DEPARTMENT OF HEALTH AND HUMAN SERVICES

Date: February 12, 2013

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: CMS #393133

Rodolfo Negrini, General Manager
Productos Negrini S.A.
Del Megasuper de la Valencia 200 metros
Este y 200 metros norte
La Valencia, Heridia CR

Dear Mr. Negrini:

On November 1- November 2, 2012, the U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at Del Megasuper de la Valencia 200 metros, este y 200 metros norte, La Valencia, Heredia, 3000, Costa Rica. This inspection revealed that you manufacture acidified food products at this facility.

We found that you have serious deviations from the Acidified Food regulations described in Title 21, Code of Federal Regulations (CFR), Part 108, Emergency Permit Control (21 CFR Part 108), and Part 114, Acidified Foods (21 CFR 114). As a manufacturer of acidified food products, you are required to comply with the Federal Food, Drug, and Cosmetic Act (the Act), and the federal regulations relating to the processing of acidified food products. The Emergency Permit Control regulation was issued, in part, pursuant to Section 404 of the Act [21 U.S.C. § 344]. A temporary emergency permit may be required for acidified food products whenever a processor has failed to fulfill the requirements of 21 CFR Part 108, Subpart B, including registration and filing of process information, and the mandatory requirements of 21 CFR Part 114. In addition, based on certain criteria in Part 114, acidified food products may be adulterated within the meaning of Section 402(a)(3) of the Act [21 U.S.C. § 342(a)(3)] in that they may have been manufactured under such conditions that they are unfit for food, or within the meaning of Section 402(a)(4) [21 U.S.C. § 342(a)(4)] in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. For your reference, the Act and the Emergency Permit Control and Acidified Food regulations can be accessed through links in FDA's home page at http://www.fda.gov.

During the inspection, the FDA investigators discussed with you observations noted on the Form FDA-483, Inspectional Observations, which was issued to you on November 2, 2012. FDA has evaluated your firm's responses to the FDA-483, received by CFSAN on November 16 and December 12, 2012 and found that you adequately addressed two of the three violations. However, after evaluation we determined that your firm has the following significant violation that is not resolved:

- You must manufacture acidified foods according to the scheduled process filed with the FDA as required by 21 CFR 114.80(a)(l). However, your firm failed to manufacture Iguana brand Golden Habanero Pepper Sauce according to the filed scheduled process. The filed scheduled process for Iguana brand Golden Habanero Pepper Sauce identifies a "(b)(4) (b)(4)" However, on November 1, 2012, glass bottles containing this acidified food product were observed being filled at (b)(4) .

  During the inspection, and confirmed in an email to the FDA on December 12, 2012, you indicated that your firm intends to file revised scheduled processes for the acidified food products you manufacture. As a commercial processor engaged in the processing of acidified food products, you must, not later than 60 days after registration, and before packaging any new products, provide the Food and Drug Administration information on the scheduled process, including conditions of heat processing and control of pH, salt, sugar, and preservative levels and source and date of the establishment of the process, for acidified food in each container size as required by 21 CFR 108.25 (c)(2). In addition, these scheduled processes must be established by using a qualified person who has expert knowledge acquired through appropriate training and experience in acidification and processing of acidified foods as required by 21 CFR 114.83.

  Scheduled process information for acidified foods must be submitted on From FDA 2541a [Filing for all Processing Methods Except Low Acid Aseptic]. More information on registration and filing can be found in the publication "Instructions for Establishment Registration and Processing Filing for Acidified and Low-Acid Canned Foods," available at: http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/AcidifiedLow-AcidCannedFoods/EstablishmentRegistrationThermalProcessFiling/Instructions/ucm2007436.htm.

  As of February 5, 2013, there is no record of any new or revised scheduled process for Iguana brand Golden Habanero Pepper Sauce, SID #2000-06-07 /006. If your firm does not submit a new scheduled process for this product, it must follow the scheduled process registered under SID #2000-06-071006. .

  The other (b)(4) products that you manufacture, that were listed in your December 12, 2012 correspondence, which were determined to be acidified, must also have filed scheduled processes. All SIDs that have been returned to you need to be corrected and resubmitted.

Please respond in writing within thirty (30) working days from your receipt of this letter. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If you cannot complete all corrective actions before you respond, we expect that you will explain the reason for the delay and state when you will correct the remaining deficiencies. Please include copies of any available documentation demonstrating the corrections have been made.

Please send your reply to the U.S. Food and Drug Administration, Attention: Nicholas Long, 5100 Paint Branch Parkway, College Park, MD 20740. If you have questions regarding any issues in this letter, please contact me at 240-402-1612.

Sincerely,

/s/

Nicholas Long