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Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

July 17, 2003

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

Ref. KAN 2003-08

Mr. Hadwen A. Kleiss, President
Stardell Farms, Inc.
2644 260th St.
Fredericksburg, IA 50630

Dear Mr. Kleiss:

A tissue residue report received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of illegal drug residues in a cow owned by Stardell Farms, Inc that was leased to a related dairy, Holstein Marketing Center of Iowa, Inc. As a follow-up to USDA's finding, our investigator performed an inspection of your operation located in Fredericksburg, Iowa, on March 12, 2003. The inspection confirmed that you offered an animal for sale for slaughter as food in violation of sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), and that you may have caused animal drugs to become adulterated within the meaning of section 501(a)(5) of the Act.

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On January 22, 2003, USDA-FSIS (United States Department of Agriculture - Food Safety and Inspection Service) collected a sample which tested positive for the presence of tilmicosin residues at 17.29 parts per million (ppm) in the kidney, 6.00 ppm in the muscle, and 38.96 ppm in the liver of tissue samples collected from a culled dairy cow identified as number 7389 with back tag number 35GK9396, and USDA Sample Number 417824. A tolerance in cattle is established for residues of parent tilmicosin (marker residue) in liver (target residue) at 1.2 ppm and in muscle at 0.1 ppm (21 Code of Federal Regulations (21 CFR) 556.735).

Your failure to follow the labeled withdrawal periods for tilmicosin renders the drug unsafe under section 512 of the Act; you are thus adulterating the drug tilmicosin within the meaning of Section 501(a)(5) of the Act. Furthermore, the presence of tilmicosin in edible tissue from this animal causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the Act.

A food is also adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions whereby . . . it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues.

This 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.

We note that this is not the first time cows owned by your firm and assigned to the care of your contract grower and associate firm Holstein Marketing Center of Iowa, Inc., that were culled for slaughter for human food were found to contain illegal levels of drug residues by the USDA) testing.

On April 12, 2002, USDA – FSIS collected a sample which tested positive for the presence of Penicillin residues at 00.08 ppm in the kidney and 00.34 ppm in the liver of tissue samples collected from a culled dairy cow identified with USDA carcass Condemn Number 44335589, and USDA Sample Number 419782. A tolerance is established for residues of Penicillin at 0.05 ppm (negligible residues) in uncooked edible tissues of cattle (21 CFR 556.510).

On August 20, 1999, USDA – FSIS collected a sample which tested positive for the presence of Penicillin residues at 00.07 ppm in the kidney of a tissue sample collected from a culled dairy cow identified with USDA Sample Number 287875.

You should take prompt action to correct the violations noted in this letter 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 be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

You should notify our office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct these violations and

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preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Nadine Nanko Johnson, Compliance Officer, at the address listed above.

Sincerely,



for Charles W. Sedgwick
District Director
Kansas City District