WARNING LETTER

Sprouts Unlimited IncMARCS-CMS 603883 — FEBRUARY 21, 2020

Delivery Method:

VIA UNITED PARCEL SERVICE
Signature Required

Product:

Food & Beverages

Recipient:

William C. Beach

President

Sprouts Unlimited Inc

799 51st StreetMarion, IA 52302United States

Issuing Office:

Division of Human and Animal Food Operations West II

United States

WARNING LETTER

603883

Dear Mr. Beach:

The U.S. Food and Drug Administration (FDA) inspected your sprouting operation located at 799 51st Street, Marion, Iowa, from December 31, 2019, to January 9, 2020. FDA conducted this

inspection because sprouts grown at your operation were linked by the state of Iowa Department of Inspections and Appeals, Department of Public Health, and the **(b)(4)** to an outbreak of human infections with Shiga toxin-producing *Escherichia coli* O103 (*E. coli* O103) in the state of Iowa. This outbreak sickened 22 people between November 21 and December 14, 2019. Shiga toxin-producing *E. coli* is a pathogenic bacterium that can cause serious illness in humans, including diarrhea, often with bloody stools. Although most healthy adults can recover completely within a week, some people can develop a form of kidney failure called hemolytic uremic syndrome (HUS). HUS is most likely to occur in young children and the elderly. This condition can lead to serious kidney damage and death.

Based on the combined evidence, summarized below, linking clover sprouts from your firm to this outbreak, we have determined that your clover sprouts are adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 342(a)(1)] in that your clover sprouts bear or contain an added poisonous or deleterious substance which may render them injurious to health. In this letter, we outline the evidence that we used to make this determination.

During our December 31, 2019, to January 9, 2020, inspection, FDA investigators documented numerous serious violations of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption regulation (PSR), Title 21, Code of Federal Regulations, Part 112 (21 CFR Part 112) that may have resulted in the contamination of your sprouts with human pathogens. Accordingly, your mung bean, red bean, alfalfa, clover, broccoli, onion, radish, pea, and lentil sprout products, and any combination thereof, are further adulterated within the meaning of section 402(a)(4) of the Act [21 U.S.C. § 342(a)(4)], in that they were prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or been rendered injurious to health. The deviations from the PSR are detailed in this letter. Failure to comply with the PSR is a prohibited act under section 301(vv) of the Act [21 U.S.C. § 331(vv)]. You can find the Act and its implementing regulations through internet links in FDA's home page at http://www.fda.gov.

We received your response, dated January 31, 2020, concerning our investigators' observations noted on the Form FDA 483, Inspectional Observations (FDA 483), issued to you on January 9, 2020. We address your response below, in relation to each of the noted violations.

Outbreak and Microbial Analysis

Epidemiological and traceback data as documented by the state of Iowa Department of Public Health, local public health departments in Iowa, and the Iowa Department of Inspections and Appeals, support the conclusion that clover sprouts grown and distributed by your firm were the source of this single-state outbreak of *E. coli* O103 infections. A summary of the evidence used to make this determination is as follows:

As of January 7, 2020, a total of 22 people from Iowa had been infected with the outbreak strain of *E. coli* O103. Of the 21 case patients interviewed, 45% reported eating sprouts in the week before their illness. The Iowa Department of Public Health identifies this proportion to be significantly higher than results from a survey of healthy people in which 3.3% of people interviewed reported eating sprouts.

Based on a traceback investigation conducted by Iowa Department of Inspections and Appeals for this outbreak, ill persons reported the source or likely source of their sprout exposures as one of 15 sandwich restaurants that are a part of the same restaurant franchise. During the outbreak investigation, epidemiological and traceback analyses of records and information supplied by sandwich restaurants identified your **(b)(4)** clover sprouts to **(b)(4)** of the 15 sandwich restaurants.

