DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

February 22, 2012

VIA OVERNIGHT DELIVERY

Mr. Antonie Wassner, General Director/ CEO
Sabarot Wassner S.A.
ZA La Combe
43320 Chaspuzac, France

Reference No: 278717

Dear Mr. Wassner:

The U.S. Food and Drug Administration inspected your low-acid canned food facility, Sabarot Wassner S.A., located at Za Bleu, 43000 Polignac, France, on September 19- 21, 2011. During that inspection, we found that your firm had serious deviations from the low-acid canned food regulations. These regulations are described in Title 21, Code of Federal Regulations, Part 108, Emergency Permit Control (21 CFR 108), and Part 113, Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers (21 CFR 113). As outlined in these regulations, a commercial processor that does not adhere to all of the mandatory requirements of 21 CFR 108.35 and 21 CFR Part 113 could be subjected to an immediate application of the emergency permit control provisions of Section 404 of the Act (21 U.S.C. 344). As stated in 21 CFR 108.35(k), for imported products, in lieu of issuing an order of determination that a permit is required before products from such commercial processor can be introduced into interstate commerce, FDA may take steps to refuse admission of the commercial processor's products under section 801 of the Act (21 U.S.C. 381) when offered for entry into the United States. In addition, violation of the mandatory requirements set forth in 21 CFR 108.35 and 21 CFR Part 113 renders your low-acid canned mushrooms 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 acidified 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, listing the deviations found at your firm at the conclusion of the inspection. We acknowledge your September 30, 2011, response indicating corrective actions to the FDA-483. Upon further review of the inspectional findings, documentation provided in your firm's response, and additional information provided during the inspection, we have the following concerns with regard to your low-acid canned mushroom products:

- Your firm failed to process each low-acid canned food in conformity with at least the scheduled process filed with FDA, as required by 21 CFR 108.35(c)(3)(i). Specifically, your firm filed a thermal process with FDA for your canned Mushrooms Wild Forest

Whole in Brine (SID (b)(4)) stating the cans rely on a (b)(4) to (b)(4) mm mushroom particle size as a critical factor. However, during our inspection, your firm was not measuring particle size during processing. In your response dated September 30, 2011, you stated that a new process will be filed with FDA removing particle size as a critical factor; however, a new process has not been filed to reflect this change.

- Your firm failed to determine and record the initial temperature of the contents of the containers prior to processing to ensure that the temperature of the product is no lower than the minimum initial temperature specified in the scheduled process as required by 21 CFR 113.87(c). Specifically, you are not removing the coldest container of every retort load just prior to processing and recording the initial temperature. In your written response dated September 30, 2011, you state that the initial temperature critical factor has been changed in your process filings with FDA; however, you did not indicate you are currently taking the initial temperature of the cans and you did not provide documentation showing the initial temperature readings are in accordance with the scheduled process.

- Your firm failed to measure and record at intervals of sufficient frequency the maximum drain weight as specified in your scheduled process to ensure that the weight does not exceed the maximum for the given container size specified in the filed scheduled process as required by 21 CFR 113.40(a)(13)(i). Specifically, on May 18, 2011 and September 23, 2010, the drained weight for your canned mushrooms exceeded the maximum drained weight as specified in your filed scheduled process. In your response dated September 30, 2011, you state that you will conduct a new study with your process authority to determine if the drained weight can be increased; however, a new study or a new process has not been submitted to reflect this change.

- Your firm's operators of the retorts and persons who perform container closure examinations are not under the operating supervision of a person who has attended and successfully completed a thermal processing school approved by FDA, as required by 21 CFR 108.35(g).

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

Please 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. In addition, responding in English will help to assist us in our review of your documentation. 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: Leslie Hintz, 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 any issue in this letter, you may contact Ms. Hintz at (240)402-2073 or via email at Leslie.Hintz@fda.hhs.gov.

Sincerely,

/s/

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