

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax: (510) 337-6702		DATE(S) OF INSPECTION 3/11/2025-3/26/2025* FEI NUMBER 3002363195			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Arthur (nmi) Kao, Corporate Development Manager					
FIRM NAME Sheng Kee of California, Inc dba Sheng Kee Bakery		STREET ADDRESS 201 S Hill Dr			
CITY, STATE, ZIP CODE, COUNTRY Brisbane, CA 94005-1204		TYPE ESTABLISHMENT INSPECTED Manufacturer			
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. Your hazard analysis did not identify the following hazards as requiring allergen, sanitation, or process preventive controls when one was needed: 1) <i>undeclared allergens due to allergen cross-contact</i>, 2) <i>undeclared allergens due to incorrect labeling</i>, 3) <i>recontamination with environmental pathogens</i>, and 4) <i>metal</i>. Allergen Controls Your firm manufactures products that contain several allergen ingredients, such as wheat, milk, soy, egg, peanut, sesame, and tree nut (walnut and almond). Not all finished products contain all seven major food allergens and there is no dedicated equipment for each allergen profile. Your written hazard analysis and food safety plan for ready-to-eat (RTE) ambient products dated 7-31-2024 did not determine the chemical hazard of (1) <i>undeclared allergens due to allergen cross-contact</i> requires a preventive control at steps in the process where a control is required. Additionally, your hazard analysis identified the hazard of allergens as requiring an "Allergen Control – allergen labeling at packaging", however, you did not implement an allergen preventive control for the chemical hazard of (2) <i>undeclared allergens due to incorrect labeling</i> at the appropriate step in the process. 1) Equipment that is used to store, weigh, mix, dispense, divide, roll, knead, bake, cool, and package ingredients and finished products are shared among all finished products and therefore the hazard of <i>undeclared allergens due to allergen cross-contact</i> requires a preventive control. Your written hazard analysis identified the chemical hazard of Allergens as "potential food safety hazards introduced, controlled, or enhanced at this step" for the following processing steps: (b) (4)					
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FOOD AND DRUG ADMINISTRATION**

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Arthur (nmi) Kao, Corporate Development Manager

FIRM NAME Sheng Kee of California, Inc dba Sheng Kee Bakery	STREET ADDRESS 201 S Hill Dr
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(b) (4)

However, your hazard analysis shows that the potential food safety hazard of Allergens does not require a preventive control for all steps above. Your written procedure for ALLERGEN CONTROL PROGRAM dated 5-12-2024 shows that cleaning will be verified through pre-operational visual inspection to ensure the area is properly cleaned and the cross-contamination risk has been eliminated, however, you are not implementing monitoring, corrective action, or verification for allergen changeover or cleaning. Your employees do not complete records associated with monitoring cleaning and sanitation and they do not perform visual inspections of equipment to verify cleaning and sanitation. When we observed deficiencies in cleaning and sanitation described below, there were no corrective actions performed. Further, employees did not consistently clean and sanitize equipment and utensils with detergent and sanitizer in accordance with your written procedure.

This hazard is not being controlled, as evidence by the following:

- On 03/17/2025, we observed a (b) (4) mixer used for mixing the walnut filling which would later be included in the *Coffee Walnut Bread* finished product. An employee cleaned the (b) (4) attachment with (b) (4) water and a clean cloth. The employee returned the (b) (4) to the storage rack. We noted that the (b) (4) was not adequately cleaned and had residue on the food contact surfaces despite the employee confirming that the equipment was in the designated clean equipment storage. Later in the shift, another employee used the same (b) (4) attachment to make the base dough for *Mini Cream Puffs* with good before date of 03/24/2025, which do not contain walnuts, without cleaning or inspecting the equipment.
- On 03/14/2025, we observed a (b) (4) container storing powdered sugar and dry milk powder ingredients that separated the two powder ingredients by a (b) (4) divider. The dry milk powder contains milk allergen. The (b) (4) divider was adhered to the walls of the container with (b) (4) brackets, however, in some areas there appeared to be gaps in the brackets, which could lead to mixing of ingredients. Additionally, when opened, the lid of the container slid over both divided compartments and had powder residue on the underside of the lid, which could lead to cross-contamination of the powdered sugar with the dry milk powder ingredient.
- On 03/12/2025, we noted potential allergen cross contact regarding handling and weighing of dry ingredients in the weigh room, specifically dry milk powder and salt. Ingredients were being weighed and portioned into intermediate containers to later be used in production of several bread doughs. Each ingredient had a dedicated (b) (4) scoop stored with the ingredient within respective dedicated (b) (4) containers. We observed an employee weigh dry milk powder, during which they touched the handle of the dedicated dry milk powder scoop. The scoop had dry milk powder residue, which transferred to the employee's gloved hand. After weighing the dry milk powder, the employee returned the scoop to the dedicated container where we saw the handle come into direct contact with the dry milk powder again. Without removing gloves and washing their hands, the employee grabbed the dedicated salt scoop by the handle to weigh out the salt ingredient. After weighing the salt, the employee returned the salt scoop to the container where the handle came into direct contact with the salt ingredient.
- On 03/14/2025, we observed the chestnut cake finished product, which contains slivered almonds as decoration on the sides of the cake, stored on sheet pans on a baking rack directly above the taro cake finished product, which does not contain almond as an ingredient. Both cakes were uncovered and were exposed to the environment. We observed some loose

