DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
College Park, MD 20740

August 30, 2016

VIA HAND DELIVERY

Ricardo Fairclough-Leslie, President
Island Soups Company, Inc.
194-22 115th Avenue
Saint Albans, NY 11412

ORDER
DETERMINATION OF NEED FOR AN EMERGENCY PERMIT

Dear Mr. Fairclough-Leslie:

Your facility manufactures low-acid canned food (LACF) products for distribution into interstate commerce. These products are subject to regulation under Title 21, Code of Federal Regulations (21 CFR), Parts 108 and 113. The United States Food and Drug Administration (FDA) inspected your commercial processing facility on June 22, 2016. We have determined after investigation that you do not meet the mandatory conditions and requirements established in 21 CFR Parts 108 and 113 as outlined in this letter. Therefore, in accordance with 21 CFR 108.5(a), 21 CFR 108.7(a), and Section 404 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 344), FDA is issuing this Order to advise you that you must obtain and hold an Emergency Permit before any FDA-regulated LACF products manufactured, processed, or packed in your facility may be introduced or delivered for introduction into interstate commerce. Any FDA-regulated LACF products manufactured, processed, or packed in your facility without a permit cannot be introduced or delivered for introduction into interstate commerce unless you obtain advance written approval from FDA under 21 CFR 108.12(a).

FDA previously inspected your facility in July 2015, and found that your firm had serious violations of the LACF regulations, Title 21, Code of Federal Regulations (CFR), Parts 108 and 113 which were documented on the FDA Form 483, List of Inspectional Observations, issued to your firm at the conclusion of that inspection. During that inspection, your firm was manufacturing a variety of LACF soup products, including Red Peas Soup (No Meat), Gungo Peas Soup (No Meat), and Fish Soup, and you distributed these LACF soup products into interstate commerce. The violations noted during the July 2015 inspection were similar to those violations found during the inspection conducted on June 22, 2016. At the conclusion of the July 2015 inspection, you signed an affidavit stating that you would cease production and distribution of LACF products until such time that you met all applicable FDA regulatory requirements, including filing your scheduled processes with FDA. To date, you have failed to file any scheduled processes for your LACF soup products. Our June 2016 inspection found no correction of the violations observed during our prior inspection, although evidence obtained by the FDA shows your interstate shipment of LACF soup products in 2016 via orders placed on your website www.islandsoups.com.

Specifically, FDA has evidence that you fulfilled online orders for your Gungo Peas Soup (No Meat) and Red Peas Soup (No Meat) by shipping those products in interstate commerce in both March

2016 and June 2016. However, during the most recent inspection you repeatedly denied that your firm is manufacturing or distributing any LACF soup products—and signed an affidavit attesting to this fact—despite being informed that the FDA had obtained evidence of your shipment of soups since the last inspection. Further, you were informed by our investigator that lying to a federal officer is a criminal act under Title 18 punishable by fines and/or jail time prior to signing your affidavit on June 22, 2016.

We acknowledge receipt of your firm's response on June 29, 2016, responding to the FDA Form 483 issued at the conclusion of our June 2016 inspection, in which you outlined corrections you have taken or plan to undertake. Your June 29, 2016 response states that you will cease use of your (b)(4) and contract with a co-packer to manufacture your soups. Your response implies that your co-packer will file your scheduled processes, maintain processing records, conduct container integrity examinations, and otherwise address the violations that the investigator identified. Please note that if you decide to apply for the issuance of an Emergency Permit, 21 CFR 108.7(b) requires that your application contain such data and information as is necessary to show that all mandatory requirements and conditions for the manufacturing, processing, and packing of your products are met, and in particular, that the violations specified in this Order have been corrected or suitable interim measures established. More information about applying for an Emergency Permit is described below.

This Determination of Need for an Emergency Permit Order ("Order") is based on your firm's violations of the mandatory requirements of 21 CFR Parts 108 and 113 observed during our June 2016 inspection of your facility as cited below:

1. As a commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers you must, not later than 60 days after registration and prior to the packing of a new product, provide the Food and Drug Administration information as to the scheduled processes for each such low-acid food in each container size, to comply with 21 CFR 108.35(c)(2).

   Specifically, your firm's scheduled processes for Gungo Peas (No Meat) Soup, Red Peas (No Meat) Soup, and Fish Soup were returned to you on October 30, 2012, and therefore are not considered to be filed with FDA. These scheduled processes were submitted with incomplete processing information based on invalid process source documentation. You were advised to correct the noted errors and resubmit promptly as the forms were not considered to be filed under 21 CFR 108.25(c)(2) and 21 CFR 108.35(c)(2). Your firm must file completed scheduled processes in order to be in compliance with 21 CFR 108.35(c)(2).

   Scheduled process information for LACF products thermally processed by a retorted method must be submitted on Form FDA 2541d (Process Filing for Low-Acid Retorted Method). Additional information on registration and filing can be found in the publication "Establishment Registration & Process Filing for Acidified and Low-Acid Canned Foods (LACF)," available at:

www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/default.htm.

In addition, scheduled processes must be established by qualified persons having expert knowledge in the thermal processing of low-acid foods in hermetically sealed containers, as required by 21 CFR 113.83.

