

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
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VIA FEDERAL EXPRESS

July 29, 2004

Edward A. Stoll, President/Owner
Todd E. Stoll, Vice-President/Owner
Stoll Farms, Inc.
6818 Coal Bank Road
Marshallville, OH 44645-9729

WARNING LETTER CIN-04-21892

Dear Mr. Stoll:

An inspection of your dairy farm located in Marshallville, OH by Food and Drug Administration (FDA) Investigator Mishelle L. Harriger from 4/27/2004 – 4/29/2004 confirmed that you offered animals for sale as human food in violation of the Federal Food, Drug, and Cosmetic Act (the Act). The animals (bob veal calves) were adulterated food within the meaning of sections 402(a)(2)(C)(ii) and 402(a)(4) of the Act.

The United States Department of Agriculture (USDA)/Food Safety Inspection Service (FSIS) analyses of tissues collected from the animal disclosed the presence of the following drugs:

Animal ID	Drug	Tissue	Level	Tolerance
Back Tag 8674	Neomycin	Kidney	8.01ppm	None Established
	Neomycin	Muscle	detected	None Established
Back Tag 8676	Neomycin	Kidney	11.65ppm	None Established
Back Tag 8741	Neomycin	Kidney	13.04ppm	None Established

Tolerance levels for residues of new animal drugs are found in Title 21, Code of Federal Regulations, Part 556. There is no established tolerance for Neomycin in bob veal calves. As such, the presence of this drugs in the edible tissues of these animals causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the Act.

The investigation also found that you hold animals under conditions that could allow medicated animals, bearing potentially harmful drug residues, to enter the food supply. For example:

- There is no inventory list of drugs or medicated feeds used.
- You do not maintain any records regarding the use of medicated milk replacer in the herd.

Food from animals held under such conditions is adulterated within the meaning of Section 402(a)(4) of the Act.

We also note that your employee signed a certificate (or guarantee) from your firm stating that the animals you sell do not contain any illegal drug residues. If you continue to medicate animals without maintaining the records and procedures listed above, you may be giving a false guarantee. Giving a false guarantee is prohibited by section 301(h) of the Act.

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

The violations listed above are not intended to be an all-inclusive list. It is your responsibility to assure that your operations are in compliance with the law.

You should be aware that it is not necessary for you to have personally shipped an animal in interstate commerce. The fact that you caused the adulteration of an animal that was subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken or that will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be addressed to Food and Drug Administration, 6751 Steger Drive, Cincinnati, OH 45237-3097, Attention: Stephen J. Rabe, Compliance Officer.

Sincerely

Carol A. Hepp
As Carol A. Hepp
District Director
Cincinnati District Office

Original to addressee