



March 13, 2012

Mr. Marcelino Real Ibanez
General Manager
Arte Serena S.L.
Ctra. Ex-104 Km. 21,100
Campanario, Badajoz, Spain 06460

RE: 285148

Dear Mr. Ibanez:

We inspected your processing facility, Arte Serena S.L., located at Ctra. Ex-104 Km. 21,100, Campanario, Badajoz, Spain, on November 3-4, 2011. We found that you had significant deviations from the current Good Manufacturing Practices (cGMP) regulations for food manufacturers (Title 21, Code of Federal Regulations (CFR), Part 110). At the conclusion of the inspection, our investigator issued an FDA-483 listing observations of concern. Those violations cause the cheese manufactured at your facility to be adulterated within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 342(a)(4)] in that it was prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth. You may find the Act and FDA's regulations through links on FDA's home page at www.fda.gov.

We received your correspondence concerning corrective actions taken in response to the observations via electronic mail on December 13, 2011. Our evaluation of that information finds your corrective actions satisfactory with respect to the violations identified during the inspection. However, further evaluation of the inspection report identified an additional concern which we bring to your attention in this letter.

The following insanitary condition was noted during the review of the inspection report:

- Cheese is placed directly on wooden shelves. All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and all adjacent spaces. Food contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from

being contaminated by any source, including unlawful indirect food additives to comply with 21 CFR 110.40(a).

The use of wooden shelves for cheese ripening does not conform to the regulations in 21 CFR 110. Wood cannot be adequately cleaned and sanitized. The porous structure of wood enables it to absorb and retain bacteria.

The above violation is not meant to be an all-inclusive list of deficiencies in your plant. It is your responsibility to assure that your processing plant operates in compliance with applicable laws and regulations enforced by the FDA. You should take prompt action to correct the violation noted in this letter.

Please respond within thirty (30) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct this violation. Your response should include documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations.

Please send your reply to the Food and Drug Administration, Attention: Sandra Purnell, Compliance Officer, Office of Compliance, Division of Enforcement, Food Adulteration Assessment Branch (HFS-607), 5100 Paint Branch Parkway, College Park, MD 20740 U.S.A. If you have any questions regarding this letter, you may contact Ms. Purnell by phone at (240) 402-1613 or via email at standra.purnell@fda.hhs.gov.

Sincerely,
/s/

Jennifer Thomas
Director
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition