CFSAN HEALTH HAZARD EVALUATION

HHE # 9420 RES# 75996 CLASS: III

Section A. Incident Summary (to be completed by requesting CSO)

1. PRODUCT INFORMATION (Include relevant lot information if appropriate.)

Starkey Spring Water, 16 fl oz. glass bottles, Produced (b) (4)

2. FIRM INFORMATION (Include supplier information if appropriate and note if domestic or foreign.)

Recalling Firm:
Starkey Water
102 Council Ave
Council, Idaho 83612
FEI#3010863196
(Domestic)

3. SOURCE OF PROBLEM

☐ Undeclared allergen:
☒ Presence of contaminant or impurities (specify): arsenic
☐ Microbial contamination (specify): 
☐ Presence of foreign bodies:
☐ Other:

4. NATURE OF PROBLEM (What happened to create the hazard/ problem? What is the extent of the problem and/or how was the problem identified? Include GMP, labeling errors, consumer complaints, etc.)

Starkey Spring Water was sampled and found to contain arsenic. The arsenic level in lot# (b) (4) tested by the Florida Department of Agriculture and Consumer Services Laboratory # 2016/FL-18831 was at 11.7 ppb. The 11.7 ppb value exceeds the 10 ppb FDA permissible level of arsenic in water in accordance with 21 CFR 165.110.

5. Have any adverse reaction reports or other indication of injuries or diseases been reported relating to this problem?

☒ No ☐ Yes
6. **PRECEDENT HHEs** (Using the CFSAN HHE database, please summarize any related precedents. Please include reference numbers or copies of supporting precedent cases.)

<table>
<thead>
<tr>
<th>HHE #</th>
<th>Date Signed</th>
<th>Hazard Identified</th>
</tr>
</thead>
<tbody>
<tr>
<td>9287</td>
<td>09/19/2016</td>
<td>Arsenic in apple nectar</td>
</tr>
<tr>
<td>8786</td>
<td>09/18/2014</td>
<td>Arsenic in apple juice</td>
</tr>
<tr>
<td>8257</td>
<td>07/20/2012</td>
<td>Arsenic in apple juice</td>
</tr>
</tbody>
</table>

**Section B. Health Effects Review (to be completed by HHEB member)**

7. **ADVERSE REACTION INFORMATION**

What are anticipated health effects associated with this problem? (i.e., consumption of the product and/or specific ingredients) Include narrative and please describe severity. Explain and cite literature references when applicable.

In most drinking water sources, the inorganic form of arsenic tends to be more prominent than organic forms. At low levels of exposure, the primary concern from exposure to inorganic arsenic are effects that result from chronic exposure. The main adverse effects reported to be associated with long-term ingestion of inorganic arsenic in humans are cancer, skin lesions, cardiovascular disease, neurodevelopmental toxicity, adverse pregnancy outcomes, and diabetes. Of these, the greatest strength of evidence for a causal association is for cancers of the skin, bladder and lung and for skin lesions (hyperkeratosis, hyperpigmentation and hypopigmentation) that were observed in studies in which inorganic arsenic exposure was high due to inorganic arsenic in drinking water (e.g., >100 µg/L).

The level of 11.7 ppb arsenic in bottled exceeds the 10 ppb FDA allowable level for arsenic in water in accordance with 21 CFR 165.110, but is not likely to be a health concern from short term consumption.

8. **AT RISK POPULATION**

Are there certain population(s) of consumers most likely to use and/or be most at risk from exposure to this problem or hazard? (Please list all that apply and provide additional explanation if necessary.)

- No – the general population is at risk
- Yes – check all that apply
  - Infants
  - Children
  - Pregnant women, nursing women, or women of childbearing age
  - Elderly consumers
  - Individuals with allergy/intolerance to (food/product)
☐ Immunosuppressed individuals
☐ Medical conditions (e.g., diabetes, celiac disease)
☐ Other (please describe):

9. Is the problem easily identified by the user or are there other mitigating circumstances that lessen the probability that the product will be consumed?