As further evidence that your clover sprouts were linked to the outbreak, an analysis of clover sprouts and spent sprout irrigation water (SSIW) collected by your firm and analyzed by the **(b)(4)** yielded a strain of *E. coli* O103 highly related to the outbreak strain of *E. coli* O103. On December 23, 2019, you collected sixteen samples of clover sprouts and two SSIW samples and delivered these samples to the **(b)(4)** for pathogen analysis. Analysis revealed fifteen of the sixteen sprout samples and one of the water samples yielded *E. coli* O103. **(b)(4)** conducted whole genome sequencing (WGS) on the *E. coli* O103 isolates obtained from one of your clover sprouts samples and one of your spent sprout irrigation water samples and compared them with whole genome sequencing of isolates of *E. coli* O103 obtained from clinical specimens. Whole genome sequencing analysis of bacterial human pathogens provides high-resolution data, enabling links to be established between clinical isolates and food or environmental sources of bacterial contamination and illness. Through this WGS analysis, FDA and the Iowa Department of Public Health determined that these isolates of *E. coli* O103 likely came from the same source.

Produce Safety Rule Violations

During the inspection, FDA investigators observed the following significant violations of the PSR, 21 CFR Part 112:

1. You did not test spent sprout irrigation water (SSIW) from each production batch of sprouts for *E. coli* O157:H7 and *Salmonella*, as required by 21 CFR 112.144(b). Specifically, you must either: (1) Test spent sprout irrigation water from each production batch of sprouts for *E. coli* O157:H7, *Salmonella* species, and any pathogens meeting the criteria in paragraph (c) of this section, in accordance with the requirements of 21 CFR 112.147 or (2) If testing spent sprout irrigation water is not practicable (for example, soil-grown sprouts harvested with roots or for hydroponically grown sprouts that use very little water), test each production batch of sprouts at the in-process stage (i.e., while sprouts are still growing) for *E. coli* O157:H7, *Salmonella* species, and any pathogens meeting the criteria in paragraph (c) of this section, in accordance with the requirements of 21 CFR 112.147. During our inspection, your food safety manager stated that he conducts spent sprout irrigation water testing **(b)(4)** and your SSIW analytical records indicate **(b)(4)** collected **(b)(4)** from sprouting racks and **(b)(4)** collected **(b)(4)** from sprout bins. However, your records from August 25, 2019, to January 2, 2020, show that you plant sprouts approximately **(b)(4)**. Each planting occasion corresponds to at least one production batch of sprouts. Because of the timing of your **(b)(4)** SSIW testing, you failed to collect at least one SSIW sample for every production batch of sprouts. Specifically, between August 25, 2019, and January 3, 2020, you had **(b)(4)** planting occasions, but collected only **(b)(4)** SSIW samples during this timeframe. Due to your practice of moving trays of growing sprouts **(b)(4)**, it cannot be determined how many production batches of sprouts were planted during this timeframe.

We acknowledge your response dated January 31, 2020; however, we are unable to evaluate the adequacy of your corrective actions. Your response states that you have developed a lot number system for all of the sprouts you manufacture and that you are collecting SSIW **(b)(4)** into the

growing cycle of every production batch of sprouts. We are unable to evaluate the adequacy of your response because you have not provided any supporting documents demonstrating that you are currently assigning lot numbers to production batches and currently collecting SSIW from every production batch of sprouts your grow. We will verify your corrective actions during our next inspection.

2. You did not take steps to hold all product from entering commerce before receiving results from the spent sprout irrigation water tests, as required by 21 CFR 112.147(b). Specifically, FDA investigators observed you frequently moving trays of growing product **(b)(4)** at your operation, without keeping track of where each tray is placed. This practice makes it difficult to determine which in-process sprouts correspond to each set of test results, and which trays of sprouts have not been tested. Since you cannot determine which trays of sprouts have been tested, you are unable to prevent production batches of sprouts from entering commerce unless the results of the testing of spent sprout irrigation water or sprouts are negative for *E. coli* O157:H7 and *Salmonella* species, as required by 21 CFR 112.147(b).