2. Your firm failed to provide information concerning processes and procedures deemed necessary to determine the adequacy of your processes when requested by FDA in writing, as required by 21 CFR 108.35(c)(3)(ii). Specifically, on June 22, 2016, the investigator issued you Form FDA 482b, requesting all documents and records mandated by 21 CFR Part 108 relating to or having a bearing on the establishment and adequacy of processes for all LACF products processed in your firm's (b)(4) You have not responded to this request.

3. Your firm failed to have all operators of thermal processing systems and container closure inspectors under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction in retort operations, aseptic processing, packaging system operations or other thermal processing systems operations, and container closure inspections, and has satisfactorily completed the prescribed course of instruction, as required by 21 CFR 108.35(g) and 21 CFR 113.10. Specifically, no one associated with your firm, or operating your firm's thermal processing equipment, has satisfactorily completed or is under the supervision of someone having satisfactorily completed a Better Process Control school approved by the Commissioner.

4. Your firm failed to record processing and production information at the time it was observed as required by 21 CFR 113.100(a). Specifically, for a still retort, records were not maintained for the time that steam was turned on, the time that the retort reached processing temperature, the time that steam was shut off, the venting time and the venting temperature in accordance with 21 CFR 113.100(a)(1). Documentation of this information is evidence that a particular shelf-stable food product is processed sufficiently to destroy *Clostridium botulinum* and its spores.

   You stated that your firm has not manufactured or distributed any thermally processed low acid foods since the previous inspection and therefore does not have any "process monitoring records." However, as noted above, FDA has obtained evidence that you fulfilled online orders for your Gungo Peas Soup (No Meat) and your Red Peas Soup (No Meat) by shipping those products in interstate commerce in both March 2016 and June 2016. However, during the inspection you were unable to provide our investigator with processing and production records.

5. Your firm failed to equip its (b)(4) with a temperature recording device or temperature indicating device as required by 21 CFR 113.40(a)(1).

6. Your firm failed to ensure that your retort is equipped with an (b)(4) maintain the retort temperature, as required by 21 CFR 113.40(a)(4). Specifically, your firm's (b)(4) is equipped with (b)(4), which is operated in

conjunction with a (b)(4) manufacturing operations. In addition, venting times and temperatures are not posted or being recorded during manufacturing operations.

7. Your firm failed to check capper efficiency, for glass containers with vacuum closures, by a measurement of the (b)(4) before actual filling operations as required by 21 CFR 113.60(a)(2). Specifically, you are not performing testing to validate capper efficiency of hermetically sealed containers for any batch of LACF soup products manufactured and distributed by your firm.

8. Your firm failed to mark each hermetically sealed container of low-acid processed foods with an identifying code that identifies in code the establishment where packed, the product contained therein, the year packed, the day packed, and the period during which packed, as required by 21 CFR 113.60(c). Specifically, our inspection revealed the manufacturing codes on your firm's LACF soup products reflect the expiration date in the form of a "BEST BEFORE" date consisting of month and year that represents a two year shelf life from the month of packing. This code does not meet the regulatory requirements for product container coding.

You have three (3) working days after receipt of this Order during which you may file objections per 21 CFR 108.5(a)(1). If you decide to file objections, such objections should include information that you believe shows there is a genuine and substantial issue of fact that justifies a hearing. Such objections must be filed in writing and addressed to Sabina Reilly, Director, Division of Enforcement, Office of Compliance, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS-605), 5001 Campus Dr., College Park, MD 20740, 240-402-2112. We will give prompt consideration to any objection which you may have. In accordance with 21 CFR 108.5(a)(1), if such objections are filed, the determination that you need to obtain an Emergency Permit will be stayed pending a hearing to be held within five working days after the filing of objections on the issues involved unless FDA determines that the objections raise no genuine and substantial issue of fact to justify a hearing.

If you do not submit an objection within three working days after receipt of this Order, we will consider this Order that your facility needs an Emergency Permit to introduce or deliver for introduction into interstate commerce your LACF products to be a final agency decision. You may apply for the issuance of an Emergency Permit as provided in 21 CFR 108.7. An application to request an Emergency Permit should be submitted in writing and addressed to Sabina Reilly, Director, Division of Enforcement, Office of Compliance, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS-605), 5001 Campus Drive, College Park, Maryland 20740. Until such time as you hold an Emergency Permit or receive advance written approval of the FDA, as provided in 21 CFR 108.12, you may not introduce or deliver for introduction into interstate commerce any LACF products that are manufactured, processed, or packed in your facility. This prohibition includes food produced before your receipt of this Order which is currently under your control.

Furthermore, please note that Section 743 of the FD&C Act (21 U.S.C. Parts 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 FD&C 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 the re-inspection and assessing and collecting the re-inspection fees (21 U.S.C. 379j-31(a)(2)(B)). For a domestic facility, FDA will assess and collect fees for re-inspection-related costs from the responsible party for the facility. The inspection noted in this Order identified non-compliance materially related to a food safety requirement of the FD&C Act. Accordingly, FDA may assess fees to cover any costs related to re-inspection.

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

(b)(5) [redacted]

(b)(5) [redacted]