DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Kansas City District
Southwest Region
11630 W. 80th Street
Lenexa, Kansas 66214
Telephone: (913) 752-2100

January 7, 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

Dear

An inspection of your veterinary drug compounding facility, located at , conducted by a Food and Drug Administration (FDA) Investigator representing this office, between the dates of August 24 and 30, 2004, disclosed significant violations of the Federal Food, Drug, and Cosmetic Act (the Act). The investigator was accompanied by Mr. Tony Kopf, Pharmacy/Health Professions Inspector, with the Nebraska Health and Human Services.

Our inspection confirmed that your company has compounded and distributed veterinary drugs, including Altrenogest, Amikacin Sulfate, Dipyrone, Flunixin Meglumine, Ketoprofen, Ivermectin, Omeprazole, Phenylbutazone, and Tripelennamine Hydrochloride, among many others, using bulk active pharmaceutical ingredients (bulk APIs). The veterinary drugs you are compounding are unsafe within the meaning of section 512 of the Act (21 U.S.C. § 360b) since they are not the subject of approved New Animal Drug Applications. As such, they are adulterated under section 501(a)(5) of the Act (21 U.S.C. § 351(a)(5)). Sections 512(a)(4) and (5) of the Act (21 U.S.C. 360b(a)(4) and (5)), and their implementing regulations, allow some extralabel use of approved animal and human drugs, including compounding from approved animal and human drugs. These provisions, however, apply only to approved drugs and do not permit compounding from bulk APIs (see Title 21, Code of Federal Regulations (CFR), 530.13(a)).

FDA's policy regarding the compounding of drugs for use in animals is articulated in Compliance Policy Guide, Section 608.400, issued July 2003. As stated in this policy, FDA is greatly concerned about veterinarians and pharmacies that manufacture and distribute unapproved new animal drugs in a manner that is clearly outside the bounds of traditional pharmacy practice and that violates the Act.

One of our concerns is that you are not compounding for individual patients, but are compounding for third parties who resell to individual patients. A significant number of your compounded veterinary drugs appear to be compounded outside the context of a valid veterinarian-client-patient relationship for administration by an end user. Instead, they appear to be sales to veterinarians for use as office stock in their professional practice and/or for subsequent general distribution. For example, your recent consignee information provided to investigators for each of the above listed drugs confirmed that most of these compounded drugs were shipped to veterinarians. In addition, most of your prescription drug labeling does not identify the animal to receive treatment, provide the dosage frequency, or provide the duration of treatment.

Another concern is that you are compounding drugs for use when an approved drug, in the available dosage form and concentration, would appropriately treat the animal. For example, some of your compounded prescription veterinary drugs, such as Amikacin 250 mg/ml Injectable, Flunixin 50 mg/ml Injectable, Ketoprofen 100 mg/ml Injectable, Ivermectin 10 mg/ml Injectable, Phenylbutazone 1g/scoop Powder, and Tripelennamine 20 mg/ml Injectable are duplicates of FDA approved animal drug products available on the market. Others have only slightly different dosages and/or concentrations than FDA approved animal drugs, such as Stanozolol 2 mg capsules where Stanozolol 2 mg chewable tablets are approved and available, and these differences appear to be clinically insignificant.

The above is not intended to be an all-inclusive list of violations by your firm. It is your responsibility to ensure that your firm's operations and products are in compliance with the law and applicable regulations. Our findings were listed on a Form FDA 483, Inspectional Observations, which was issued and discussed with you at the end of the inspection.

You should take prompt action to correct the noted violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory sanctions, including, but not limited to, seizure and/or injunction.

We acknowledge receipt of your response to the FDA-483 dated September 17, 2004. We consider your response to be inadequate because it does not completely address the observation conveyed to you on the FDA-483 in an appropriate manner. It is recommended that specific details be provided in your response, such as what specific procedures have or will be implemented to eliminate the compounding of approved veterinary drugs. The response is also inadequate in that you stated that you will not make any changes in your veterinary compounding operations until the current Compliance Policy Guide review is completed. This is an unacceptable response in that you are in violation of the Act and the implementing regulations. We urge you to review your position and strongly recommend you base your decision of continued illegal activity on this fact.

Please notify this office within fifteen (15) working days of receiving this letter of the specific steps you have taken to correct the violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time period within which the corrections will be completed. You may address your reply to Ralph J. Gray, Compliance Officer, at the above address.

Sincerely,

John W. Thorsky
Acting District Director
Kansas City District