



Dallas District  
3310 Live Oak Street  
Dallas, Texas 75204-6191

December 18, 1998

Ref. 99-DAL-WL-5

**WARNING LETTER**

**VIA FACSIMILE**  
**and FEDERAL EXPRESS**

Mr. R. Arthur Dean  
President  
Evergreen Mills Inc.  
P.O. Box 548  
Ada, OK 74821

Dear Mr. Dean:

An inspection of your medicated feed mill located at Ada, Oklahoma, conducted by a Food and Drug Administration investigator on September 16 and 24, 1998, found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title 21, Code of Federal Regulations, 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).

Our investigation found that your firm does not flush or clean mixing equipment between batches of feed medicated with different active drug ingredients. Also, your firm does not flush or clean mixing equipment between batches of medicated and non medicated feed. Accurate daily drug inventories and complete files and production records, were not maintained. The potency assays were not performed at periodic intervals during the calendar year, on at least three representative samples of each feed requiring a Medicated Feed Application. Inaccurate or non calibrated measuring devices were used to measure the drug ingredients in the product.

The above is not intended to be 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 and follow procedures whereby such violations do not recur. Failure to promptly correct these CGMPs

Page 2 - Mr. Dean  
Evergreen Mills, Inc.  
December 18, 1998

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 Form FDA 1900s (Medicated Feed Applications) 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 the September 16 and 24, 1998 inspection, evaluated together with the evidence before the FDA when the Form FDA 1900s were approved, 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.

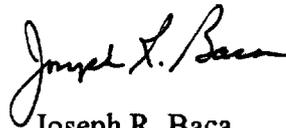
Until the CGMP violations have been corrected and the corrections verified by the FDA, the Center for Veterinary Medicine will not approve medicated feed applications for your facility.

You should notify this office in writing within 15 working days of 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 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 the Food and Drug Administration at the above address to the attention of Mariza Ujaque-Pesante, Acting Compliance Officer. If you have specific questions about this letter, you can contact me at (214) 655-5313 extension 534.

Sincerely,



Joseph R. Baca  
District Director