



October 31, 2002

**CERTIFIED MAIL**  
**RETURNED RECEIPT REQUESTED**

Mr. Herminio Cruz Cardona  
Owner  
Requeson Cruz-Pitre  
HC-03 Box 33325  
Hatillo, P.R. 00659

Dear Mr. Cruz Cardona:

On April 30, 2002, investigators from the Food and Drug Administration (FDA) inspected your soft cheese manufacturing plant located at Road 129 Ramal 489, Km 2.4 Bo. Aibonito, Hatillo, P.R. The inspection was intended to determine whether your firm is operating in compliance with the Federal Food, Drug, and Cosmetic Act (the FD&C Act), 21 U.S.C. § 301 *et seq.*, and FDA regulations establishing current good manufacturing practice (GMP) requirements for food manufacturing, 21 C.F.R. Part 110. The inspection revealed deviations from GMP requirements that render your food products adulterated under Section 402(a)(4) of the FD&C Act, 21 U.S.C. § 342(a)(4), as follows:

1. Your plant uses an old milk storage tank as a cistern to store water for cleaning equipment and utensils when there is a water shortage. The cistern is fed by a water inlet pipe that connects to the potable water supply line. This pipe was submerged below the flood level rim of the tank. You have not installed any device to prevent backflow from or cross-connection between the two piping systems. This presents a risk that your water supply will become contaminated. Under FDA regulations, your plant must be equipped with adequate sanitary facilities and accommodations. 21 C.F.R. § 110.37(b)(5).
2. The top lid of the cistern that stores water used to clean equipment and utensils in the event of a water shortage has openings to the outside environment. These openings could admit rodents, lizards, insects, and microorganisms that could contaminate the water in the cistern. Under FDA regulations, your plant is required to be equipped with plumbing that is adequately installed and maintained to avoid constituting a source of contamination to food, water supplies, equipment, or utensils. 21 C.F.R. § 110.37(b)(3).
3. A dial stem thermometer used to monitor the air temperature in a cheese storage refrigerator read 70° F when an FDA-calibrated digital thermometer operated by our investigators read 36° F. FDA's GMP regulations provide that instruments and controls used for measuring, regulating, or recording temperatures must be accurate and adequately maintained. 21 C.F.R. § 110.40(f).

**Mr. Herminio Cruz Cardona**

**October 31, 2002**

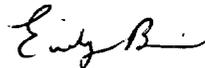
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4. There is an unshielded light bulb over a working table in the cheese manufacturing area of your plant. Your food products could become adulterated with broken glass from this bulb. Under FDA's GMP requirements, all reasonable precautions must be taken to ensure that production procedures do not contribute contamination to food from any source. 21 C.F.R. § 110.80.
5. You did not accurately measure the amount of chlorine added to water in preparing sanitizing solution. This resulted in a sanitizing solution with a concentration of chlorine that was too low to be effective. FDA regulations provide that sanitizing agents must be adequate. Moreover, procedures for sanitizing equipment and utensils must routinely render equipment and utensils clean, and must provide adequate cleaning and sanitizing treatment. 21 C.F.R. § 110.35(d)(5).

You should take prompt action to correct these deficiencies and prevent them from recurring. During our next inspection, we will investigate whether you have corrected these problems. In addition, we will investigate whether your facility is in violation of other applicable requirements of the FD&C Act and FDA regulations. It is your responsibility to assure that your operations comply with these requirements.

If you have any questions concerning the violations listed in this letter, or about cGMP or other compliance issues generally, please contact Compliance Officer Jorge L. González of the FDA San Juan District Office, 466 Fernandez Juncos Ave., San Juan, Puerto Rico 00901-3223 (telephone number 787-729-6894 ext. 2134).

Sincerely,



Evelyn Bonnin  
Acting District Director