☐ No ☐ Yes

10. What is the hazard associated with use of the product? (Select one. If more than one is selected, please explain.)

☐ Life-threatening (death has or could occur)
☐ Results in permanent impairment of a body function or permanent damage to a body structure
☐ Necessitates medical or surgical intervention (including hospitalization) to preclude or reverse permanent damage to a body structure or permanent impairment of a body function
☐ Temporary or reversible (without medical intervention)
☒ Limited (transient, minor impairment or complaints)
☐ No adverse health consequences
☐ Hazard cannot be assessed with the data currently available

11. What is the probability of each adverse event occurring, as specified in Item 10? (If more than one item is selected below, specify the corresponding health hazard.)

☐ Highly likely to occur (every time the product is used)
☐ Likely to occur (reasonable probability of occurrence)
☐ Might occur (remote probability of occurrence)
☒ Unlikely to occur
☐ Unknown (please explain):
☐ Not applicable

Conclusion:

With prolonged use of the product for many years, a wide variety of adverse effects may occur. No significant effects are expected with short term use.
SIGNATURES

Dehlia R. Young
Consumer Safety Officer
Requested By:
Dehlia Young
Date: 12/29/2016

Deborah Smegal, M.P.H.
Branch Chief, Contaminant Assessment Branch
Health Hazard Evaluation Board Member

Linda M. Katz
 Acting Chief Medical Officer
Chairperson, Health Hazard Evaluation Board
Section A. Incident Summary (to be completed by requesting CSO)

1. PRODUCT INFORMATION (Include relevant lot information if appropriate.)
   Starkey Spring Water, 16.9 fl oz. (550 ml), 15 Glass Bottles in a cardboard box,
   Produced on [b] (4)

2. FIRM INFORMATION (Include supplier information if appropriate and note if domestic
   or foreign.)
   Starkey Water, Council, Idaho (Domestic)

3. SOURCE OF PROBLEM
   □ Undeclared allergen:
   ☑ Presence of contaminant or impurities (specify): Arsenic
   □ Microbial contamination (specify):
   □ Presence of foreign bodies:
   □ Other:

4. NATURE OF PROBLEM (What happened to create the hazard/problem? What is the extent of
   the problem and/or how was the problem identified? Include GMP, labeling errors, consumer complaints, etc.)
   Starkey Spring Water was sampled and found to contain arsenic. The Florida Department
   of Agriculture and Consumer Services found 12 ppb arsenic level in lot# [b] (4). This
   level exceeds the 10 ppb FDA permissible level of arsenic in water in accordance with 21
   CFR 165.110.

5. Have any adverse reaction reports or other indication of injuries or diseases been
   reported relating to this problem?
   ☑ No □ Yes

6. PRECEDENT HHEs (Using the CFSAN HHE database, please summarize any related precedents. Please
   include reference numbers or copies of supporting precedent cases.)
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<td>Arsenic in Apple Juice</td>
</tr>
<tr>
<td>9420</td>
<td>01/04/2017</td>
<td>Arsenic in Bottled Water</td>
</tr>
</tbody>
</table>
Section B. Health Effects Review (to be completed by HHEB member)

7. ADVERSE REACTION INFORMATION

What are anticipated health effects associated with this problem? (i.e., consumption of the product and/or specific ingredients) Include narrative and please describe severity. Explain and cite literature references when applicable.

In most drinking water sources, the inorganic form of arsenic tends to be more prominent than organic forms. At low levels of exposure, the primary concern from exposure to inorganic arsenic are effects that result from chronic exposure. The main adverse effects reported to be associated with long-term ingestion of inorganic arsenic in humans are cancer, skin lesions, cardiovascular disease, neurodevelopmental toxicity, adverse pregnancy outcomes, and diabetes. Of these, the greatest strength of evidence for a causal association is for cancers of the skin, bladder and lung and for skin lesions (hyperkeratosis, hyperpigmentation and hypopigmentation) that were observed in studies in which inorganic arsenic exposure was high due to inorganic arsenic in drinking water (e.g., >100 µg/L).

The level of 12 ppb arsenic in bottled water exceeds the 10 ppb FDA allowable level for arsenic in water in accordance with 21CFR 165.110, but is not likely to be a health concern from short term consumption.

