

From: [Alicia White \(CE CEN\)](#)
To: [Wisecup, Tyra](#)
Subject: [EXTERNAL] Whole Foods Market Undeclared Milk in Beef Meatballs in Marinara
Date: Wednesday, February 24, 2021 7:41:13 PM

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Thanks for the follow-up. I just received confirmation that we are pushing up the timeline on the execution of an allergen change. The new dates are: 3/15 to communicate and 3/29 to implement.

Thanks,

Alicia

Alicia K. White
Vice President and Associate General Counsel-
Merchandising, Operations and Regulatory
Whole Foods Market Legal Team
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Austin, TX 78703
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From: "Wisecup, Tyra" <Tyra.Wisecup@fda.hhs.gov>
Date: Wednesday, February 24, 2021 at 1:11 PM
To: "Alicia White (CE CEN)" <Alicia.White@wholefoods.com>
Subject: [External] RE: [EXTERNAL] Whole Foods Market Undeclared Milk in Beef Meatballs in Marinara

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Afternoon,

We have already had a discussion with USDA/FSIS who is the regulatory agency for meat products (with caveats). We will be providing them the information that has been submitted and they will take it from here. So I don't think that I need to meet with you about it.

As to your meeting held today – are you going to be able to expedite the changes? Every opportunity to do so would be helpful. Not just to us, but to your customers and I know they are important to you.

Oh wait. I see another email from you. Let me see what it says before I hit send...not a concern – information that I already had.

Okay. If you could tell me what the decision was from your meeting, I would appreciate it.

Have a lovely day!

Tyra

From: Alicia White (CE CEN) <Alicia.White@wholefoods.com>

Sent: Wednesday, February 24, 2021 11:57 AM

To: Wisecup, Tyra <Tyra.Wisecup@fda.hhs.gov>

Subject: [EXTERNAL] Whole Foods Market Undeclared Milk in Beef Meatballs in Marinara

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Tyra-The attached press release hasn't gone out yet, but I wanted you to see it first. I am available today to discuss the issue and how our new process in Section 4.b and c will prevent this type of event. We also had a call today to see if we can further expedite this new process. It is currently set for 4/19/21. Let me know if you want me to set up a call.

Thanks,

Alicia

Alicia K. White
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Memorandum

Date: October 8, 2020
From: Compliance Officer
Dietary Supplement and Labeling Assessment Branch, HFS-608
Division of Enforcement
CFSAN, Office of Compliance
Subject: Center Decision Memorandum: Warning Letter Recommendation
To: Office of Chief Counsel, GCF-1

CMS # [610862](#)
Manufacturer: Whole Foods Market
FEI 3007331558

CFSAN supports issuance of a Warning Letter to the above referenced firm for violations of sections 301(k) and 301(c) of the Act [21 U.S.C. §§ 331(k) and 331(c)]. All charges are added.

As a grocery store chain, Whole Foods Market (WF) is not subject to 21 CFR 117 Subpart C, Preventive Controls and, while they may be (b) (5)

Recalls for which WF was evaluated (b) (5)

(b) (5)

for the time frame of October 2014 through June 2020. It was determined that not all of these RES events were related to misbranding. A decision was made to (b) (5)

The RES event details for each of the events were uploaded into the Firm Background tab in CMS. These details were provided by WF and entered by the Recall Coordinator for the recalling ORA Division. The event details ho (b) (5)

However, interstate is reported by Whole Foods for the recalls listed in the letter. In some instances, (b) (5)

However, it is our belief (b) (5)

All RES events are now captured in CMS as Work Activities (b) (5). All 11 RES related Work Activities related to this letter are linked in CMS to this case. (b) (5) recalls are listed in the examples of recalls included in the (b) (5) Warning Letter for (b) (5) review. Labels and additional information are available in the linked Work Activities. The following are the RES events covered in this action:

Recall Event ID	Firm FEI	Recall Initiation Date	Center Classification Date	CMS WA	# of products
(b) (5)	(b) (5)	(b) (5)	(b) (5)	(b) (5)	(b) (5)

Note: RES events highlighted are included as examples in the (b) (5) Warning Letter for (b) (5) review.

CFSAN's draft letter is attached for the (b) (5) review. This draft letter has been approved by CFSAN and is pending final (b) (5) review and clearance. Per (b) (5) most recent directive, (b) (5) will review all charges.

If you have any questions or need to discuss this case, you may contact me by e-mail at tyra.wisecup@fda.hhs.gov or by telephone at 240-402-5854.

Tyra S. Wisecup



550 Bowie Street, Austin, Texas 78703
WWW.WHOLEFOODSMARKET.COM
WHOLE FOODS, WHOLE PEOPLE, WHOLE PLANET.

Ms. Tyra Wisecup
Compliance Officer
United States Food and Drug Administration
Center for Food Safety and Applied Nutrition
5001 Campus Drive
Office of Compliance (HFS- 608), Division of Enforcement
College Park, Maryland 20740- 3835

Re: Response to Warning Letter CMS # 610862 (December 16, 2020)

Dear Ms. Wisecup:

I write in response to the Warning Letter that Whole Foods Market received from the Food and Drug Administration on December 16, 2020, asserting that Whole Foods Market has engaged in a pattern of receiving and offering for sale certain food products that are misbranded because they do not bear accurate allergen information as required under section 403(w) of the Federal Food, Drug, and Cosmetic Act. I am the Chief Operating Officer of Whole Foods Market, and in that capacity oversee all store operations, including system improvements, process, controls, and procedures. I am also a member of the Whole Foods Market Executive Team. I want to convey that Whole Foods Market takes this issue very seriously. As described in detail below, the company has undertaken and continues to implement, company-wide efforts to improve our ability to ensure that food we sell in all of our retail stores is labeled with accurate allergen information.

We have taken a comprehensive approach to identify the potential causes of allergen-related recalls and the corrective actions that would be most effective in addressing those causes. We have determined that the allergen-related recalls that Whole Foods Market has conducted have occurred for one of two reasons: (1) a system error for our “prepared food products” (those products prepared at an individual retail store), which could include both incorrect information in our data system for a particular ingredient or product, or error at the retail level in preparing and/or labeling a food product for sale in a specific retail store; or (2) a supplier error, where a “supplier-provided finished product” (products received by a retail store already packaged and labeled) is not labeled correctly. We have taken extensive measures to address both of these areas of potential vulnerability, and we have bolstered these actions by centralizing our oversight of retail food safety at the corporate level, which will help ensure consistency across all regions and strengthen our food safety processes and culture.¹

As background, Whole Foods Market believes customers within different regions around the country have different tastes and needs. We take pride in a region’s ability to create different

¹ While the Warning Letter cites five specific recalls, we understand that these recalls were just intended to be examples. We think the actions described in this response would clearly address the causes of those five recalls. However, we have not addressed each recall specifically in this response. Our specific corrective actions for each recall were submitted to the applicable FDA recall coordinator as part of our overall efforts in effectuating each recall. The efforts we describe in this response are intended to address broadly the potential causes of an allergen-related recall.

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and we request it be handled accordingly.

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prepared food recipes, procure unique ingredients, and take region-specific initiatives that meet the tastes and needs of customers within their region. While Whole Foods Market still holds these values, we believe that lack of centralized corporate oversight into these decisions led to many of the recalls that we have conducted due to undeclared allergen ingredients. To minimize this risk, over the past few years Whole Foods Market has undertaken a company-wide effort to centralize many functions at a corporate level, including our food safety program, data operations, and oversight of our retail stores. This centralization includes coordinated purchasing and supply chain decisions for foods sold in retail stores and for ingredients used to prepare foods at retail stores, recipe development for retail prepared foods, and development and implementation of and training on centralized food safety processes and procedures, including specifically with respect to allergen management.

Before this centralization effort, certain purchasing, supply chain, and recipe formulation decisions were made at the regional or store level, and some recalls were also effectuated at that level. This means that prepared food recipes, as well as ingredient sourcing and purchasing, may have varied by regions or even individual stores, and product composition was more challenging and complex to track and ensure accuracy. Under the new centralized framework, prepared food recipes will be standardized globally at the corporate headquarters, and purchasing and sourcing decisions will be centrally managed. Each prepared food item will have a single recipe and either a single supply chain for each ingredient or multiple sources of exactly the same ingredient; the data for each item used to generate product labels will also be managed centrally. Further, data regarding already manufactured products that are sold in stores will be managed at a corporate level, as will approval for product suppliers. In Appendix A, we have provided a case study example of how the changes we have made will impact product preparation and information accuracy.

As discussed in more detail below and documented in the attached, we have initiated and are undertaking the following actions:

1. Centralized oversight of all retail operations at a corporate level. We created a Vice President position to oversee global retail food safety, and developed and implemented standardized food safety protocols, recipe development processes for foods prepared in-house, and supplier approval processes.
2. Created a global allergen recall task force, which is charged with assessing allergen recalls, identifying any needed process improvements company-wide, and overseeing corrective actions.
3. Enhanced our supplier approval program for regionally sourced prepared foods and bakery products. This process is now centralized at the corporate level and conforms to the standards we use to approve suppliers of packaged food products.
4. Reviewed and made necessary changes to internal procedures relating to product preparation, label accuracy, and accountability for errors.
5. Implemented a policy for the Recipe Execution across all retail locations. This policy increases in-store requirements for adhering to approved recipes for foods prepared in-house. Our Team Members at each retail location received training in this policy and other enhanced food safety protocols.

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6. Significantly enhanced our retail audit program. This enhanced audit program includes a retroactive audit, or “clean-up,” of our ingredient information, recipe storage, and label generating systems, as well as regular future company-wide audits of the accuracy of recipe and ingredient information.
7. Began the roll-out of a Food Safety Accountability Policy that includes compliance with product labeling to ensure that each team member is held to the same food safety requirements and expectations company-wide.

We are confident that these actions will collectively ensure that food products sold in our stores are properly labeled and accurately declare the presence of allergens. We hope this information helps to convey how critical this issue is to Whole Foods Market. We would appreciate the opportunity to meet with you and Mr. Correll, and anyone else appropriate at the agency to discuss our actions in more detail, answer any questions you might have, and receive any feedback on the information that we have provided. We can make our team available at your convenience, and will follow up shortly to schedule this meeting.

I. Centralized Oversight of Retail Operations and Supplier Approval

As you indicate in the Warning Letter, over the past year, Whole Foods Market has conducted a number of recalls of products that did not properly declare the presence of major food allergens. Our regulatory compliance team and senior food safety leaders identified this as a particular area of concern at the start of 2020, and immediately undertook a number of initiatives at the corporate level to strengthen our allergen controls and our broader food safety system.

In addition, we are in the midst of a multi-year process of centralizing all of our food safety organization and processes, our data operations, our prepared foods system, our data information system, and our supplier approval programs. We believe this centralization and increased corporate oversight will significantly reduce the opportunities for undeclared allergens and other food labeling errors. These centralization efforts have been underway for the past few years and implementation will continue throughout this year. We provide more detail below about the various specific steps we have taken to help strengthen our allergen control program.

A. Centralizing Food Safety Organization and Processes

We have taken a number of measures to centralize our oversight of food safety, which we believe will broadly ensure consistency across retail locations and allow us to streamline and verify the accuracy of key information. Specifically:

- In October 2019, Whole Foods Market created a new position for Vice President, Retail Food Safety, which is intended to globally oversee food safety in our retail stores. Before this, we did not have a senior corporate position dedicated specifically to oversight of retail food safety. This position is responsible for developing store level Standard Operating Procedures and training programs, investigating in-store safety issues, and ensuring that continuous improvement programs are developed, implemented, and audited. We hired Jeff Edelen, a former leader at The Kroger Co. who was a senior manager in retail food safety and regulatory compliance across 2800+ stores in the United States.

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With the creation of this new role, we separated our food safety processes into two components: Retail Food Safety and Supply Chain Food Safety. Our goal in doing this was to allow the newly created Vice President of Retail Food Safety position to focus exclusively on retail operations and the Vice President of Quality and Food Safety position to manage our supply chain. Our Incident Management Team, which is responsible for managing recalls and withdrawals, is part of the Supply Chain Food Safety Team; they identify corrective actions for recalls, including any at the retail level that are ultimately implemented by the Retail Food Safety Team, so that both teams coordinate to ultimately ensure food safety across all Whole Foods Market operations.

- In April 2020, we reorganized the Retail Food Safety Team so that all team members supporting food safety in the regional offices now report directly up to the Vice President of Retail Safety. This centralized all retail food safety oversight and removed direct regional oversight for retail food safety, in order to allow us to focus on common goals company-wide and create more consistent retail food safety policies and processes. The Retail Food Safety Team includes three Senior Team Leaders, seven Area Team Leaders, twenty-six Field Food Safety Analysts who report to the Area Team Leaders, a Project Manager, a Data Analyst, and a newly created role of Documentation Manager, in order to continue work to drive SOP clarity, including specific procedures relating to allergen control.

Under this team's leadership, we issued new and updated food safety procedures in July 2020 to be incorporated into daily store operations for all of our retail outlets. These updated procedures included a "Recipe Management Policy," which requires the following steps for any prepared food products in order to help reduce the risk of mislabeled allergen information due to error at the retail level.

- All prepared items must follow a current approved recipe, which is standardized and approved at a corporate level.
- Recipes must be followed precisely and accurately, which is monitored by store leadership.
- Any temporary recipe modifications and substitutions (typically to address an ingredient shortage) that would result in changes to the amount of existing ingredients, changes to the cooking method, or the addition or removal of ingredients require corporate approval, including verification of any revisions to the ingredient statement by the Data Operations Team.
- Production items with multi-ingredients or multi-steps, or those that require cooking, require a batched and printed recipe; any production items with multi-ingredients or multi-steps that do not have a recipe must be formally requested following the Data Operations Team's process, in order to obtain approval at a corporate level.
- All recipes must be current, accurate, printed, and organized.

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- Any out-of-date recipes must be removed; this effort is centralized and communicated to individual stores weekly.

B. Allergen Recalls Task Force

In September 2020, we established a global Allergen Recalls Task Force to help us improve specifically in the area of allergen recalls. This group is a cross-functional team consisting of Incident Management, Retail Food Safety, Culinary leadership, Legal, Team Member Services, Retail Operations, Data Operations, Continuous Improvement, and Regional leadership. We assigned this Task Force a project manager and charged it with creating various work-streams to further enhance food safety processes and internal systems to prevent allergen recalls. Since its inception this group has met regarding each Whole Foods Market allergen recall to assess the cause of the recall and any necessary corrective actions, and to prepare and provide reports regarding the recall to regional leadership. This task force is now responsible for allergen recall improvement efforts company-wide.

C. Enhancing Supplier Approval Program

Our Whole Foods Market private label team (Exclusive Brands) has a well-established program to support supplier and product food safety for private label packaged products sold in our retail stores. We emulated a similar comprehensive program for regionally sourced prepared foods and bakery products in June 2019, as this is the category of supplier-provided products where we identified the most significant errors in ingredient information. The regionally sourced prepared foods and bakery suppliers provide us with branded products that are packed and labeled by the supplier and ready to be placed directly on the shelf. They also provide us with products intended to be transformed, repacked, or used as an ingredient within a store recipe and labeled with a Whole Foods Market brand.

The supplier oversight program is a centrally managed program with dedicated food safety and quality resources. As detailed in our Supplier Approval (Appendix B) and Supplier Facility Risk Assessment (Appendix C) SOPs, review of suppliers consists of a product risk assessment, reviewing each facility's food safety programs including supplier approval procedures, allergen controls, environmental monitoring, sanitation, and label control programs. Historical regulatory performance is taken into consideration, and a passing third-party (b) (4) Food Safety audit is required. In collaboration with business teams, supplier manufacturing sites are enrolled into and approved through (b) (4) Supplier food safety issues, including regulatory non-conformances, withdrawals, and recalls, trigger escalated due diligence, including root-cause analysis, and requirements for corrective and preventive actions. A decision can be made based on risk to determine if an on-site follow-up is needed to assure appropriate control measures have been implemented.

II. Streamlining Internal Systems and Audit Efforts to Prevent and Detect System Error

As background, we use a system called (b) (4) to host prepared food recipes, which includes specifications for specific ingredients to be used in each recipe. We have now established and implemented new processes so that the centralized Prepared Foods Team develops and approves recipes for all foods prepared in-house, often with input from regional teams, and within (b) (4) each recipe for a food prepared in-house is assigned a PLU code and an

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ingredient statement record. Ingredients can only be added to recipes in (b) (4) if they have been approved within our (b) (4) process, our supplier and product management system that houses and maintains food safety supporting information, as meeting all Whole Foods Market ingredient requirements that have been established by our global compliance and food safety teams. Once approved, our centralized purchasing teams generally coordinate ingredient ordering. The Data Monster Recipe Request (Appendix D) flowchart demonstrates the updated steps for initiating and developing a new recipe.

We use (b) (4) as a central location to host all nutrition information, ingredient data, and allergen information for ingredients we use in prepared food recipes. This information is then translated in (b) (4) in order to generate customer facing nutrition and ingredient information. As part of our continuous improvement efforts in food safety, in 2019 we initiated a comprehensive review and clean-up effort to centralize recipe data and reduce information managed at individual retail stores and to ensure that ingredient information is accurate and consistent across all of our internal systems, including (b) (4) (b) (4), and (b) (4). One main objective of this on-going effort is to remove recipes that are no longer in use, primarily because the recipes did not have nutrition data verified or used ingredients that were not purchased through our centralized ordering system. We are doing this to reduce the amount of overall data in our system, which will reduce the risk of retail store employees selecting an incorrect recipe when generating labeling information.

We undertook this review by producing reports for each region with items that we deemed were misaligned and purged the affected data from all systems. Specifically, these reports identified ingredients that were not in the ordering system, recipes that had not yet been approved, recipes in (b) (4) that included ingredients that were not available in the purchasing system, and ingredients that were in the purchasing system and not attached to recipes in (b) (4). By removing this data from our system, we reduced the risk that a recipe that is not actively hosted in (b) (4) could be produced and labeled with outdated information.

Further, as part of the clean-up effort, we enhanced the gatekeeping system for new prepared foods purchase items within (b) (4) (Valid Item One-Pager, Appendix E) to ensure that we have up-to-date ingredients and allergens on all recipes labeled in-house. The workflow required the addition of a nutrition gatekeeping step to ensure purchase items were in (b) (4). No new items for use in prepared foods can be purchased without validating nutrition source and updating ingredients, including allergens, in our recipe database. In addition, no new recipes or PLUs can be created unless all items have a valid nutrition source within (b) (4). Ultimately, this clean-up effort also identified certain products that we determined needed to be recalled due to inaccurate labeling information, which we believe has concentrated the frequency and volume of recalls into a condensed time period over the past year. These efforts were, and continue to be, critical in ensuring that the prepared food products we sell are labeled correctly.

