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PURGED *RFK*

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

February 9, 1999

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 -16

James E. Cherwinka
President
Wausau Chemical Corporation
2001 N. River Drive, P. O. Box 953
Wausau, Wisconsin 55402-0953

Dear Mr. Cherwinka:

During a recent inspection of your veterinary drug manufacturing facility located at Wausau, WI, our investigators found major deviations from the Good Manufacturing Practice 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 significant deviations from the requirements of 21 CFR 211 including the following examples:

No written specifications, standards, or test procedures have been established for components, containers or drug products.

Ingredient components, containers, and closures are not examined or sampled and tested according to written specifications.

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There is no written testing program designed to assess the stability characteristics of the drug product, nor are reserve samples for testing retained.

No written procedures exist for the cleaning and maintenance of equipment used in the manufacture of drug products.

Failure to maintain adequate batch production and control records. For example: (a) lack of a review and approval of each batch prior to shipment of each drug products; (b) production record for teat dip manufactured on August 13, 1998 (lot code 890813), is missing.

For a more complete listing of the adverse findings please refer to the form FDA-483 issued on January 14, 1999, at the conclusion of the inspection.

In addition, the articles 0.5 % teat dip and teat spray 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). You will find enclosed with this letter Drug Establishment Registration and Drug Product Listing forms with an instruction booklet.

The sample of Teat Dip Spray 5000 was analyzed and the pH was found to 5.38. The labeling states a pH range of 5.0-5.3.

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.

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You should notify this office in writing within 15 days of 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 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 Acting Compliance Officer John T. Quaife at the address indicated on the letterhead.

Sincerely,


James A. Rahto
Director
Minneapolis District

JTQ/ccl

Enclosures: Forms FDA-2656, 2657