

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

December 12, 2002

**WARNING LETTER  
KAN #2003-03**

John E. Gherty  
President and CEO  
Land O' Lakes, Inc.  
P.O. Box 64101  
St Paul, MN 55164

Dear Mr. Gherty:

Recently an inspection was made at your Land O' Lakes, Inc. facility located at 2827 8<sup>th</sup> Avenue, South, Fort Dodge, Iowa, to cover the operations of your contract swine grower program. The inspection was made as part of our investigation into a USDA report of a tissue residue of penicillin in a sow, which originated from [REDACTED] a contract grower

The inspection was conducted from August 9 to 30, 2002, by a Food and Drug Administration Investigator from this office who documented violations of Sections 512(a)(4)(A) and 512(a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act) and deviations from Title 21, Code of Federal Regulations, (21 CFR) Part 530, Extralabel Drug Use In Animals.

Our inspection determined that your contract swine grower program uses a Service Manager (field representative), an employee of Land O' Lakes, to make regular visits to the aforementioned contract swine grower, 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

Your Service Manager, who is not a veterinarian, recommended drugs for extralabel use in swine you own. Because this extralabel use of drugs approved for use in animals is not in compliance with Section 512(a)(4)(A) of the Act and 21 CFR 530, the drugs are unsafe under Section 512 of the Act. Similarly, because this extralabel use of drugs approved for human use is not in compliance with Section 512(a)(5) of the Act and 21 CFR 530, these drugs are also unsafe under Section 512 of the Act. These violations render the drugs adulterated under Section 501(a)(5) of the Act.

The extralabel use of Pen-G Procaine/Pen-G Benzathine long acting penicillin at the Winter Farms facility resulted in penicillin residues in kidney and liver tissues of a sow slaughtered at USDA Est. [REDACTED] on March 18, 2002. Because these residues exceeded the tolerance level established in 21 CFR 556.510 for penicillin, the extralabel use of penicillin was in violation of 21 CFR 530.11(d)

Based on preliminary evaluations of the health conditions of swine at the aforementioned contract swine grower, the Service Manager has recommended the extralabel use of several drug products. Examples include:

1. Pen-G Procaine/Pen-G Benzathine long acting penicillin (a non-Rx drug approved for use in cattle, but not in swine)
2. Predef 2X (Rx animal drug used at higher than labeled dosage)
3. Oxytocin (Rx animal drug used at higher than labeled dosage)
4. Lutalyse (Rx animal drug used at higher than labeled dosage)
5. Adspec (Rx drug approved for use in cattle, but not in swine)
6. Naxcel (Rx animal drug used at higher than labeled dosage)
7. Dexamethasone (Rx drug approved for use in horses, but not in swine)
8. SMZTMP (a human Rx drug)
9. Amoxicillin (a human Rx drug)

Land O' Lakes staff veterinarians do not review and/or approve recommendations made by the Service Manager concerning the use of various drugs by the contract grower. Staff veterinarians have not established a valid Veterinarian-Client-Patient Relationship (VCPR).

In October of 1994, Congress passed the Animal Medicinal Drug Use Clarification Act, which permits extralabel use of approved animal drugs. Under Sections 512(a)(4) and 512(a)(5) of the Act, extralabel 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 21 CFR Part 530.

A valid VCPR exists when:

- (1) the veterinarian assumes the responsibility for making medical judgments regarding the health of the animal(s) and the need for medical treatment, and the client (owner or other 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), and (3) the practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when 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. 21 CFR 530.3(i).

The use of the drugs in a species for which they are not approved, or at a higher than labeled dosage, in violation of the requirements of 21 CFR Part 530 causes the drugs to be unsafe for use under Section 512 of the Act. You are thus adulterating the above drugs within the meaning of Section 501(a)(5) of the Act when you fail to use the drugs in conformance with approved labeling.

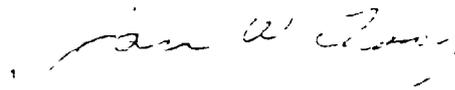
The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law and established regulations.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence at any contract grower location within your company. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction.

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

Sincerely, ..



Charles W. Sedgwick  
District Director  
Kansas City District

cc: Dennis Petersen, Vice President  
Swine Production Division  
Land O' Lakes, Inc.  
2827 8<sup>th</sup> Avenue, South  
Fort Dodge, IA 50501