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Food and Drug Administration  
Minneapolis District  
240 Hennepin Avenue  
Minneapolis MN 55401-1999  
Telephone: 612-334-4100

**PURGED**

April 11, 2000

xc: HFI-35  
DWA

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**Refer to MIN 00 - 27**

Steven C. Uselman  
Owner  
Uselman Electric, Inc.  
Highway 71 South  
Wadena, Minnesota 56482

Dear Mr. Uselman:

During our inspection of your Uselman Electric, Inc. veterinary drug repacking facility located in Wadena, MN, our investigator found serious violations of the current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 [21 CFR 211]. Your veterinary drug products are adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

The violations observed during our inspection include but are not limited to the following:

1. Failure to establish written procedures for cleaning and maintenance of equipment, including utensils, used in the packing and holding of a drug product [21 CFR 211.67].
2. Failure to establish written procedures for the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures [21 CFR 211.80].
3. Failure to establish written procedures and prepare master production and control records for each drug product to assure uniformity from batch to batch [21 CFR 211.186].
4. Failure to prepare batch production and control records for each batch of drug product produced [21 CFR 211.188].

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5. Failure to establish written procedures for the receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials [21 CFR 211.122].
6. Failure to establish written procedures describing the distribution of drug products [21 CFR 211.150].
7. Failure to establish written procedures describing the handling of all written and oral complaints regarding a drug product [21 CFR 211.198].

The above indication of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction. This is official notification that FDA expects all your locations to be in compliance.

You should notify this office in writing within 15 working days of receipt of this letter of 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 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be sent to Acting Compliance Officer Michael W. Roosevelt at the address on the letterhead.

Sincerely,



James A. Rahto  
Director  
Minneapolis District

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