



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-983-8100
FAX: 313-983-8139

WARNING LETTER
2003-DT-20

August 20, 2003

Mr. Patrick M. Hunter, President
H&H Feed & Grain, Inc.
14096 Portage Road
Vicksburg, Michigan 49097

Dear Mr. Hunter:

An investigation of your feed mill located at 14096 Portage Road, Vicksburg, Michigan, conducted by a Food and Drug Administration (FDA) investigator on February 6 and 14, 2003, found significant deviations from the requirements relating to animal drugs and medicated feeds, including the Veterinary Feed Directive (VFD) regulations (Title 21, Code of Federal Regulations, section 558.6). Such deviations caused an animal drug to be adulterated under Section 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act) and misbranded under Section 504(a)(3) of the Act. The deviations also caused animal feed to be adulterated under Section 501(a)(6) of the Act and misbranded under Section 504(b) of the Act.

Our investigation found your feed mill to be manufacturing complete medicated swine feeds containing the Veterinary Feed Directive (VFD) drug Tilmicosin in a manner that does not conform to the requirements of the Act and the agency's regulations.

The deviations include:

- (1) Your feed mill failed to use the Type B medicated feed containing Tilmicosin in accordance with labeled mixing directions, which resulted in sub-potent feeds. This caused it to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(6) of the Act.
- (2) Your feed mill failed to follow the product's conditions of use by not feeding continuously for a 21-day period. This caused the drug to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(6) of the Act.
- (3) Your feed mill manufactured Type C medicated feed containing Tilmicosin that failed to contain labeling conforming to the animal drug's approval.

For example, it did not contain ingredient statements, cautionary statements, or withdrawal information. This caused the medicated feed to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(6) of the Act.

(4) The VFD medicated feed labeling did not contain the cautionary statement: *"Caution: Federal law limits this drug to use under the professional supervision of a licensed veterinarian. Animal feed bearing or containing this veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice."* 21 CFR 558.6(f) requires all labeling and advertising of VFD drugs and animal feeds containing VFD drugs to prominently and conspicuously display this statement. Your failure to do so caused the animal feed to be misbranded within the meaning of Section 504(b) of the Act.

(5) Your firm manufactured, in June, October, and November of 2002, for its own use and for distribution, at least **two** batches of VFD feeds containing Tilimicosin when no VFD was in effect. Also, in October of 2002 and February of 2003, you manufactured complete feeds not covered by a complete and valid VFD. For example, some VFDs on file at your firm lacked the statement required in 21 CFR 558.6 (a)(4)(xii), *"Extra-label use, (i.e., use of this VFD feed in a manner other than as provided for in the VFD drug approval) is strictly prohibited."* Failure to follow the VFD requirements caused the medicated feed to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(6) of the Act.

(6) Your firm has been distributing feeds containing a VFD drug since early 2002, but has not submitted a notification letter to FDA's Center for Veterinary Medicine that you intend to distribute animal feed containing a VFD drug as required by 21 CFR 558.6(d). This causes the drug to be misbranded within the meaning of Section 504(a)(3)(C) of the Act.

The above is not intended as an all-inclusive list of violations. As a manufacturer of medicated and non-medicated feeds, you are responsible for ensuring that you are in compliance with the law. You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

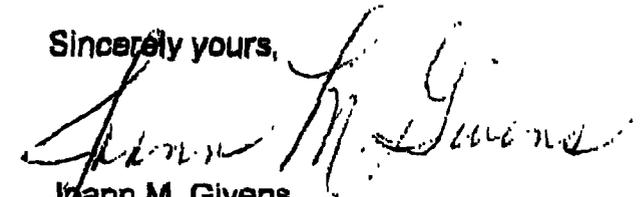
You should notify this office, in writing, within fifteen (15) working days of receiving this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the

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violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Mr. David M. Kaszubski, Director Compliance Branch, at the address above.

Sincerely yours,



Joann M. Givens
District Director
Detroit District Office

cc:

