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Certified/Return Receipt Requested

July 16, 1998

Food and Drug Administration  
Kansas City District Office  
11630 West 80th Street  
P.O. Box 15905  
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

**WARNING LETTER**

Dr. Keith E. Weber, DVM  
President  
Animal Medical Centers, P.C.  
6570 320th Street  
Hartley, IA 51346

Ref.# - KAN-98-021

Dear Dr. Weber:

During an inspection of your veterinary clinic/drug compounding facility located at the above address, on December 3 to 9, 1997, Food and Drug Administration Investigators from this office documented deviations from Title 21, Code of Federal Regulations, Part 530, Extralabel Drug Use In Animals, which cause certain animal drugs compounded by you, to be adulterated within the meaning of Section 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (Act), in that they are new animal drugs which are unsafe within the meaning of Section 512.

As you are aware, the Animal Drug Use Clarification Act was signed into law in 1994. This law legalized the extra-label use of approved drugs for animals by veterinarians provided they meet the conditions, limitations and provisions of the regulations implementing this Act. Your veterinary clinic fails to meet these regulations. Our inspection found the following deviations:

Drugs dispensed by the clinic veterinarians do not bear or are not accompanied by labels which include the name and address of the specific authorizing veterinarian. The services performed by the satellite firms for your clinic are similar to those of a pharmacy. Drugs dispensed by the "pharmacy" do not bear or are not accompanied by labels which include the name and address of the "pharmacy" (satellite firm) as well as the name of the authorizing veterinarian in accordance with 21 CFR 530.12(a).

Drugs compounded by your firm do not always include the name of the active ingredients. For example, Pigamycin, Foot Rot Med, TN Pig, NAT324, S33 and

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several other compounded product labels fail to identify the active ingredients. 21 CFR 530.12(b).

Compounded drugs are prepared from unapproved products and bulk ingredients rather than approved products. For example, Foot Rot Med is formulated with neoprontisol; PDR is formulated with dipyrone. We are unaware of any approved products with these ingredients. 21 CFR 530.13.

Products are compounded when there are approved animal drugs or human drugs which could be used as formulated and labeled, or by simple extra-labeling. For example, Gentamicin products are unnecessarily repackaged with a preservative or diluted from an approved level to another approved level and repackaged with a preservative. 21 CFR 530.13(b)(2).

Products are compounded without adequate procedures or processes to assure the safety and effectiveness of the compounded product. 21 CFR 530(b)(4). For example:

Approved products in their original sterile packaging are diluted and repackaged as above. The removal of sterile products from their original containers for repackaging under the firm's label cannot be scientifically justified.

Compounded products are routinely assigned 6 month expiration dates, diluted products are assigned the expiration dates of the original products. There is no scientific information that supports the expiration dates assigned. Expiration dates on medically necessary compounded products should be limited to the duration of the treatment regimen.

Combination products are prepared without regard to their interaction. T-S is formulated to contain Tylan 200 and Spectam injectable, yet Tylan 200 is labeled *"Do not mix Tylan 200 with other injectable solutions."* Greasy Pig injection is compounded from amoxicillin, gentocin, penicillin and DMSO, a 4-way combination of suspect effectiveness, unknown interactions and questionable safety to animals or humans consuming animal products.

You are dispensing drugs pre-labeled for extra-label use from satellite operations. You have labeled drugs with statements such as *"susceptible bacterial infections of swine"* and *"repeat dose at 12 to 24 hour intervals depending on severity of infection."* This does not appear to be extra-label use based upon a specific diagnosis

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by the attending veterinarian; it appears the diagnosis and medical decisions are to be made by the animal producer. Prior to using drugs for extra-label use in food animals there must be a careful diagnosis of the conditions for which the drug is to be used. 21 CFR 530(a)(2)(i).

The above is not intended to be an all-inclusive list of violations. As a compounder of veterinary drugs, you are responsible for assuring that your overall operation and the products you compound and dispense are in compliance with the law and related regulations. At the conclusion of the inspection a Form FDA 483, Inspectional Observations, was issued to and discussed with Dr. Mark G. Schulz, DVM, Partner. This form is a comprehensive listing of the investigators' observations of deviations found during the inspection. A copy is enclosed for your information.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

Prescription veterinary drugs are exempt from certain labeling requirements if in the possession of a veterinarian or other facility regularly and lawfully engaged under state law in distributing animal drugs and they are dispensed under authority of an attending veterinarian. The veterinarian-client-patient relationship used to support drug sales made by your satellite firms appears to be very tenuous. Although your firm apparently does provide veterinary services to the customers of the satellite stores where your prescription or compounded drugs are sold it is not obvious that sufficient medical oversight is provided to allow the labeling exemption.

You should re-evaluate your firm's extra-label drug use and compounding practices. The purpose of extra-label drug use as expressed by AMDUCA is for *"treatment modalities when the health of an animal is threatened or suffering or death may result from failure to treat."* Extra-label drug use is to be limited, extra-label use from compounded products is to be limited further. Your labeling, distribution and compounding practices do not appear limited to situations where the health of the animal is threatened; they seem to be routine. We are especially concerned with products containing multiple active ingredients which are placed in satellite operations for unknown periods of time and compromising the sterility of legally manufactured products by diluting them to levels which are commercially available. We cannot comprehend any medical rationale for these activities.

You should notify this office in writing, within fifteen (15) working days of receipt of 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

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cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Michael Rogers", with a long horizontal flourish extending to the right.

W. Michael Rogers  
District Director  
Kansas City District

Enclosure - Form FDA 483