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**PURGED** RK

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

July 14, 1998

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 41

Russell C. Smith, D.V.M.  
dba Gomers, Inc.  
121 Lake Road  
Portage, Wisconsin 53901

Dear Dr. Smith:

During a recent inspection of your facility located at Portage, WI, our investigator found significant violations of the Federal Food, Drug, and Cosmetic Act (the Act). Under the Act any article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals, or intended to affect the structure or function of man or other animals is regarded as a drug. Unless a drug is generally recognized as safe and effective for its labeled intended uses, it is a new animal drug under the law. A new animal drug may not be legally marketed unless it is the subject of an approved New Animal Drug Application (NADA). NADAs may be approved on the basis of adequate scientific data obtained through controlled studies in which the applicant submits evidence of safety and effectiveness of the product (Section 512 of the Act).

Our investigation revealed that the following articles are adulterated within the meaning of Section 501(a)(5) of the Act in that these are new animal drugs by definition of Section 201(v)(1) of the Act and are unsafe within the meaning of Section 512 of the Act: Karbo Flour; Karbo Caps-Cows; Karbo Caps-Calves; Tetra 343 (Oxytet HCl) and Viracide; Soft Oil Ovine; EPIC II; and Ultra-Aid.

The above indication of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

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You must take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Should you obtain approval for and manufacture any veterinary drug, these must be manufactured in conformity with the current Good Manufacturing Practice for Finished Pharmaceuticals (GMPs) as required under Title 21, Code of Federal Regulations (CFR), Parts 210 and 211. For example, (1) you have no quality control unit; (2) no drug testing is conducted on any drug components or finished product; (3) there is a lack of written procedures; and (4) there is no drug product stability testing program and expiration dates are not used. In addition, establishments engaged in the manufacture, preparation, propagation or compounding, or processing of drugs must register and drug list their products with the FDA.

Our investigator noted that you intend to sell individually to your farmer customers and have your customers mix the components into finished product. This practice would not alleviate your responsibilities under the Act.

You also informed our investigator that you have sold to establishments and clinics believing that just the act of writing a prescription would establish a valid Veterinarian-Client/Patient Relationship (VCPR). According to the American Veterinary Medical Association a VCPR exists when: (1) the veterinarian assumes the responsibility for making medical judgements regarding the health of the animal(s) and the need for medical treatment, and the client (owner or caretaker) agrees to follow the instructions of the veterinarian; and (2) the veterinarian has sufficient knowledge of the circumstances to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s), i.e., the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of an examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept; and (3) the practicing veterinarian is readily available for follow-up cases of adverse reactions or failure of the therapy regimen. According to our investigation, it appears that none of these conditions were present when you sold veterinary drug products to other establishments and clinics.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the stated violations. You should

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also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. 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 implemented.

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

Sincerely,



James A. Rahto  
Director

Minneapolis District  
Minneapolis District

CAH/ccl