8. AT RISK POPULATION

Are there certain population(s) of consumers most likely to use and/or be most at risk from exposure to this problem or hazard? (Please list all that apply and provide additional explanation if necessary.)

☒ No – the general population is at risk
☐ Yes – check all that apply
  ☐ Infants
  ☐ Children
  ☐ Pregnant women, nursing women, or women of childbearing age
  ☐ Elderly consumers
  ☐ Individuals with allergy/intolerance to (food/product)
  ☐ Immunosuppressed individuals
  ☐ Medical conditions (e.g., diabetes, celiac disease)
  ☐ Other (please describe):

9. Is the problem easily identified by the user or are there other mitigating circumstances that lessen the probability that the product will be consumed?

☒ No ☐ Yes
10. What is the hazard associated with use of the product? (Select one. If more than one is selected, please explain.)

☐ Life-threatening (death has or could occur)
☐ Results in permanent impairment of a body function or permanent damage to a body structure
☐ Necessitates medical or surgical intervention (including hospitalization) to preclude or reverse permanent damage to a body structure or permanent impairment of a body function
☐ Temporary or reversible (without medical intervention)
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☐ Highly likely to occur (every time the product is used)
☐ Likely to occur (reasonable probability of occurrence)
☐ Might occur (remote probability of occurrence)
☒ Unlikely to occur
☐ Unknown (please explain):
☐ Not applicable

Conclusion:

With prolonged use of the product for many years, a wide variety of adverse effects may occur. No significant effects are expected with short term use.
SIGNATURES

Requested By:
Kerri Harris-Garner,
Ph.D.
Consumer Safety Officer

Date: 1/12/2017

Deborah Smegal, M.P.H.
Branch Chief, Contaminant Assessment Branch
Health Hazard Evaluation Board Member

Deborah Smegal, M.P.H.

Date:

Linda M. Katz, M.D., M.P.H.
Acting Chief Medical Officer
Chairperson, Health Hazard Evaluation Board

Linda M. Katz, M.D., M.P.H.

Date:
Recall Classified for 75996

Comments - 75996

- Center Comments:
  
  Class III. CFSAN concurs with audit check strategy.

- Email Comments:

Recall Date Information - 75996

- Firm Awareness: 12/12/2016
- Recall Initiation: 12/15/2016
- District Awareness: 12/15/2016
- HHE Sent: 12/29/2016
- Distribution Chain Notified: 12/16/2016
- Alert: 12/16/2016
- Recommendation: 12/21/2016
- Classification: 01/12/2017
- Recall Completed:
- Termination:
- State Press Issued:
- Firm Press Issued:
- FDA Press Issued:

Recall Firm Information - 75996

- Recalling Firm:
  
  Starkey Water
  102 Council Ave
  Council Idaho 83612
  United States

- Manufacturing Firm 1:
  
  Starkey Water
  Confidential: N
  102 Council Ave
  Council Idaho 83612
  United States

Product 1 - 75996

- Product Description:
  
  Starkey Spring Water, item code STC.5, 16.9 fl. oz. (500 mL) glass bottle. Product UPC 8 11904 02000 7. Case UPC 8 11904 02002 1.
Starkey Spring Water, 16.9 fl oz. glass bottles, are recalled because 11.7 ppb of arsenic was detected in water sample.

- **Product Public Reason for Recall:**

- **Code Information:**

  produced on (B) (4)

- **Industry-Product Code:**

  29-RCY01

- **District Recommended Classification:**

  Class II

- **Center Classification:**

  Class III

- **Product Effect. Check Level / Percent:**

  A / 100

- **Product Audit Check Level / Percent:**

  B / 40

- **Recall Number:**

  F-1179-2017

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### Recall Event Level Information - 75996

- **Recall Status:**

  Ongoing

  Retail

- **Firm Recommended Recall Depth:**

- **Voluntary/Mandated:**

  FDA Initiated

  12/16/2016

  - Effectiveness Check Level / Percent:
SEA-DO recommends to call or visit two direct accounts and three sub-accounts per direct account.

The firm notified their consignees by telephone on 12/15/16 and sent the notification via email on 12/16/16. Distributors and retailers were instructed to destroy any remaining affected product. Customers with questions about recall can call Susan Drexel at 303-920-5441.

