



M2250n

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

# PURGED

December 10, 1998

cc: HFI-35/FOI Staff  
DWA

## WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 07

Sam Scimemi  
President  
Falls Chemical Products, Inc.  
123 Caldwell Avenue  
Oconto Falls, Wisconsin 54154

Dear Mr. Scimemi:

During a recent inspection of your veterinary drug manufacturing facility located at Oconto Falls, WI, our investigator found major deviations from the Good Manufacturing Practice Regulations for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). These deviations cause the 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 investigations found that *none* of the requirements of 21 CFR 211 are being followed. The following are examples:

1. You have no written records or procedures. The Good Manufacturing Practice Regulations for Finished Pharmaceuticals requires various written records to be maintained and all procedures to be reduced to writing.

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2. The equipment used to manufacture the teat dips is rusted and in need of cleaning.
3. The components of the teat dips are not tested for strength and identity before being used in the production of the teat dips. No certificates of analysis are on file.
4. The finished products are not tested for strength and identity before release for sale.
5. Garbage, old containers, and unmarked containers are in the manufacturing area.
6. An unenclosed toilet is in the manufacturing area.

In addition, the articles, 0.5% iodine teat dip with skin conditioners and 1% iodine teat dip with skin conditioners, are misbranded within the meaning of Section 502(o) of the Act in that they were manufactured in an establishment not duly registered under Section 510 of the Act and the articles have not been listed as required by Section 510(j).

The above is not intended to be an all-inclusive list of violations. As a manufacturer of veterinary drugs you are responsible for ensuring 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 within 15 days or 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 15 working days, state

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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 Compliance Officer Robert P. Snell at the address indicated on the letterhead.

Sincerely,

  
James A. Rahto  
Director  
Minneapolis District

RPS/ccl