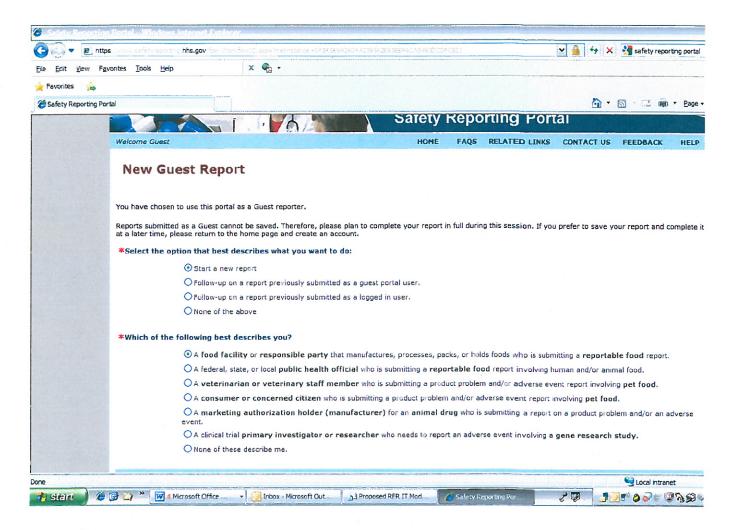
Description of 5 Scenarios

| Filename | Conditionality Demonstrated |
|--|--|
| Scenario1 Salmonella as Agent.pub | Salmonella is an example of a microbiological hazard. Shows the questions "*Is a Bacterial Isolate Available for collection?" and "*Was product treated to reduce microorganisms?" displayed when a microbiological agent is chosen in response to "*Reason this food is |
| Scenario2 Salmonella and Treatment.pub | reportable (agent)." Salmonella is an example of a microbiological hazard. In addition to Scenario1's questions, this shows "Microbial Reduction Treatment Details" question when Yes is chosen in response to "*Was product |
| Scenario3 Foreign Object.pub | treated to reduce microorganisms?" Shows what questions are displayed when a non-microbiological agent is chosen in response to "*Reason this food is reportable (agent)." |
| Scenario4 Foreign Object for Animal.pub | In addition to Scenario3's questions, this shows the two questions displayed when "*Intended Product Use" is answered with the selection of "Animal:" "*Animal Species Intended For," and "*Lifestage of Animal Intended For." |
| Scenario5 Foreign Object Received and Distributed for Animal.pub | Building on Scenario4, shows the followup questions presented when "*Did you receive the reportable food from an outside source?" and "*Was the product distributed in any other form to another location?" are answered "Yes." |



1st high level condition- must be a mandatory reportable food submission in RFR RQ

Scenario 1 -> microbiological hazard condition (Salmonella)

