DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD

December 1, 2011

VIA EXPRESS MAIL

Mr. Lee Min-Jea, President
Wooil Food & Beverage Co., Ltd.
311-35 Jinae-ri, Yecheon-up
Yecheon-Gun
Republic of South Korea

Reference No.: 244594

Dear Mr. Min-Jea:

The U.S. Food and Drug Administration (FDA) inspected your low-acid canned food and acidified foods facility located at 311-35 Jinae-ri, Yecheon-up, Yecheon-Gun, Republic of South Korea on July 18-19, 2011. The inspection revealed that you manufacture low-acid canned food products, namely Green Flavored Beverages (Green Tea).

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 July 26, 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 "Green Flavored Beverage (Green Tea)" ((b)(4)) lists a steam still retort with (b)(4) ; however, in practice, your firm is using a (b)(4) (b)(4) process that does not include a retort to achieve commercial stability. You stated in your response that you will make a correction to your scheduled process so that it represents your current process, but at this time, this revised process filing has not been received by FDA. We acknowledge that you have submitted eight (8) new process filings for your acidified Aloe Juice products since the close of this inspection, but no new LACF processes have been submitted. Therefore, your firm needs to submit a revised scheduled process that includes substantiation by a qualified scientific authority as to its adequacy in order for FDA to determine whether your "sterilization system" for this low-acid canned food product is adequate.

- Your firm's required container identification failed to include the establishment where packed and type of product as required by 21 CFR 113.60(c). Specifically, the date codes used on your firm's green tea products manufactured at your facility do not include a code for the name of the facility and the type of product. Your firm's response indicated that you would immediately make a correction, but you failed to provide any documented evidence of your new container code.

In addition, there is no one at your firm that has completed a thermal processing school approved by FDA as required by 21 CFR 108.35(g). Your firm's response states that there are no approved schools available in Korea and you requested that we provide you with information about such schools in the United States. Please refer to the following link that lists the current schools available in the United States: http://www.gmaonline.org/file-manager/Events/Bro_BPCS-011411.pdf.

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.

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 acidified food regulations (21 CFR Parts 108 and 114), 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.

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