In January 2020, we initiated a project to align all existing purchase items in our recipe database to a nutrition source in (b) (4). We began outreach to all suppliers to upload their ingredient information into (b) (4). Over the past year we have aligned over 5,000 purchase items at the ingredient level between (b) (4) and (b) (4). We are targeting mid-2021 to have all items in (b) (4) aligned to an ingredient record in (b) (4). Previously we did not have a renewal requirement in place, so we often were not notified by the supplier when a product ingredient changed. We now can automatically determine when ingredients used in

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foods that we prepare in-house are updated in (b) (4) and update our data systems accordingly, through a status alert that occurs when a product record is changed. This status alert notifies the Compliance Team via a report that will be sent to Data Operations. Data Operations will use that report to assess any changes in the ingredients, including allergens.

To ensure that the streamlined system is working properly, in 2020 the Data Operations Team implemented a company-wide ingredient and allergen audit program. Through this audit program, we compare the information in each product's recipe with the information that is communicated on each product label in order to verify the accuracy of ingredient information, including allergen information, on the product label. We will run this audit annually on every recipe in the database (currently approximately 55,000 recipes) as well as quarterly for new or seasonal products. We will run the quarterly audit before recipes are used to ensure there is a gate to eliminate misalignment of our recipe data system with customer facing ingredients/allergens. We expect that this audit program will eliminate the risk of mislabeling due to misalignment of data between our recipe system and customer-facing ingredient information.

In October 2020, we conducted the first company-wide audit, which identified a number of errors (primarily with recipes that are no longer in use); we corrected each of these errors, which included updating ingredient information as needed. We conducted a second company-wide audit in December 2020 and found no errors, indicating that the ingredient information that we provide consumers for every product we prepare in-house matches the recipes in (b) (4) that are used to prepare the products.

III. Food Safety at the Retail Level – Recipe Management, Audit, and Accountability

While we have extensively overhauled our food safety processes at the corporate level to help ensure allergen control, we believe it is equally important that such enhancements are implemented down to the retail store level and that our team members understand how best to ensure food safety, especially in regards to allergen labeling. Specifically, team members are required to follow various SOPs when preparing food to ensure the correct ingredients and ingredient labels are being used, including Recipe Execution SOP for Prepared Foods (Appendix F), The Daily Work List (Appendix G), Recipe Execution SOP for Bakery (Appendix H), Food Labeling and Identification Policy (Appendix I), and Food Safety All-in-One User Guide (Appendix J).

As noted above, most critically, in July 2020 we released a new Recipe Management Policy, in addition to new and updated food safety materials to incorporate required food safety protocols into daily store operations.

In addition, in order to centralize the recipe system, we eliminated the ability of individual stores to create their own recipes. We also established a communication escalation process for recipe issues, which supplements the Recipe Execution Policy and is part of the Store Process SOPs. For example, Team Members must execute only one recipe at a time and collect all ingredients prior to starting each recipe. If an ingredient is not available, then the Team Member must immediately notify their leadership. Leadership is only allowed to approve single ingredient substitutions for the same item (e.g., Roma tomatoes for cherry tomatoes). Other ingredient changes (including substituting a different single or multi-ingredient product) must

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be escalated to designated regional and global points, who then make recipe and labeling updates using menu and nutritional analysis software. The recipe is not made available for use until the new data is accurately reflected on all recipes, labels, and signs. Finally, to address communication between shifts, Team Members must complete an “Incomplete Production Log” so no one else attempts to make the recipe until the approval process has been completed.

To reinforce these systems, the Global Retail Food Safety Team assigned all store team members and store leadership required allergen training in October 2020, and of those assigned, more than 90 percent have already completed that training; the remainder are expected to complete the training by early this year. As part of the Allergen Job Aid SOP (Appendix K), a team lead or production writer will assign the label and conduct the ingredient verification process for all items produced and packaged in-house. A team member will verify each item made or packaged in-house matches the applicable ingredient information on the following:

- Product signs
- Ingredient labels
- Beauty labels
- Recipes
- Schematics/planograms

In addition, the team member will review the ingredients to make sure the following requirements are met:

- Allergens must be clearly identified:
 - Packaged items must have the label on the packaging.
 - Unpackaged items must have ingredients displayed with the product.
 - Sub-ingredients must be identified [e.g. mayonnaise (expeller pressed canola oil, eggs, water, honey, distilled vinegar, contains less than 2% of salt, spice, lemon juice concentrate)].
- Allergen information must include the name of the food source:
 - Tree nuts and fish must list the specific species (e.g. Fish Stick Ingredients: Cod, Egg, Milk, Salt)

At that same time, we developed and released a Food Safety Self-Audit Tool for team leadership to reflect on their department’s practices and take active managerial control to address potential learning gaps. The Food Safety Self-Audit Tool directs team leadership as follows, “Pick 3 in-house produced or packaged products and verify the PLU and ingredient list against the recipe used or ingredients on the package.” Retail stores that have consistently received satisfactory scores through this tool and through third-party audits facilitated by Everclean are required to perform these self-audits weekly; all other stores must perform a self-audit each day. We

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continue to make system improvements by standardizing schematics and planograms, eliminating outdated recipes and PLU data, and evaluating recipe nomenclature for consistency across our company. Finally, we have developed a unified Food Safety Accountability Policy (Appendix L) addressing the responsibilities each team member must uphold to mitigate food safety risk as part of team member duties. This new policy went into effect this month.

* * *

We believe we have taken significant steps in the last two years to streamline and enhance our food safety processes. As we continue to further enhance these processes and accountability mechanisms, we expect to see a reduction in undeclared allergens recalls. By centralizing the system at the corporate level, we have created uniform policies and action items across all our retail stores. With the enhancement to our internal systems and supplier programs, we are confident we will reduce the opportunities for undeclared allergens and mislabeling. Finally, with the Corporate Food Safety Team working directly with regional and store team leadership to take corrective actions, we hope to foster an environment that empowers food safety at the retail level. We will continue to monitor our processes and procedures through our audit program and will assess if any additional actions are needed in the future.

Please do not hesitate to contact Alicia White at alicia.white@wholefoods.com if you have any questions about any of the above. We look forward to the opportunity to discuss our efforts further with you at your convenience.

Best Regards,

DocuSigned by:

6DE779DAD47845E...

Jason J. Buechel
Chief Operating Officer

Home

Recall Details

1. Event Information
2. Summary and Termination Information
3. Center Information
4. Product Information
5. Firm and Contact Information
6. Recall Summary

Event Information

Recall Event ID	86836	RFR EON ID	
Recall Number(s)	F-0168-2021	RFR EON URLs	
District	Human And Animal Food West V	Coordinator	Rochelle Blair
Firm Awareness Date	11/22/2020	District Awareness Date	11/23/2020
Center (Int)	Center for Food Safety and Applied Nutrition	Coordinator	Leonara K Darlington
Recalling Firm FEI	3007331558	Name (Int)	Whole Foods Market
Manufacturer FEI	3007331558	Name (Int)	Whole Foods Market
Responsible Firm FEI	3007331558	Name	Whole Foods Market
Public Reason for Recall	Undeclared allergen (shrimp) due to product mislabeling.		
Edit Mode	Viewable	Recall Status (Int)	Ongoing
Voluntary/Mandated (Int)	Firm Initiated	Date (Int)	11/22/2020
Firm Recommended Recall Depth	Consumers/User	Date Distribution Chain Notified	11/23/2020
Recall Initiation Date (Int)	11/23/2020	Firm Initial Notification	E-Mail
Determination Date	12/10/2020	Center Coordinator Assigned Date	12/02/2020
Classification Date	12/10/2020	FDA Sample Number	None

Complete Reason for Recall	Undeclared allergen (shrimp) due to product mislabeling; product was labeled Popcorn Chicken with Sweet Chili when it actually contained popcorn shrimp. The firm was alert to the issue by a customer who had an allergic reaction.		
Root Cause	Other		
Root Cause Narrative	Incorrect PLU number was provided to the stores, and therefore when product was repacked into retail sized containers at the store level the incorrect label was placed on it.		
Center Comments	Class I, CFSAN concurs with audit check strategy.		
Type Of Injury	The firm received one consumer report of illness/injury and one complain regarding product defect.		
Quantity Manufactured	(b) (4)		
Quantity Distributed (Int)	(b) (4)		
Number of Domestic Consignees	(b) (4)		
Number of Foreign Consignees	0		
Distributed From	11/05/2020To 11/22/2020		
Distribution Pattern (Int)	U.S distribution to the following: CA and NV. No foreign distribution.		
Manufactured From	11/05/2020To 11/22/2020		
Public Summary of Recall Strategy (Int)	On 11/22/20 an email went out to all stores across the region. Stores were instructed to check the fresh pack to ensure that Popcorn Chicken Shaker with Sweet Chili (PLU #81789) does not contain Sweet Chili Popcorn Shrimp. Stores were told to pull and destroy any packages of Popcorn Chicken Shaker with Sweet Chili that contains Popcorn Shrimp, and report quantities in their system. The firm issued a press release on 11/23/20.		
Recall Strategy	On 11/22/20 an email through their (b) (4) system to all stores across the region (48 stores). Stores were instructed to pull and destroy the effected product. The firm also removed the PLU code from their system so it would no longer scan at checkout. The firm issued a press release on 11/23/20. The firm ran a movement report in their inventory system to show which stores had showed movement against the PLU, the stores that showed movement were included in the press release.		
Effectiveness Check Level	APercent 100		
Audit Check Level	BPercent 20		
Audit/Effectiveness Check Modification			
RAC Assignment Date Issued	12/01/2020	RAC Assignment Date Completed	12/11/2020
District RAC Assignment Needed?	Yes	District Justification for No Audit Check	
District Recommendation for No Audit Check Comments		Center Agrees with District RAC Assignment Recommendation	Yes
Center RAC Assignment Needed?		Center Justification for No Audit Check	
Center Recommendation Justification Comments		Center Entering Recall	
What Consumers Should Do (Int)			

Expanded Comments for
What Consumers Should Do (Int)

Firm Press Issued (Int) 11/23/2020 URL (Int) <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/allergy-alert-issued-undeclared-shrimp-mislabeled-popcorn-chicken-26-whole-foods-market-stores>

State Press Issued (Int) URL (Int)

FDA Press Issued (Int) URL (Int)

Additional Medical Product Information (Int) URL (Int)

Consignee Details

List of Domestic and/or Foreign Consignees, Distribution addresses or comments No foreign consignees. No VA consignees. No DoD consignees.

Consignees	Approx. Number	Consignees	Approx. Number
Distributor	0	Repacker/Relabeler	0
Retailer	(b) (4)	Direct Accounts	0
Institution	0	Veterans Administration	0
Medical Facility	0	Department of Defense	0
Internet Sales	0	Manufacturer	0
Physician	0	USDA	0
Consumer/Patient	0	Other	0

Summary/Termination Information

Quantity Recovered/Number of
Units Corrected

Product Disposition

Number of Consignees Responding
to Notification

Effectiveness Check Information

Recall Audit Check Count Audit Count Summary : Not Available

Audit Check Information

Section of Law Violated

Preventive Action Taken by Firm

District Follow-Up

District Review

Legal Action

Class I Termination
Recommendation
Recommended/Prepared By
District Management Approval **Date**

Center Concurrence
Recall Completed Date
Termination Letter Date

CFSAN Center Information

Docs Rcvd at Ctr Date

HHE Sent

HHE Signed

HHE Precedent

Outbreak Associated N

CFSAN CORE Incident EON ID

Product Information

Product : 1

Industry-Product Code 16-KGT05

Precedent Recall P-7951

Precedent Policy

Precedent Policy Comment

Product Description (**Int**) Whole Foods Market Popcorn Chicken Shaker with Sweet Chili Variable weight sold by lb.
(Label/Packaging) Packed For Whole Foods Market

Trade Name (**Int**)

Generic Name (**Int**)

Product Usage Ready-to-eat for human consumption.

Product Quantity Distributed (**Int**) (b) (4)

Recall Number (**Int**) F-0168-2021

Product Public Reason for Recall (**Int**) Undeclared allergen (shrimp) due to product mislabeling.

Field Recommended Classification Class I

Center Determination/Classification (**Int**) Class I

Center Recommended Depth Consumers/User

Product Effectiveness Check Level A **Percent** 100

Product Audit Check Level B **Percent** 20

Code Information (**Int**) PLU number 81789 Sell by dates through November 27, 2020

Expected Life

Shelf Life

CFSAN Reason

Labeling/undeclared allergen

Recalling Firm Information

FEI 3007331558

Firm Name **(Int)** Whole Foods Market

Address **(Int)** 550 Bowie St

City **(Int)** Austin

State/Province **(Int)** Texas

Country **(Int)** United States

Postal Code **(Int)** 78703-4644

Telephone **Ext** **Country Code**

Comment

Most Responsible Individual

Official's Name John Mackey

Title CEO

Firm Name **(Int)** Whole Foods Market

Address **(Int)** 550 Bowie St

City **(Int)** Austin

State/Province **(Int)** Texas

Country **(Int)** United States

Postal Code **(Int)** 78703-4644

Telephone **Ext** **Country Code**

Facsimile **Ext** **Country Code**

E-mail Address john.mackey@wholefoods.com

Comment

Manufacturer Information

FEI 3007331558

Firm Name **(Int)** Whole Foods Market

Address **(Int)** 550 Bowie St

City **(Int)** Austin

State/Province **(Int)** Texas

Country **(Int)** United States

Postal Code **(Int)** 78703-4644

Telephone **Ext** **Country Code**

Comment

Responsible Firm Information

FEI	3007331558
Firm Type	Manufacturer
Firm Name (Int)	Whole Foods Market
Address (Int)	550 Bowie St
City (Int)	Austin
State/Province (Int)	Texas
Country (Int)	United States
Postal Code (Int)	78703-4644
Telephone	Ext Country Code
Comment	

Recall Contact

Official's Name	Deirdre Dillon
Title	Senior Food Safety Analyst
Firm Name (Int)	Whole Foods Market
Address (Int)	6401 Hollis St. Ste. 150
City (Int)	Emeryville
State/Province (Int)	California
Country (Int)	United States
Postal Code (Int)	94608
Telephone	Ext Country Code
Facsimile	Ext Country Code
E-mail Address	Deirdre.Dillon@wholefoods.com
Comment	

Public Contact

Official's Name	Rachel Malish
Title	Communications
Firm Name (Int)	Whole Foods Market
Address (Int)	550 Bowie St
City (Int)	Austin
State/Province (Int)	Texas
Country (Int)	United States
Postal Code (Int)	78703-4644
Telephone	Ext Country Code
Facsimile	Ext Country Code
E-mail Address	Rachel.malish@wholefoods.com

Comment

Summary

Help

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Event Information

Recall Event ID	84020	RFR EON ID	
Recall Number(s)	F-0131-2020	RFR EON URLs	
District	Human And Animal Food West III	Coordinator	Casey Hamblin
Firm Awareness Date	10/09/2019	District Awareness Date	10/09/2019
Center (Int)	Center for Food Safety and Applied Nutrition	Coordinator	Dehlia Young
Recalling Firm FEI	3007331558	Name (Int)	Whole Foods Market
Manufacturer FEI	3012452762	Name (Int)	H&F Bread Co LLC
Responsible Firm FEI	3007331558	Name	Whole Foods Market
Public Reason for Recall	Undeclared milk and eggs		
Edit Mode	Viewable	Recall Status (Int)	Terminated
Voluntary/Mandated (Int)	Firm Initiated	Date (Int)	10/09/2019
Firm Recommended Recall Depth	Consumers/User	Date Distribution Chain Notified	10/09/2019
Recall Initiation Date (Int)	10/09/2019	Firm Initial Notification	Combination
Determination Date	11/07/2019	Center Coordinator Assigned Date	10/31/2019
Classification Date	11/07/2019	FDA Sample Number	None

Complete Reason for Recall	The retail store employees would previously apply a PLU label to the recalled rolls as they came in unlabeled. The manufacturer then changed its operations and began providing UPC labeled units for retail sale. The employees used the previous procedure and continued to "overlabel" the recalled rolls with the PLU labels that did not list the milk and eggs in the ingredient statement.		
Root Cause	Other		
Root Cause Narrative	Employees placed a label over the manufacturer's label. The Whole Foods Market label failed to declare milk and egg.		
Center Comments	Class I. CFSAN concurs with audit check strategy.		
Type Of Injury	None reported		
Quantity Manufactured	(b) (4)		
Quantity Distributed (Int)	(b) (4)		
Number of Domestic Consignees	(b) (4)		
Number of Foreign Consignees	0		
Distributed From	9/23/2019 To 10/8/2019		
Distribution Pattern (Int)	Michigan, Wisconsin, Illinois		
Manufactured From	9/23/2019 To 10/8/2019		
Public Summary of Recall Strategy (Int)	The recalling firm issued press on 10/9/19. Affected stores were notified via the online recall notification system on 10/9/19 as well.		
Recall Strategy	The recalling firm issued press on 10/9/19. Affected stores were notified via the online recall notification system on 10/9/19 as well.		
Effectiveness Check Level	A Percent 100		
Audit Check Level	A Percent 100		
Audit/Effectiveness Check Modification			
RAC Assignment Date Issued	10/23/2019	RAC Assignment Date Completed	11/15/2019
District RAC Assignment Needed?	Yes	District Justification for No Audit Check	
District Recommendation for No Audit Check Comments		Center Agrees with District RAC Assignment Recommendation	Yes
Center RAC Assignment Needed?		Center Justification for No Audit Check	
Center Recommendation Justification Comments		Center Entering Recall	
What Consumers Should Do (Int)			
Expanded Comments for What Consumers Should Do (Int)			
Firm Press Issued (Int)	10/10/2019	URL (Int)	https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/allergy-alert-undeclared-milk-egg-white-parkerhouse-rolls-issued-four-whole-foods-market-stores

State Press Issued (Int) URL (Int)
 FDA Press Issued (Int) URL (Int)
 Additional Medical Product Information (Int) URL (Int)

Consignee Details

List of Domestic and/or Foreign Consignees, Distribution addresses or comments

(b) (4)
 [Redacted]
 [Redacted]
 [Redacted]
 [Redacted]

Consignees	Approx. Number	Consignees	Approx. Number
Distributor	0	Repacker/Relabeler	0
Retailer	(b) (4)	Direct Accounts	0
Institution	0	Veterans Administration	0
Medical Facility	0	Department of Defense	0
Internet Sales	0	Manufacturer	0
Physician	0	USDA	0
Consumer/Patient	0	Other	0

Summary/Termination Information

Quantity Recovered/Number of Units Corrected: None

Product Disposition: Product was pulled and PLU labels were removed

Number of Consignees Responding to Notification: (b) (4) retail stores

Effectiveness Check Information: 4/4 = 100%

Recall Audit Check Count: Audit Count Summary : Not Available

Audit Check Information: Four recall audit checks were conducted for this recall. All 3177s were endorsed as effective.

Section of Law Violated: Section 402(a)(1) of the Food, Drug and Cosmetic Act

Preventive Action Taken by Firm: Verify previously used PLUs are deactivated before introducing a product containing a UPC.

