



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

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Purged Edw 7/1/98

60 8th Street, N.E.
Atlanta, Georgia 30309

June 2, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

J. Gordon Dixon, President
Animal Repellants Inc. (ARI)
2523 South McDonough Highway
Orchard Hill, GA 30266

WARNING LETTER

Dear Mr. Dixon:

During an inspection of your veterinary drug manufacturing facility located at 2523 South McDonough Road, Orchard Hill, GA 30266, conducted on March 11, 13, 16, 18, 1998, our investigator found significant deviations from the Good Manufacturing Practice for Finished Pharmaceutical (Title 21, Code of Federal Regulations, Part 211). Such deviations cause veterinary drugs 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 the following deviations from Good Manufacturing Practices:

- Failure of batch records to have documentation of labeling for the lots manufactured.
- Failure of batch records to have documentation of a determination of yield.
- Failure of batch records to have a signature of the person weighing out components.
- Failure to have STANDARD OPERATING PROCEDURES for equipment cleaning.
- Failure to document equipment cleaning and to validate the cleaning method and products used.
- Failure to calibrate the two scales used to weigh drug components in production.
- Failure of the firm's master formulas to have approving signatures.
- Incomplete batch records.
- Failure to document a final review of batch records.
- Failure to have a defined quarantined area in the warehouse for drug components and products prior to release.
- Failure to record temperatures for the firm's accelerated stability apparatus or the hot water bath used in production quality control.
- Failure to have most of the firm's STANDARD OPERATING PROCEDURES dated and signed.

FURAL (NADA product)

- Failure to document steps used to produce the first batch of Fural.
- Failure to have signature of the person(s) who mixed the batch.
- Failure to perform an in-process assay for the furazolidone as the NADA states.
- Failure to submit to FDA the same batch records with the NADA that were actually developed at the firm during the production of the batch.
- Failure to perform an identity test on any drug component and failure to have a STANDARD OPERATING PROCEDURE for an identity examination for the components upon receipt.

The above is not intended to be an all-inclusive list of violations. As a manufacturer of veterinary drugs, 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 violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

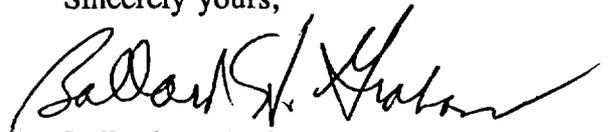
You should notify this office in writing upon receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within a reasonable number of days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

Due to the deficiencies listed in this letter and on the FDA-483 issued at the conclusion of the inspection, we have recommended to the CENTER FOR VETERINARY MEDICINE that approval of the ALTERNATE PACKAGER OF THE FINISHED DRUG PRODUCT, FURAL AEROSOL POWDER (fuzolidone) application be withheld.

Federal agencies are advised on the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

Your reply should be directed to the Food and Drug Administration, attention John J. McCall, Compliance Officer, at the address listed in the letterhead.

Sincerely yours,



Ballard H. Graham
Director, Atlanta District