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Certified/Return Receipt Requested

April 29, 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

Harry Cleberg, Chief Executive Officer
Farmland Industries
3315 North Oak Trafficway
P.O. Box 7305
Kansas City, MO 64116

Ref.# - KAN-98-015

Dear Mr. Cleberg:

During an investigation of your contract hog growing operation, located at the farms of Steven Reding and Jerel Kerber, Cylinder, Iowa, a Food and Drug Administration Investigator from this office documented deviations from Title 21, Code of Federal Regulations, Part 530, Extralabel Drug Use In Animals, which cause certain animal drugs used to medicate food producing animals, 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(a)(4).

Our investigation determined that Mr. Charles L. Groom, Swine Production Specialist for Farmland Industries, regularly visits the two aforementioned contract hog growers, among others, to evaluate the confinement facilities and animals, and provide recommendations to the grower. These recommendations include the use of various drugs to improve the health of the animals. Mr. Groom is not a veterinarian.

Based on preliminary evaluations of the health conditions of pigs and/or hogs, Mr. Groom has recommended the use of several drug products. Examples include:

PRESCRIPTION DRUGS (not approved for use in swine)

1. Tribissen (actual drug used is Sulfatrim Pediatric Suspension, which is a human drug).
2. Cephalexin (a human drug).
3. Dexamethasone.
4. Gentamicin.

OVER-THE-COUNTER DRUGS (not approved for use in swine)

1. LS50 (lincomycin/spectinomycin).
2. Long acting penicillin (Pen-G Procaine/Pen-G Benzathine).
3. LA200 (Oxytetracycline) which is approved for use in swine, but being recommended for use at dose levels above the labeled levels).

You are adulterating the above drugs which your firm uses on swine within the meaning of Section 501(a)(5) when you fail to use the drug in conformance with its approved labeling. Your use of the drugs in a species for which they are not approved, or at a higher than labeled dosage, causes the drugs to be unsafe for use.

In October of 1994, Congress passed the Animal Medicinal Drug Use Clarification Act, which permits extra-label use under certain controlled conditions, specified in 21 CFR Part 530. Extra label use is only permitted if the use is by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/client/patient relationship and in conformance with criteria set forth in Part 530.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law and established regulations.

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.

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

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Farmland Industries

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