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<tr>
<td>Number of USDA Consignees</td>
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<tr>
<td>District Management Approval</td>
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<td>District Management Approval Date</td>
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<tr>
<td>Class I Termination Recommendation</td>
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<tr>
<td>Firm Initial Notification</td>
<td>Combination</td>
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### Event Information

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<td>EON ID</td>
<td>F-1179-2017</td>
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<td><strong>Recall Number(s)</strong></td>
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<td>Seattle District Office</td>
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<td>Firm Awareness Date</td>
<td>12/12/2016</td>
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<tr>
<td>Center (Int)</td>
<td>Center for Food Safety and Applied Nutrition</td>
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<tr>
<td>Recalling Firm FEI</td>
<td>3010863196</td>
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<tr>
<td>Manufacturer FEI</td>
<td>3010863196</td>
</tr>
<tr>
<td>Responsible Firm FEI</td>
<td>3010863196</td>
</tr>
</tbody>
</table>

**Public Reason for Recall:** Starkey Spring Water, 16.9 fl oz. glass bottles, are recalled because 11.7 ppb of arsenic was detected in water sample.

**Edit Mode:** Viewable

**Recall Status (Int):** Terminated

**Voluntary/Mandated (Int):** FDA Initiated

**Date (Int):** 12/16/2016

**Firm Recommended Recall Depth:** Retail

**Date Distribution Chain Notified:** 12/16/2016

**Recall Initiation Date (Int):** 12/15/2016

**Firm Initial Notification:** Combination

**Center Coordinator Assigned Date:** 12/29/2016

**FDA Sample Number:** none
Starkey Spring Water, 16.9 FL oz. glass bottles, are recalled because 11.7 ppb of arsenic was detected in water sample. The sample of lot # (b) (4) was collected on 07/07/16 and the results were included in a report dated 12/09/16 by the Florida Department of Agriculture and Consumer Services (FDACS). The arsenic level in lot # (b) (4) tested by the FDACS Laboratory # 2016/FL-18831 was at 11.7 ppb. On 12/12/16, according to the firm, testing result was provided to Whole Foods Market store in Florida by Florida Department of Agriculture and Consumer Services (FDACS). On 12/13/16: SEA-DO became aware of bottled water sample result provided by FDACS (11.7 ppb of arsenic) and consulted with CFSAN Recalls. On 12/14/16: CFSAN Recalls responded and stated that 11.7 ppb value exceeds the 10 ppb FDA permissible level of arsenic in water (21 CFR 165.100) and is a health concern. It would be a class 2 recall. On 12/14/16 and 12/15/16: SEA-DO notified the firm of sample result, notified the firm about a potential class II result, and asked for the firm plan on distributed product. On 12/15/16: the firm agreed to recall. On 12/16/16: the firm submitted the Attachment A information. On 12/21/16: the firm submitted the Attachment B information.

Root Cause
Other

Root Cause Narrative
unknown. The firm reported that the testing from the (b) (4) for this week of production was at 10 ppb.

Center Comments
Class III. 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 (b) (4)

Distribution Pattern (Int) distributed in (b) (4)

Manufactured From (b) (4)

Public Summary of Recall Strategy
The firm notified their consignees by telephone on 12/15/16 and sent the notification via email on 12/16/16. Distributors and retailers were instructed to destroy any remaining affected product. Customers with questions about recall can call Susan Drexel at 303-920-5441.

Recall Strategy
The firm notified their consignees by telephone on 12/15/16 and sent the notification via email on 12/16/16. Distributors and retailers were instructed to destroy any remaining affected product. Customers with questions about recall can call Susan Drexel at 303-920-5441.

Effectiveness Check Level
APercent 100

Audit Check Level
BPercent 40

Audit/Effectiveness Check Modification
SEA-DO recommends to call or visit two direct accounts and three sub-accounts per direct account.

