DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD 20740

October 24, 2016

VIA EXPRESS DELIVERY

Mr. Lantao Li
Legal Chairman
Beijing Lorain Foodstuff Co.
NO. 26 Keji Road
Miyun Industrial Area
Beijing, China

Reference #507092

Dear Mr. Li:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your low-acid canned food (LACF) facility, Beijing Lorain Foodstuff Co., located at No. 26 Keji Road, Miyun Industrial Area, Beijing, China on April 26-29, 2016. That inspection revealed violations of the Emergency Permit Control regulation (Title 21, Code of Federal Regulations, Part 108 (21 CFR 108)) and the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation (21 CFR 113). That 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 receipt of your responses and supporting documentation to that FDA-483 received between August 15 and September 6, 2016. Our evaluation of the documentation submitted revealed that your responses were not adequate, as further described in this letter.

As a manufacturer of LACF products intended for export to the United States, you are required to comply with the Act and the federal regulations relating to the processing of low-acid foods packaged in hermetically sealed containers. The Emergency Permit Control regulations were issued, in part, pursuant to Section 404 of the Act, Emergency Permit Control, 21 U.S.C. § 344. A temporary emergency permit may be required for thermally processed low-acid foods packaged in hermetically sealed containers whenever a processor has failed to fulfill the requirements of 21 CFR 108.35, including registration and filing of process information, and the mandatory requirements in 21 CFR Parts 113. Regulations specific to the processing of LACF are described in 21 CFR Part 108 and 21 CFR Part 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 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. Violation of the mandatory requirements set forth in 21 CFR

108.35 and 21 CFR Part 113 renders your LACF products adulterated within the meaning of Section 402(a)(4) of the Act, 21 U.S.C. 342(a)(4).
We note the following significant deviations:

1. You must ensure that each retort shall have an accurate temperature-recording device, as required by 21 CFR 113.40(a)(2). Specifically, during our inspection you explained to our investigator that temperature-recording devices on your automated retort system, which both records and controls temperature in your cascading water retorts had not been validated for accuracy. Your response included two print screens of the retort control program used in your retort systems with a translated written description of, "(b)(4) " Your response did not indicate if or how the systems were validated. Computerized systems are used not only for the generation of LACF processing records, but for control functions such as process temperature, process pressure, and process timing. The control of functions that may be critical to ensuring a safe food product, must meet the intent of the LACF regulations.

2. You must maintain recording thermometer chart records, as required by 21 CFR 113.100(b). Specifically, our investigator discovered during our inspection that you deleted all original recording thermometer charts associated with Retort #2, and did not retain backup records of recording thermometer charts for your black bean production dated 1/15/16, your ginko nut production dated 1/15/16, and your shelled chestnut production dated 3/8/16. Your processing records for these dates were signed off as reviewed; however, the recording thermometer charts were missing. Additionally, these records were not identified with date and retort number, and the chart scale does not allow for an adequate review of temperature and time (scale shows only (b)(4), (b)(4) , and (b)(4)°C). Your response included one example of a thermometer chart record showing a hand written time, date, and retort # that corresponds to the retort log and heat sensitive tape records for that run. The scale on the chart remains at (b)(4) and (b)(4)°C. The recording thermometer charts, and all records of critical processing limits, are necessary to demonstrate that the scheduled process was delivered, and provides a means to verify such by the records reviewer.

3. You must examine the pouch container closures for your LACF product pouches to ensure proper closing machine performance and consistently reliable hermetic seal production, as required by 21 CFR 113.60(a)(3). However, you explained to our investigator during the inspection that you rely only on certificates of analysis for your packaging material when it is received. However, you do not conduct any examinations or testing to ensure adequate hermetic seals were maintained for your LACF product packaging. Your response stated that you purchased testing equipment and would conduct "(b)(4) " tests (b)(4) . You then provided a photo of testing equipment, a completed packaging test record dated August 23, 2016 with translation of the results showing (b)(4) visual exams and destructive inspections (tension values) at (b)(4) (b)(4). However, you did not submit your test requirements or procedures. If you have fully implemented this correction, please submit documentation of such. Otherwise, we will verify your corrective actions during our next inspection.

4. You must mark each container with the required identification code specifying the establishment where the product was packed, product contained therein, and the year, day, and packing period, as required by 21 CFR 113.60(a)(3). However, the production code you place on your LACF product packaging does not include the year and day packed. Your response included a photo showing one product package with the production code indicating the year, day, and a numeric code which apparently corresponds to the retort used. The code does not indicate the facility or product packed.

You should respond in writing within 30 working days from your receipt of this letter. Your response should outline the specific steps you are taking to correct these violations and should include documentation that would assist us in evaluating your corrections, such as validation of your computerized retort systems, processing records including recording thermometer charts, container closure procedures and records, and photo of corrected production code. Responding in English will help to assist us in our review of your documentation. If you cannot complete all corrections within 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 your facility operates in compliance with the Act and all applicable regulations, including the LACF regulations (21 CFR 108 and 113) and the current Good Manufacturing Practices regulation (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Aleta T. Flores, Compliance Officer, Food Adulteration Assessment Branch, Division of Enforcement, Office of Compliance, Center for Food Safety and Applied Nutrition, HFS-607, 5001 Campus Drive, College Park, MD 20740 U.S.A. You may submit documentation accompanying your reply to: aleta.flores@fda.hhs.gov. Please reference #CMS 507092 on any submissions and within the subject line of any emails to us. You may also contact Aleta Flores via email if you have any questions about this letter.

Sincerely,

/s/

Mildred Benjamin
Acting Director
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition