DEPARTMENT OF HEALTH AND HUMAN SERVICE

9510Sd

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 9, 2004

WARNING LETTER NO. 2005-NOL-07

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Alan O. Bostick, President
Sunshine Mills, Inc.
500 6th Street SW
Red Bay, Alabama 35582

Dear Mr. Bostick:

On September 7 and 14, 2004, a United States Food and Drug Administration (FDA) investigator inspected your animal feed manufacturing facility, located at 2103 South Gloster Street, Tupelo, Mississippi. The inspection revealed significant deviations from the requirements set forth in Title 21, *Code of Federal Regulations*, Part 589.2000 (21 CFR 589.2000) – Animal Proteins Prohibited in Ruminant Feed. The regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). Because you failed to follow the requirements of this regulation, products you manufactured and/or distributed are misbranded within the meaning of Section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection indicated you manufacture products containing beef meat and bone meal. Products that contain or may contain protein derived from mammalian tissues, as defined by 21 CFR 589.2000(a), and are intended for use in animal feed, must be labeled with the cautionary statement "Do not feed to cattle or other ruminants." This is required by 21 CFR 589.2000(c)(1)(i). Your firm failed to label your non-ruminant products with this required cautionary statement. Specifically, the products that contained protein derived from mammalian tissues but lacked the required statement included your "Happy Fisherman" and "Premier" catfish feeds. Under 21 CFR 589.2000(g)(2), failure of these feeds to bear the required cautionary statement causes them to be misbranded under Section 403(a)(1) of the Act.

The above is not intended to be an all-inclusive list of deviations from regulations. As a manufacturer of materials intended for animal feed use, you are responsible for assuring your overall operation and products you manufacture and distribute are in compliance with the law. A copy of FDA's Small Entity Compliance Guide is enclosed to assist you in complying with the regulations.

You should take prompt action to correct these violations and establish a system whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action, such as seizure and/or injunction, without further notice.

We are aware you sent label corrections for the last shipment of each of the mislabeled products. You also stated you plan [redacted] However, you should notify this office in writing, within 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 taken to correct violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for delay and date by which corrections will be completed. Include copies of any available documentation demonstrating corrections have been made.

Please send your reply to the U.S. Food and Drug Administration, Attention: Nicole F. Hardin, Compliance Officer, at the above address. If you have questions regarding any issue in this letter, please contact Ms. Hardin at (504) 253-4519.

Sincerely,

H. Tyler Thornburg
District Director
New Orleans District

Enclosures: FDA Form 483
FDA's Small Entity Compliance Guide
21 CFR 589.2000

cc: [redacted]
General Manager
Sunshine Mills, Inc.
2103 South Gloster Street
Tupelo, Mississippi 38801