RAC Assignment Date Issued
12/28/2016

RAC Assignment Date Completed

District RAC Assignment Needed?
Yes

District Justification for No Audit Check

District Recommendation for No Center Concur with District RAC

Audit Check Comments
Recommendation
Consignee Details

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

List of five direct accounts: Allegro Coffee Manufacturer HQ 12799 Claude Court Thornton, CO (b) (4)

<table>
<thead>
<tr>
<th>Consignees</th>
<th>Approx. Number</th>
<th>Consignees</th>
<th>Approx. Number</th>
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<tbody>
<tr>
<td>Distributor</td>
<td>0</td>
<td>Repacker/Relabeler</td>
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<tr>
<td>Retailer</td>
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<td>Direct Accounts</td>
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<tr>
<td>Institution</td>
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<td>Medical Facility</td>
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</tr>
<tr>
<td>Consumer/Patient</td>
<td>0</td>
<td>Other</td>
<td>0</td>
</tr>
</tbody>
</table>

Summary/Termination Information

Quantity Recovered/Number of Units Corrected: No inventory remained at the consignees

Product Disposition: None remaining

Number of Consignees Responding to Notification: The (b) (4) consignees have one point of contact and did respond to the recall notification. Allegro Coffee was visited by the recalling firm

Effectiveness Check Information: 100%

Recall Audit Check Count: Audit Count Summary: Not Available
Audit Check Information: SEA-DO sent RAC assignment to MIN-DO and PHI-DO. PHI-DO responded with 1 E D and 2 E S. MIN-DO responded with 1 E D (submitted 3177 on 3/2/17). E=effective D=direct account S=sub account.

Section of Law Violated: 403(a)(1)

Preventive Action Taken by Firm: Lower the internal testing threshold of acceptability for arsenic to 9 ppb. Hold and re-test all lots over the 9 ppb threshold. Retrain and reinforce requirement to re-test any lots above the threshold. Only lots passing the threshold may be released for distribution. Increases holding period from.(b) (4).

District Follow-Up: SEA-DO recalls received notification from Florida Dept. of Ag. regarding high arsenic levels in the bottled water. SEA-DO recalls worked with the firm to collect Attachment B information, document the recall and review the documents to verify the recall is effective and complete.

District Review: Recall appears effective and complete.

Legal Action: None

Class I Termination: Recommended/Prepared By: Jean R McCurry

District Management Approval: Jean R McCurry Date 03/03/2017

Center Concurrence: Recall Completed Date 01/23/2017

Termination Letter Date: 03/03/2017

CFSAN Center Information:

Docs Rcvd at Ctr Date: 12/21/2016

HHE Sent: 12/29/2016

HHE Signed: 01/04/2017

HHE Precedent: 9420

Outbreak Associated: N

Outbreak Event Number:

Product Information:

Product : 1

Industry-Product Code: 29-RCY01

Precedent Recall: 9420

Precedent Policy

Precedent Policy Comment


Trade Name (Int): Starkey Spring Water

Generic Name (Int): Starkey Spring Water

Product Usage: human consumption

Product Quantity Distributed (Int): (b) (4)
Recall Number (Int) F-1179-2017

Product Public Reason for Recall (Int) Starkey Spring Water, 16.9 fl oz. glass bottles, are recalled because 11.7 ppb of arsenic was detected in water sample.

Field Recommended Classification Class II

Center Determination/Classification (Int) Class III

Center Recommended Depth Retail

Product Effectiveness Check Level A Percent 100

Product Audit Check Level B Percent 40

Code Information (Int) produced on [b] (4)

Expected Life

Shelf Life

CFSAN Reason Chemical contaminant

Recalling Firm Information

FEI 3010863196

Firm Name (Int) Starkey Water

Address (Int) 102 Council Ave

City (Int) Council

State/Province (Int) Idaho

Country (Int) United States

Postal Code (Int) 83612

Telephone Ext Country Code

Comment

Most Responsible Individual

Official's Name Jeff Teter

Title President/General Manager

Firm Name (Int) Starkey Water

Address (Int) 102 Council Ave

City (Int) Council

State/Province (Int) Idaho

Country (Int) United States

Postal Code (Int) 83612

Telephone Ext Country Code

Facsimile 303-920-5468 Ext Country Code

E-mail Address Jeff.Teter@allegrocoffee.com

Comment Company headquarters is located in Thornton, Colorado
## Manufacturer Information

