

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913) 495-5100 Fax: (913) 495-5115	DATE(S) OF INSPECTION 12/28/2022-1/6/2023* FEI NUMBER 1931336
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Michael J. Rhodes, President
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FIRM NAME Rhodes Legacy Inc. DBA Sun Sprouts	STREET ADDRESS 13315 A St
CITY, STATE, ZIP CODE, COUNTRY Omaha, NE 68144-3642	TYPE ESTABLISHMENT INSPECTED Grower

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

You allowed sprouts to enter commerce prior to receipt of negative pathogen test results.

Specifically,

On 11/22/2022, following PCR analysis, you received presumptive positive Salmonella spp. analysis results from your third party laboratory associated with spent sprout irrigation water sample collected on 11/21/2022 from lot 4211 alfalfa sprouts. You subsequently collected a new sample of spent sprout irrigation water, on 11/22/2022 for lot 4211 and submitted it for PCR analysis to your lab. On 11/23/2022 following the second PCR analysis showing a negative results you released the product for shipment into interstate commerce to your customers including ones located in Kansas, Iowa and Missouri. The original presumptive positive result you received on 11/22/2022 did not have confirmation testing completed.

Furthermore, your spent sprout irrigation water sampling plan does not include actions you should take in the event of a presumptive positive analysis result.

OBSERVATION 2

You did not test spent irrigation water from each production batch of sprouts for E. coli O157:H7 and Salmonella.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Kristi B Panzer, Investigator Lionell L Thomas, Investigator	Kristi B Panzer Investigator Signed By: 2001931375 Date Signed: 01-06-2023 05 45 21 X _____	DATE ISSUED 1/6/2023

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You do not conduct spent sprout irrigation water testing or any other testing on your spicy sprout blend, your broccoli sprouts or your sunflower shoots. You stated you have not conducted any testing on your spicy sprout blend, your broccoli sprouts or your sunflower shoots since April of 2022. From April 21, 2022 to December 23, 2022 you produced your spicy sprout blend (b) (4) times, your broccoli sprouts (b) (4) times and and your sunflower shoots (b) (4) times. On (b) (4) you sold (b) (4) of 4oz clam shell containers to a customer in Iowa, per your invoice number 40829. You sold these sprouts without conducting spent sprout irrigation water testing or any other testing.

OBSERVATION 3

You did not test the spent sprout irrigation water or sprouts from each production batch of sprouts for pathogens using a scientifically valid method.

Specifically,

You send your spent sprout irrigation water samples to your third party lab who conducts PCR testing using test method: (b) (4). You use this test and receive the results as negative or presumptive positive. When you receive a presumptive positive result, you do not complete any further testing on that sample. When you receive a presumptive positive result you collect a second separate sample to test using the PCR method. Not completing further testing on the original sample does not allow you to determine if the presumptive positive was a positive or negative result.

On 11/22/2022 you received presumptive positive Salmonella spp. analysis results from your third party laboratory associated with lot 4211 alfalfa sprouts. You subsequently collected a new sample of spent sprout irrigation water for lot 4211 on 11/22/2022 and submitted it for analysis to your lab. Following the second analysis showing a negative result you released the product for shipment into interstate commerce to your customers including ones located in Kansas, Iowa and Missouri. You then treated the

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lot 4211 as negative without any justification of discrediting the initial presumptive positive result.

OBSERVATION 4

You did not maintain food contact surfaces as frequently as necessary to protect against the contamination of produce.

Specifically,

On 01/04/2022 the irrigation nozzles for your mister were observed with significant build up on them. These nozzles are used to water your sprouts growing (b) (4). You stated the nozzles were last cleaned (b) (4).

On 01/04/2022 you (b) (4) was observed to have build up around the washers, to have a rough surface and some of the (b) (4) washers were observed to be cracked providing potential harborage areas for pathogens. You stated you cleaned the (b) (4) after your last planting on (b) (4) as well as conducting a deep clean.

OBSERVATION 5

You did not employ at least one supervisor or responsible party that has successfully completed appropriate food safety training.

Specifically,

As you stated neither you nor a supervisor has successfully completed at least the equivalent of the standardized curriculum, food safety training for sprouts growers (sprouts safety alliance training). You

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also have (b) (4) employees and none of them have successfully completed at least the equivalent of the standardized curriculum, food safety training for sprouts growers (sprouts safety alliance training).

OBSERVATION 6

Your required records were not accurate.

Specifically,

Your seed treatment records had errors as to when seed lots were planted and lot numbers. These records are transcribed from the notes made at the time of seed treatment and planting. Therefore the original records are not maintained. For example:

- Your alfalfa seed treatment and planting record indicates on (b) (4) alfalfa lot 3210 was treated and planted, on (b) (4) alfalfa lot 3210 was treated and planted and on (b) (4) alfalfa lot 3210 was treated and planted. Alfalfa lot 3210 was only treated and planted on (b) (4)
- On (b) (4) the lot code on your record reads 3312. You stated the lot number actually is 3212.
- Your record has dates out of order with 11/04/2022 coming after 11/18/2022. Showing the entries were not concurrent.

***DATES OF INSPECTION**

12/28/2022(Wed), 12/29/2022(Thu), 12/30/2022(Fri), 1/03/2023(Tue), 1/04/2023(Wed), 1/05/2023(Thu), 1/06/2023(Fri)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."