



DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEI 1150085

53204.1
Food and Drug Administration
Baltimore District Office
Central Region
6000 Metro Drive, Suite 101
Baltimore, MD 21215-3215
Telephone: (410) 779-5454
FAX: (410) 779-5707

02-BLT-03

November 14, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

David Vanhouse, Chief Executive Officer
Pilgrim's Pride Corporation
P.O. Box 5000
Pittsburgh, TX 95686

Dear Mr. Vanhouse,

The Food and Drug Administration inspected your medicated feed mill located at Rt. 220 South Industrial Park, Moorefield, West Virginia, on September 26, 2001. Our inspection found significant deviations from Current Good Manufacturing Practice (CGMP) Regulations for Medicated Feeds, Title 21, Code of Federal Regulations (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 (the Act).

The observations of concern to us are as follows:

1. A drug inventory shall be maintained of each lot or shipment of drug by means of a daily comparison of the actual amount of drug used with the theoretical drug usage. Any significant discrepancy shall be investigated and corrective action taken, to comply with 21 CFR 225.42 (b)(7). Your firm failed to perform investigations and document the causes of discrepancies in daily inventory records in at least 36 instances since September 01, 2001, in which the limit for drug inventory reconciliation was outside of the stated 3 - 4 percentage range.
2. Batch production records shall be checked by a responsible individual at the end of the working day in which the product was manufactured to determine whether all required production steps have been performed, to comply with 21 CFR 225.102 (b) (4). Your firm failed to review production records on a daily basis.
3. All scales and metering devices shall be tested for accuracy upon installation and at least once a year thereafter, or more frequently to insure their accuracy, to comply with 21 CFR 225.30 (b)(4). Your firm failed to produce documentation to identify when feed scales were last calibrated.

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4. Accompanying labeling must include drug level, directions for use, and any required withdrawal or warning statements for safe and effective use of medicated feed, to comply with 21 CFR 225.80. Your firm failed to include on the labeling for bulk chicken feed, the BSE caution statement, even though prohibited material is used in these feeds.
5. Labels and labeling, including placards, upon receipt from the printer, shall be proofread against the Master Record File to verify their suitability and accuracy, to comply with 21 CFR 225.80. You failed to validate the computerized bulk feed labeling program to verify that all entered information is printed.

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.

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 violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction, and/or notice of an opportunity for a hearing on a proposal to withdraw approval of your application under Section 512 (m)(4)(B)(ii) of the Act and 21 CFR 514.115 (c)(2). Based on the results of the September 26, 2001 inspection, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feed 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.

Your letter dated October 18, 2001, responding to the FDA inspection of your establishment on September 26, 2001, has been received. Items #2, #4, and #5 appear to be adequately addressed. However, for item #1 you should define "excessive inventory deviations", as a matter of company policy. Also, for item #3, we advise that you document the bi-weekly calibration of all scales. Corrective actions addressed in your letter may be referenced in your response to this letter, as appropriated.

Please notify this office in a detailed written response within 15 working days of receipt of this letter, of the steps you have taken to correct the noted violations and to prevent recurrence. If corrective action can not be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

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You should direct your response and questions to the Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215-3215, to the attention of Vinetta Howard-King, Compliance Officer. Ms. Howard-King can be contacted at telephone number (410) 779-5454.

Sincerely,

A handwritten signature in black ink, appearing to read 'L. Bowers', written in a cursive style.

Lee Bowers
Director, Baltimore District

Cc: Mr. Mark T. Nazelrodt
Feed Mill Manufacturing Manager
Rt. 220 South Industrial Park
Moorefield, WV 26836