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7/8/98



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

PURGED *PK*

March 6, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98-17

Clemence A. Fischer
President
Fischer's Mills, Inc.
N1273 Highway 73
Princeton, WI 54968

Dear Mr. Fischer:

During our inspection of your veterinary drug manufacturing facility located at Markesan, WI, conducted on February 12 & 20, 1998, 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). 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).

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

- (1) Failure to adequately test your finished product, teat dip, for the percent of available iodine [21 CFR 211.165(a)];
- (2) Failure to determine actual yields and percentages of theoretical yields at the conclusion of each batch production in that your final recorded yield is more than the actual total amounts of water and *~~~~~* used to manufacture a batch [21 CFR 211.103];
- (3) Failure to adequately test your incoming raw material, *~~~~~* and failure to receive a certificate of analysis (COA) in lieu of such testing [21 CFR 211.84 (d)(2)];
- (4) Failure to conduct stability studies on finished products and to assign

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expiration dates based on these studies [21 CFR 211.137(a)];

- (5) Failure to follow the Operations Manual in that you are not changing the water filter cartridges on the  Mixing and Filling stations at three month intervals and you are not documenting when the water filter cartridges are changed [21 CFR 211.160(a)];
- (6) Failure to maintain adequate batch production records in that:
 - a. they do not contain operators initials;
 - b. they fail to document that labels are verified;
 - c. they list duplicate lot numbers which cannot distinguish between individual batches produced in a give day[21 CFR 211.100].

The above indication of violations is not intended to be an all-inclusive list of deficiencies at your facility. 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

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. Possible actions include seizure and or injunction.

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. Also include copies of any available documentation demonstrating that corrections have been made.

Your reply should be sent to Compliance Officer Carrie A. Hoffman at the address on the letterhead.

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Clemence Fisher
March 6, 1998

Sincerely,



James A. Rahto
Director
Minneapolis District

xc: Robert C. Fischer
Vice President
Fisher's Mills Inc.
900 W. Manchester
Markesan, WI 53946