District Follow-Up: None planned. The issue occurred at the retail level.

District Review: A review of the recall file and 3177s was completed during evaluation of this recall. The recall appears to be complete and effective.

Legal Action: None planned

Class I Termination Recommendation	DRC recommends termination of this recall.
Recommended/Prepared By	Casey Hamblin
District Management Approval	Jessica Havranek, DCB Date 01/09/2020
Center Concurrence	Angela Alexander
Recall Completed Date	10/09/2019
Termination Letter Date	01/17/2020

CFSAN Center Information

Docs Rcvd at Ctr Date 10/29/2019

HHE Sent

HHE Signed

HHE Precedent P-7907, P-7968

Outbreak Associated N

CFSAN CORE Incident EON ID

Product Information

Product : 1

Industry-Product Code 03-Y99

Precedent Recall P-7907, P-7968

Precedent Policy

Precedent Policy Comment The level of risk to health posed by the violative product is similar to the level or risk previously evaluated in the identified precedent HHE.

Product Description (**Int**) Whole Foods Market White Parkerhouse Rolls PLU 49557 NET WT. 0 lb 12 oz (340g) packaged in a clear plastic bag 12 rolls per bag

Trade Name (**Int**) Whole Foods Market

Generic Name (**Int**)

Product Usage Food for human consumption

Product Quantity Distributed (**Int**) (b) (4)

Recall Number (**Int**) F-0131-2020

Product Public Reason for Recall (**Int**) Undeclared milk and eggs

Field Recommended Classification Class I

Center Determination/Classification (**Int**) Class I

Center Recommended Depth Consumers/User

Product Effectiveness Check Level A **Percent** 100

Product Audit Check Level A **Percent** 100

Code Information (**Int**) PLU 49557 all lots within date

Expected Life

Shelf Life 10/13/19

CFSAN Reason Labeling/undeclared allergen

Recalling Firm Information

FEI 3007331558

Firm Name **(Int)** Whole Foods Market

Address **(Int)** 550 Bowie St

City **(Int)** Austin

State/Province **(Int)** Texas

Country **(Int)** United States

Postal Code **(Int)** 78703-4644

Telephone **Ext Country Code**

Comment

Most Responsible Individual

Official's Name John Mackey

Title President/CEO

Firm Name **(Int)** Whole Foods Market

Address **(Int)** 550 Bowie St

City **(Int)** Austin

State/Province **(Int)** Texas

Country **(Int)** United States

Postal Code **(Int)** 78703-4644

Telephone **Ext Country Code**

Facsimile **Ext Country Code**

E-mail Address

Comment

Manufacturer Information

FEI 3012452762

Firm Name **(Int)** H&F Bread Co LLC

Address **(Int)** 1500 Marietta Blvd NW

City **(Int)** Atlanta

State/Province **(Int)** Georgia

Country **(Int)** United States

Postal Code **(Int)** 30318-3643

Telephone 404-3508877 **Ext Country Code**

Comment

Responsible Firm Information

FEI	3007331558
Firm Type	Relabeler
Firm Name (Int)	Whole Foods Market
Address (Int)	550 Bowie St
City (Int)	Austin
State/Province (Int)	Texas
Country (Int)	United States
Postal Code (Int)	78703-4644
Telephone	Ext Country Code
Comment	

Recall Contact

Official's Name	Craig Penigar
Title	Global Quality Assurance
Firm Name (Int)	Whole Foods Market
Address (Int)	550 Bowie St
City (Int)	Austin
State/Province (Int)	Texas
Country (Int)	United States
Postal Code (Int)	78703-4644
Telephone	512-831-8372 Ext Country Code
Facsimile	Ext Country Code
E-mail Address	
Comment	

Public Contact

Official's Name	
Title	
Firm Name (Int)	Whole Foods Market
Address (Int)	550 Bowie St
City (Int)	Austin
State/Province (Int)	Texas
Country (Int)	United States
Postal Code (Int)	78703-4644
Telephone	Ext Country Code
Facsimile	Ext Country Code
E-mail Address	

Comment

Contact: Olivia Petersen, oliviapetersen@wholefoods.com; Consumers with additional questions can call 1-844-936-8255 between the hours of 7:00 a.m. and 10:00 p.m. CST, Monday through Friday, or 8:00 a.m. and 6:00 p.m. Saturday through Sunday.

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Event Information

Recall Event ID	84345	RFR EON ID	
Recall Number(s)	F-0408-2020	RFR EON URLs	
District	Human And Animal Food West III	Coordinator	Casey Hamblin
Firm Awareness Date	11/21/2019	District Awareness Date	11/21/2019
Center (Int)	Center for Food Safety and Applied Nutrition	Coordinator	Melanie Butler
Recalling Firm FEI	3007331558	Name (Int)	Whole Foods Market
Manufacturer FEI	3015252759	Name (Int)	EMILIA FOODS SRL
Responsible Firm FEI	3015252759	Name	EMILIA FOODS SRL
Public Reason for Recall	Undeclared egg		
Edit Mode	Viewable	Recall Status (Int)	Terminated
Voluntary/Mandated (Int)	Firm Initiated	Date (Int)	11/22/2019
Firm Recommended Recall Depth	Consumers/User	Date Distribution Chain Notified	11/22/2019
Recall Initiation Date (Int)	11/22/2019	Firm Initial Notification	Combination
Determination Date	12/12/2019	Center Coordinator Assigned Date	12/10/2019
Classification Date	12/19/2019	FDA Sample Number	None

Complete Reason for Recall	It was reported to WFM that a pint of Raspberry Cheesecake Italian Gelato was on the shelf in the West Loop WFM store in the Midwest region and inside the pint it appeared to contain the WFM Butter Cookies & Sweet Cream Gelato, as it was stocked with the Butter Cookies & Sweet Cream Gelato. The manufacturer is in Modena, Italy and produces both of these products that launched this summer. Allergens were cross checked for these two items and it was found that the WFM Butter Cookies & Sweet Cream Italian Gelato contains: Tree nuts (coconut), Milk, Wheat, and Eggs while the WFM Raspberry Cheesecake Italian Gelato declares: Tree nuts (coconut), Milk, Wheat. Leading to undeclared egg in the one pint that was discovered to be mislabeled.		
Root Cause	Other		
Root Cause Narrative	The pint labeled as Raspberry Cheesecake Italian Gelato SKU has been mistakenly placed in the case containing the pints of Butter Cookies and Sweet Cream Italian Gelato SKU by the pints suppliers personnel. The mistake occurred because of a lack of controls at the beginning and at the end of packaging production. The random intake check control decided that the packaging product was conforming with the specs. Further random check controls before the finished product production start was also indicating that the pack was conform with the specs. Even the final control to the finished product made before pints are placed in the case did not produce evidence of mislabeling pints.		
Center Comments	Class II. CFSAN concurs with audit check strategy.		
Type Of Injury	None reported		
Quantity Manufactured	(b) (4)		
Quantity Distributed (Int)	(b) (4)		
Number of Domestic Consignees	(b) (4)		
Number of Foreign Consignees	0		
Distributed From	To		
Distribution Pattern (Int)	Nationwide		
Manufactured From	06/03/2019 To 06/19/2019		
Public Summary of Recall Strategy (Int)	The firm made the decision to recall on 11/21-22/19. A press release was sent out on 11/22/19. The affected consignees were notified via email beginning on 11/22/19.		
Recall Strategy	The firm made the decision to recall on 11/21-22/19. Consignees were notified via emails to the stores affected through our recall management tool, (b) (4) and email to UNFI for the official notice on 11/22/19.		
Effectiveness Check Level	A Percent 100		
Audit Check Level	M Percent 0		
Audit/Effectiveness Check Modification	RAC will be assigned per OSPOP recall guidance doc		
RAC Assignment Date Issued	12/11/2019	RAC Assignment Date Completed	12/26/2019
District RAC Assignment Needed?	Yes	District Justification for No Audit Check	
District Recommendation for No Audit Check Comments		Center Agrees with District RAC Assignment Recommendation	Yes
Center RAC Assignment Needed?		Center Justification for No Audit Check	

Center Recommendation

Center Entering Recall

Justification Comments

What Consumers Should Do (Int)

Expanded Comments for

What Consumers Should Do (Int)

Firm Press Issued (Int) 11/22/2019 URL (Int) https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/allergy-alert-issued-due-undeclared-egg-whole-foods-market-brand-raspberry-cheesecake-italian-gelato

State Press Issued (Int) URL (Int)

FDA Press Issued (Int) URL (Int)

Additional Medical Product Information (Int) URL (Int)

Consignee Details

List of Domestic and/or Foreign Consignees, Distribution addresses or comments 1 distribution company, (b) (4) (distributor) then to (b) (4) No VA/DOD/Foreign consignees

Consignees	Approx. Number	Consignees	Approx. Number
Distributor	(b) (4)	Repacker/Relabeler	0
Retailer	(b) (4)	Direct Accounts	0
Institution	0	Veterans Administration	0
Medical Facility	0	Department of Defense	0
Internet Sales	0	Manufacturer	0
Physician	0	USDA	0
Consumer/Patient	0	Other	0

Summary/Termination Information

Quantity Recovered/Number of Units Corrected (b) (4) from Whole Foods Market Stores

Product Disposition Destroyed. No CODs are available from stores.

Number of Consignees Responding to Notification 1 distribution company, (b) (4) (distributor) then to (b) (4) all responded to the recall.

Effectiveness Check Information 100%

Recall Audit Check Count Audit Count Summary : Not Available

Audit Check Information 25 EFFECTIVE 4 INEFFECTIVE BY RECALLING FIRM 1 COULD NOT BE DETERMINED. Some of the affected product was see for sale on the retail shelves. Per the recalling firm, "We have received notice that FDA officials are finding the recalled pints of the WFM Raspberry Gelato with best by date JUN 11 2021. The reason this product is being found on shelves now is because all of our stores completed the recall and removed any possible affected product on shelf. Separate instructions were given to DCs and that was to remove and destroy all master cases of the WFM Butter Cookies & Sweet Cream Italian Gelato (bb JUN 11 2021) because the misfiled product would have been packed with the Butter Cookies Gelato. The product that stores are now carrying in store is correctly labeled and unaffected."

Section of Law Violated Section 402 of the Food, Drug and Cosmetic Act

Preventive Action Taken by Firm Specific training will be provided to the packaging suppliers personnel highlighting all rules and procedures that must be followed during a change of SKU. Registration modules will be introduced to give evidence of SKU change: in this module the change of SKU will be verified and it will be signed by person Responsible for that control. In the gelato manufacturing facility will be placed a further training to the relevant operatives and supervisors. The number of controls during the whole production process will be implemented. QA Emilia Foods will be present for production controls at least once a month at the gelato manufacturing facility. The personnel of gelato manufacturing facility will verify that every single pint corresponds to the SKU starting from the ongoing production to the end of the production; at the end of every production all the remaining packaging must be removed. Moreover the personnel at the end of the cooling tunnel will verify that all the pints are corresponding to the on going production and they will also check the matching between the produced pints and the carton label of the finished product.

District Follow-Up No follow-up is planned by the division. The responsible firm will be inspected at the discretion of CFSAN.

District Review A review of the recall file, mfrs CAPA and RACs was completed during evaluation of this recall. The recall appears to be complete and effective.

Legal Action None planned.

Class I Termination

Recommendation

Recommended/Prepared By Casey Hamblin

District Management Approval Jessica Havranek, DCB **Date** 01/10/2020

Center Concurrence

Recall Completed Date 11/22/2019

Termination Letter Date 01/13/2020

CFSAN Center Information

Docs Rcvd at Ctr Date 12/09/2019

HHE Sent 12/12/2019

HHE Signed 12/19/2019

HHE Precedent 10293

Outbreak Associated N

CFSAN CORE Incident EON ID

Product Information

Product : 1

Industry-Product Code

13-AGT03

Precedent Recall	10293
Precedent Policy	
Precedent Policy Comment	
Product Description (Int) (Label/Packaging)	Whole Foods Market Raspberry Cheesecake Italian Gelato 1 Pint (473mL) UPC 9948248024 packaged in a clear plastic container
Trade Name (Int)	Whole Foods Market
Generic Name (Int)	
Product Usage	Food for human consumption
Product Quantity Distributed (Int)	(b) (4)
Recall Number (Int)	F-0408-2020
Product Public Reason for Recall (Int)	Undeclared egg
Field Recommended Classification	Class I
Center Determination/Classification (Int)	Class II
Center Recommended Depth	Consumers/User
Product Effectiveness Check Level	A Percent 100
Product Audit Check Level	M Percent 0
Code Information (Int)	L.P. JUN/11/19 E. JUN/11/21 A103-1
Expected Life	
Shelf Life	6/11/2021
CFSAN Reason	Labeling/undeclared allergen

Recalling Firm Information

FEI	3007331558
Firm Name (Int)	Whole Foods Market
Address (Int)	550 Bowie St
City (Int)	Austin
State/Province (Int)	Texas
Country (Int)	United States
Postal Code (Int)	78703-4644
Telephone	Ext Country Code
Comment	

Most Responsible Individual

Official's Name	John Mackey
Title	CEO
Firm Name (Int)	Whole Foods Market
Address (Int)	550 Bowie St

City **(Int)** Austin
State/Province **(Int)** Texas
Country **(Int)** United States
Postal Code **(Int)** 78703-4644
Telephone **Ext** **Country Code**
Facsimile **Ext** **Country Code**
E-mail Address
Comment

Manufacturer Information

FEI 3015252759
Firm Name **(Int)** EMILIA FOODS SRL
Address **(Int)** Via Emilia Est 903
City **(Int)** Modena
State/Province **(Int)**
Country **(Int)** Italy
Postal Code **(Int)**
Telephone **Ext** **Country Code**
Comment

Responsible Firm Information

FEI 3015252759
Firm Type Manufacturer
Firm Name **(Int)** EMILIA FOODS SRL
Address **(Int)** Via Emilia Est 903
City **(Int)** Modena
State/Province **(Int)**
Country **(Int)** Italy
Postal Code **(Int)**
Telephone **Ext** **Country Code**
Comment

Recall Contact

Official's Name Ashley Dia Zuaiter
Title Quality Assurance Incident Analyst
Firm Name **(Int)** Whole Foods Market
Address **(Int)** 550 Bowie St
City **(Int)** Austin
State/Province **(Int)** Texas

Country (Int) United States
Postal Code (Int) 78703-4644
Telephone Ext Country Code
Facsimile Ext Country Code
E-mail Address ashley.zuaiter@wholefoods.com
Comment Office: 512 542-0426 Cell: 512-815-5701

Public Contact

Official's Name
Title
Firm Name (Int) Whole Foods Market
Address (Int) 550 Bowie St
City (Int) Austin
State/Province (Int) Texas
Country (Int) United States
Postal Code (Int) 78703-4644
Telephone Ext Country Code
Facsimile Ext Country Code
E-mail Address
Comment Betsy.Harden@wholefoods.com 512.542.3198

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Event Information

Recall Event ID	84888	RFR EON ID	
Recall Number(s)	F-0764-2020 F-0765-2020 F-0766-2020 F-0767-2020	RFR EON URLs	
District	Human And Animal Food West III	Coordinator	Casey Hamblin
Firm Awareness Date	02/04/2020	District Awareness Date	02/04/2020
Center (Int)	Center for Food Safety and Applied Nutrition	Coordinator	Leonara K Darlington
Recalling Firm FEI	3007331558	Name (Int)	Whole Foods Market
Manufacturer FEI	3007331558	Name (Int)	Whole Foods Market
Responsible Firm FEI	3007331558	Name	Whole Foods Market
Public Reason for Recall	Undeclared milk		
Edit Mode	Viewable	Recall Status (Int)	Terminated
Voluntary/Mandated (Int)	Firm Initiated	Date (Int)	02/04/2020
Firm Recommended Recall Depth	Consumers/User	Date Distribution Chain Notified	02/04/2020
Recall Initiation Date (Int)	02/04/2020	Firm Initial Notification	Combination
Determination Date	03/02/2020	Center Coordinator Assigned Date	02/18/2020
Classification Date	03/02/2020	FDA Sample Number	None
Complete Reason for Recall	Undeclared milk due to an internal label error. Milk declaration was not included on the initial label creation.		

Root Cause	Other		
Root Cause Narrative	Internal labeling error discovered through a label inspection.		
Center Comments	Class I, CFSAN concurs with audit check strategy.		
Type Of Injury	No allergic reactions have been reported to date.		
Quantity Manufactured	(b) (4)		
Quantity Distributed (Int)	(b) (4)		
Number of Domestic Consignees	(b) (4)		
Number of Foreign Consignees	0		
Distributed From	02/03/2020To 02/03/2020		
Distribution Pattern (Int)	Kentucky, Maryland, New Jersey, Pennsylvania, Ohio, Virginia and Washington D.C.		
Manufactured From	02/03/2020To 02/03/2020		
Public Summary of Recall Strategy (Int)	The recalling firm issued a press release on 2/4/2020. The affected retail stores were notified of the recall electronically on 2/4/2020 via an internal recall system.		
Recall Strategy	The recalling firm issued a press release on 2/4/2020. The affected retail stores were notified of the recall electronically on 2/4/2020 via an internal recall system. Notified stores must confirm theyve completed the recall online.		
Effectiveness Check Level	A Percent 100		
Audit Check Level	E Percent 0		
Audit/Effectiveness Check Modification			
RAC Assignment Date Issued	RAC Assignment Date Completed		
District RAC Assignment Needed?	No	District Justification for No Audit Check	Firm has history of effective audit checks
District Recommendation for No Audit Check Comments	Firm has a very extensive history of effective recalls. The firm has an effective in house recall monitoring system. The root cause was an internal label printing error.	Center Agrees with District RAC Assignment Recommendation	Yes
Center RAC Assignment Needed?		Center Justification for No Audit Check	
Center Recommendation Justification Comments		Center Entering Recall	
What Consumers Should Do (Int)			
Expanded Comments for What Consumers Should Do (Int)			
Firm Press Issued (Int)	02/04/2020	URL (Int) https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/allergy-alert-issued-undeclared-milk-bundt-cake-and-chocolate-dipped-cookies-sold-44-whole-foods	
State Press Issued (Int)	URL (Int)		

FDA Press Issued (Int)

URL (Int)

Additional Medical Product Information (Int)

URL (Int)

Consignee Details

List of Domestic and/or Foreign Consignees, Distribution addresses or comments (b) (4) . No Foreign/DOD/VA consignees

Consignees	Approx. Number	Consignees	Approx. Number
Distributor	0	Repacker/Relabeler	0
Retailer	(b) (4)	Direct Accounts	0
Institution	0	Veterans Administration	0
Medical Facility	0	Department of Defense	0
Internet Sales	0	Manufacturer	0
Physician	0	USDA	0
Consumer/Patient	0	Other	0

Summary/Termination Information

Quantity Recovered/Number of Units Corrected (b) (4) cases, (b) (4)

Product Disposition The recalled product was destroyed

Number of Consignees Responding to Notification (b) (4) consignees

Effectiveness Check Information 44/44 = 100%

Recall Audit Check Count Audit Count Summary : Not Available

Audit Check Information No recall audit checks were done for this recall. The firm has a history of effective recalls using their FoodiQ system.

