# Weifang Sunwoo Foods Co., Ltd. 9/21/16

**Department of Health and Human Services**

Public Health Service
Food and Drug Administration
College Park, MD 20740

SEPT 21, 2016
**VIA EXPRESS DELIVERY**

Mr. Zhang Fengquan
General Manager and Owner
Weifang Sunwoo Foods Co., Ltd.
No. 1 Sunwoo Rd., Guanggong Town,
Amqui City (Weifang),
Shandong Province, China 262133

Reference No.: 499185

Dear Mr. Fengquan:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your acidified food (AF) facility Weifang Sunwoo Foods Co., Ltd. on April 26-28, 2016. During that inspection, we found that your firm had serious deviations from the Emergency Permit Control regulation, Title 21, Code of Federal Regulations, Part 108 (21 CFR 108) and the Acidified Foods regulation (21 CFR 114). At the conclusion of the inspection, the FDA investigator issued an FDA-483, Inspectional Observations that lists the serious deviations found at your firm. We have not received any correspondence from your firm in response to the FDA-483.

As a manufacturer of AF 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 the AF products you export to the United States. These regulations are described in 21 CFR 108, Emergency Permit Control and 21 CFR 114, Acidified Foods. The Emergency Permit Control regulations were issued, in part, pursuant to section 404 of the Act, Emergency Permit Control (21 U.S.C. § 344). As outlined in these regulations, a commercial processor that does not adhere to all of the mandatory requirements of 21 CFR Part 108.25 and 21 CFR Part 114 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 108.250), for imported products, in lieu of issuing an order of determination that a permit is required before products from a 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. Consequently, your violations of the mandatory requirements set forth in 21 CFR 108 and 114 render your AF 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 AF regulations through links in FDA's home page at **www.fda.gov (/default.htm)**.

Your significant violations are as follows:

1. Your firm failed to handle processing deviations involving acidified radish products in accordance with the requirements of 21 CFR 114.89 (e.g., reprocess or set aside for evaluation). For example, on January 2, 2016, "pickled sweet radish cut" was processed for 20 minutes which is lower than the minimum process time of **(b)(4)** minutes listed on your filed scheduled process. In addition, on April 2, 2016, "pickled sweet radish cut" was processed at a temperature range of from 35- 58°C (94 op to 136.4°F) according to computer records which is lower than the minimum temperature of **(b)(4)** listed on your filed scheduled process.

2. Your firm does not **(b)(4)** critical factors specified in the scheduled processes for your acidified foods products in accordance with 21 CFR 114.100(b) as observed during our inspection. These include the following:

a. For your pickled sweet radish products:

- cut - maximum cut diameter, maximum thickness in retort and maximum residual air
- strips -minimum strip diameter, maximum thickness in retort and maximum residual air
- sliced - minimum slice thickness, maximum thickness in retort and maximum residual air

b. For your seasoned sweet ginger:

- sliced - initial temperature and total processing time in minutes

c. For your seasoned burdock:

- cut- maximum cut diameter, maximum thickness in retort and maximum residual air

3. Your firm failed to adequately mark each container in accordance with 21 CFR Part 114.80(b). Specifically, your containers are not marked with a code identifying establishment where packed, product contained, year, date and packing period.

4. Your firm failed to maintain required records in accordance with 21 CFR Part 114.100(e) for a period of 3 years from the date of product manufacture. Concerning our request for temperature recording data records for a lot of Burdock manufactured on 4/13/2015, your firm replied that you keep computerized records for less than a year on a computerized file.

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your request should outline the specific steps you are taking to correct the deviation. More specifically, your request should include documentation that reflects the changes you made, such as a copy of your filed scheduled processes, five (5) consecutive days of completed monitoring records (i.e., records for the production of five (5) production date codes of the products), and any additional information that you wish to supply that provides assurance of your intent to fully comply now and in the future with the applicable laws and regulations. Submission of the information in English will assist in our review. If you cannot complete all corrections within 15 days, you should explain the reason for the delay and state when you will correct any remaining violations.

If you do not respond to this letter or if we find your response inadequate, we may take further action. For instance, we may take action to refuse admission of your imported AF products under section 801(a) of the Act, 21 U.S.C. § 381(a), including placing them on detention without physical examination (DWPE). FDA's DWPE is an administrative procedure whereby products offered for import into the United States may be detained without physical examination upon entry. DWPE information may be conveyed in FDA's Import Alerts. For your information, an example of an Import Alert that conveys information specific to foreign firms that are not in compliance with the LACF and acidified

food regulations (21 CFR 108, 113 and 114) is Import Alert #99-38. This alert can be found on FDA's web site at: **http://www.accessdata.fda.gov/cms_ia/importalert_1132.html (/default.htm)**.

We note that the processing of products at your facility included a **(b)(4)** If this step would be considered a fermentation of major ingredients in the product we recommend that you have a processing authority qualified in the acidification of foods evaluate your products for determination of the regulatory requirements applicable to these products and submit their findings and conclusions to us along with your response.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act and all applicable regulations, including the acidified food regulations (21 CFR 108 and 114) and the Good Manufacturing Practice regulation (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Additionally, Section 743 of the Act (21 U.S.C. § 379j-31) authorizes FDA to assess and collect fees to cover FDA's costs for certain activities, including re-inspection-related costs. A re-inspection is one or more inspections conducted subsequent to an inspection that identified noncompliance materially related to a food safety requirement of the Act, specifically to determine whether compliance has been achieved. Re-inspection-related costs means all expenses, including administrative expenses, incurred in connection with FDA's arranging, conducting, and evaluating the results of there-inspection and assessing and collecting there-inspection fees (21 U.S.C. § 379j-31(a)(2)(B)). For a foreign facility, FDA will assess and collect fees for re-inspection-related costs from the U.S. Agent for the foreign facility. The inspection noted in this letter identified noncompliance materially related to a food safety requirement of the Act. Accordingly, FDA may assess fees to cover any reinspection-related costs. Please consider providing a copy of this letter to your U.S. Agent.

Please send your reply to the Food and Drug Administration, Attention: Donald Greaves, Compliance Officer, Food Adulteration Assessment Branch (HFS-607), Division of Enforcement, Office of Compliance, 5001 Campus Drive, College Park, MD 20740 U.S.A. You may send any information related to this case and/or any questions you may have regarding this letter to Mr. Greaves via email at: Donald.Greaves@fda.hhs.gov. Please reference #499185 on any submissions and within the subject line of any emails to us.

Sincerely,
/S/
William A. Correll
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

**More in 2016 (/ICECI/EnforcementActions/WarningLetters/2016/default.htm)**