



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

93662d

Food and Drug Administration
New Orleans District Office
Nashville Branch
297 Plus Park Blvd
Nashville, TN 37217 JEF

November 1, 2002

VIA FEDERAL EXPRESS

Mr. John H. Tyson, CEO
Tyson Foods, Inc.
P.O. Box 2020
Springdale, AR 72765

Dear Mr. Tyson:

Warning Letter No. 03-NSV-03

An investigation of your medicated feed mill located at 35800 Alabama Highway 21 North, Talladega, Alabama, conducted by a Food and Drug Administration investigator on September 23-25, 2002 found significant deviations from the Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title 21 Code of Federal Regulations (CFR), Part 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.

Our investigation found failure to 1) maintain an accurate daily inventory record for each drug used (21 CFR 225.42(b)(7)); 2) investigate and implement corrective action for significant discrepancies between actual drug usage and theoretical drug usage (21 CFR 225.42(b)(7)); 3) investigate and implement corrective action when production records document the manufacture and shipment of super potent medicated feed (21 CFR 225.102(b)(4)); 4) flush all manufacturing equipment and failure to ensure that the amount of flush material used is adequate to prevent cross contamination (21 CFR 225.65(b)); and 5) document the supplier's lot number or other identifying number for each lot of medicated article received (21 CFR 225.42(b)(5)).

The above is not intended as 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).

Based on the results of the September 23-25, 2002 inspection, 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 licensed 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 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 directed to Kari L. Batey, Compliance Officer, at 297 Plus Park Blvd., Nashville, TN 37217.

Sincerely,


Carl E. Draper
Director, New Orleans District

CED: KLB:bd

Enclosures:

21 CFR Part 225
21 CFR Part 515.22

cc: Roland B. Dyess, Manager
Tyson Foods, Inc.
35800 Alabama Hwy 21 N.
Talladega, AL 35160