



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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11/30/00

Public Health Service

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Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

November 29, 2000

VIA FEDERAL EXPRESS

Koch Poultry Company, Inc.
4404 West Beteau Avenue
Chicago, IL 60641

ATTN: Joseph C. Grendys

Warning Letter No. 01-NSV-06

Dear Mr. Grendys:

An inspection of your medicated feed mill located at 1001 Birmingham Highway, Chattanooga, Tennessee, on August 14-18, 2000, found continuing, 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 the medicated feeds 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).

Noted deviations included: (1) failure to conduct daily drug inventories comparing the actual amounts of drugs used with the theoretical amounts used in manufacturing; (2) failure to investigate significant discrepancies in the daily drug inventory; (3) failure to record receipts of incoming [REDACTED] and failure to include this medicated premix in the daily drug inventory; (4) failure to document all flushes of the pellet mill between runs of medicated and withdrawal feeds; (5) failure to have master record files that include all necessary manufacturing and control directions; and (6) failure to review batch production records timely to ensure all production steps were completed and documented.

This letter is not intended to be an all-inclusive list of the deficiencies at this facility. It remains your responsibility to ensure compliance with all requirements of the Act and regulations. We are enclosing a copy of the Form FDA 483 that was issued to David A. Parker, Feed Mill Manager, at the termination of our inspection.

You should take prompt action to correct the noted violations and prevent any recurrence. Failure to do so can result in regulatory action, such as seizure and/or injunction, without further notice.

Please notify this office in writing, within 30 days of receipt of this letter, of the specific steps you have taken to address the noted deviations and to prevent any recurrence.

Your reply should be directed to the attention of Frank J. Jancarek, Compliance Officer, at the following address:

Food and Drug Administration
297 Plus Park Boulevard
Nashville, Tennessee 37217

Sincerely,



Carl E. Draper
Director, New Orleans District

CED:FJJ:man

Enclosure