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slivered almonds on the sheet pan with the chestnut cake which could lead to cross contamination if employees handle both sheets pans without washing their hands or if slivered almonds fall from the upper sheet pan to sheet pans underneath. - On 03/12/2025, we observed apparent white sesame seeds in the corners of the food contact surface of the bread pans. Your Factory Supervisor stated the pans would be used later to make custard toast and that they had already been cleaned. The custard toast does not contain sesame as an ingredient. 2) Your written hazard analysis identified the hazard of Allergens as requiring a preventive control at the (b) (4) step to control for <i>undeclared allergens due to improper labeling</i>. Your written procedure for ALLERGEN CONTROL PROGRAM dated 5-12-2024 shows that printed labels are compared to the approved label during each production run. However, you are not implementing any monitoring, corrective action, or verification for the printing or application of finished product labeling. Your employees do not compare printed labels to the approved label during each production run and there are no records for the monitoring of this preventive control. Additionally, this preventive control is identified as being applied at the (b) (4) step as opposed to the (b) (4) step. However, some finished products, such as cakes, are not placed into (b) (4) and therefore this step does not apply to the cake process despite this hazard still being applicable to the finished product. Sanitation Controls You manufacture RTE finished products that will not undergo further processing prior to consumption, such as <i>Taiwan Toast</i> and <i>Large Walnut Cookie</i>, that are exposed to the environment during all steps between baking and final packaging, including cooling, assembling, and slicing steps. 3) You did not identify the hazard of recontamination with <i>environmental pathogens</i> at all steps in the process where a control is required. Additionally, you did not implement sanitation preventive controls at all applicable steps in the process. Your written hazard analysis and food safety plan for RTE ambient products dated 7-31-2024 identified "Introduction of environmental pathogens" as a potential biological hazard, however, a preventive control is not identified at the following steps where RTE finished products are exposed to the environment: - Move rack into cooling room (ambient cooling) - Package (bag) for retail store Additionally, your hazard analysis does not include the bread slicing step, where the hazard of <i>recontamination with environmental pathogens</i> would require a preventive control, since the applicable RTE finished products would be exposed to the environment. Your written procedure for Cleaning and Sanitation dated 5-12-2024 shows that equipment, food contact surfaces, floors, and walls will be visually inspected prior to production and following cleaning, however, you are not implementing monitoring or corrective action for cleaning and sanitation. Your employees do not complete records associated with monitoring cleaning and sanitation and they do not perform visual inspections of equipment to verify cleaning and sanitation. Further, employees did not consistently clean and sanitize equipment and utensils with detergent and sanitizer in accordance with your written procedure. Lastly, your written procedure addresses personnel processing practices and operational sanitation that require employees to sanitize hands and gloves during processing to avoid contamination of products. However, this hazard is not being controlled, as evidenced by the following: - On 03/12/2025, during the assembly of <i>Lemon Sponge Roll</i> with best before date of 03/25/2025, an employee was observed					
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directly handling RTE vanilla sponge cake that is used to make <i>Lemon Sponge Roll</i>. We observed the employee drop a piece of (b) (4) paper on the production room floor, pick up the (b) (4) paper from the floor, toss it in the trash, and continue to handle RTE vanilla sponge cake without washing their hands or changing gloves. This finished product does not undergo further processing. Process Controls Specifically, your written hazard analysis for RTE ambient products dated 7-31-2024, which includes items such as <i>Taiwan Toast</i> and <i>Large Walnut Cookie</i>, did not include the physical hazard of (4) metal as requiring a preventive control. 4) For finished products such as <i>Taiwan Toast</i> and <i>Large Walnut Cookie</i>, dough is mixed in a large (b) (4) bowl with (b) (4) mixer equipment, such as a (b) (4) or (b) (4) attachment, which introduces metal on metal in the processing. Additionally, for sliced bread finished products such as <i>Taiwan Toast</i>, baked and cooled bread loaves are run through the slicer machine with metal blades, which introduced another metal hazard. Process controls, such as a metal detector or blade inspection, are not in place for these finished products.					
OBSERVATION 2 You did not exclude pests from your food plant to protect against contamination of food. Specifically, on 03/12/2025, 03/13/2025, and 03/17/2025 we observed the following during the inspection: - We observed a folded and wrinkled wad of (b) (4) covered in loose powder ingredient that was wedged in a crevice of one of the dough press machines between the food contact conveyor belt and the framing of the machine. This (b) (4) was in direct contact with the food contact surface of the conveyor belt. The (b) (4) had approximately 20 apparent live beetle larvae and approximately 10 apparent live adult beetles in, on, and around it. There were apparent larvae trails in the loose powder ingredient on and adjacent to the food contact surfaces of the machine. There was powder residue in, on, and around the food contact surfaces of this dough press machine and the dough divider machine, which had been cleaned (b) (4) nights prior, according to your (b) (4). These machines are used in processing bread dough prior to the bake step. - Approximately 20 apparent rodent excreta pellets (REPs) and apparent nesting material inside the framing of the dedicated pastry oven located in the (b) (4) corner of the filling room. RTE in-process products such as mini cream cheese cakes, were seen temporarily stored on baking racks approximately one foot from the oven. - Approximately five apparent REPs on the plastic containers stacked in the (b) (4) corner of the packaging room where RTE finished products are packaged and stored. (b) (4) containers are used to distribute packaged and sealed finished products to retail stores. - Approximately ten apparent REPs on the floor adjacent to the (b) (4) sink located in the (b) (4) corner of the (b) (4) room where RTE finished products are packaged and RTE bread is sliced and packaged. The sink is approximately ten feet from the bread slicers and (b) (4) tables where exposed finished product would be packaged. - Approximately one apparent REP on the floor in the (b) (4) corner of the cake room, approximately eight to ten feet from					
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FORM FDA 483 (09/08)		PREVIOUS EDITION OBSOLETE			
		INSPECTIONAL OBSERVATIONS			
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racks storing exposed RTE cake bases. - Approximately five apparent REPs in the (b) (4) corner of the main production room (b) (4) to the ovens and (b) (4) table that are dedicated to baking, cooling, and preparing cake bases. - Approximately five apparent REPs along the perimeter of the floor in the (b) (4) and (b) (4) side of the weighing and scaling room where ingredients, such as butter, margarine, dry milk powder, calcium propionate, and salt, are weighed and staged to be made into doughs and batters. - Approximately five apparent REPs on and around pieces of a disassembled (b) (4) rack in the (b) (4) corner of the (b) (4) room where non-RTE pastry dough is sheeted and prepared. - Apparent rodent footprints and tail marks and apparent insect larvae trails on the tile floor directly underneath the (b) (4) (b) (4) machine located on the (b) (4) wall of the (b) (4) room. - Approximately one REP on the floor in the (b) (4) corner of the (b) (4) room. - Approximately five apparent REPs and apparent dried fluorescing stains on and (b) (4) to the (b) (4) refrigerator/preparation table being stored in the (b) (4) corner of the ambient warehouse approximately ten feet from stored powder ingredients such as dough conditioners. The refrigerator/prep table was not in use. - Approximately three apparent REPs on the floor of the center warehouse rack located in the center of the (b) (4) warehouse approximately six inches from pallets storing packaged and sealed powder ingredients. - An approximately half inch gap along approximately three feet of the bottom of the small roll up door on the (b) (4) wall of the (b) (4) warehouse approximately 15 feet from stored ingredients. - An approximately half inch gap along approximately four feet of the bottom of the large roll up door located along the (b) (4) wall of the (b) (4) warehouse approximately 20 feet from (b) (4) ingredients and approximately five feet from the (b) (4) door leading to the (b) (4) storage. - Third party pest control monitoring report which shows "Rats noted during service inside bait stations, found feeding of rats" or "Mice noted during service inside bait stations." located in the "EXTERIOR AREA" on eight of the last (b) (4) reports (b) (4) duration), including the most recent dated 02/24/2025.					
OBSERVATION 3 You did not clean your non-food contact surface in a manner and as frequently as necessary to protect against contamination. Specifically, on 03/14/2025, we observed the fan used to cool RTE finished product after it exits the oven had brown residue on the (b) (4) blades and front metal grill. We observed this fan being used to cool RTE finished product on 03/12/2025, 03/13/2025, and 03/14/2025, including the RTE vanilla sponge cake, which was then used to make the vanilla sponge cake with lemon jam. Your Factory Supervisor stated that this fan is also used to cool RTE finished products such as <i>Taiwan Toast</i> and <i>Large Walnut Cookie</i>.					
OBSERVATION 4 You did not clean and sanitize your utensils or equipment as frequently as necessary to protect against contamination of food. Specifically, we observed the following during the inspection on 03/17/2025:					
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- (b) (4) dough mixers had product residue on the food contact surfaces, including the (b) (4) mixing bowl and kneading attachment, following the changeover cleaning and prior to (b) (4) production operations. We observed the mixers were used to prepare the dough for *Taiwan Toast* without being adequately cleaned.
- After the manufacturing of black sesame cake, an employee was observed washing the mixing bowls and whisk used to mix the cake batter. The employee was observed rinsing the equipment with water, scrubbing the surfaces with a sponge, and rinsing the equipment with water again. The mixing bowls and whisk were then put away. The employee was not observed using soap or sanitizer.
- Bread pan that had at least one apparent raisin in the corner of the food contact surface. Your Factory Supervisor confirmed that the bread pans would be used, without further cleaning, to make *Taiwan Toast*, which does not contain raisins.

OBSERVATION 5

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

Specifically, we observed the following during the inspection:

- On 03/17/2025 during the dough mixing for *Taiwan Toast*, we observed a bucket of (b) (4) ingredient stored directly on the production floor. An employee transferred the (b) (4) to the dough mixer and touched the bottom of the bucket that had been in direct contact with the floor. The employee transferred the mixed dough from the dough mixer into (b) (4) totes by directly touching and moving the dough. The employee did not wash their hands.

***DATES OF INSPECTION**

3/11/2025(Tue), 3/12/2025(Wed), 3/13/2025(Thu), 3/14/2025(Fri), 3/17/2025(Mon), 3/19/2025(Wed), 3/20/2025(Thu), 3/24/2025(Mon), 3/26/2025(Wed)

X Breena L D'Ambrogio
Investigator
Signed By: Breena L. D'Ambrogio -S
Date Signed: 03-26-2025 14:58:13

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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."