We acknowledge your response dated January 31, 2020; however, we are unable to evaluate the adequacy of your corrective actions. Your response states that you have implemented a new lot tracking system and that all sprout products are placed on hold until the spent sprout irrigation water test result is received. We are unable to evaluate the adequacy of your response because you have not provided any supporting documents. We will verify your corrective actions during our next inspection.

3. You did not take corrective actions when environmental samples of your growing, harvesting, packing, or holding areas tested positive for *Listeria* species or *Listeria monocytogenes* (*L. monocytogenes*), including conducting additional testing to evaluate the extent of the problem, conducting additional cleaning and sanitation of affected surfaces and surrounding areas, testing finished product when appropriate, taking any other actions necessary to prevent the recurrence of contamination, and taking appropriate action to prevent adulterated food from entering commerce, as required by 21 CFR 112.146(a), 112.146(d), 112.146(e) and 112.146(f), respectively.

L. monocytogenes is a pathogenic bacterium that is widespread in the environment and may be introduced into a sprouting operation from raw materials, humans, or equipment. Without proper sanitation practices, it can proliferate in a sprouting operation where it may contaminate food. Consuming food contaminated with *L. monocytogenes* can lead to a severe, sometimes life-threatening illness called listeriosis, a foodborne illness, which is a major public health concern due to the severity of the disease, its high case-fatality rate, long incubation time, and tendency to affect individuals with underlying conditions.

Our findings below indicate you have not complied with the actions required under 21 CFR 112.146 after environmental samples tested positive for *L. monocytogenes*, resulting in potential contamination of your processing environment and finished product. Specifically:

a. On September 16, 2019, you were notified by your contract laboratory that an environmental sample collected on September 9, 2019, from sprout rack **(b)(4)** yielded *L. monocytogenes*. You did not conduct finished product testing of sprouts that were growing on rack **(b)(4)** between **(b)(4)** perform other actions to prevent the recurrence of *L. monocytogenes* in your sprout production area, or take appropriate measures to prevent adulterated sprouts from entering

commerce to comply with 21 CFR 112.146(d), (e), and (f) respectively. Although you discarded the broccoli sprouts that were on rack **(b)(4)** in response to the September 16, 2019, notification, you did not conduct finished product testing on other sprouts that were growing on rack **(b)(4)** between **(b)(4)**. FDA investigators observed you routinely move racks and in-process **(b)(4)**, without keeping track of these movements. This practice makes it difficult to determine which in-process sprouts came in contact with the affected food contact surfaces. You did not take these movements into account when evaluating products which could have been affected by swabs confirmed positive for *L. monocytogenes* for sprout rack **(b)(4)**.

b. On October 24, 2019, you were notified by your contract laboratory that a sample collected from the sprout room drain on October 21, 2019, confirmed the presence of *L. monocytogenes*. However, you did not conduct additional testing of surfaces and areas surrounding where *L. monocytogenes* was detected to evaluate the extent of the problem to comply with 21 CFR 112.146(a)

c. While you discarded **(b)(4)** of broccoli sprouts in response to the September 16, 2019, notification, you did not discard all other trays of sprouts that were on sprout rack **(b)(4)** at the time of sampling and through September 16, 2019, in order to comply with 21 CFR 112.146(f), which requires you to take appropriate action to prevent any food that is adulterated from entering into commerce. You only discarded product that was on sprout rack **(b)(4)** at the time you received your test results and failed to consider any other production batches that had been on sprout rack **(b)(4)** from **(b)(4)**.