Section of Law Violated Section 402(a)(1) of the Food, Drug and Cosmetic Act

Preventive Action Taken by Firm Labels are being audited at the Global and store locations prior to product deployment

District Follow-Up The issue was an internal label error by Whole Foods Market. No manufacturing location was implicated therefore no follow-up will be conducted outside of this recall.

District Review A review of the recall file was conducted during evaluation of this recall. The recall appears to be complete and effective.

Legal Action None planned.

Class I Termination Recommendation DRC is recommending termination concurrence.

Recommended/Prepared By Casey Hamblin

District Management Approval Chad Whitwell, ADCB **Date** 04/06/2020

Center Concurrence Angela Alexander

Recall Completed Date 02/04/2020

Termination Letter Date

CFSAN Center Information

Docs Rcvd at Ctr Date 02/18/2020

HHE Sent

HHE Signed

HHE Precedent P-7907

Outbreak Associated N

CFSAN CORE Incident EON ID

Product Information

Product : 1

Industry-Product Code 03-R02

Precedent Recall P-7907

Precedent Policy

Precedent Policy Comment The level of risk to health posed by the violative product is similar to the level or risk previously evaluated in the identified precedent HHE.

Product Description (**Int**) Chocolate Fudge Mini Bundt Cake sold by the slice packaged in Self Serve and Plastic clam
(Label/Packaging) shell containers PLU 21287

Trade Name (**Int**) Whole Foods Market

Generic Name (**Int**)

Product Usage Food for human consumption

Product Quantity Distributed (**Int**) (b) (4) (total)

Recall Number (**Int**) F-0764-2020

Product Public Reason for Recall (**Int**) Undeclared milk

Field Recommended Classification Class I

Center Determination/Classification (**Int**) Class I

Center Recommended Depth Consumers/User

Product Effectiveness Check Level A **Percent** 100

Product Audit Check Level E **Percent** 0

Code Information (**Int**) Best by Dates Through Feb 08 2020

Expected Life

Shelf Life 2/8/2020

CFSAN Reason Labeling/undeclared allergen

Product : 2

Industry-Product Code

03-R02	Precedent Recall
P-7907	Precedent Policy
	Precedent Policy Comment
The level of risk to health posed by the violative product is similar to the level or risk previously evaluated in the identified precedent HHE.	Product Description (Int) (Label/Packaging)
Marble Bundt Cake sold by the slice packaged in Self Serve and Plastic clam shell containers PLU 45162	Trade Name (Int)
Whole Foods Market	Generic Name (Int)
	Product Usage
Food for human consumption	Product Quantity Distributed (Int)
(b) (4) (total)	Recall Number (Int)
F-0765-2020	Product Public Reason for Recall (Int)
Undeclared milk	Field Recommended Classification
Class I	Center Determination/Classification (Int)
Class I	Center Recommended Depth
Consumers/User	Product Effectiveness Check Level
A Percent 100	Product Audit Check Level
E Percent 0	Code Information (Int)
Best by Dates Through Feb 08 2020	Expected Life
	Shelf Life
2/8/2020	CFSAN Reason
Product : 3	Industry-Product Code
03-H02	Precedent Recall
P-7907	Precedent Policy
	Precedent Policy Comment
The level of risk to health posed by the violative product is similar to the level or risk previously evaluated in the identified precedent HHE.	Product Description (Int) (Label/Packaging)
Dark Chocolate Dipped Almond Horn Cookie sold by the individual cookie packaged in Self Serve and Plastic clam shell containers PLU 33579	Trade Name (Int)
Whole Foods Market	Generic Name (Int)
	Product Usage
Food for human consumption	Product Quantity Distributed (Int)
(b) (4) (total)	Recall Number (Int)
F-0766-2020	Product Public Reason for Recall (Int)

Undeclared milk

Class I

Class I

Consumers/User

A **Percent** 100

E **Percent** 0

Best by Dates Through Feb 17 2020

2/17/2020

Product : 4

03- H02

P-7907

The level of risk to health posed by the violative product is similar to the level or risk previously evaluated in the identified precedent HHE.

Chocolate Dipped Coconut Macaroon Cookie sold by the individual cookie packaged in Self Serve and Plastic clam shell containers PLU 48454

Whole Foods Market

Food for human consumption

(b) (4) (total)

F-0767-2020

Undeclared milk

Class I

Class I

Consumers/User

A **Percent** 100

E **Percent** 0

Best by Dates Through Feb 8 2020

2/8/2020

Recalling Firm Information

FEI

3007331558

Field Recommended Classification

Center Determination/Classification
(Int)

Center Recommended Depth

Product Effectiveness Check Level

Product Audit Check Level

Code Information **(Int)**

Expected Life

Shelf Life

CFSAN Reason

Industry-Product Code

Precedent Recall

Precedent Policy

Precedent Policy Comment

Product Description **(Int)**
(Label/Packaging)

Trade Name **(Int)**

Generic Name **(Int)**

Product Usage

Product Quantity Distributed **(Int)**

Recall Number **(Int)**

Product Public Reason for Recall
(Int)

Field Recommended Classification

Center Determination/Classification
(Int)

Center Recommended Depth

Product Effectiveness Check Level

Product Audit Check Level

Code Information **(Int)**

Expected Life

Shelf Life

CFSAN Reason

Firm Name (Int)	Whole Foods Market
Address (Int)	550 Bowie St
City (Int)	Austin
State/Province (Int)	Texas
Country (Int)	United States
Postal Code (Int)	78703-4644
Telephone	Ext Country Code
Comment	

Most Responsible Individual

Official's Name	John Mackey
Title	President/CEO
Firm Name (Int)	Whole Foods Market
Address (Int)	550 Bowie St
City (Int)	Austin
State/Province (Int)	Texas
Country (Int)	United States
Postal Code (Int)	78703-4644
Telephone	512-542-2200 Ext Country Code
Facsimile	Ext Country Code
E-mail Address	
Comment	

Manufacturer Information

FEI	3007331558
Firm Name (Int)	Whole Foods Market
Address (Int)	550 Bowie St
City (Int)	Austin
State/Province (Int)	Texas
Country (Int)	United States
Postal Code (Int)	78703-4644
Telephone	Ext Country Code
Comment	

Responsible Firm Information

FEI	3007331558
Firm Type	Manufacturer
Firm Name (Int)	Whole Foods Market

Address **(Int)** 550 Bowie St
City **(Int)** Austin
State/Province **(Int)** Texas
Country **(Int)** United States
Postal Code **(Int)** 78703-4644
Telephone **Ext** **Country Code**

Comment

Recall Contact

Official's Name Craig Penigar
Title
Firm Name **(Int)** Whole Foods Market
Address **(Int)** 550 Bowie St
City **(Int)** Austin
State/Province **(Int)** Texas
Country **(Int)** United States
Postal Code **(Int)** 78703-4644
Telephone **Ext** **Country Code**
Facsimile **Ext** **Country Code**

E-mail Address

Comment

Public Contact

Official's Name
Title
Firm Name **(Int)** Whole Foods Market
Address **(Int)** 550 Bowie St
City **(Int)** Austin
State/Province **(Int)** Texas
Country **(Int)** United States
Postal Code **(Int)** 78703-4644
Telephone **Ext** **Country Code**
Facsimile **Ext** **Country Code**

E-mail Address

Comment Rachel Malish Rachel.Malish@wholefoods.com

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Recall Details

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Event Information

Recall Event ID	85135	RFR EON ID	
Recall Number(s)	F-0846-2020	RFR EON URLs	
District	Human And Animal Food West III	Coordinator	Casey Hamblin
Firm Awareness Date	03/01/2020	District Awareness Date	03/02/2020
Center (Int)	Center for Food Safety and Applied Nutrition	Coordinator	Angela Alexander
Recalling Firm FEI	3007331558	Name (Int)	Whole Foods Market
Manufacturer FEI	3007331558	Name (Int)	Whole Foods Market
Responsible Firm FEI	3007331558	Name	Whole Foods Market
Public Reason for Recall	Contains undeclared milk		
Edit Mode	Viewable	Recall Status (Int)	Terminated
Voluntary/Mandated (Int)	Firm Initiated	Date (Int)	03/02/2020
Firm Recommended Recall Depth	Consumers/User	Date Distribution Chain Notified	03/02/2020
Recall Initiation Date (Int)	03/02/2020	Firm Initial Notification	Other
Determination Date	03/20/2020	Center Coordinator Assigned Date	03/18/2020
Classification Date	03/20/2020	FDA Sample Number	None

Complete Reason for Recall	The recalling firm noticed that the product label did not declare a missing allergen, Milk. Supplier uploaded a spec sheet with an ingredient statement that added a MILK allergen to item identified by the manufacturer as item 1362-3. The previous spec sheet with the same manufacturer item number did not contain MILK.		
Root Cause	Other		
Root Cause Narrative	Supplier changed ingredient statements on product without confirming with WFM of the change.		
Center Comments	Class I. CFSAN concurs with audit check strategy.		
Type Of Injury	None reported		
Quantity Manufactured	(b) (4)		
Quantity Distributed (Int)	(b) (4)		
Number of Domestic Consignees	(b) (4)		
Number of Foreign Consignees	0		
Distributed From	02/28/2020To 03/02/2020		
Distribution Pattern (Int)	Alabama, Arizona, California, Colorado, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Mexico, North Carolina, South Carolina, Tennessee, Texas, Utah and Wisconsin.		
Manufactured From	02/28/2020To 03/01/2020		
Public Summary of Recall Strategy (Int)	A press release was issued on 3/3/2020. The recalling firm notified their affected stores via online platform on 3/2/2020.		
Recall Strategy	The recalling firm used the (b) (4) and online platform used to communicate with the affected stores on 3/2/2020. A press release was issued on 3/3/2020. Our retail stores acknowledge the receipt of the recall communication and close out once quantities, if any are tallied.		
Effectiveness Check Level	APercent 100		
Audit Check Level	EPercent 0		
Audit/Effectiveness Check Modification	The issue occurred in WFM stores, not at a manufacturing facility. WFM in store recall system has a history of facilitating effective recalls.		
RAC Assignment Date Issued	RAC Assignment Date Completed		
District RAC Assignment Needed?	District Justification for No Audit Check	Due to firm's past history of successful recall strategy and effectiveness checks, RACs not needed	
	No		
District Recommendation for No Audit Check Comments	Additionally, the issue occurred in WFM stores, not at a manufacturing facility. WFM in store recall system has a history of facilitating effective recalls.	Center Agrees with District RAC Assignment Recommendation	Yes
Center RAC Assignment Needed?	Center Justification for No Audit Check		
Center Recommendation Justification Comments	Center Entering Recall		

What Consumers Should Do (Int)

Expanded Comments for
What Consumers Should Do (Int)

Firm Press Issued (Int) 03/03/2020 URL (Int) <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/allergy-alert-issued-undeclared-milk-green-chile-chicken-tamales-sold-whole-foods-market-stores>

State Press Issued (Int) URL (Int)

FDA Press Issued (Int) URL (Int)

Additional Medical Product Information (Int) URL (Int)

Consignee Details

List of Domestic and/or Foreign Consignees, Distribution addresses or comments (b) (4)

Consignees	Approx. Number	Consignees	Approx. Number
Distributor	0	Repacker/Relabeler	0
Retailer	(b) (4)	Direct Accounts	0
Institution	0	Veterans Administration	0
Medical Facility	0	Department of Defense	0
Internet Sales	0	Manufacturer	0
Physician	0	USDA	0
Consumer/Patient	0	Other	0

Summary/Termination Information

Quantity Recovered/Number of Units Corrected (b) (4) cases, (b) (4)

Product Disposition The affected product was destroyed.

Number of Consignees Responding to Notification (b) (4) retail locations

Effectiveness Check Information 204/204 = 100%

Recall Audit Check Count Audit Count Summary : Not Available

Audit Check Information NO RACs were performed for this recall. The firm has a history of performing effective recalls.

Section of Law Violated Section 402(a)(1) of the Food, Drug and Cosmetic Act

Preventive Action Taken by Firm Whole Foods Market has instructed the supplier to inform the firm when product spec sheets are updated/changed.

District Follow-Up The issue occurred at Whole Foods Market retail stores, therefore no follow-up is planned by HAFW3.

District Review	A review of the recall file and termination information was completed during evaluation of this recall. The recall appears to be complete and effective.
Legal Action	None planned.
Class I Termination Recommendation	DRC recommends termination concurrence.
Recommended/Prepared By	Casey Hamblin
District Management Approval	Chad Whitwell, ADCB Date 04/06/2020
Center Concurrence	Angela Alexander
Recall Completed Date	03/02/2020
Termination Letter Date	

CFSAN Center Information

Docs Rcvd at Ctr Date 03/18/2020

HHE Sent

HHE Signed

HHE Precedent P-7907

Outbreak Associated N

CFSAN CORE Incident EON ID

Product Information

Product : 1

Industry-Product Code 37-BYT21

Precedent Recall P-7907

Precedent Policy

Precedent Policy Comment The level of risk to health posed by the violative product is similar to the level or risk previously evaluated in the identified precedent HHE.

Product Description (**Int**) (Label/Packaging) Whole Foods Market Green Chile Chicken Tamale served as a Family Meal, Chef's Case, Packaged, Frozen and on the hot bar PLU 72429 packaged in plastic containers and in family-style meal kits

Trade Name (**Int**) Whole Foods Market

Generic Name (**Int**)

Product Usage Food for human consumption

Product Quantity Distributed (**Int**) (b) (4)

Recall Number (**Int**) F-0846-2020

Product Public Reason for Recall (**Int**) Contains undeclared milk

Field Recommended Classification Class I

Center Determination/Classification (**Int**) Class I

Center Recommended Depth Consumers/User

Product Effectiveness Check Level A **Percent** 100

Product Audit Check Level

E Percent 0

Code Information (Int)

Product Code (begins with) 224401, 237593, 272405,237597, 272429, 277626, 272435; Best
By Through 3/7/2020-3/31/2020; Packed date from February 28th 2020 to March 1st, 2020

Expected Life

Shelf Life

3/31/20

CFSAN Reason

Labeling/undeclared allergen

Recalling Firm Information

FEI

3007331558

Firm Name (Int)

Whole Foods Market

Address (Int)

550 Bowie St

City (Int)

Austin

State/Province (Int)

Texas

Country (Int)

United States

Postal Code (Int)

78703-4644

Telephone

Ext

Country Code

Comment

Most Responsible Individual

Official's Name

John Mackey

Title

CEO/President

Firm Name (Int)

Whole Foods Market

Address (Int)

550 Bowie St

City (Int)

Austin

State/Province (Int)

Texas

Country (Int)

United States

Postal Code (Int)

78703-4644

Telephone

Ext

Country Code

Facsimile

Ext

Country Code

E-mail Address

Craig.Penigar@wholefoods.com

Comment

Manufacturer Information

FEI

3007331558

Firm Name (Int)

Whole Foods Market

Address (Int)

550 Bowie St

City (Int)

Austin

State/Province (Int)

Texas

Country (**Int**) United States
Postal Code (**Int**) 78703-4644
Telephone **Ext** **Country Code**
Comment

Responsible Firm Information

FEI 3007331558
Firm Type Manufacturer
Firm Name (**Int**) Whole Foods Market
Address (**Int**) 550 Bowie St
City (**Int**) Austin
State/Province (**Int**) Texas
Country (**Int**) United States
Postal Code (**Int**) 78703-4644
Telephone **Ext** **Country Code**
Comment

Recall Contact

Official's Name Craig Penigar
Title
Firm Name (**Int**) Whole Foods Market
Address (**Int**) 550 Bowie St
City (**Int**) Austin
State/Province (**Int**) Texas
Country (**Int**) United States
Postal Code (**Int**) 78703-4644
Telephone **Ext** **Country Code**
Facsimile **Ext** **Country Code**
E-mail Address Craig.Penigar@wholefoods.com
Comment

Public Contact

Official's Name
Title
Firm Name (**Int**) Whole Foods Market
Address (**Int**) 550 Bowie St
City (**Int**) Austin
State/Province (**Int**) Texas
Country (**Int**) United States

Postal Code (Int) 78703-4644
Telephone Ext Country Code
Facsimile Ext Country Code
E-mail Address
Comment Contact: Rachel Malish Rachel.malish@wholefoods.com

[Summary](#) [Help](#)

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Recall Details

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Event Information

Recall Event ID	85465	RFR EON ID	
Recall Number(s)	F-0925-2020	RFR EON URLs	
District	Human And Animal Food West III	Coordinator	Casey Hamblin
Firm Awareness Date	04/10/2020	District Awareness Date	04/10/2020
Center (Int)	Center for Food Safety and Applied Nutrition	Coordinator	Melanie Butler
Recalling Firm FEI	3007331558	Name (Int)	Whole Foods Market
Manufacturer FEI	1222010	Name (Int)	Kettle Cuisine, LLC
Responsible Firm FEI	3007331558	Name	Whole Foods Market
Public Reason for Recall	May contain undeclared milk		
Edit Mode	Viewable	Recall Status (Int)	Terminated
Voluntary/Mandated (Int)	Firm Initiated	Date (Int)	04/10/2020
Firm Recommended Recall Depth	Consumers/User	Date Distribution Chain Notified	04/10/2020
Recall Initiation Date (Int)	04/10/2020	Firm Initial Notification	Combination
Determination Date	04/29/2020	Center Coordinator Assigned Date	04/23/2020
Classification Date	04/29/2020	FDA Sample Number	None
Complete Reason for Recall	Milk was not declared as an allergen on the scale label. A store employee noticed that the ingredient list on the case label didn't match with the stores scale label.		

