



M 2050N

September 9, 1998

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER
CHI-40-98

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Bruce Baker, CEO
Agri-Nutrition Group
13801 Riverport Drive, Ste. 111
Riverport Executive Center
Maryland Heights, Missouri 63043

Dear Mr. Baker:

During an inspection of your veterinary drug manufacturing and repackaging facility located at Glendale Heights, Illinois, conducted on July 9, 13 and 15, 1998, our investigator found significant deviations from the Good Manufacturing Practice regulations for Finished Pharmaceuticals (Title 21, Code of Federal Regulations, Part 211). Such deviations cause veterinary drugs manufactured/repackaged 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 inspection found:

- Lack of written procedures for:
 - cleaning stripping machine used to repack antibiotic tablets;
 - examination and issuance of labeling and packaging materials; and
 - conducting recalls.
- Batch records do not include documentation for:
 - cleaning of manufacturing/repackaging equipment;
 - issuance of labeling and line clearance;
 - calculation of finished product yield/actual; and
 - review of the complete batch record by QC prior to final distribution.
- Lack of data/validation study to show that repackaging process for "DriTail" (neomycin solution) ensures homogeneity of the packaged drug.
- Lack of an ongoing stability program for manufactured/repackaged drugs.

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The inspection also determined this facility in Glendale Heights, IL, is not currently registered as a drug establishment as required by Section 510 of the Act and 21 CFR Section 207 of the regulations. Registration forms were sent to Mr. Mulholland at the conclusion of the inspection.

The above is not intended to be an all-inclusive list of violations. As a manufacturer/ repacker of veterinary drugs, you are responsible for assuring that your overall operation and the drugs 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 within 15 working days of receipt of this letter, of the specific steps you have taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working 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.

Your reply should be directed to the Food and Drug Administration, Attention: Paul Boehmer, Compliance Officer.

Sincerely,

\s\
Raymond V. Mlecko
District Director

cc: Michael Mulholland, General Manager
Mardel Laboratories, Inc.
1958 Brandon Court
Glendale Heights, IL 60139