



March 1, 2012

Mr. Javier Alonso Casares
Owner
Queserias Picos de Europa, S.L.
Poligono Industrial de Vidanes
Parcela 21-22
Vidanes, Leon, Spain 24950

Dear Mr. Alonso Casares:

The Food and Drug Administration has determined that your facility is subject to the registration requirement in § 415 of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 350d, and our implementing regulation at 21 CFR Part 1, Subpart H. During an inspection of your facility located at Poligono Industrial de Vidanes, Parcela 21-22, Vidanes, Leon, Spain on November 7-8, 2011, you were (or your representative was) advised of this requirement. The failure to register a facility as required is a prohibited act under § 301(dd) of the Act, 21 U.S.C. § 331(dd). Our records indicate that, to date, this facility has not been registered with FDA.

As a responsible official of a facility that manufactures/processes, packs, or holds food for human or animal consumption in the United States, you are responsible for ensuring that your overall operation and the products you distribute are in compliance with the law.

We request that the owner, operator, or agent in charge of this facility, or an individual authorized by this facility's owner, operator, or agent in charge, register the facility with FDA within 30 working days of the date of this letter. Registration may be accomplished on-line at <http://www.access.fda.gov>. We strongly encourage the use of electronic registration because it will result in an automatic confirmation of registration and automatic issuance of a registration number.

Alternatively, the owner, operator, or agent in charge of this facility, or an individual authorized by the facility's owner, operator, or agent in charge, may register the facility by mail or fax (e.g., if you do not have reasonable access to the Internet) using FDA's food facility registration form, Form 3537. This form may be obtained by calling the FDA Industry Systems Help Desk at 1-800-216-7331 or 301-575-0156, or by writing to the agency at the following address:

U.S. Food and Drug Administration, HFS-681
Food Facility Registration
5100 Paint Branch Parkway
College Park, MD 20993

When completed, the form may be faxed to (301) 436-2804 or mailed to the address above. FDA will process registrations submitted by mail or fax and provide a facility's registration number using the same method used to submit the registration to FDA.

We request that you reply to this letter in writing within 30 working days. If you are unable to register this facility within 30 working days, please inform us of the reason for the delay and the timeframe within which you plan to register. Your response should be directed to the above address.

If you have any questions about this letter, please call this office the FURLS Helpdesk at 800-216-7331 or via email at furls@fda.gov.

Sincerely,

/s/

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