Root Cause	Other	
Root Cause Narrative	The old formulation was still in the system as teams worked through inventory, and was never removed once inventory was gone. The wrong item was used in the new recipes that had incorrect ingredients/allergens and was missing MILK.	
Center Comments	Class I. CFSAN concurs with audit check strategy.	
Type Of Injury	None reported.	
Quantity Manufactured	(b) (4)	
Quantity Distributed (Int)	(b) (4)	
Number of Domestic Consignees	(b) (4)	
Number of Foreign Consignees	0	
Distributed From	03/17/2020To 04/10/2020	
Distribution Pattern (Int)	Alabama, Arizona, California, Colorado, Connecticut, District of Columbia, Georgia, Hawaii, Idaho, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Maine, Missouri, Mississippi, North Carolina, New Hampshire, New Jersey, New Mexico, Nevada, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Virginia and Washington.	
Manufactured From	03/17/2020To 04/10/2020	
Public Summary of Recall Strategy (Int)	On 4/10/2020, all affected stores were notified of the recall via online communication and response software. Additionally, the firm issued a press release on 4/10/2020.	
Recall Strategy	On 4/10/2020, the (b) (4) system notified all affected stores of the recall via online communication and response software. Additionally, the firm issued a press release on 4/10/2020.	
Effectiveness Check Level	APercent 100	
Audit Check Level	EPercent 0	
Audit/Effectiveness Check Modification	Due to the firm's extensive history of effective recalls, DRC recommends no RACs to be conducted. The firm utilizes an internal in store FoodIQ system that assists in effectuating the recalls.	
RAC Assignment Date Issued	RAC Assignment Date Completed	
District RAC Assignment Needed?	No	District Justification for No Audit Check Other (explain in comments)
District Recommendation for No Audit Check Comments	Due to the firm's extensive history of effective recalls, DRC recommends no RACs to be conducted. The firm utilizes an internal in store FoodIQ system that assists in effectuating the recalls.	Center Agrees with District RAC Assignment Recommendation Yes
Center RAC Assignment Needed?	Center Justification for No Audit Check	
Center Recommendation Justification Comments	Center Entering Recall	
What Consumers Should Do (Int)		

Expanded Comments for
What Consumers Should Do (Int)

Firm Press Issued (Int) 04/10/2020 URL (Int) <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/allergy-alert-issued-undeclared-milk-minestrone-soup-sold-whole-foods-market-stores-32-states-and>

State Press Issued (Int) URL (Int)

FDA Press Issued (Int) URL (Int)

Additional Medical Product Information (Int) URL (Int)

Consignee Details

List of Domestic and/or Foreign Consignees, Distribution addresses or comments (b) (4) No VA/DOD/Foreign consignees

Consignees	Approx. Number	Consignees	Approx. Number
Distributor	0	Repacker/Relabeler	0
Retailer	(b) (4)	Direct Accounts	0
Institution	0	Veterans Administration	0
Medical Facility	0	Department of Defense	0
Internet Sales	0	Manufacturer	0
Physician	0	USDA	0
Consumer/Patient	0	Other	0

Summary/Termination Information

Quantity Recovered/Number of Units Corrected (b) (4)

Product Disposition The affected product within date was relabeled with the correct label and allergen declaration.

Number of Consignees Responding to Notification (b) (4)

Effectiveness Check Information 367/367 = 100%

Recall Audit Check Count Audit Count Summary : Not Available

Audit Check Information No recall audit checks were conducted for this recall. The firm has an extensive history of effective recalls.

Section of Law Violated Section 402(a)(1) and 403 of the Food, Drug, and Cosmetic Act

Preventive Action Taken by Firm The recalling firm will re-defining end of life cycle process for items with reformulations

District Follow-Up The labeling issue occurred at the retail store level, therefore there is not planned inspectional follow-up.

District Review A review of the recall file was conducted during evaluation of this recall. The recall appears to be complete and effective.

Legal Action	None planned.
Class I Termination Recommendation	DRC recommends recall termination.
Recommended/Prepared By	Casey Hamblin
District Management Approval	Jessica Havranek, DCB Date 05/22/2020
Center Concurrence	Angela Alexander
Recall Completed Date	04/10/2020
Termination Letter Date	

CFSAN Center Information

Docs Rcvd at Ctr Date 04/22/2020

HHE Sent

HHE Signed

HHE Precedent P-7907

Outbreak Associated N

CFSAN CORE Incident EON ID

Product Information

Product : 1

Industry-Product Code	38-AGT18
Precedent Recall	P-7907
Precedent Policy	
Precedent Policy Comment	The level of risk to health posed by the violative product is similar to the level of risk previously evaluated in the identified precedent HHE.
Product Description (Int) (Label/Packaging)	Whole Foods Market Minestrone Soup PLU code printed on the product scale labels beginning with 248529 for soup sold in clear plastic deli-style containers of various weight and 246691 for soup sold in clear plastic bags weighing 7 lbs. 12 oz.
Trade Name (Int)	Whole Foods Market
Generic Name (Int)	
Product Usage	Food for human consumption
Product Quantity Distributed (Int)	(b) (4)
Recall Number (Int)	F-0925-2020
Product Public Reason for Recall (Int)	May contain undeclared milk
Field Recommended Classification	Class I
Center Determination/Classification (Int)	Class I
Center Recommended Depth	Consumers/User
Product Effectiveness Check Level	A Percent 100
Product Audit Check Level	E Percent 0
Code Information (Int)	sell-by dates of 4/17/2020 and prior

Expected Life

Shelf Life 7 days

CFSAN Reason Labeling/undeclared allergen

Recalling Firm Information

FEI 3007331558

Firm Name **(Int)** Whole Foods Market

Address **(Int)** 550 Bowie St

City **(Int)** Austin

State/Province **(Int)** Texas

Country **(Int)** United States

Postal Code **(Int)** 78703-4644

Telephone **Ext Country Code**

Comment

Most Responsible Individual

Official's Name John Mackey

Title President/CEO

Firm Name **(Int)** Whole Foods Market

Address **(Int)** 550 Bowie St

City **(Int)** Austin

State/Province **(Int)** Texas

Country **(Int)** United States

Postal Code **(Int)** 78703-4644

Telephone 512-477-4455 **Ext Country Code**

Facsimile **Ext Country Code**

E-mail Address John.Mackey@wholefoods.com

Comment

Manufacturer Information

FEI 1222010

Firm Name **(Int)** Kettle Cuisine, LLC

Address **(Int)** 330 Lynnway

City **(Int)** Lynn

State/Province **(Int)** Massachusetts

Country **(Int)** United States

Postal Code **(Int)** 01901-1706

Telephone 617-409-7011 **Ext Country Code**

Comment

Responsible Firm Information

FEI 3007331558

Firm Type Repacker

Firm Name **(Int)** Whole Foods Market

Address **(Int)** 550 Bowie St

City **(Int)** Austin

State/Province **(Int)** Texas

Country **(Int)** United States

Postal Code **(Int)** 78703-4644

Telephone **Ext Country Code**

Comment

Recall Contact

Official's Name Craig Penigar

Title Incident Management Team Lead

Firm Name **(Int)** Whole Foods Market

Address **(Int)** 550 Bowie St

City **(Int)** Austin

State/Province **(Int)** Texas

Country **(Int)** United States

Postal Code **(Int)** 78703-4644

Telephone 512-477-4455 **Ext Country Code**

Facsimile **Ext Country Code**

E-mail Address Craig.Penigar@wholefoods.com

Comment

Public Contact

Official's Name Nathan Cimbala

Title

Firm Name **(Int)** Whole Foods Market

Address **(Int)** 550 Bowie St

City **(Int)** Austin

State/Province **(Int)** Texas

Country **(Int)** United States

Postal Code **(Int)** 78703-4644

Telephone 844-936-8255 **Ext Country Code**

Facsimile **Ext Country Code**

E-mail Address Nathan.Cimbala@wholefoods.com

Comment Consumers with additional questions can call 1-844-936-8255 between the hours of 7:00 a.m. and 10:00 p.m. CST, Monday through Friday, or 8:00 a.m. and 6:00 p.m. Saturday through Sunday.

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Event Information

Recall Event ID	85947	RFR EON ID	
Recall Number(s)	F-1024-2020	RFR EON URLs	
District	Human And Animal Food West III	Coordinator	Casey Hamblin
Firm Awareness Date	06/24/2020	District Awareness Date	06/29/2020
Center (Int)	Center for Food Safety and Applied Nutrition	Coordinator	Kelly Abraham
Recalling Firm FEI	3007331558	Name (Int)	Whole Foods Market
Manufacturer FEI	3002823211	Name (Int)	Chuckanut Bay Foods LLC
Responsible Firm FEI	3002823211	Name	Chuckanut Bay Foods LLC
Public Reason for Recall	Undeclared walnuts		
Edit Mode	Viewable	Recall Status (Int)	Terminated
Voluntary/Mandated (Int)	Firm Initiated	Date (Int)	06/24/2020
Firm Recommended Recall Depth	Consumers/User	Date Distribution Chain Notified	06/24/2020
Recall Initiation Date (Int)	06/24/2020	Firm Initial Notification	E-Mail
Determination Date	07/14/2020	Center Coordinator Assigned Date	07/07/2020
Classification Date	07/15/2020	FDA Sample Number	None

Complete Reason for Recall	The recall was initiated when a store began individually packaging the product and discovered the manufacturer had mislabeled the product as Red Velvet Layered Cheesecake when it contained Carrot Cake Layered Cheesecake instead leading to an undeclared tree nut (walnut) allergen. The manufacturer initiated a recall as well under event 85941.		
Root Cause	Other		
Root Cause Narrative	According to the supplier, (b) (4)		
Center Comments	Class II. CFSAN agrees with audit check strategy.		
Type Of Injury	None reported		
Quantity Manufactured	(b) (4)		
Quantity Distributed (Int)	(b) (4)		
Number of Domestic Consignees	(b) (4)		
Number of Foreign Consignees	0		
Distributed From	6/24/2020 To 6/26/2020		
Distribution Pattern (Int)	California; Boise, Idaho; and Reno, Nevada		
Manufactured From	6/24/2020 To 6/24/2020		
Public Summary of Recall Strategy (Int)	A press release was issued on 6/29/2020. Stores were notified of the issue via the internal electronic email system on 6/24/2020. The recalling firm began removing product from their shelves on 6/24/2020 and it was held for destruction.		
Recall Strategy	A press release was issued on 6/29/2020. The recalling firm began removing product from their shelves on 6/24/2020 and it was held for destruction. The WFM stores were notified of the issue via the internal electronic email system on 6/24/2020.		
Effectiveness Check Level	A Percent 100		
Audit Check Level	E Percent 0		
Audit/Effectiveness Check Modification			
RAC Assignment Date Issued	RAC Assignment Date Completed		
District RAC Assignment Needed?	No	District Justification for No Audit Check	Firm has history of effective audit checks
District Recommendation for No Audit Check Comments		Center Agrees with District RAC Assignment Recommendation	Yes
Center RAC Assignment Needed?		Center Justification for No Audit Check	
Center Recommendation Justification Comments		Center Entering Recall	
What Consumers Should Do (Int)			
Expanded Comments for What Consumers Should Do (Int)			

Firm Press Issued (Int) 06/29/2020 URL (Int) <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/allergy-alert-undeclared-tree-nut-red-velvet-cheesecake-slices-issued-whole-foods-market-stores>

State Press Issued (Int) URL (Int)

FDA Press Issued (Int) URL (Int)

Additional Medical Product Information (Int) URL (Int)

Consignee Details

List of Domestic and/or Foreign Consignees, Distribution addresses or comments No VA/DOD/Foreign consignees

Consignees	Approx. Number	Consignees	Approx. Number
Distributor	0	Repacker/Relabeler	0
Retailer	(b) (4)	Direct Accounts	0
Institution	0	Veterans Administration	0
Medical Facility	0	Department of Defense	0
Internet Sales	0	Manufacturer	0
Physician	0	USDA	0
Consumer/Patient	0	Other	0

Summary/Termination Information

Quantity Recovered/Number of Units Corrected (b) (4) cases and (b) (4) of the Red Velvet cake

Product Disposition The product was destroyed at the store level

Number of Consignees Responding to Notification (b) (4) stores

Effectiveness Check Information 47/47 = 100%

Recall Audit Check Count Audit Count Summary : Not Available

Audit Check Information No RACs were performed. The firm has an extensive history of effective recalls. However, HAFW6 forwarded 3 RACs conducted at Whole Foods Market stores that were conducted under the recall RES 85941. The RACs were all endorsed as effective.

Section of Law Violated Section 402 of the Food, Drug and Cosmetic Act

Preventive Action Taken by Firm The supplier noted (b) (4)

District Follow-Up HAFW6 will perform any follow-up actions at the manufacturing location.

District Review A review of the recall file was conducted during evaluation of this recall. The recall appears to be complete and effective.

Legal Action	None planned
Class I Termination Recommendation	N/A
Recommended/Prepared By	Casey Hamblin
District Management Approval	Jessica Havranek, DCB Date 07/23/2020
Center Concurrence	
Recall Completed Date	06/29/2020
Termination Letter Date	

CFSAN Center Information

Docs Rcvd at Ctr Date 07/07/2020

HHE Sent

HHE Signed

HHE Precedent P-8063

Outbreak Associated N

CFSAN CORE Incident EON ID

Product Information

Product : 1

Industry-Product Code	03-Y99
Precedent Recall	P-8063
Precedent Policy	
Precedent Policy Comment	The level of risk to health posed by the violative product is similar to the level of risk previously evaluated in the identified precedent HHE.
Product Description (Int) (Label/Packaging)	Whole Foods Market Red Velvet Layered Cheesecake Slice PLU: 78620 packaged in plastic clam shell with scale label applied
Trade Name (Int)	Whole Foods Market
Generic Name (Int)	
Product Usage	Food for human consumption
Product Quantity Distributed (Int)	(b) (4)
Recall Number (Int)	F-1024-2020
Product Public Reason for Recall (Int)	Undeclared walnuts
Field Recommended Classification	Class II
Center Determination/Classification (Int)	Class II
Center Recommended Depth	Consumers/User
Product Effectiveness Check Level	A Percent 100
Product Audit Check Level	E Percent 0
Code Information (Int)	sell-by dates through July 1, 2020

Expected Life

Shelf Life 7/1/2020

CFSAN Reason Labeling/undeclared allergen

Recalling Firm Information

FEI 3007331558

Firm Name **(Int)** Whole Foods Market

Address **(Int)** 550 Bowie St

City **(Int)** Austin

State/Province **(Int)** Texas

Country **(Int)** United States

Postal Code **(Int)** 78703-4644

Telephone **Ext Country Code**

Comment

Most Responsible Individual

Official's Name John Mackey

Title President/CEO

Firm Name **(Int)** Whole Foods Market

Address **(Int)** 550 Bowie St

City **(Int)** Austin

State/Province **(Int)** Texas

Country **(Int)** United States

Postal Code **(Int)** 78703-4644

Telephone 512-477-5566 **Ext Country Code**

Facsimile **Ext Country Code**

E-mail Address John.Mackey@wholefoods.com

Comment

Manufacturer Information

FEI 3002823211

Firm Name **(Int)** Chuckanut Bay Foods LLC

Address **(Int)** 1649 Boblett St

City **(Int)** Blaine

State/Province **(Int)** Washington

Country **(Int)** United States

Postal Code **(Int)** 98230

Telephone 360-380-1908 **Ext Country Code**

Comment

Responsible Firm Information

FEI 3002823211

Firm Type Manufacturer

Firm Name **(Int)** Chuckanut Bay Foods LLC

Address **(Int)** 1649 Boblett St

City **(Int)** Blaine

State/Province **(Int)** Washington

Country **(Int)** United States

Postal Code **(Int)** 98230

Telephone 360-380-1908 **Ext** **Country Code**

Comment

Recall Contact

Official's Name Craig Penigar

Title Incident Manager Team Lead

Firm Name **(Int)** Whole Foods Market

Address **(Int)** 550 Bowie St

City **(Int)** Austin

State/Province **(Int)** Texas

Country **(Int)** United States

Postal Code **(Int)** 78703-4644

Telephone 512-477-5566 **Ext** **Country Code**

Facsimile **Ext** **Country Code**

E-mail Address Craig.Penigar@wholefoods.com

Comment

Public Contact

Official's Name Rachel Malish

Title

Firm Name **(Int)** Whole Foods Market

Address **(Int)** 550 Bowie St

City **(Int)** Austin

State/Province **(Int)** Texas

Country **(Int)** United States

Postal Code **(Int)** 78703-4644

Telephone **Ext** **Country Code**

Facsimile **Ext** **Country Code**

E-mail Address Rachel.malish@wholefoods.com

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Event Information

Recall Event ID	86117	RFR EON ID	
Recall Number(s)	F-1048-2020	RFR EON URLs	
District	Human And Animal Food West III	Coordinator	Casey Hamblin
Firm Awareness Date	07/23/2020	District Awareness Date	07/24/2020
Center (Int)	Center for Food Safety and Applied Nutrition	Coordinator	Dehlia Young
Recalling Firm FEI	3007331558	Name (Int)	Whole Foods Market
Manufacturer FEI	3007331558	Name (Int)	Whole Foods Market
Responsible Firm FEI	3007331558	Name	Whole Foods Market
Public Reason for Recall	Potential to contain undeclared tree nuts (almond)		
Edit Mode	Viewable	Recall Status (Int)	Ongoing
Voluntary/Mandated (Int)	Firm Initiated	Date (Int)	07/23/2020
Firm Recommended Recall Depth	Consumers/User	Date Distribution Chain Notified	07/23/2020
Recall Initiation Date (Int)	07/23/2020	Firm Initial Notification	Other
Determination Date	08/04/2020	Center Coordinator Assigned Date	07/30/2020
Classification Date	08/04/2020	FDA Sample Number	None

Complete Reason for Recall	Undeclared tree nut - Almond. The recall was initiated during a routine internal audit when it was discovered that almond flour was missing from the product label. Team member discovered the ingredients on the scale label didn't match the ingredients found on the master case.		
Root Cause	Other		
Root Cause Narrative	Recipe was setup using the wrong case ordering identifier.		
Center Comments	Class I. CFSAN concurs with audit check strategy.		
Type Of Injury	No reactions reported		
Quantity Manufactured	(b) (4)		
Quantity Distributed (Int)	(b) (4)		
Number of Domestic Consignees	(b) (4)		
Number of Foreign Consignees	0		
Distributed From	7/12/2020To 7/23/2020		
Distribution Pattern (Int)	Connecticut, Maine, Massachusetts, New Hampshire and Rhode Island		
Manufactured From	7/12/2020To 7/23/2020		
Public Summary of Recall Strategy (Int)	On 7/23/2020, retail stores were notified of the recall via an internal online communication. The recalling firm followed up with a press release on 7/24/2020.		
Recall Strategy	On 7/23/2020, retail stores were notified of the recall via an internal online communication. The recalling firm followed up with a press release on 7/24/2020.		
Effectiveness Check Level	APercent 100		
Audit Check Level	EPercent 0		
Audit/Effectiveness Check Modification	The recalling firm has an extensive history of effective recalls.		
RAC Assignment Date Issued	RAC Assignment Date Completed		
District RAC Assignment Needed?	No	District Justification for No Audit Check	Firm has history of effective audit checks
District Recommendation for No Audit Check Comments		Center Agrees with District RAC Assignment Recommendation	Yes
Center RAC Assignment Needed?		Center Justification for No Audit Check	
Center Recommendation Justification Comments		Center Entering Recall	
What Consumers Should Do (Int)			
Expanded Comments for What Consumers Should Do (Int)			
Firm Press Issued (Int)	07/24/2020	URL (Int) https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/allergy-alert-undeclared-tree-nut-almond-chantilly-key-lime-tartlets-issued-whole-foods-market	
State Press Issued (Int)		URL (Int)	
FDA Press Issued (Int)		URL (Int)	

Additional Medical Product
Information (Int)

URL (Int)

Consignee Details

List of Domestic and/or Foreign Consignees, Distribution addresses or comments

No VA/DOD/Foreign consignees. All affected consignees are (b) (4)

Consignees	Approx. Number	Consignees	Approx. Number
Distributor	0	Repacker/Relabeler	0
Retailer	(b) (4)	Direct Accounts	0
Institution	0	Veterans Administration	0
Medical Facility	0	Department of Defense	0
Internet Sales	0	Manufacturer	0
Physician	0	USDA	0
Consumer/Patient	0	Other	0

Summary/Termination Information

Quantity Recovered/Number of
Units Corrected

Product Disposition

Number of Consignees Responding
to Notification

Effectiveness Check Information

Recall Audit Check Count Audit Count Summary : Not Available

Audit Check Information No RACs will be performed by FDA. The recalling firm has an effective internal recall communication system.

