 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 fifteen (15) 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 action 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 reply should be sent to the Food and Drug Administration at the above letterhead address to the attention of Philip S. Campbell, Compliance Officer.

Sincerely,



Mary Woleske, Director  
Atlanta District

Enclosure

cc: George S. Bass, General Manager  
Pilgrim's Pride Corporation  
6554 Univeter Road  
Canton, Georgia 30115-2814