DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	4/27/2026-5/1/2026
	FEI NUMBER 3010853032

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jedediah B. Fox, President/Owner

FIRM NAME	STREET ADDRESS
Salt City Baking Company, LLC	60 E Gordon Ave
CITY, STATE, ZIP CODE, COUNTRY Murray, UT 84107-2441	TYPE ESTABLISHMENT INSPECTED Manufacturer of Bakery Products

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

Your hazard analysis did not identify a hazard that required a preventive control.

This is a repeat observation from the previous inspection(s) conducted on 07/11/2024 (written observation).

Specifically, you manufacture a variety of ready-to-eat (RTE) bakery products. Your hazard analysis, "Hamburger Buns, Hoagies, Sliders, Ciabatta, Sourdough & Large Sliced Bread," DOC ID: FSM-025, Version: 2, for the 6" French Hoagie Hinge Slice was reviewed, and the following were observed:

(A) RTE bakery products, post-baking, are staged in cooling areas before proceeding to the packaging step. The cooling step was not identified in the hazard analysis. This RTE product is exposed to the environment and has the potential hazard of recontamination with environmental pathogens.

(B) RTE bakery products are conveyed through a (b) (4) slicer before they are packaged. The packaging step ((b) (4) was identified in the hazard analysis; however, the slicing step was not identified in the hazard analysis. This step has the potential hazards of recontamination with environmental pathogens and foreign material (metal fragments).

In addition, your "Process Flow Diagrams (s)" and "Process Narrative" located in the "Food Safety Plan" were reviewed, and it does not identify the cooling step. The Process Flow Diagram(s) does indicate the (b) (4) at the packaging step; however, it was not indicated in the "Process Narrative" section of the "Food Safety Plan".

(C) Your facility manufactures bakery products that contain wheat, milk, and egg allergens. Packaged RTE bakery products are either distributed in cases or packaged and delivered on racks. You did not identify undeclared allergens due to incorrect labeling as a hazard requiring preventive control.

(D) RTE 6" French Hoagie Hinge Slice contain milk and wheat allergens. Other bakery products containing wheat, milk, and egg allergens are manufactured and packaged on the same line. You did not identify allergen cross contact as a hazard needing a control at the ingredient storage, pre-scale, production, and packaging steps. You use shared equipment with wheat and dairy products with and without egg ingredients.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Ciara J Bajulai Austin, Investigator Angela M Fellows, Investigator	X Angela M Fellows Investigator Signed By: Angela M. Fellows -S Date Signed: 05-01-2026 10:31:42	5/1/2026

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(E) RTE 6" French Hoagie Hinge Slice contain milk and wheat allergens. Other bakery products containing wheat, milk, and egg allergens are manufactured and packaged on the same line. Your hazard analysis did not identify the finished product hazards such as recontamination of environmental pathogens at the cooling and packaging (b) (4) teps; foreign material (metal inclusions) at the (b) (4) step; allergen control; or finished product labeling.

OBSERVATION 2

Your written process preventive control, monitoring, corrective action and verification procedures were not appropriate to significantly minimize or prevent the hazard requiring a preventive control.

This is a repeat observation from the previous inspection(s) conducted on 07/11/2024 (written observation).

Specifically, you manufacture a variety of RTE bakery products, including the 6" French Hoagie Hinge Slice. You have identified hazards for individual ingredients; hazards at the receiving of ingredients and packaging materials, baking, metal detection, recontamination with environmental pathogens at the packaging ste(b) (4) . Written procedures for the *Allergen Control Program, Wholesale Labeling & Allergen Compliance, Master Sanitation Program, Environmental Monitoring Program,* and *Approved Supplier Program* were reviewed, and the following were observed:

Allergen Control Program

Written procedures for your *ALLERGEN CONTROL PROGRAM* were not being followed or implemented, and verification activities were not being conducted or documented.

Implementation of dedicated equipment and segregation practices is not adequate, as evidenced by:

- In the ingredient batching area, one scoop was used to transfer allergen ingredients (wheat, milk) and another scoop was used to transfer additional ingredients for staging. Per your QA Manager, this scoop is cleaned between wheat and milk allergen transfers; however, this cleaning is not being documented, nor can they ensure that this scoop is not being used for non-allergen ingredients. All bakery products are manufactured with wheat allergens, and not all bakery products are manufactured with milk allergens. In addition, the top portion of each bin contained a white powder residue. It is unclear whether the ingredient residue located on each bin was from that ingredient or from another ingredient.