Section of Law Violated Section 402 of the Food, Drug and Cosmetic Act

Preventive Action Taken by Firm When (b) (5) PLUs come back for products that are being updated, the recalling firm will look up the PLU in ICON and make sure (b) (5)

District Follow-Up

District Review

Legal Action None planned.

Class I Termination

Recommendation

Recommended/Prepared By

District Management Approval Date

Center Concurrence

Recall Completed Date

Termination Letter Date

CFSAN Center Information

Docs Rcvd at Ctr Date 07/29/2020

HHE Sent

HHE Signed

HHE Precedent P-7983

Outbreak Associated N

CFSAN CORE Incident EON ID

Product Information

Product : 1

Industry-Product Code 03-Y99

Precedent Recall P-7983

Precedent Policy

Precedent Policy Comment The level of risk to health posed by the violative product is similar to the level or risk previously evaluated in the identified precedent HHE.

Product Description (**Int**) Chantilly Key Lime Tartlets Net Wt 1 oz. individually packaged in plastic clamshell containers
(Label/Packaging) with Whole Foods Market scale labels, a PLU code of 268564

Trade Name (**Int**) Whole Foods Market

Generic Name (**Int**)

Product Usage Food for human consumption

Product Quantity Distributed (**Int**) (b) (4)

Recall Number (**Int**) F-1048-2020

Product Public Reason for Recall (**Int**) Potential to contain undeclared tree nuts (almond)

Field Recommended Classification Class I

Center Determination/Classification (**Int**) Class I

Center Recommended Depth Consumers/User

Product Effectiveness Check Level **A Percent** 100

Product Audit Check Level **E Percent** 0

Code Information (**Int**) PLU code of 2685640000, and product sell-by date through July 26, 2020

Expected Life

Shelf Life 7/26/2020

CFSAN Reason Labeling/undeclared allergen

Recalling Firm Information

FEI 3007331558

Firm Name (**Int**) Whole Foods Market

Address (Int)	550 Bowie St
City (Int)	Austin
State/Province (Int)	Texas
Country (Int)	United States
Postal Code (Int)	78703-4644
Telephone	Ext Country Code
Comment	

Most Responsible Individual

Official's Name	John Mackey
Title	President
Firm Name (Int)	Whole Foods Market
Address (Int)	550 Bowie St
City (Int)	Austin
State/Province (Int)	Texas
Country (Int)	United States
Postal Code (Int)	78703-4644
Telephone	Ext Country Code
Facsimile	Ext Country Code
E-mail Address	john.mackey@wholefoods.com
Comment	

Manufacturer Information

FEI	3007331558
Firm Name (Int)	Whole Foods Market
Address (Int)	550 Bowie St
City (Int)	Austin
State/Province (Int)	Texas
Country (Int)	United States
Postal Code (Int)	78703-4644
Telephone	Ext Country Code
Comment	

Responsible Firm Information

FEI	3007331558
Firm Type	Manufacturer
Firm Name (Int)	Whole Foods Market
Address (Int)	550 Bowie St

City **(Int)** Austin
State/Province **(Int)** Texas
Country **(Int)** United States
Postal Code **(Int)** 78703-4644
Telephone **Ext** **Country Code**
Comment

Recall Contact

Official's Name Craig Penigar
Title Global Quality Assurance and Incident Management
Firm Name **(Int)** Whole Foods Market
Address **(Int)** 550 Bowie St
City **(Int)** Austin
State/Province **(Int)** Texas
Country **(Int)** United States
Postal Code **(Int)** 78703-4644
Telephone **Ext** **Country Code**
Facsimile **Ext** **Country Code**
E-mail Address Craig.Penigar@wholefoods.com
Comment

Public Contact

Official's Name Rachel Malish
Title Media Contact
Firm Name **(Int)** Whole Foods Market
Address **(Int)** 550 Bowie St
City **(Int)** Austin
State/Province **(Int)** Texas
Country **(Int)** United States
Postal Code **(Int)** 78703-4644
Telephone **Ext** **Country Code**
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E-mail Address Rachel.malish@wholefoods.com
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Event Information

Recall Event ID	86118	RFR EON ID	
Recall Number(s)	F-1145-2020	RFR EON URLs	
District	Human And Animal Food West III	Coordinator	Casey Hamblin
Firm Awareness Date	07/24/2020	District Awareness Date	07/24/2020
Center (Int)	Center for Food Safety and Applied Nutrition	Coordinator	Dehlia Young
Recalling Firm FEI	3007331558	Name (Int)	Whole Foods Market
Manufacturer FEI	3003814927	Name (Int)	Boston Gourmet Chefs, Inc.
Responsible Firm FEI	3007331558	Name	Whole Foods Market
Public Reason for Recall	Potential to contain undeclared eggs		
Edit Mode	Viewable	Recall Status (Int)	Ongoing
Voluntary/Mandated (Int)	Firm Initiated	Date (Int)	07/24/2020
Firm Recommended Recall Depth	Consumers/User	Date Distribution Chain Notified	07/24/2020
Recall Initiation Date (Int)	07/24/2020	Firm Initial Notification	Combination
Determination Date	08/07/2020	Center Coordinator Assigned Date	08/04/2020
Classification Date	08/07/2020	FDA Sample Number	None

Complete Reason for Recall	The recall was initiated when a store team member noticed the discrepancy on the label leaving off the egg allergen. Team member discovered the ingredients on the scale label didn't match the ingredients found on the master case.		
Root Cause	Other		
Root Cause Narrative	Regional team was using a WFM provided identifier instead of the UPC provided by the supplier.		
Center Comments	Class I. CFSAN concurs with audit check strategy.		
Type Of Injury	None reported		
Quantity Manufactured	(b) (4)		
Quantity Distributed (Int)	(b) (4)		
Number of Domestic Consignees	(b) (4)		
Number of Foreign Consignees	0		
Distributed From	7/24/2020To 7/24/2020		
Distribution Pattern (Int)	Colorado, Kansas, Missouri, Nebraska, New Mexico, Texas and Utah.		
Manufactured From	7/24/2020To 7/24/2020		
Public Summary of Recall Strategy (Int)	On 7/24/2020, the recalling firm notified all affected WFM retail stores via an online communication via the internal recall platform. Additionally, a press release was issued on 7/24/2020.		
Recall Strategy	On 7/24/2020, the recalling firm notified all affected WFM retail stores via an online communication via the internal recall platform. Additionally, a press release was issued on 7/24/2020. The affected product was relabeled in stores.		
Effectiveness Check Level	APercent 100		
Audit Check Level	EPercent 0		
Audit/Effectiveness Check Modification	The firm has an extensive history of effective recalls.		
RAC Assignment Date Issued	RAC Assignment Date Completed		
District RAC Assignment Needed?	No	District Justification for No Audit Check	Firm has history of effective audit checks
District Recommendation for No Audit Check Comments		Center Agrees with District RAC Assignment Recommendation	Yes
Center RAC Assignment Needed?		Center Justification for No Audit Check	
Center Recommendation Justification Comments		Center Entering Recall	
What Consumers Should Do (Int)			
Expanded Comments for What Consumers Should Do (Int)			
Firm Press Issued (Int)	07/24/2020	URL (Int) https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/allergy-alert-undeclared-egg-kouign-amann-pastries-issued-select-whole-foods-market-stores-seven	
State Press Issued (Int)		URL (Int)	

FDA Press Issued (Int)

URL (Int)

Additional Medical Product Information (Int)

URL (Int)

Consignee Details

List of Domestic and/or Foreign Consignees, Distribution addresses or comments

No VA/DOD/Foreign consignees

Consignees	Approx. Number	Consignees	Approx. Number
Distributor	0	Repacker/Relabeler	0
Retailer	(b) (4)	Direct Accounts	0
Institution	0	Veterans Administration	0
Medical Facility	0	Department of Defense	0
Internet Sales	0	Manufacturer	0
Physician	0	USDA	0
Consumer/Patient	0	Other	0

Summary/Termination Information

Quantity Recovered/Number of Units Corrected

Product Disposition The recalled product was relabeled in the retail stores.

Number of Consignees Responding to Notification

Effectiveness Check Information

Recall Audit Check Count Audit Count Summary : Not Available

Audit Check Information

Section of Law Violated Section 402 (a)(1) of the Food, Drug and Cosmetic Act

Preventive Action Taken by Firm 1) Worked with the Supplier to update spec sheets to clearly state the allergens present. 2) All data was cleaned up in WFM system. 3) (b) (5) to prevent this in the future.

District Follow-Up

District Review

Legal Action None planned

Class I Termination

Recommendation

Recommended/Prepared By

District Management Approval **Date**

Center Concurrence

Recall Completed Date

Termination Letter Date

CFSAN Center Information

Docs Rcvd at Ctr Date 08/03/2020

HHE Sent

HHE Signed

HHE Precedent P-7968

Outbreak Associated N

CFSAN CORE Incident EON ID

Product Information

Product : 1

Industry-Product Code 03-Y99

Precedent Recall P-7968

Precedent Policy

Precedent Policy Comment The level of risk to health posed by the violative product is similar to the level or risk previously evaluated in the identified precedent HHE.

Product Description (**Int**)
(Label/Packaging) Kouign-Amann Pastry available in plastic clamshell 4-packs with Whole Foods Market scale labels, a PLU code 26739400000

Trade Name (**Int**) Whole Foods Market

Generic Name (**Int**)

Product Usage Food for human consumption

Product Quantity Distributed (**Int**) (b) (4)

Recall Number (**Int**) F-1145-2020

Product Public Reason for Recall (**Int**) Potential to contain undeclared eggs

Field Recommended Classification Class I

Center Determination/Classification (**Int**) Class I

Center Recommended Depth Consumers/User

Product Effectiveness Check Level A **Percent** 100

Product Audit Check Level E **Percent** 0

Code Information (**Int**) PLU code 26739400000 and a sell through date of July 27, 2020

Expected Life

Shelf Life 7/27/2020

CFSAN Reason Labeling/undeclared allergen

Recalling Firm Information

FEI	3007331558
Firm Name (Int)	Whole Foods Market
Address (Int)	550 Bowie St
City (Int)	Austin
State/Province (Int)	Texas
Country (Int)	United States
Postal Code (Int)	78703-4644
Telephone	Ext Country Code
Comment	

Most Responsible Individual

Official's Name	John Mackey
Title	President
Firm Name (Int)	Whole Foods Market
Address (Int)	550 Bowie St
City (Int)	Austin
State/Province (Int)	Texas
Country (Int)	United States
Postal Code (Int)	78703-4644
Telephone	Ext Country Code
Facsimile	Ext Country Code
E-mail Address	john.mackey@wholefoods.com
Comment	

Manufacturer Information

FEI	3003814927
Firm Name (Int)	Boston Gourmet Chefs, Inc.
Address (Int)	2 Watson Pl
City (Int)	Framingham
State/Province (Int)	Massachusetts
Country (Int)	United States
Postal Code (Int)	01701-4109
Telephone	508-877-0000 Ext Country Code
Comment	

Responsible Firm Information

FEI	3007331558
Firm Type	Repacker

Firm Name **(Int)** Whole Foods Market
Address **(Int)** 550 Bowie St
City **(Int)** Austin
State/Province **(Int)** Texas
Country **(Int)** United States
Postal Code **(Int)** 78703-4644
Telephone **Ext Country Code**
Comment

Recall Contact

Official's Name Craig Penigar
Title Global Quality Assurance and Incident Management
Firm Name **(Int)** Whole Foods Market
Address **(Int)** 550 Bowie St
City **(Int)** Austin
State/Province **(Int)** Texas
Country **(Int)** United States
Postal Code **(Int)** 78703-4644
Telephone **Ext Country Code**
Facsimile **Ext Country Code**
E-mail Address Craig.Penigar@wholefoods.com
Comment

Public Contact

Official's Name
Title
Firm Name **(Int)** Whole Foods Market
Address **(Int)** 550 Bowie St
City **(Int)** Austin
State/Province **(Int)** Texas
Country **(Int)** United States
Postal Code **(Int)** 78703-4644
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Event Information

Recall Event ID	86252	RFR EON ID	
Recall Number(s)	F-1354-2020 F-1355-2020 F-1356-2020 F-1357-2020 F-1358-2020 F-1359-2020 F-1360-2020 F-1361-2020 F-1362-2020	RFR EONURLs	
District	Human And Animal Food West III	Coordinator	Casey Hamblin
Firm Awareness Date	08/09/2020	District Awareness Date	08/12/2020
Center (Int)	Center for Food Safety and Applied Nutrition	Coordinator	Dehlia Young
Recalling Firm FEI	3007331558	Name (Int)	Whole Foods Market
Manufacturer FEI	3007331558	Name (Int)	Whole Foods Market
Responsible Firm FEI	3007331558	Name	Whole Foods Market
Public Reason for Recall	Undeclared lysozyme (from egg whites)		
Edit Mode	Viewable	Recall Status (Int)	Ongoing
Voluntary/Mandated (Int)	Firm Initiated	Date (Int)	08/10/2020
Firm Recommended Recall Depth	Retail	Date Distribution Chain Notified	08/10/2020
Recall Initiation Date (Int)	08/10/2020	Firm Initial Notification	E-Mail
Determination Date	09/01/2020	Center Coordinator Assigned Date	08/27/2020

Classification Date	09/01/2020	FDA Sample Number	None
Complete Reason for Recall	<p>The issue was discovered when a customer was comparing the El Trigal 12-month-old Manchego cheese to the 6-month and 60-day aged Manchego cheeses and discovered that egg was missing from the 12-month label. This was reported to a store on 8/9/2020. Whole Foods Market Global Incident Management Team began investigating and pulling mislabeled product from affected stores. The investigation has determined that there are 12 cheese products including Manchego that contain lysozyme (from egg white) as an ingredient but egg is not listed on the ingredient statement. In the El Trigal Manchego Cheese, lysozyme is at very low levels, 0.002% of ingredients.</p>		
Root Cause	Other		
Root Cause Narrative	<p>Whole Foods Market regions individually control the ingredient statement data listed on the label. Certain regions had not updated their (b) (5)</p>		
Center Comments	Class I. CFSAN concurs with audit check strategy.		
Type Of Injury	None reported to date		
Quantity Manufactured	(b) (4)		
Quantity Distributed (Int)	(b) (4)		
Number of Domestic Consignees	(b) (4)		
Number of Foreign Consignees	0		
Distributed From	07/11/2020To 08/11/2020		
Distribution Pattern (Int)	Nationwide throughout the United States		
Manufactured From	07/11/2020To 08/10/2020		
Public Summary of Recall Strategy (Int)	<p>The recall was communicated to stores via email through (b) (4) on 8/10/2020, which is the recall management tool.</p>		
Recall Strategy	<p>The recall was communicated to stores via email through (b) (4) on 8/10/2020, which is the recall management tool. The Recall team enters the product information, withdrawal instructions, select affected stores, and communicate to stores through this portal. Amount destroyed/removed is also documented through this portal.</p>		
Effectiveness Check Level	APercent 100		
Audit Check Level	EPercent 0		
Audit/Effectiveness Check Modification	The firm has a history of effective recalls		
RAC Assignment Date Issued	RAC Assignment Date Completed		
District RAC Assignment Needed?	No	District Justification for No Audit Check	Firm has history of effective audit checks
District Recommendation for No Audit Check Comments		Center Agrees with District RAC Assignment Recommendation	Yes
Center RAC Assignment Needed?		Center Justification for No Audit Check	
Center Recommendation Justification Comments		Center Entering Recall	

What Consumers Should Do (Int)

Expanded Comments for
What Consumers Should Do (Int)

Firm Press Issued (Int) URL (Int)

State Press Issued (Int) URL (Int)

FDA Press Issued (Int) URL (Int)

Additional Medical Product
Information (Int) URL (Int)

Consignee Details

List of Domestic and/or Foreign Consignees, Distribution addresses or comments No VA/DOD/Foreign consignees.

Consignees	Approx. Number	Consignees	Approx. Number
Distributor	0	Repacker/Relabeler	0
Retailer	(b) (4)	Direct Accounts	0
Institution	0	Veterans Administration	0
Medical Facility	0	Department of Defense	0
Internet Sales	0	Manufacturer	0
Physician	0	USDA	0
Consumer/Patient	0	Other	0

Summary/Termination Information

Quantity Recovered/Number of
Units Corrected

Product Disposition

Number of Consignees Responding
to Notification

Effectiveness Check Information

Recall Audit Check Count Audit Count Summary : Not Available

Audit Check Information

Section of Law Violated

Preventive Action Taken by Firm

District Follow-Up

District Review

Legal Action

Expected Life

Shelf Life 30 days

CFSAN Reason Labeling/undeclared allergen

Product : 2

12-Y99

P-7968

The level of risk to health posed by the violative product is similar to the level or risk previously evaluated in the identified precedent HHE.

Whole Foods Market Artequeso Manchego 6 month aged raw Raw Milk - Aged 60 days or more PLU 20057900000 Individual sliced cheese wrapped in plastic wrap with scale label on top.

Whole Foods Market

Food for human consumption

(b) (4)

F-1355-2020

Undeclared lysozyme (from egg whites)

Class II

Class I

Retail

A **Percent** 100

E **Percent** 0

Sell by dates: until September 11, 2020

30 days

Product : 3

12-Y99

P-7968

The level of risk to health posed by the violative product is similar to the level or risk previously evaluated in the identified precedent HHE.

Whole Foods Market La Marquesa Herb Manchego Raw Milk - Aged 60 days or More PLU 29399800000 Individual sliced cheese wrapped in plastic wrap with scale label on top.

