



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Refer to: CFN/3002924558

g1233d  
Food and Drug Administration  
Baltimore District Office  
Central Region  
900 Madison Avenue  
Baltimore, MD 21201-2199  
Telephone: (410) 962-3396  
FAX: (410) 962-2307

01-BLT-30

May 9, 2001

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Robert H. Stolman, Owner  
Drinking Swamp Farm  
430 Blues Lane  
P.O. Box 57  
Haynesville, Virginia 22472

Dear Mr. Stolman:

A Food and Drug Administration (FDA) inspection of your goat cheese manufacturing facility located at 430 Blues Lane, Haynesville, Virginia, conducted April 3-4, 2001, revealed serious deviations from the Control of Communicable Diseases regulations, Title 21, Code of Federal Regulations, Part 1240 (21 CFR Part 1240) and the Good Manufacturing Practice (GMP) regulations for food firms (21 CFR Part 110). The deviations included:

1. Failure to pasteurize all milk and milk products in final package form intended for direct human consumption (21 CFR 1241.61) in that,
  - a. Goats' milk used to manufacture Feta, Chevre, Mozzarella, and Fromage goat cheeses is only heated to [REDACTED]
  - b. The temperatures in your goat cheese aging refrigerators #3 and #7 were 34 °F and 30 °F, respectively.

You must pasteurize all dairy ingredients (milk or milk products including goats' milk) used to manufacture the various cheeses that your firm distributes in interstate commerce, except where alternative procedures to pasteurization are provided, such as in 21 CFR Part 133 (Requirements for Specific Standardized Cheese and Related Products). If the milk is not pasteurized, the cheese you make must be cured at a temperature of not less than 35 °F for not less than 60 days.

2. Failure to pasteurize goats' milk in properly designed and operated equipment to comply with 21 CFR 1240.61(b) in that,

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- a. The vat pasteurizer used to manufacture a limited number of batches of goats' cheese is not equipped with an adequate sweep agitator to ensure the pasteurization of every particle of milk.
  - b. Records were not maintained of the time and temperature of the pasteurization process in order to demonstrate that the pasteurization process is adequate.
  - c. Thermometers used to monitor the pasteurization of goats' milk have not been calibrated.
3. Failure to clean all food-contact surfaces, including utensils and food-contact surfaces of equipment as frequently as necessary to protect against contamination of food (21 CFR Part 110.35(d)) in that, food residue was found on the interior food contact surfaces of the vat pasteurizer.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. We may take further regulatory action if you do not promptly correct these violations. For instance, we may enjoin your firm from operating under these conditions.

This letter does not list all the deviations observed at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Food, Drug, and Cosmetic Act, the Control of Communicable Diseases regulations (21 CFR 1240.61), and the Good Manufacturing Practice regulation for food firms (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Samples of goat cheese, specifically Mild and Strong Feta, Plain Chevre, Garlic Cheddar, and Marinated Goat Feta, were collected for analysis by the FDA laboratory. The FDA laboratory detected phosphatase in 2 subs of Goat Feta Cheese (sample #127915) at levels of 39.66 and 75.72 ug/g phenol equivalents of alkaline phosphatase. This indicates that the Feta Cheese was manufactured using insufficiently pasteurized milk.

In addition, FDA analysis of the Marinated Goat Feta Cheese disclosed a pH of 4.67 in 1 of 6 subs examined. The original analysis pH range was 4.47-4.58 and the check analysis pH range was 4.48-4.67. The pH results indicate that your Marinated Goat Feta Cheese meets the definition of a "low-acid" food in that, it has a finished equilibrium pH greater than 4.6. We are particularly concerned because at that pH value your product will support the growth of harmful bacteria such as C. botulinum, especially when packed in olive oil, causing an anaerobic condition in the glass jar. According to FDA's acidified foods regulations (21 CFR 114), a manufacturer must manufacture, process and pack acidified foods so that a finished equilibrium pH value of 4.6 or below is achieved and maintained in all finished foods (21 CFR 114.80 (a)(1)). We understand that you have contacted [REDACTED] regarding the evaluation of this product by the university to determine if it is an acidified food. Please provide this office with additional information regarding the Marinated Goat Feta Cheese and its status as an acidified food and your intent to process and market this product.

We acknowledge receipt of your letter dated April 11, 2001 responding to the Form FDA 483. We have determined that the actions you are taking or have taken in response to each inspectional observation appear adequate. However, your response did not indicate whether you intend to pasteurize all milk

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used in the future manufacture of "fresh" cheese or aged cheese, in accordance with the requirements set forth in 21 CFR Part 133.

Please respond in writing within 15 working days of receipt of this letter, and indicate your intentions regarding pasteurization of all milk used in the manufacture of goat cheese. Your response should address any corrections taken or planned that were not included in your April 11, 2001 response. If you need additional time to complete all the corrections, explain the reasons for the delay and provide a time frame for their completion.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, at 10710 Midlothian Turnpike, Suite 424, Richmond, VA 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire may be reached at 804-379-1627, extension 14.

Sincerely,



*LB* Lee Bowers  
Director, Baltimore District

cc: Virginia Department of Agriculture  
and Consumer Services  
Division of Consumer Protection  
Office of Dairy and Food  
1100 Bank Street, Suite 510  
Richmond, Virginia 23219