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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139

WARNING LETTER
2003-DT-05

December 24, 2002

Mr. David G. Hoover, President
Hoover Feed Service, Inc.
518 North 5th Street
Goshen, Indiana 46528

Dear Mr. Hoover:

An investigation of your feed mill located at 518 North 5th Street, Goshen, Indiana conducted by a Food and Drug Administration investigator on March 20-21, 2002 found significant violations of the Federal Food, Drug, and Cosmetic Act (The Act). The inspection found that the use of the new animal drug, [REDACTED] in feed you manufactured does not conform with an approved New Animal Drug Application as required by section 512 of the Act. For this reason, the drug is unsafe under section 512 of the Act and thus is adulterated under section 501(a)(5) of the Act. The medicated feed you manufactured is unsafe under section 512(a)(2) of the Act because it bears or contains a new animal drug that does not conform with an approved application. The feed is thus adulterated under section 501(a)(6) of the act.

Our investigator found your feed mill to be manufacturing a medicated feed containing the new animal drug, [REDACTED] as a complete feed (Type C) for lactating dairy cattle. [REDACTED] is not approved for use in lactating dairy cows as provided in 21 CFR 558.95. Your firm distributed at least [REDACTED] batches of the adulterated medicated feed from approximately June 16, 1999 through March 12, 2002.

Custom formula medicated feeds manufactured to the specifications of your customer must only be manufactured from animal drugs that have been approved for such use as specified by section 512 of the Federal Food Drug and Cosmetic Act.

Additionally, you should be aware that you must implement controls over feed labeling to insure the information is correct and that the appropriate label is used on all feeds to assure its safe use. Appropriate labeling identifies the medicated feed, and provides

the user with directions for use which, if adhered to, will assure that the article is safe and effective for its intended purpose.

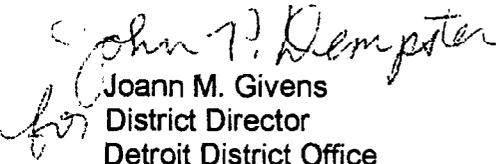
For bulk medicated feeds, 21 CFR 225 allows a placard or other label to be attached to a sales invoice or allows the manufacturer's invoice to be labeling for these products, provided this labeling bears adequate directions for safe and effective use.

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 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 you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions could include, but are not limited to, seizure, injunction, or revocation of your feed mill license. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

You should notify this office, in writing, within fifteen (15) working days of the receipt of 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 violations and prevent their recurrence. If corrective action cannot be completed within 30 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 above address.

Sincerely yours,


for Joann M. Givens
District Director
Detroit District Office