Whole Foods Market

Industry-Product Code

Precedent Recall

Precedent Policy

Precedent Policy Comment

Product Description (**Int**)
(Label/Packaging)

Trade Name (**Int**)

Generic Name (**Int**)

Product Usage

Product Quantity Distributed (**Int**)

Recall Number (**Int**)

Product Public Reason for Recall
(**Int**)

Field Recommended Classification

Center Determination/Classification
(**Int**)

Center Recommended Depth

Product Effectiveness Check Level

Product Audit Check Level

Code Information (**Int**)

Expected Life

Shelf Life

CFSAN Reason

Industry-Product Code

Precedent Recall

Precedent Policy

Precedent Policy Comment

Product Description (**Int**)
(Label/Packaging)

Trade Name (**Int**)

Generic Name (**Int**)

Food for human consumption

(b) (4)

F-1356-2020

Undeclared lysozyme (from egg whites)

Class II

Class I

Retail

A **Percent** 100

E **Percent** 0

Sell by dates: until September 11, 2020

30 days

Product : 4

12-Y99

P-7968

The level of risk to health posed by the violative product is similar to the level or risk previously evaluated in the identified precedent HHE.

Whole Foods Market Mitica La Dama Sagrada Raw Milk - Aged 60 Days or More PLU 20656400000

Individual sliced cheese wrapped in plastic wrap with scale label on top.

Whole Foods Market

Food for human consumption

(b) (4)

F-1357-2020

Undeclared lysozyme (from egg whites)

Class II

Class I

Retail

A **Percent** 100

E **Percent** 0

Product Usage

Product Quantity Distributed **(Int)**

Recall Number **(Int)**

Product Public Reason for Recall **(Int)**

Field Recommended Classification

Center Determination/Classification **(Int)**

Center Recommended Depth

Product Effectiveness Check Level

Product Audit Check Level

Code Information **(Int)**

Expected Life

Shelf Life

CFSAN Reason

Industry-Product Code

Precedent Recall

Precedent Policy

Precedent Policy Comment

Product Description **(Int)**
(Label/Packaging)

Trade Name **(Int)**

Generic Name **(Int)**

Product Usage

Product Quantity Distributed **(Int)**

Recall Number **(Int)**

Product Public Reason for Recall **(Int)**

Field Recommended Classification

Center Determination/Classification **(Int)**

Center Recommended Depth

Product Effectiveness Check Level

Product Audit Check Level

Code Information **(Int)**

Sell by dates: until September 11, 2020

30 days

Product : 5

12-Y99

P-7968

The level of risk to health posed by the violative product is similar to the level or risk previously evaluated in the identified precedent HHE.

Whole Foods Market Chimay Biere PLU 29351700000 Individual sliced cheese wrapped in plastic wrap with scale label on top.

Whole Foods Market

Food for human consumption

(b) (4)

F-1358-2020

Undeclared lysozyme (from egg whites)

Class II

Class I

Retail

A **Percent** 100

E **Percent** 0

Sell by dates: until September 11, 2020

30 days

Product : 6

12-Y99

P-7968

The level of risk to health posed by the violative product is similar to the level or risk previously evaluated in the identified precedent HHE.

Whole Foods Market IL FORTETO Genovese Pesto PLU 20017100000 Individual sliced cheese wrapped in plastic wrap with scale label on top.

Whole Foods Market

Expected Life

Shelf Life

CFSAN Reason

Industry-Product Code

Precedent Recall

Precedent Policy

Precedent Policy Comment

Product Description **(Int)**
(Label/Packaging)

Trade Name **(Int)**

Generic Name **(Int)**

Product Usage

Product Quantity Distributed **(Int)**

Recall Number **(Int)**

Product Public Reason for Recall
(Int)

Field Recommended Classification

Center Determination/Classification
(Int)

Center Recommended Depth

Product Effectiveness Check Level

Product Audit Check Level

Code Information **(Int)**

Expected Life

Shelf Life

CFSAN Reason

Industry-Product Code

Precedent Recall

Precedent Policy

Precedent Policy Comment

Product Description **(Int)**
(Label/Packaging)

Trade Name **(Int)**

Generic Name **(Int)**

Food for human consumption

(b) (4)

F-1359-2020

Undeclared lysozyme (from egg whites)

Class II

Class I

Retail

A **Percent** 100

E **Percent** 0

Sell by dates: until September 11, 2020

30 days

Product : 7

12-Y99

P-7968

The level of risk to health posed by the violative product is similar to the level or risk previously evaluated in the identified precedent HHE.

Whole Foods Market Chimay Grand Cru PLU 29388800000 and Whole Foods Market Lactalis MIMOLETTE Aged 12 MONTHS PLU 25704400000 Individual sliced cheese wrapped in plastic wrap with scale label on top.

Whole Foods Market

Food for human consumption

(b) (4)

F-1360-2020

Undeclared lysozyme (from egg whites)

Class II

Class I

Retail

A **Percent** 100

E **Percent** 0

Product Usage

Product Quantity Distributed **(Int)**

Recall Number **(Int)**

Product Public Reason for Recall **(Int)**

Field Recommended Classification

Center Determination/Classification **(Int)**

Center Recommended Depth

Product Effectiveness Check Level

Product Audit Check Level

Code Information **(Int)**

Expected Life

Shelf Life

CFSAN Reason

Industry-Product Code

Precedent Recall

Precedent Policy

Precedent Policy Comment

Product Description **(Int)**
(Label/Packaging)

Trade Name **(Int)**

Generic Name **(Int)**

Product Usage

Product Quantity Distributed **(Int)**

Recall Number **(Int)**

Product Public Reason for Recall **(Int)**

Field Recommended Classification

Center Determination/Classification **(Int)**

Center Recommended Depth

Product Effectiveness Check Level

Product Audit Check Level

Code Information **(Int)**

Sell by dates: until September 11, 2020

30 days

Product : 8

12-Y99

P-7968

The level of risk to health posed by the violative product is similar to the level or risk previously evaluated in the identified precedent HHE.

Whole Foods Market Mitica Mahon PLU 29341800000 Individual sliced cheese wrapped in plastic wrap with scale label on top.

Whole Foods Market

Food for human consumption

(b) (4)

F-1361-2020

Undeclared lysozyme (from egg whites)

Class II

Class I

Retail

A **Percent** 100

E **Percent** 0

Sell by dates: until September 11, 2020

30 days

Product : 9

12-Y99

P-7968

The level of risk to health posed by the violative product is similar to the level or risk previously evaluated in the identified precedent HHE.

Whole Foods Market AGRIFORM PIAVE VECCHIO PLU 29336200000 Individual sliced cheese wrapped in plastic wrap with scale label on top.

Whole Foods Market

Expected Life

Shelf Life

CFSAN Reason

Industry-Product Code

Precedent Recall

Precedent Policy

Precedent Policy Comment

Product Description (**Int**)
(Label/Packaging)

Trade Name (**Int**)

Generic Name (**Int**)

Product Usage

Product Quantity Distributed (**Int**)

Recall Number (**Int**)

Product Public Reason for Recall
(**Int**)

Field Recommended Classification

Center Determination/Classification
(**Int**)

Center Recommended Depth

Product Effectiveness Check Level

Product Audit Check Level

Code Information (**Int**)

Expected Life

Shelf Life

CFSAN Reason

Industry-Product Code

Precedent Recall

Precedent Policy

Precedent Policy Comment

Product Description (**Int**)
(Label/Packaging)

Trade Name (**Int**)

Generic Name (**Int**)

Food for human consumption

(b) (4)

F-1362-2020

Undeclared lysozyme (from egg whites)

Class II

Class I

Retail

A **Percent** 100

E **Percent** 0

Sell by dates: until September 11, 2020

30 days

Recalling Firm Information

FEI	3007331558
Firm Name (Int)	Whole Foods Market
Address (Int)	550 Bowie St
City (Int)	Austin
State/Province (Int)	Texas
Country (Int)	United States
Postal Code (Int)	78703-4644
Telephone	Ext Country Code
Comment	

Most Responsible Individual

Official's Name	John Mackey
Title	CEO/President
Firm Name (Int)	Whole Foods Market
Address (Int)	550 Bowie St
City (Int)	Austin
State/Province (Int)	Texas
Country (Int)	United States
Postal Code (Int)	78703-4644
Telephone	512-542-2200 Ext Country Code

Product Usage

Product Quantity Distributed **(Int)**

Recall Number **(Int)**

Product Public Reason for Recall **(Int)**

Field Recommended Classification

Center Determination/Classification **(Int)**

Center Recommended Depth

Product Effectiveness Check Level

Product Audit Check Level

Code Information **(Int)**

Expected Life

Shelf Life

CFSAN Reason

Comment

Public Contact

Official's Name

Title

Firm Name **(Int)** Whole Foods Market

Address **(Int)** 550 Bowie St

City **(Int)** Austin

State/Province **(Int)** Texas

Country **(Int)** United States

Postal Code **(Int)** 78703-4644

Telephone **Ext** **Country Code**

Facsimile **Ext** **Country Code**

E-mail Address

Comment

[Summary](#)

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Recall Details

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Event Information

Recall Event ID	86275	RFR EON ID	
Recall Number(s)	F-1257-2020	RFR EON URLs	
District	Human And Animal Food West III	Coordinator	Casey Hamblin
Firm Awareness Date	08/05/2020	District Awareness Date	08/06/2020
Center (Int)	Center for Food Safety and Applied Nutrition	Coordinator	Melanie Butler
Recalling Firm FEI	3007331558	Name (Int)	Whole Foods Market
Manufacturer FEI	3007331558	Name (Int)	Whole Foods Market
Responsible Firm FEI	3007331558	Name	Whole Foods Market
Public Reason for Recall	Undeclared soy allergen		
Edit Mode	Viewable	Recall Status (Int)	Ongoing
Voluntary/Mandated (Int)	Firm Initiated	Date (Int)	08/06/2020
Firm Recommended Recall Depth	Retail	Date Distribution Chain Notified	08/06/2020
Recall Initiation Date (Int)	08/06/2020	Firm Initial Notification	E-Mail
Determination Date	08/21/2020	Center Coordinator Assigned Date	08/20/2020
Classification Date	08/21/2020	FDA Sample Number	None
Complete Reason for Recall	Undeclared soy allergen from an ingredient. The source of the soy is Soy Shortening Flakes. A team member discovered the discrepancy while labeling the product.		

Root Cause	Other		
Root Cause Narrative	The ingredient deck and allergen declaration was not updated once the raw material (biscuit mix) was switched.		
Center Comments	Class II. CFSAN concurs with audit check strategy.		
Type Of Injury	None reported		
Quantity Manufactured	(b) (4)		
Quantity Distributed (Int)	(b) (4)		
Number of Domestic Consignees	(b) (4)		
Number of Foreign Consignees	0		
Distributed From	8/5/2020To 8/6/2020		
Distribution Pattern (Int)	North Carolina, Alabama, South Carolina, Georgia, Tennessee, Mississippi		
Manufactured From	8/5/2020To 8/5/2020		
Public Summary of Recall Strategy (Int)	The recalling firm notified affected stores via the online recall communication system on 8/6/2020.		
Recall Strategy	The recalling firm notified affected stores via the online recall communication system on 8/6/2020. Product was relabeled or destroyed given the short shelf life.		
Effectiveness Check Level	A Percent 100		
Audit Check Level	E Percent 0		
Audit/Effectiveness Check Modification			
RAC Assignment Date Issued	RAC Assignment Date Completed		
District RAC Assignment Needed?	No	District Justification for No Audit Check	Firm has history of effective audit checks
District Recommendation for No Audit Check Comments		Center Agrees with District RAC Assignment Recommendation	Yes
Center RAC Assignment Needed?		Center Justification for No Audit Check	
Center Recommendation Justification Comments		Center Entering Recall	
What Consumers Should Do (Int)			
Expanded Comments for What Consumers Should Do (Int)			
Firm Press Issued (Int)	URL (Int)		
State Press Issued (Int)	URL (Int)		
FDA Press Issued (Int)	URL (Int)		
Additional Medical Product Information (Int)	URL (Int)		

Consignee Details

List of Domestic and/or Foreign Consignees, Distribution addresses or comments

No VA/DOD/Foreign consignees

Consignees	Approx. Number	Consignees	Approx. Number
Distributor	0	Repacker/Relabeler	0
Retailer	(b) (4)	Direct Accounts	0
Institution	0	Veterans Administration	0
Medical Facility	0	Department of Defense	0
Internet Sales	0	Manufacturer	0
Physician	0	USDA	0
Consumer/Patient	0	Other	0

Summary/Termination Information

Quantity Recovered/Number of Units Corrected

Product Disposition

Number of Consignees Responding to Notification

Effectiveness Check Information

Recall Audit Check Count Audit Count Summary : Not Available

Audit Check Information

Section of Law Violated Section 402 and 403 of the Food, Drug and Cosmetic Act

Preventive Action Taken by Firm Team is to thoroughly review any item change to determine if ingredient or allergen change will occur. Item must have a new PLU created when ingredient swap contains an allergen change.

District Follow-Up

District Review

Legal Action None planned

Class I Termination

Recommendation

Recommended/Prepared By

District Management Approval **Date**

Center Concurrence

Recall Completed Date

Termination Letter Date

CFSAN Center Information

Docs Rcvd at Ctr Date 08/19/2020

HHE Sent

HHE Signed

HHE Precedent P-7799

Outbreak Associated N

CFSAN CORE Incident EON ID

Product Information

Product : 1

Industry-Product Code 03-AGT03

Precedent Recall P-7799

Precedent Policy

Precedent Policy Comment The level of risk to health posed by the violative product is similar to the level of risk previously evaluated in the identified precedent HHE.

**Product Description (Int)
(Label/Packaging)** Whole Foods Market Buttermilk Biscuits, 4pk NET WT 1lb 0 oz PLU: 30561 packaged in plastic clam shell

Trade Name (Int) Whole Foods Market

Generic Name (Int)

Product Usage Food for human consumption

Product Quantity Distributed (Int) (b) (4)

Recall Number (Int) F-1257-2020

Product Public Reason for Recall (Int) Undeclared soy allergen

Field Recommended Classification Class II

Center Determination/Classification (Int) Class II

Center Recommended Depth Retail

Product Effectiveness Check Level A **Percent** 100

Product Audit Check Level E **Percent** 0

Code Information (Int) Sell though 8/8/20

Expected Life

Shelf Life 3 days

CFSAN Reason Labeling/undeclared allergen

Recalling Firm Information

FEI 3007331558

Firm Name (Int) Whole Foods Market

Address (Int) 550 Bowie St

City (Int) Austin

State/Province **(Int)** Texas
Country **(Int)** United States
Postal Code **(Int)** 78703-4644
Telephone **Ext** **Country Code**
Comment

Most Responsible Individual

Official's Name John Mackey
Title President
Firm Name **(Int)** Whole Foods Market
Address **(Int)** 550 Bowie St
City **(Int)** Austin
State/Province **(Int)** Texas
Country **(Int)** United States
Postal Code **(Int)** 78703-4644
Telephone 512-542-2200 **Ext** **Country Code**
Facsimile **Ext** **Country Code**
E-mail Address John.mackey@wholefoods.com
Comment

Manufacturer Information

FEI 3007331558
Firm Name **(Int)** Whole Foods Market
Address **(Int)** 550 Bowie St
City **(Int)** Austin
State/Province **(Int)** Texas
Country **(Int)** United States
Postal Code **(Int)** 78703-4644
Telephone **Ext** **Country Code**
Comment

Responsible Firm Information

FEI 3007331558
Firm Type Manufacturer
Firm Name **(Int)** Whole Foods Market
Address **(Int)** 550 Bowie St
City **(Int)** Austin
State/Province **(Int)** Texas

Country (Int) United States
Postal Code (Int) 78703-4644
Telephone Ext Country Code
Comment

Recall Contact

Official's Name Craig Penigar
Title Incident Management Team Lead
Firm Name (Int) Whole Foods Market
Address (Int) 550 Bowie St
City (Int) Austin
State/Province (Int) Texas
Country (Int) United States
Postal Code (Int) 78703-4644
Telephone 512-542-2200 Ext Country Code
Facsimile Ext Country Code
E-mail Address Craig.penigar@wholefoods.com
Comment

Public Contact

Official's Name
Title
Firm Name (Int) Whole Foods Market
Address (Int) 550 Bowie St
City (Int) Austin
State/Province (Int) Texas
Country (Int) United States
Postal Code (Int) 78703-4644
Telephone Ext Country Code
Facsimile Ext Country Code
E-mail Address
Comment

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Recall Details

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Event Information

Recall Event ID	86277	RFR EON ID	
Recall Number(s)	F-1430-2020	RFR EON URLs	
District	Human And Animal Food West III	Coordinator	Casey Hamblin
Firm Awareness Date	08/18/2020	District Awareness Date	08/19/2020
Center (Int)	Center for Food Safety and Applied Nutrition	Coordinator	Melanie Butler
Recalling Firm FEI	3007331558	Name (Int)	Whole Foods Market
Manufacturer FEI	3007331558	Name (Int)	Whole Foods Market
Responsible Firm FEI	3007331558	Name	Whole Foods Market
Public Reason for Recall	undeclared soy (soy milk) allergen		
Edit Mode	Viewable	Recall Status (Int)	Ongoing
Voluntary/Mandated (Int)	Firm Initiated	Date (Int)	08/18/2020
Firm Recommended Recall Depth	Consumers/User	Date Distribution Chain Notified	08/18/2020
Recall Initiation Date (Int)	08/18/2020	Firm Initial Notification	Other
Determination Date	09/08/2020	Center Coordinator Assigned Date	09/03/2020
Classification Date	09/08/2020	FDA Sample Number	None
Complete Reason for Recall	The recalled is initiated due to an undeclared soy (soy milk) allergen. The recall was initiated when a Team Member conducting a labeling audit identified the missing ingredient.		

Root Cause	Other		
Root Cause Narrative	The recalling firm did not update the product scale labels to reflect Soy as an allergen when we switched to a new frosting.		
Center Comments	Class I. CFSAN concurs with audit check strategy.		
Type Of Injury	No allergic reactions have been reported to date		
Quantity Manufactured	(b) (4)		
Quantity Distributed (Int)	(b) (4)		
Number of Domestic Consignees	(b) (4)		
Number of Foreign Consignees	0		
Distributed From	8/19/2020To 8/19/2020		
Distribution Pattern (Int)	Alabama, Georgia, Mississippi, North Carolina, South Tennessee and one store in Tallahassee, Florida		
Manufactured From	8/18/2020To 8/18/2020		
Public Summary of Recall Strategy (Int)	The recalling firm issued a press release on 8/20/2020. Additionally, affected stores were notified via electronic recall system on 8/18/2020		
Recall Strategy	The recalling firm issued a press release on 8/20/2020. Additionally, affected stores were notified via electronic recall system on 8/18/2020		
Effectiveness Check Level	APercent 100		
Audit Check Level	EPercent 0		
Audit/Effectiveness Check Modification			
RAC Assignment Date Issued	RAC Assignment Date Completed		
District RAC Assignment Needed?	No	District Justification for No Audit Check	Firm has history of effective audit checks
District Recommendation for No Audit Check Comments		Center Agrees with District RAC Assignment Recommendation	Yes
Center RAC Assignment Needed?		Center Justification for No Audit Check	
Center Recommendation Justification Comments		Center Entering Recall	
What Consumers Should Do (Int)			
Expanded Comments for What Consumers Should Do (Int)			
Firm Press Issued (Int)	08/20/2020	URL (Int) https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/allergy-alert-undeclared-soy-soy-milk-vegan-vanilla-cake-issued-whole-foods-market-stores-seven	
State Press Issued (Int)		URL (Int)	
FDA Press Issued (Int)		URL (Int)	
Additional Medical Product Information (Int)		URL (Int)	

Consignee Details

List of Domestic and/or Foreign Consignees, Distribution addresses or comments

No VA/DOD/Foreign consignees

Consignees	Approx. Number	Consignees	Approx. Number
Distributor	0	Repacker/Relabeler	0
Retailer	(b) (4)	Direct Accounts	0
Institution	0	Veterans Administration	0
Medical Facility	0	Department of Defense	0
Internet Sales	0	Manufacturer	0
Physician	0	USDA	0
Consumer/Patient	0	Other	0

Summary/Termination Information

Quantity Recovered/Number of Units Corrected

Product Disposition

Number of Consignees Responding to Notification

Effectiveness Check Information

Recall Audit Check Count Audit Count Summary : Not Available

Audit Check Information

Section of Law Violated

Preventive Action Taken by Firm Going forward, all ingredient changes will require spec sheets to be reviewed by multiple stakeholders to ensure the update process is followed.