- (b) (4) bins, intended for milk allergen products as your President explained, were observed to contain raw ingredients and were staged for production. One (b) (4) bin was observed containing only a wheat allergen and no milk, yet it was stored in a container intended for milk allergen products.

- A bag of cut cracked wheat was observed being stored on top of (b) (4) milk). Per your President, this wheat ingredient is not incorporated into a product that contains milk. Bags of milk ingredients were observed being stored above bins containing (b) (4) These ingredients are not incorporated into a product that contains milk.

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- Milk ingredients were observed stored in direct contact with (b) (4) (b) (4) is incorporated into numerous products that do not contain milk.

- One dedicated table, located in the (b) (4) Room and intended for applying sesame toppings to non-RTE bakery products, was observed being used to add Italian toppings to Focaccia bread. This bakery product does not contain sesame allergens.

- Used sesame trays were observed being stored directly next to trays that are not used in the manufacture of sesame products.

Procedures for your *ALLERGEN CONTROL PROGRAM* are not adequate to address undeclared allergens for finished products at the labeling step, as evidenced by:

- You manufacture products containing wheat, milk, and egg allergens. All finished products contain wheat allergens, only two finished products contain egg allergens, and some products contain milk allergens. Your *ALLERGEN CONTROL PROGRAM*, dated 01/30/2025 and 02/28/2025, indicates "All allergens in a finished product must be declared on the product label"; however, it does not identify how to ensure the correct label is placed on the correct finished product, how this will be monitored, verification activities, or corrective actions. In addition, you do not have any records related to confirming that the correct labels were applied to the correct products.

Master Sanitation Program

Your *Master Sanitation Program*, including (b) (4) (b) (4) (b) (4) was reviewed and appears to be inadequate, as it does not indicate corrective actions, monitoring activities, or verification activities, as evidenced by:

- (b) (4) and allergen swabs are obtained (b) (4) Per your QA Manager, between allergen changeovers and between different allergen products, (b) (4) and allergen swabs may not be obtained. Per your hazard analysis for *Hamburger Buns, Hoagies, Sliders, Ciabatta, Sourdough & Large Sliced Bread*, sanitation of all production equipment is swabbed and tested for (b) (4) and allergens after each production run is (b) (4) has been conducted. On 04/28/2026, I requested to review the *Allergen Swab Log*, and your QA Manager explained that this activity was not being documented.

On 04/28/2026, Post Cleaning Verification Log — (b) (4) Swab Logs were reviewed, and test results for 01/27/2026, 01/29/2026, and 01/30/2026 were observed with results indicated as "Pass" but did not include the actual numerical results. In addition, the initials of the individual conducting the test appeared to be the same individual who signed as "Verified By" from 01/27/2026 to 04/22/2026.

Pre-Op Inspection Lists were reviewed for February through April of 2026, and I observed that some documents did not indicate the specific area and/or equipment that was inspected. These documents also indicate "Reviewed By"; however, they are being completed by both the production manager and the quality manager. These documents do not indicate which individual was performing which step of the checklist. In addition, it appears that these documents were not being reviewed by a qualified

individual and were being signed by the employee conducting the pre-operational activities. Per your Master Sanitation Program SOP, the Quality Manger is responsible for reviewing and finalizing all sanitation logs for correctness and completion.

Per your Quality Manger and President, line (b) (4) and line (b) (4) are dedicated to wheat and milk allergens. They further explained that two products, containing eggs, are scheduled to run (b)(4) line (b) (4) and have occasionally been scheduled on lin (b) (4) On 04/28/2026, Brioche Glaze Overnight dough was produced on line (b) (4) — Bun Line. This product contains wheat and milk ingredients. On 04/28/2026, (b) (4) Brioche dough was the second-to-last item produced on line (b) (4) — Baguette Line. This product contains wheat and milk allergens. The (b) (4) Hoagie dough was the last item produced on line (b) (4) This product contains wheat, milk, and egg allergens. On 04/29/2026, we observed line (b) (4) with visible residue, on the equipment from the previous day production run, during the morning pre-op. On 04/29/2026, the first product produced on line (b) (4) was (b) (4) — Italian Krispy Special. This product contains wheat allergens and did not contain egg allergens. The second product produced on line (b) (4) was (b) (4) (b) (4) Hoagie Dough. This product contains buttermilk, wheat allergens, and did not contain egg allergens.