<table>
<thead>
<tr>
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<th>Value</th>
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<tbody>
<tr>
<td>FEI</td>
<td>3010863196</td>
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<tr>
<td>Firm Name (Int)</td>
<td>Starkey Water</td>
</tr>
<tr>
<td>Address (Int)</td>
<td>102 Council Ave</td>
</tr>
<tr>
<td>City (Int)</td>
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<td>State/Province (Int)</td>
<td>Idaho</td>
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## Responsible Firm Information

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## Recall Contact

<table>
<thead>
<tr>
<th>Field</th>
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<tbody>
<tr>
<td>Official's Name</td>
<td>Susan Drexel</td>
</tr>
<tr>
<td>Title</td>
<td>Director of Plant Operations and Purchasing</td>
</tr>
<tr>
<td>Firm Name (Int)</td>
<td>Starkey Water</td>
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<tr>
<td>Telephone</td>
<td>303-920-5468</td>
</tr>
<tr>
<td>Facsimile</td>
<td>303-920-5468</td>
</tr>
<tr>
<td>E-mail Address</td>
<td><a href="mailto:susan.drexel@allegrocoffee.com">susan.drexel@allegrocoffee.com</a></td>
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## Public Contact

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<tr>
<td>Official’s Name</td>
<td>Tara Cross</td>
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<tr>
<td><strong>Title</strong></td>
<td>Director of Marketing</td>
</tr>
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<td>-----------------------</td>
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<td><strong>Telephone</strong></td>
<td>303-920-5468 Ext</td>
</tr>
<tr>
<td><strong>Facsimile</strong></td>
<td>Country Code</td>
</tr>
<tr>
<td><strong>E-mail Address</strong></td>
<td><a href="mailto:Tara.Cross@allegrocoffee.com">Tara.Cross@allegrocoffee.com</a></td>
</tr>
</tbody>
</table>

**WARNING!** Sensitive/critical information. This information is proprietary and confidential. It should not be disclosed to unauthorized parties and should be maintained in a secure environment.

Printed by: Thomas Kuntz
Recall Classified for 76172

Comments - 76172

- Center Comments:
  Class III. CFSAN concurs with audit check strategy.

- Email Comments:

Recall Date Information - 76172

<table>
<thead>
<tr>
<th>Firm Awareness</th>
<th>Classification</th>
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</thead>
<tbody>
<tr>
<td>01/04/2017</td>
<td>01/19/2017</td>
</tr>
<tr>
<td>Recall Initiation</td>
<td>Recall Completed</td>
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<tr>
<td>01/04/2017</td>
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<tr>
<td>District Awareness</td>
<td>Termination</td>
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<tr>
<td>03/05/2017</td>
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<td>HHE Sent</td>
<td>State Press Issued</td>
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<tr>
<td>01/12/2017</td>
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<tr>
<td>Distribution Chain Notified</td>
<td>FDA Press Issued</td>
</tr>
<tr>
<td>01/04/2017</td>
<td>01/05/2017</td>
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<tr>
<td>Alert</td>
<td></td>
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<tr>
<td>01/05/2017</td>
<td></td>
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<tr>
<td>Recommendation</td>
<td></td>
</tr>
<tr>
<td>01/11/2017</td>
<td></td>
</tr>
</tbody>
</table>

Recall Firm Information - 76172

- Recalling Firm:
  Starkey Water
  102 Council Ave
  Council Idaho 83612
  United States

- Manufacturing Firm 1:
  Starkey Water
  Confidential : N
  102 Council Ave
  Council Idaho 83612
  United States

Product 1 - 76172

- Product Description:
12 ppb of arsenic was detected in water sample

Produced On (B) (4)

29-RCY01

Class II

Class III

B / 50

B / 25

F-1333-2017

Recall Event Level Information - 76172

Recall Status: Ongoing

Retail

Firm Initiated

01/04/2017
SEA-DO recommends level B (25%) or 2 distribution centers (DC) and two sub-accounts per DC for the RAC assignment. They can be done by telephone.

The firm notified their consignee(s) on 1/4/17 by email. Customers are advised to destroy product with this lot number. Customers with questions can call the firm at 303-920-5441 office or 720-470-1739 cell.

