DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD

December 27, 2011

VIA EXPRESS MAIL

Mr. Manuel E. Sanchez, General Manager
EPROMAR LTDA
Calle 12 de Febrero 168
Coquimbo, Chile

Reference No.: 255634

Dear Mr. Sanchez:

The U.S. Food and Drug Administration (FDA) inspected your low-acid canned food facility located at Calle 12 de Febrero 168, Coquimbo, Chile on August 8-9, 2011. The inspection revealed that you manufacture low-acid canned food products, namely canned squid.

As a manufacturer of low-acid canned food products, you are required to comply with the U.S. Federal Food, Drug, and Cosmetic Act (the Act), and the federal regulations relating to the processing of low-acid canned food products. These regulations are described in Title 21, Code of Federal Regulations, Part 108, Emergency Permit Control (21 CFR 108) and Part 113, Low-Acid Canned Foods (21 CFR 113). Failure to comply with all of the mandatory requirements of 21 CFR 108.35 and 21 CFR Part 113 constitutes a basis for the immediate application of the emergency permit control provisions of Section 404 of the Act and particularly implementation of 21 CFR 108.35(k) for products offered for entry into the United States. In addition, such failure renders your low-acid canned food products 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). You can find the Act and the low-acid canned food regulations through links in FDA's home page at http://www.fda.gov.

This inspection resulted in FDA's issuance of an FDA-483, Inspectional Observations, at the conclusion of the inspection which listed the deviations found at your firm. Your firm's November 21, 2011 response to the FDA-483 did not adequately address all of these deviations. Therefore, we have the following remaining concerns with regard to your low-acid canned food products:

- Your firm failed to obtain substantiation by a qualified scientific authority as to the adequacy of any intentional change in a previously filed scheduled process as required by 21 CFR 108.35(c)(2)(ii). Specifically, your firm's filed scheduled process for "Giant Calamari (Imitation Abalone), Chunk, in Brine" ((b)(4)) lists a thermal process of (b)(4) ; however, in practice, your firm is using a thermal process of (b)(4) . We acknowledge that your firm submitted a revised process filing ((b)(4)) on September 21, 2011; however, this process filing was returned on November 11, 2011 for a low F_o value. Therefore, your firm, in conjunction with your process authority, needs to re-submit a revised process filing for this Giant Calamari product and delete the current process filing ((b)(4) (b)(4)) that is no longer valid.

- Your firm failed to properly adjust the temperature-recording device in order for it to read no higher than the known accurate mercury-in-glass (MIG) thermometer during the process time as required by 21 CFR 113.40(a)(2). Specifically, during processing on 8/8/2011, the recording chart thermometer on Retort #2 read (b)(4) and the MIG on the retort read (b)(4) . In addition, on 8/9/2011, our investigator checked the temperature of the recording chart on Retorts #1 and #2 against the MIGs on each retort and the recording charts read (b)(4) and the MIGs read (b)(4) . Also during our investigators record review of 35 retort loads, the MIG reading was recorded as (b)(4) while the recording chart showed the temperature varying between (b)(4) and (b)(4) . Your November 21, 2011 response indicates that you have added a new automated temperature instrument that matches the MIG temperature exactly and that your thermograph has been adjusted. However, your response failed to address how the product that was processed under these conditions was evaluated by your process authority and what was the final disposition of the product.

This letter may not list all the violations at your facility. You are responsible for ensuring that you firm operates in compliance with the Act, the low-acid canned food regulations (21 CFR Parts 108 and 113), the Current Good Manufacturing Practice regulation (21 CFR Part 110), and other applicable regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

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

Please send your reply to the U. S. Food and Drug Administration, Attention: Robyn R. Jones, Consumer Safety Officer, Office of Compliance, Division of Enforcement, Manufacturing and Storage Adulteration Branch (HFS-607), 5100 Paint Branch Parkway, College Park, MD 20740 U.S.A. If you have any questions regarding any issue in this letter, you may contact Ms. Jones at (240) 402-2575 or via email at robyn.jones@fda.hhs.gov.

Sincerely,

/s/

Kathleen M. Lewis, J.D.
Acting Director
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition