



PUNGED *RAK*

Food and Drug Administration  
Minneapolis District  
240 Hennepin Avenue  
Minneapolis MN 55401-1999  
Telephone: 612-334-4100

October 6, 2000

**WARNING LETTER**

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

**Refer to MIN 01 - 02**

Greg Dryer  
Executive Vice President of Operations  
Saputo Cheese USA, Inc.  
25 Tristate International Office Center, Suite 250  
Lincolnshire, Illinois 60069.

Dear Mr. Dryer:

Between July 31 and August 9, 2000, investigators from the Food and Drug Administration (FDA) conducted inspections at your cheese manufacturing plant in Lena, WI. Those investigations confirmed that you manufactured and sold cheese products in violation of Sections 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (the Act).

On June 19, 2000, you received a shipment of raw milk (from *~~~~~*  
*~~~~~*) that was contaminated with Sulfamethazine, a drug that is prohibited for use in lactating dairy cattle. You subsequently produced and sold cheese and other milk products that contained the contaminated milk.

Our investigation found practices whereby potentially harmful drug residues are likely to enter the food supply. After being informed that the incoming milk was contaminated your quality system failed to immediately reject and/or recall the affected cheese and milk products.

The above is not intended to be an all-inclusive list of violations. As a food manufacturer you are responsible for ensuring that your operations are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not occur. Failure to do so may result in regulatory action (such as seizure or injunction) without further notice to you.

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You should notify this office in writing within 15 working days of the steps you have taken to bring your operations into compliance with the law. Your response should include each step that has been taken or 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 that corrections have been made.

Your reply should be directed to Compliance Officer Timothy G. Philips at the address indicated on the letterhead. If you have questions regarding this matter please contact Mr. Philips at (612) 334-4100 ext. 192.

Sincerely,



James A. Rahto  
Director  
Minneapolis District

TGP/ccl

*ab*

cc: Bruce A. Unterbrunner  
Vice President  
Saputo Cheese USA, Inc.  
317 Highway 141 North, P.O. Box 198  
Lena, WI 54139

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