District Follow-Up

District Review

Legal Action None planned

Class I Termination

Recommendation

Recommended/Prepared By

District Management Approval **Date**

Center Concurrence

Recall Completed Date

Termination Letter Date

CFSAN Center Information

Docs Rcvd at Ctr Date 09/02/2020

HHE Sent

HHE Signed

HHE Precedent P-7841

Outbreak Associated N

CFSAN CORE Incident EON ID

Product Information

Product : 1

Industry-Product Code 03-RGT01

Precedent Recall P-7841

Precedent Policy

Precedent Policy Comment The level of risk to health posed by the violative product is similar to the level of risk previously evaluated in the identified precedent HHE.

**Product Description (Int)
(Label/Packaging)** Whole Foods Market Vegan Vanilla Cake 6 Inch NET WT 2lb 11oz (1219g) Packed for Whole Foods Market PLU 41070 packaged in plastic dome containers with Whole Foods Market scale labels

Trade Name (Int) Whole Foods Market

Generic Name (Int)

Product Usage Food for human consumption

Product Quantity Distributed (Int) (b) (4)

Recall Number (Int) F-1430-2020

Product Public Reason for Recall (Int) undeclared soy (soy milk) allergen

Field Recommended Classification Class I

Center Determination/Classification (Int) Class I

Center Recommended Depth Consumers/User

Product Effectiveness Check Level A **Percent** 100

Product Audit Check Level E **Percent** 0

Code Information (Int) PLU code of 41070 and product sell-by date through August 24, 2020.

Expected Life

Shelf Life 8/24/2020

CFSAN Reason Labeling/undeclared allergen

Recalling Firm Information

FEI 3007331558

Firm Name (Int) Whole Foods Market

Address (Int) 550 Bowie St

City (Int) Austin

State/Province (Int)	Texas
Country (Int)	United States
Postal Code (Int)	78703-4644
Telephone	Ext Country Code
Comment	

Most Responsible Individual

Official's Name	John Mackey
Title	President
Firm Name (Int)	Whole Foods Market
Address (Int)	550 Bowie St
City (Int)	Austin
State/Province (Int)	Texas
Country (Int)	United States
Postal Code (Int)	78703-4644
Telephone	Ext Country Code
Facsimile	Ext Country Code
E-mail Address	John.Mackey@wholefoods.com
Comment	

Manufacturer Information

FEI	3007331558
Firm Name (Int)	Whole Foods Market
Address (Int)	550 Bowie St
City (Int)	Austin
State/Province (Int)	Texas
Country (Int)	United States
Postal Code (Int)	78703-4644
Telephone	Ext Country Code
Comment	

Responsible Firm Information

FEI	3007331558
Firm Type	Manufacturer
Firm Name (Int)	Whole Foods Market
Address (Int)	550 Bowie St
City (Int)	Austin
State/Province (Int)	Texas

Country (Int) United States
Postal Code (Int) 78703-4644
Telephone Ext Country Code
Comment

Recall Contact

Official's Name Craig.Penigar
Title Incident Management Team Lead
Firm Name (Int) Whole Foods Market
Address (Int) 550 Bowie St
City (Int) Austin
State/Province (Int) Texas
Country (Int) United States
Postal Code (Int) 78703-4644
Telephone Ext Country Code
Facsimile Ext Country Code
E-mail Address Craig.Penigar@wholefoods.com
Comment

Public Contact

Official's Name
Title
Firm Name (Int) Whole Foods Market
Address (Int) 550 Bowie St
City (Int) Austin
State/Province (Int) Texas
Country (Int) United States
Postal Code (Int) 78703-4644
Telephone Ext Country Code
Facsimile Ext Country Code
E-mail Address
Comment

Media Contact: Rachel Malish Rachel.malish@wholefoods.com Consumers with additional questions can call 1-844-936-8255 between the hours of 7:00 a.m. and 10:00 p.m. CST, Monday through Friday, or 8:00 a.m. and 6:00 p.m. Saturday through Sunday.

[Summary](#)

[Help](#)

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Home

Recall Details

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Event Information

Recall Event ID	86682	RFR EON ID	
Recall Number(s)		RFR EON URLs	
District	Human And Animal Food West III	Coordinator	Casey Hamblin
Firm Awareness Date	10/24/2020	District Awareness Date	10/28/2020
Center (Int)	Center for Food Safety and Applied Nutrition	Coordinator	
Recalling Firm FEI	3007331558	Name (Int)	Whole Foods Market
Manufacturer FEI	3007331558	Name (Int)	Whole Foods Market
Responsible Firm FEI	3007331558	Name	Whole Foods Market
Public Reason for Recall	Potential to contain undeclared egg		
Edit Mode	Viewable	Recall Status (Int)	Ongoing
Voluntary/Mandated (Int)	Firm Initiated	Date (Int)	10/27/2020
Firm Recommended Recall Depth	Consumers/User	Date Distribution Chain Notified	10/28/2020
Recall Initiation Date (Int)	10/27/2020	Firm Initial Notification	Combination
Determination Date		Center Coordinator Assigned Date	
Classification Date		FDA Sample Number	None

Complete Reason for Recall	Whole Foods Market Stores within our Mid Atlantic region transitioned to a new Mac and cheese, which contains Egg on 10/23. During a review of the new Mac and Cheese, a team member noticed that the new products used old labels that do not list Egg in the ingredients or contains statements.		
Root Cause	Other		
Root Cause Narrative	It was not clear to the MA regional PFDS team that they needed to submit recipe adjustments for Globally managed product. Regional was not aware of a major allergen (EGG) change in the new Enterprise product. Regional PFDS contacted the Global Category team and CT team on Saturday 10/24 (after it was discovered no ingredient swaps were made) and sent a follow up email on 10/27. After the follow up email on 10/27, the Global procurement and CT nutrition team quickly helped take action.		
Center Comments			
Type Of Injury	None reported		
Quantity Manufactured	(b) (4)		
Quantity Distributed (Int)	(b) (4)		
Number of Domestic Consignees	(b) (4)		
Number of Foreign Consignees	0		
Distributed From	10/23/2020To 10/27/2020		
Distribution Pattern (Int)	Maryland, New Jersey, Pennsylvania, Virginia and Washington, D.C.		
Manufactured From	10/23/2020To 10/27/2020		
Public Summary of Recall Strategy (Int)	The initial recall notification was sent to affected stores on 10/27/2020 via electronic recall system. A press release as issued on 10/28/2020.		
Recall Strategy	The initial recall notification was sent to affected stores on 10/27/2020 via electronic recall system. A press release as issued on 10/28/2020.		
Effectiveness Check Level	APercent 100		
Audit Check Level	EPercent 0		
Audit/Effectiveness Check Modification			
RAC Assignment Date Issued	RAC Assignment Date Completed		
District RAC Assignment Needed?	No	District Justification for No Audit Check	Firm has history of effective audit checks
District Recommendation for No Audit Check Comments	Center Agrees with District RAC Assignment Recommendation		
Center RAC Assignment Needed?	Center Justification for No Audit Check		
Center Recommendation Justification Comments	Center Entering Recall		
What Consumers Should Do (Int)			
Expanded Comments for What Consumers Should Do (Int)			

Firm Press Issued (Int) 10/28/2020 URL (Int) <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/allergy-alert-issued-undeclared-egg-prepared-macaroni-cheese-sold-whole-foods-market-stores-five>

State Press Issued (Int) URL (Int)

FDA Press Issued (Int) URL (Int)

Additional Medical Product Information (Int) URL (Int)

Consignee Details

List of Domestic and/or Foreign Consignees, Distribution addresses or comments No VA/DOD/Foreign consignees

Consignees	Approx. Number	Consignees	Approx. Number
Distributor	0	Repacker/Relabeler	0
Retailer	(b) (4)	Direct Accounts	0
Institution	0	Veterans Administration	0
Medical Facility	0	Department of Defense	0
Internet Sales	0	Manufacturer	0
Physician	0	USDA	0
Consumer/Patient	0	Other	0

Summary/Termination Information

Quantity Recovered/Number of Units Corrected

Product Disposition The individual stores applied the corrected labels with the allergens declared as soon as the issue was discovered.

Number of Consignees Responding to Notification

Effectiveness Check Information

Recall Audit Check Count Audit Count Summary : Not Available

Audit Check Information No RACs will be completed for this recall. The firm has a history of effective recalls due to their internal recall notification system.

Section of Law Violated Section 402(a)(1) of the Foods, Drug and Cosmetic Act

Preventive Action Taken by Firm Regional PFDS Team to improve communication with CT and Procurement team to ensure ingredient swaps are planned and properly in place before product hits region.

District Follow-Up

District Review

Legal Action CFSAN planned action under CMS case 610862

Class I Termination
Recommendation
Recommended/Prepared By
District Management Approval **Date**
Center Concurrence
Recall Completed Date

Termination Letter Date

CFSAN Center Information

Docs Rcvd at Ctr Date

HHE Sent

HHE Signed

HHE Precedent

Outbreak Associated

CFSAN CORE Incident EON ID

Product Information

Product : 1

Industry-Product Code 04-Y99

Precedent Recall

Precedent Policy

Precedent Policy Comment

Product Description (**Int**) Macaroni & Cheese, chef s case; Macaroni & Cheese, packaged in clear plastic container;
(Label/Packaging) Macaroni & Cheese, online and catering product code begins with 286501, 263608, 114449, or
109866

Trade Name (**Int**) Whole Foods Market

Generic Name (**Int**)

Product Usage Food for human consumption

Product Quantity Distributed (**Int**) (b) (4)

Recall Number (**Int**)

Product Public Reason for Recall (**Int**) Potential to contain undeclared egg

Field Recommended Classification Class I

Center Determination/Classification (**Int**)

Center Recommended Depth

Product Effectiveness Check Level **A Percent 100**

Product Audit Check Level **E Percent 0**

Code Information (**Int**) Best by dates through 10/28/2020

Expected Life

Shelf Life

10/28/2020

CFSAN Reason

Product : 2

04- Y99

Rotisserie Chicken Meals with Mac & Cheese and Broccoli, packaged in clear plastic container with printed label product code begins with 261596 261580, 261590, 261601, 261608, or 261616

Whole Foods Market

Food for human consumption

(b) (4)

Potential to contain undeclared egg

Class I

A **Percent** 100

E **Percent** 0

Best by dates through 10/28/2020

10/28/2020

Product : 3

04-Y99

Fried Chicken Meal with Mac & Cheese, packaged in clear plastic container with printed label product code begins with 247257; Fried Chicken Meal with Mac & Cheese, packaged on hot bar product code begins with 237444

Whole Foods Market

Industry-Product Code

Precedent Recall

Precedent Policy

Precedent Policy Comment

Product Description **(Int)**
(Label/Packaging)

Trade Name **(Int)**

Generic Name **(Int)**

Product Usage

Product Quantity Distributed **(Int)**

Recall Number **(Int)**

Product Public Reason for Recall
(Int)

Field Recommended Classification

Center Determination/Classification
(Int)

Center Recommended Depth

Product Effectiveness Check Level

Product Audit Check Level

Code Information **(Int)**

Expected Life

Shelf Life

CFSAN Reason

Industry-Product Code

Precedent Recall

Precedent Policy

Precedent Policy Comment

Product Description **(Int)**
(Label/Packaging)

Trade Name **(Int)**

Generic Name **(Int)**

Food for human consumption

(b) (4)

Potential to contain undeclared egg

Class I

A Percent 100

E Percent 0

Best by dates through 10/28/2020

10/28/2020

Product : 4

04-Y99

Chicken Rustico Romano Chef Plate with Mac & Cheese and Broccoli, packaged in clear plastic container with printed label product code begins with 241442

Whole Foods Market

Food for human consumption

(b) (4)

Potential to contain undeclared egg

Class I

A Percent 100

E Percent 0

Product Usage

Product Quantity Distributed (Int)

Recall Number (Int)

Product Public Reason for Recall (Int)

Field Recommended Classification

Center Determination/Classification (Int)

Center Recommended Depth

Product Effectiveness Check Level

Product Audit Check Level

Code Information (Int)

Expected Life

Shelf Life

CFSAN Reason

Industry-Product Code

Precedent Recall

Precedent Policy

Precedent Policy Comment

Product Description (Int) (Label/Packaging)

Trade Name (Int)

Generic Name (Int)

Product Usage

Product Quantity Distributed (Int)

Recall Number (Int)

Product Public Reason for Recall (Int)

Field Recommended Classification

Center Determination/Classification (Int)

Center Recommended Depth

Product Effectiveness Check Level

Product Audit Check Level

Code Information (Int)

Best by dates through 10/28/2020

10/28/2020

Product : 5

04-Y99

Chicken Breast Chef Plate with Mac & Cheese and Broccoli, packaged in clear plastic container with printed label product code begins with 299430

Whole Foods Market

Food for human consumption

(b) (4)

Potential to contain undeclared egg

Class I

A **Percent** 100

E **Percent** 0

Best by dates through 10/28/2020

10/28/2020

Product : 6

04-Y99

BBQ Turkey Meatballs Chef Plate with Mac & Cheese and Green Beans, packaged in clear plastic container with printed label product code begins with 241464

Whole Foods Market

Expected Life

Shelf Life

CFSAN Reason

Industry-Product Code

Precedent Recall

Precedent Policy

Precedent Policy Comment

Product Description **(Int)**
(Label/Packaging)

Trade Name **(Int)**

Generic Name **(Int)**

Product Usage

Product Quantity Distributed **(Int)**

Recall Number **(Int)**

Product Public Reason for Recall
(Int)

Field Recommended Classification

Center Determination/Classification
(Int)

Center Recommended Depth

Product Effectiveness Check Level

Product Audit Check Level

Code Information **(Int)**

Expected Life

Shelf Life

CFSAN Reason

Industry-Product Code

Precedent Recall

Precedent Policy

Precedent Policy Comment

Product Description **(Int)**
(Label/Packaging)

Trade Name **(Int)**

Generic Name **(Int)**

Food for human consumption

(b) (4)

Potential to contain undeclared egg

Class I

A Percent 100

E Percent 0

Best by dates through 10/28/2020

10/28/2020

Product : 7

04-Y99

Roasted Turkey Chef Plate with Mac & Cheese and Broccoli, packaged in clear plastic container with printed label product code begins with 242019

Whole Foods Market

Food for human consumption

(b) (4)

Potential to contain undeclared egg

Class I

A Percent 100

E Percent 0

Product Usage

Product Quantity Distributed (Int)

Recall Number (Int)

Product Public Reason for Recall (Int)

Field Recommended Classification

Center Determination/Classification (Int)

Center Recommended Depth

Product Effectiveness Check Level

Product Audit Check Level

Code Information (Int)

Expected Life

Shelf Life

CFSAN Reason

Industry-Product Code

Precedent Recall

Precedent Policy

Precedent Policy Comment

Product Description (Int) (Label/Packaging)

Trade Name (Int)

Generic Name (Int)

Product Usage

Product Quantity Distributed (Int)

Recall Number (Int)

Product Public Reason for Recall (Int)

Field Recommended Classification

Center Determination/Classification (Int)

Center Recommended Depth

Product Effectiveness Check Level

Product Audit Check Level

Code Information (Int)

Best by dates through 10/28/2020

Expected Life

Shelf Life

10/28/2020

CFSAN Reason

Recalling Firm Information

FEI 3007331558

Firm Name **(Int)** Whole Foods Market

Address **(Int)** 550 Bowie St

City **(Int)** Austin

State/Province **(Int)** Texas

Country **(Int)** United States

Postal Code **(Int)** 78703-4644

Telephone **Ext Country Code**

Comment

Most Responsible Individual

Official's Name John Mackey

Title President

Firm Name **(Int)** Whole Foods Market

Address **(Int)** 550 Bowie St

City **(Int)** Austin

State/Province **(Int)** Texas

Country **(Int)** United States

Postal Code **(Int)** 78703-4644

Telephone 512-542-2200 **Ext Country Code**

Facsimile **Ext Country Code**

E-mail Address john.mackey@wholefoods.com

Comment

Manufacturer Information

FEI 3007331558

Firm Name **(Int)** Whole Foods Market

Address **(Int)** 550 Bowie St

City **(Int)** Austin

State/Province **(Int)** Texas

Country **(Int)** United States

Postal Code **(Int)** 78703-4644

Telephone **Ext Country Code**

Comment

Responsible Firm Information

FEI 3007331558

Firm Type Manufacturer

Firm Name **(Int)** Whole Foods Market

Address **(Int)** 550 Bowie St

City **(Int)** Austin

State/Province **(Int)** Texas

Country **(Int)** United States

Postal Code **(Int)** 78703-4644

Telephone **Ext Country Code**

Comment

Recall Contact

Official's Name Craig Penigar

Title Global Incident Management

Firm Name **(Int)** Whole Foods Market

Address **(Int)** 550 Bowie St

City **(Int)** Austin

State/Province **(Int)** Texas

Country **(Int)** United States

Postal Code **(Int)** 78703-4644

Telephone 512-542-2200 **Ext Country Code**

Facsimile **Ext Country Code**

E-mail Address craig.penigar@wholefoods.com

Comment

Public Contact

Official's Name

Title

Firm Name **(Int)** Whole Foods Market

Address **(Int)** 550 Bowie St

City **(Int)** Austin

State/Province **(Int)** Texas

Country **(Int)** United States

Postal Code **(Int)** 78703-4644

Telephone **Ext Country Code**

Facsimile **Ext Country Code**

E-mail Address

Comment 1-844-936-8255 between the hours of 7:00 a.m. and 10:00 p.m. CST, Monday through Friday, or 8:00 a.m. and 6:00 p.m. Saturday through Sunday.

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