



Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4500
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February 23, 2001

WARNING LETTER NO. 2001-NOL-11

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Denny Hickman, President
Peco Foods, Inc.
1020 Lurleen B Wallace Blvd. N
Tuscaloosa, AL 35401-2225

Dear Mr. Hickman:

An inspection of your licensed medicated and non-medicated animal feed operation, located at Highway 19 North, Philadelphia, Mississippi, conducted by a U.S. Food and Drug Administration (FDA) investigator during February 13-15, 2001, found significant deviations from the requirements set forth in Title 21, *Code of Federal Regulations*, Part 589.2000 (21 CFR, Part 589.2000) – Animal Proteins Prohibited in Ruminant Feed. The animal proteins prohibited from use in ruminant feed are unapproved food additives as defined in Section 201(s) of the Federal Food, Drug, and Cosmetic Act (the Act). The regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). Such deviations cause products being manufactured and/or distributed by your facility to be adulterated within the meaning of Section 402(a)(2)(C) and misbranded within the meaning of Section 403(f) of the Act. Additionally, our investigator documented significant deviations from the Current Good Manufacturing Practice (CGMP) requirements for Medicated Feeds (21 CFR, Part 225). Such deviations cause the medicated feeds manufactured at your facility to be adulterated within the meaning of Section 501(a)(2)(B) and misbranded within the meaning of Section 502(c) of the Act.

Our investigation found a failure to label your finished product with the required cautionary statement **“Do Not Feed to Cattle or Other Ruminants.”** The FDA suggests the statement be distinguished by different type size or color or other means of highlighting the statement so that it is easily noticed by a consignee or contract grower.

Regarding CGMP violations documented, observations include failure to identify the bulk medicated feed and provide directions for safe and effective use; failure to properly identify, store, and control medicated articles to maintain their identity and integrity; and, failure to maintain complete master record files, and production and distribution records.

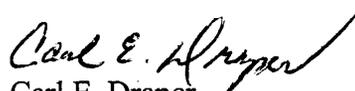
The above is not intended to be an all-inclusive list of deviations from the regulations or CGMP requirements. As a manufacturer of medicated and non-medicated animal feeds, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law. Enclosed is a copy of the FDA's Small Entity Compliance Guide to assist you with complying with the regulations.

You should take prompt action to correct these violations, and you should 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, and/or administrative sanctions without further notice. The sanctions may include 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 514.115(c)(2). (This letter constitutes official notification under the law.) Based on the results of this inspection, evaluated 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 cited 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 violations and prevent their recurrence. If corrective action cannot be completed within fifteen (15) 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 directed to Rebecca A. Asente, Compliance Officer, at the above address.

Sincerely,


Carl E. Draper
District Director
New Orleans District

Enclosures: FDA Form 483
FDA's Small Entity Compliance Guide

cc: Mr. Jerry M. Thornton, Feed Mill Manager
Peco Farms, Inc.
P.O. Box 646
Philadelphia MS 39350