On 04/29/2026, post-sanitation, post-pre-op inspection, and before manufacturing, we observed line (b) (4) — "Baguette Line" and line (b) (4) — "Bun Line" with visible product residue throughout the lines. Both lines are located in the raw processing area of the facility, (b) (4) step. Per your QA Manager, a pre-op inspection was conducted, the *Pre-Op Inspection* form was completed by the production manager, and both lines were sanitized. On 04/30/2026, the *Pre-Op Inspection List*, DOC ID: FWM-001.3, dated 04/29/2026, for line (b) (4) and line (b) (4) was reviewed, and I observed that "All equipment surfaces are clean and free of debris" and "No visible product residues from previous runs" were indicated as "P" for pass. Documentation that product residue was found on each line during the pre-op inspection was not indicated on either form. Both documents were signed as "Reviewed By" by the QA Manager on 04/29/2026.

Environmental Monitoring Program

Your *Environmental Monitoring Program* appears to be inadequate, as it does not indicate the method, identify a laboratory for use, number of samples, sampling sites, map, or frequency of testing. Additionally, this SOP references a sampling log; however, the firm does not maintain the sampling log and instead submits the log to the third-party laboratory along with the environmental samples. In addition, this SOP has not been reviewed and signed by your PCQI.

Additionally, you conduct environmental monitoring (b) (4) and swab approximately (b) (4) for *Salmonella* spp. and (b) (4) for *Listeria monocytogenes*. Your facility is approximately (b) (4) in size and is comprised of (b) (4) of packaging equipment (currently in use) located in the RTE area; (b) (4) roduction lines located in the raw areas; (b) (4) mixers; (b) (4) production line (currently in use) located in the (b) (4) room; (b) (4) raw ingredient storage areas; (b) (4) room (b) (4) (b) (4) ingredient weigh-up section; and multiple tables located throughout the manufacturing and packaging areas. Swabbing (b) (4) areas may not be adequate for a facility of this size to ensure the effectiveness of your sanitation process.

Your sanitation process to control the hazard of recontamination with environmental pathogens is not adequate, monitored, implemented, or verified, as evidenced by:

On 04/28/2026, sanitation logs were requested for June 2025 through April 2026. Your QA Manager explained that you do not have

logs for those months. Sanitation logs were reviewed for 06/10/2025, 06/11/2025, and January through April of 2026, and I observed that these logs were not filled out completely and were not signed by a PCQI. Per your Master Sanitation Program SOP, the Quality Manger is responsible for reviewing and finalizing all sanitation logs for correctness and completion.

On 04/27/2026, the (b) (4) hinge slicer, pre-blade, located in the RTE production area, was observed cracked with an apparent brown ring around the sides of the table, and didn't appear to be in a condition to be adequately cleaned. RTE 6" French Hoagie Hinge Slice (Lo (b) (4) was observed being sliced and packaged on this line.

Multiple industrial fans, located throughout the oven and packaging areas, were observed with apparent dust and visible residue on the blades, front, sides, and back of the fans. These fans are pointed in the direction of the RTE racks of bakery products and are used to help cool down RTE bakery products. Per your QA Manager, these fans were last cleaned in February of 2026.

In addition, the floors throughout the manufacturing areas, ingredient storage, oven room, and packaging area were pitted, cracked, and damaged. There is heavy foot traffic, where employees are constantly moving racks throughout the different areas of the facility. Floors in disrepair can limit the effectiveness of cleaning and sanitation operations and can potentially contribute to pathogen harborages in those areas.

Supply Chain Program

Your facility receives flour ingredients containing wheat from multiple suppliers. Known chemical hazards for wheat flour ingredients are mycotoxins (ochratoxin A, deoxynivalenol (DON), vomitoxin) and pesticides. During my review of your written procedures for the *Approved Supplier Program*, I observed this SOP was not signed by your quality unit. In addition, your "procedures (or requirements)" are for suppliers to complete a supplier qualification questionnaire; quality management conducts a risk assessment; quality management reviews and approves the supplier; approved suppliers must submit COAs, a Letter of Guarantee, or a GMP/GFSI Certificate; and approved suppliers are monitored and verified on a (b) (4) basis. However, these procedures were not followed or implemented, and verification activities were not conducted, as evidenced by the following:

(A) During my review of your supply chain program on 04/28/2026, I requested to review the initial *Supplier Questionnaire Form* and supporting qualification documents for (b) (4) suppliers - (b) (4) of which supply wheat flour ingredients and one of which supplies wheat and buttermilk ingredients. (b) (4) out (b) (4) *Supplier Questionnaire Forms* were provided. Per your President, the questionnaires were provided to the suppliers; however, one supplier did not complete the *Supplier Questionnaire Form* or provide the requested documentation.