No VA or DoD consignees. No foreign consignees. Product distributed to (b) (4) distribution Centers in the US. (b) (4)

0

0

0
- Number of DOD Consignees:
- Number of USDA Consignees:
- District Management Approval:
- District Management Approval Date:
- Class I Termination Recommendation:
- Firm Initial Notification:

E-Mail
Recall Details

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

Event Information

Recall Event ID: 76172  Status: Terminated  Updated: 09/07/2017  Role: Center Recall Coordinator

Recall Number(s)

Recall Event ID: 76172  EON ID: F-1333-2017

District
Seattle District Office
Firm Awareness Date: 01/04/2017
District Awareness Date: 01/05/2017
Center (Int)
Center for Food Safety and Applied Nutrition
Coordinator: Kerri Harris-Garner

Recalling Firm FEI: 3010863196  Name (Int): Starkey Water
Manufacturer FEI: 3010863196  Name (Int): Starkey Water
Responsible Firm FEI: 3010863196  Name: Starkey Water

Public Reason for Recall: Starkey Spring Water, 16.9 fl oz. glass bottles, is recalled because 12 ppb of arsenic was detected in water sample.

Edit Mode: Viewable  Recall Status (Int): Terminated
Voluntary/Mandated (Int): Firm Initiated  Date (Int): 01/04/2017
Firm Recommended Recall Depth: Retail  Date Distribution Chain Notified: 01/04/2017
Recall Initiation Date (Int): 01/04/2017  Firm Initial Notification: E-Mail
Determination Date: 01/12/2017  Center Coordinator Assigned Date: 01/19/2017
Classification Date: 01/19/2017  FDA Sample Number: none
Complete Reason for Recall: Starkey Spring Water, 16.9 fl oz. glass bottles, is recalled because 12 ppb of arsenic was detected in water sample. The water sample from the lot # 9:06 NV AC-51-2866 was collected on 12/12/2016 and the result was included in a report dated 12/29/16 by the Florida Department of Agriculture and Consumer Services (FDACS). The arsenic level in the sample tested by the FDACS Laboratory # 2016/FL-22279 was found at 12 ppb. The firm's private samples conducted for this lot was at .010 mg/L. uses testing method EPA 200.8 and provided a valid test showing the product met the regulatory limit; consequently the product was released for distribution. On 1/4/17: according to the firm, testing result was provided to Whole Foods Market representative by Florida Department of Agriculture and Consumer Services (FDACS). On 1/5/17: the firm submitted the Attachment A information to SEA-DO. On 1/9/17: the firm submitted the Attachment B information to SEA-DO.

Root Cause: Other

Root Cause Narrative: unknown

Center Comments: Class III. CFSAN concurs with audit check strategy.

Type Of Injury: none has been reported to date

Quantity Manufactured:

Quantity Distributed (Int)

Number of Domestic Consignees (b) (4)

Number of Foreign Consignees 0

Manufactured From

Distributed From

Distribution Pattern (Int) distributed in (b) (4)

Public Summary of Recall Strategy (Int)

Recall Strategy: The firm notified their consignee(s) on 1/4/17 by email. Customers are advised to destroy product with this lot number. Customers with questions can call the firm at 303-920-5441 office or 720-470-1739 cell.

Effectiveness Check Level B Percent 50

Audit Check Level B Percent 25

Audit/Effectiveness Check Modification SEA-DO recommends level B (25%) or 2 distribution centers (DC) and two sub-accounts per DC for the RAC assignment. They can be done by telephone.

RAC Assignment Date Issued 01/11/2017 RAC Assignment Date Completed

District RAC Assignment Needed? Yes District Justification for No Audit Check

District Recommendation for No Audit Check Comments Center Concur with District RAC Recommendation

Center RAC Assignment Needed? Center Justification for No Audit Check

Center Recommendation Center Entering Recall

Justification Comments

What Consumers Should Do (Int)
No VA or DoD consignees. No foreign consignees. Product distributed to distribution Centers in the US:

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

No recalled product remained at the consignee level.

These centers represent the (b) (4) to which product was distributed. Both regional centers replied that they had no remaining stock on hand.

100% response.