We acknowledge your response dated January 31, 2020; however, we are unable to evaluate the adequacy of your corrective actions. Your response states that in the event that a *Listeria* swab location is positive, you will conduct exploratory testing, deep cleaning, verification testing and conduct a comprehensive investigation, to comply with 21 CFR 112.146(a), (b), (c), and (e), respectively. Your response included an updated Microbial Testing Standard Operating Procedure (SOP) dated January 4, 2020. Your responsive steps for a positive *L. monocytogenes* environmental finding (pages 10 and 11) in this current SOP are consistent with your Microbial Testing SOP, revision date September 7, 2019, (pages 7 and 8) that was in effect when you received the September 16 and October 24, 2019, notifications. Your actions following the September 16 and October 24, 2019, notifications from your contract laboratory of the presence of *L. monocytogenes* in your production environment did not comply with 21 CFR 112.146 or conform to your own procedures. We are unable to evaluate the adequacy of your response because you have not identified corrections or steps to ensure the testing and cleaning are implemented following a finding of *Listeria* or *L. monocytogenes* in your production environment. In addition, you state that you destroyed the only in process sprouts at the time of the notification from your laboratory of *L. monocytogenes* on sprout rack **(b)(4)**: the **(b)(4)** trays of broccoli sprouts. Your response did not include that any consideration was given to the sprouts growing on sprout rack **(b)(4)** at the time the swab was collected or any sprouts that were grown on sprout rack **(b)(4)** between the time the sample was taken and the time you were notified of the result.

4. You did not clean and sanitize your food contact surfaces used to grow, harvest, pack, or hold sprouts before contact with sprouts or seeds or beans used to grow sprouts, as required by 21 CFR 112.143(b). Specifically, on December 26, 2019, you were notified by your contract laboratory that clover sprout samples and SSIW sample collected, and submitted for analysis on December 23, 2019, confirmed the presence of *E. coli* O103 in both your clover sprouts and SSIW. Following

this notification, you did not clean trays used for sprouting seeds prior to exposing the trays to a **(b)(4)** solution and prior to reusing the trays to sprout seeds. Furthermore, FDA investigators observed that the trays used for growing sprouts were not cleaned, only rinsed prior to exposure to **(b)(4)** solution. We note that it is common for residue to build up on sprout growing equipment if appropriate cleaning and sanitizing procedures are not followed, which could allow for biofilm formation. A **(b)(4)** solution is intended for sanitizing, not removing organic matter. Sanitizing is generally not effective unless it is preceded by a cleaning step, because residual organic material can protect pathogens from the action of the sanitizing treatment.

We acknowledge your response dated January 31, 2020; however, we are unable to evaluate the adequacy of your corrective actions. Your response states that you now conduct **(b)(4)** cleaning with **(b)(4)** to remove any potential biofilms and that you have trained your employees on cleaning procedures. We cannot evaluate the adequacy of your response because you have not provided any supporting documentation to show that you have implemented these cleaning and sanitizing procedures. We will evaluate the adequacy of your corrective actions during our next inspection.

This letter is not intended to be an all-inclusive list of the violations at your operation or in connection with your products. You are responsible for ensuring that your operation operates in compliance with the Act and all implementing regulations. You should take prompt action to correct all violations noted in this letter. Failure to promptly correct these violations may result in legal action by FDA without further notice, including seizure and/or injunction.

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific actions you are taking to address these violations and to prevent similar violations from occurring in the future. You should include in your response documentation and any other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations. If you believe that your products are not in violation of the Act, include your reasoning and any supporting information for our consideration.

Please send your reply to the Food and Drug Administration, Attention: Andrew A. Hoopes, Compliance Officer, 8050 Marshall Drive, Suite 205, Lenexa, KS 66214. If you have questions regarding this letter, please contact Compliance Officer Hoopes at (515) 244-0480 ext. 1002 or via e-mail at: andrew.hoopes@fda.hhs.gov.

Sincerely,
/S/
Cheryl A. Bigham
District Director, Kansas City District Office
Program Division Director,
Office of Human and Animal Food Operations,
West Division II

- **Content current as of:**
  02/25/2020