Both *Supplier Questionnaire Forms* were reviewed, and I observed that the *Internal Quality Review/Approval* section, intended for your quality management to complete, was not filled out and was left blank. All (b) (4) suppliers were listed on the *Approved Supplier for Ingredients/Packaging Materials* list.

(B) On 04/28/2026, *Supplier Risk Assessment Forms* fo (b) (4) uppliers were requested for review. I reviewed your *Supplier Risk Assessment Form*, Aflatoxin/Vomitoxin (DON) Statement 2024, and a third-party audit certificate dated September 04, 2024 – September

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05, 2024, for (b) (4) supplier from which your facility receives wheat flour. This ingredient was classified as a non-high-risk ingredient. The total score points were not completed and were left blank. The *Supplier Risk Assessment Form* was reviewed and approved by your President/Owner on 01/21/2026.

On 04/28/2026, I requested to review records for the (b) (4) other suppliers, from which you receive wheat flour and buttermilk. Your President explained that the supporting documents provided by the suppliers contained risk assessments. I asked if the firm relies on their suppliers' risk assessments, and your President confirmed that they do. Per your written procedures, "Quality Management conducts a risk assessment based on: Supplier History & compliance records, potential hazards associated with supplied ingredients, and third-party audit certifications." I reviewed the "risk assessments" provided by two of your suppliers, and these assessments do not appear to meet your requirements as indicated in your *Supplier Risk Assessment Form*.

(C) Your President explained that certain suppliers do not always provide COAs, nor are you requesting the suppliers to provide COAs or Letters of Guarantee. Per your *Approved Supplier Program*, "Suppliers must submit COAs for every shipment and a Letter of Guarantee confirming regulatory compliance."

In addition, your supply chain program does not appear adequate, as you are not adequately controlling the mycotoxin hazard. Per your President, your suppliers are responsible for controlling the mycotoxin hazard. However, it is unclear how your facility determined that (b) (4) out of (b) (4) suppliers from which you receive wheat flour were controlling mycotoxins, as those documents indicating their controls were not provided to you by your suppliers, nor did you request that documentation after receiving the wheat flour.

OBSERVATION 3

You did not take a reasonable measure or precaution related to personnel practices.

Specifically, you manufacture a variety of RTE bakery products. On 04/27/2026, one employee on the packaging line was observed with her sleeve touching the RTE 6" French Hoagie Hinge Slice (Lot # (b) (4) This same employee was observed rolling up her sleeves, and her forearm was observed touching the RTE 6" French Hoagie Hinge Slice (Lot (b) (4)

In addition, another employee was observed touching non-food contact surfaces, such as placing completed finished product cases on pallets, taping boxes, placing packaged RTE bakery products into the boxes, followed by packaging the RTE 6" French Hoagie Hinge Slice (Lot # (b) (4) into the plastic bag, without changing their gloves or washing their hands.

On 04/28/2026, during sanitation, one employee was observed using a (b) (4) sprayer in the oven room approximately six (6) feet from a cooling rack containing RTE (b) (4) The employee then placed the (b) (4) sprayer on the ground and walked away. This (b) (4) sprayer is used to clean all pieces of equipment, including the floors.

OBSERVATION 4

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You did not exclude pests from your food plant to protect against contamination of food.

This is a repeat observation from the previous inspection(s) conducted on 07/11/2024 (written observation).

Specifically, you are a manufacturer of a variety of RTE bread products. Your pest control "Service Summary Reports" dated 04/28/2026, 03/24/2026, and 02/24/2026, were reviewed, and apparent pests — specifically, multiple mice, beetles, and German cockroaches — were observed inside your facility by the pest technician.

In addition, we observed multiple bay doors in the warehouse with gaps and light shining into the facility. This item was observed during the previous inspection, and it was documented by the pest technician on multiple "Service Summary Reports".

X Ciara J Bajulai Austin
Investigator
Signed By: Ciara Bajulai Austin -S
Date Signed: 05-01-2026 10:32:33

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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."