DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD

December 22, 2011

VIA EXPRESS MAIL

Mr. Patrice Bourigault,
President
COVI S.A.S
341, route de Clisson,
44230 St Sebastien Sur Loire,
France

Reference No.: 255675

Dear Mr. Bourigault:

The U.S. Food and Drug Administration (FDA) inspected your low-acid canned food facility located at 341, route de Clisson, 44230 St Sebastien Sur Loire, France on September 12-13, 2011.

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 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 has not responded to the FDA-483 to address the deviations. We note the following serious deviations from the low-acid canned food regulations:

- Your firm's failure to process each food in conformity with at least the scheduled process filed with FDA as required by 21 CFR 108.25(c)(3)(i). Specifically, your firm did not

follow all critical factors identified on the schedule process for Couscous with Olive Oil in flexible retort pouches, [redacted] b(4), in that:

- Your firm has not measured and documented the initial temperature of the Couscous with Olive Oil, which is identified in the schedule process [redacted]. b(4),
- Your firm has not performed and documented the testing for maximum residual air, which is identified in the schedule process [redacted]. b(4),
- The weight control record identifies the target [redacted] b(4), and the [redacted] b(4),; however the [redacted] b(4), identifies a [redacted] b(4), The weights that were documented on the record were within the required parameters, but the target [redacted] b(4), should be changed according to the critical factors on the submission identifiers.
- The review signature/date should be included on the Specific Control for Pouches record and the Bubble Test record.

- Your firm failed to identify, from a processor check or otherwise, deviations from the scheduled process of critical factors which are not out of control as required by 21 CFR 113.89. Specifically, the following deviations from the schedule process/critical factors occurred during thermal processing of Coucous with Olive Oil [redacted] b(4), for export to the U.S. that were not identified during record review:
  - On 3/11/11 one batch of product processed in retorts #s A, B, C, & F did not achieve the critical factor of [redacted]. b(4),
  - On 3/11/11 one batch of product processed in retorts #s A, B, C, & F did not achieve the critical factor of [redacted]. b(4),
  - The same batches referenced above had an [redacted] b(4), [redacted] b(4), as identified on the schedule process.

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 and the low-acid canned food regulations (21 CFR Parts 108 and 113). 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 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: Carol D'lima, 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. D'lima at (240) 402-2033 or via email at carol.dlima@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