Audit Count Summary : Not Available

SEA-DO issued RAC to DEN-DO and DAL-DO on 1/11/17. DAL-DO submitted 3177 on 2/9/17 and it was found Effective (endorsed on 1/19/17). DEN-DO: Requested 3177 on 3/2/17. DEN-DO provided FDA 3177 to SEA-DO on 3/3/17. It was conducted on 1/26/17 and endorsed on 3/3/17. It was found to be effective.

403(a)(1)
Preventive Action Taken by Firm

Lower the internal testing threshold of acceptability for arsenic to 9 ppb. Hold and re-test all lots over the 9 ppb threshold. Retrain and reinforce requirement to re-test any lots above the threshold. Only lots below the threshold may be released for distribution. Increases holding period from (b) (4) Purchase order has been written and deposit paid for an arsenic removal filtration system from (b) (4) .

District Follow-Up

Florida Department of Agric. provided information regarding high levels of arsenic in the bottled water. SEA-DO Recalls obtained Attachment B information, documented the recall and reviewed the records to verify the recall is effective and complete.

District Review

Recall appears effective and complete. Awaited RAC prior to termination.

Legal Action

None

Class I Termination

Recommendation

Recommended/Prepared By Jean R McCurry

District Management Approval Jean R McCurry Date 03/03/2017

Center Concurrence

Recall Completed Date 01/31/2017

Termination Letter Date 03/03/2017

CFSAN Center Information

Docs Rcvd at Ctr Date 01/11/2017

HHE Sent 01/12/2017

HHE Signed 01/13/2017

HHE Precedent 9438

Outbreak Associated N

Outbreak Event Number

Product Information

Product : 1

Industry-Product Code 29-RCY01

Precedent Recall 9438

Precedent Policy

Precedent Policy Comment

Product Description (Int) Starkey Spring Water, 16.9 FL oz. (500 mL) glass bottle. packed 15 bottles in cardboard box.

(Label/Packaging) Product UPC 8 11904 02000 7. Case UPC 8 11904 02002 1.

Trade Name (Int) Starkey Spring Water

Generic Name (Int)

Product Usage human consumption

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

Recall Number (Int) F-1333-2017

Product Public Reason for Recall (Int) 12 ppb of arsenic was detected in water sample
Recalling Firm Information

FEI 3010863196
Firm Name (Int) Starkey Water
Address (Int) 102 Council Ave
City (Int) Council
State/Province (Int) Idaho
Country (Int) United States
Postal Code (Int) 83612
Telephone Ext Country Code

Comment

Most Responsible Individual

Official’s Name Jeff Teter
Title President/General Manager
Firm Name (Int) Starkey Water/Allegro Coffee
Address (Int) 12799 Claude Court
City (Int) Thornton
State/Province (Int) Colorado
Country (Int) United States
Postal Code (Int)
Telephone 303-920-5400 Ext Country Code
Facsimile 303-920-5468 Ext Country Code
E-mail Address Jeff.Teter@allegrocoffee.com
Comment Starkey Water is owned by Allegro Coffee and the company headquarters is located in Thornton, Colorado

Manufacturer Information

FEI 3010863196
Firm Name (Int) Starkey Water
Responsible Firm Information

FEI 3010863196
Firm Type Manufacturer
Firm Name Starkey Water
Address 102 Council Ave
City Council
State/Province Idaho
Country United States
Postal Code 83612
Telephone 303-920-5400 Ext Country Code

Official's Name Susan Drexel
Title Director of Plant Operations and Purchasing
Firm Name Starkey Water/Allegro Coffee
Address 12799 Claude Court
City Thornton
State/Province Colorado
Country United States
Postal Code 83612
Telephone 303-920-5441 Ext Country Code
Facsimile 303-920-5468 Ext Country Code
E-mail Address susan.drexel@allegrocoffee.com

Recall Contact

Official's Name Tara Cross
Title Director of Marketing
Firm Name Starkey Water/Allegro Coffee
Address 12799 Claude Court
<table>
<thead>
<tr>
<th>City (Int)</th>
<th>Thornton</th>
</tr>
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<tbody>
<tr>
<td>State/Province (Int)</td>
<td>Colorado</td>
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