| Welcome B. Reddington | i i | HOME FAQS | RELATED | LINKS | CONTACT US | FEEDBACK | HELP | LOGOUT |
|---|---|---|------------------------------|-----------------------|---------------------|-----------------|-------------|------------------|
| Name: Mandatory Reportable Food Report (Section 1005 of Public Law 110-85) | Problem Summary | | | | | | | |
| ID: 9470 (I) Created: 04/13/2012 | *=Required | | | | | | | |
| | Problem Summary | | | | | | | |
| ☑ Introduction☑ Contact Information | This section asks for a summary of th suspect product(s) and a description of | | ı, including l | how and w | hen you learned | about the probl | em, inform | nation about the |
| Problem Summary | If you have additional details about ar timely fashion. If you do not have an | | | | | | resolve th | e problem in a |
| □ Products | | | | | | | | |
| Distribution Information | Your organization's internal iden this report (Case ID) | tifier correspon | ding to | | | | | |
| □ Supplier Information | *Date the article of food was de | termined to be a | 9 | | | 12 | | |
| □ Attachments | Reportable Food | | | | | | | |
| My Report History | *How did your site first learn ab | out the Reporta | ble Food? | Please se | elect | | | • |
| OMB Approval Number: 0910-0645 | *Reason this food is reportable (a | agent) | | Salmonell | a | | | - |
| OMB Expiration 09/30/2012 OMB Burden Statement | *What did your investigation iden the problem (if you were required tion under section 417(d)(1)(B) of | | | | | | | |
| | *To the best of your knowledge, food been removed from commer | | oortable | Yes | O No | Onknown | ⊕ Othe | r |
| | What corrective actions have been occurrences? | en taken to prev | ent future | 1 | | | | A |
| | *Is a Bacterial Isolate Available | for collection? | |) Yes | No | Unknown | Othe | r |
| | *Do you believe the Reportable intentionally caused? | Food issue was | | Please s | elect | | | ~ |
| | For the following questions, to pro information; instead, the responsi code will permit the responsible pa- event that the responsible party n | ble party should a arty to cross-refer | ssign a code ence identif | e (e.g, the | patient's initials) | to each adverse | e event. T | he assigned |
| | *Has a human adverse event be | een reported? | | Please s | elect | | | v |
| | *Has an animal adverse event been reported? Please select | | | | | | | ₹ |
| | *You are required to give a full | account of the R | eportable | Food issu | se including th | e current stati | ıs, investi | igation |
| | progress or results to date, and a it happened, any contributing fac involves biological, physical, rad | any other releva ctors, and how lo | nt details ong this pr | as to the oblem ha | cause. If know | vn, include wh | at the pro | blem is, how |
| | | | | | | | | |
| | | | | | | | | |
| | ABC ② | | | | | | | A |
| | | | | | | | | |
| | Save Draft Exit S | ubmit Report | | | | | < E | Back Next > |

| | itseit.) | | | |
|--|---|---------------------------------|----------|--------------------|
| Welcome B. Red | *Product Type | Please select | - | LOGOUT |
| Name: Manda Food R | | | | |
| 1005 o 110-85 | Package Category | 🗇 Bulk 🔘 Institutional 🔘 Retail | | |
| ID: 9470 (Created: 04/13/ | | | | |
| ☐ Introduction | Container Type (please describe the smallest container available for retail sale or further distribution) | Please select | - | ren the |
| | Container Size (please describe the smallest | | | |
| ☐ Contact Inf | container available for retail sale or further distribution) | Select Unit of Measure | - | |
| ☑ Problem Sui | ustribution) | | | |
| Products | Universal Product Code (UPC) from label | | | Back Next > |
| □ Distribution | *Manufacturing/Production Date(s) Star | t End | 12 | |
| ☐ Supplier Inf | manufacturing/r rouderton success | | | aminal penalties.] |
| □ Attachment | *Product Commodity Type Plea | se select | | |
| | | | | |
| My Report His | *How did you determine which products/lots/batches we | re | | |
| OMB Approval | affected? | | | |
| OMB Expiration Date: | | | - 11 | |
| OMB Burden Stat | *Use-by dates, if any, or approximate Shelf Life | 13 | | |
| | | | | |
| | *Was product treated to reduce microorganisms? | OYes ONO Unknown Other | | |
| | | | | |
| | *Intended Product Use | Please select | ¥ | |
| | *Did you receive the reportable food from an outside | Please select | - | |
| | source? | Please select | _ | |
| | *Was the product recalled? | Please select | · | |
| | *Was the product distributed in any form to another | Please select | | |
| | location? | ricase select | • | |
| | | | | |
| | | Save | Cancel | |
| No. State of the Control of the Cont | | | | |

Scenario 2 > microbiological hayard (Salmonella) and Product was treated to reduce microorganisms (2 conditions)

| Welcome B. Reddington | HOME FAQS | RELATED | LINKS | CONTACT US | FEEDBACK | HELP | LOGOUT |
|---|--|---------------------------|-----------|---------------------|------------------|-------------|-----------------|
| Name: Mandatory Reportable Food Report (Section 1005 of Public Law 110-85) | Problem Summary | | | | | | |
| ID: 9470 (I) Created: 04/13/2012 | *=Required | | | | | | |
| ☐ Introduction | Problem Summary | | | | | | |
| ☑ Contact Information | This section asks for a summary of the product problem, suspect product(s) and a description of the problem. | including h | now and w | hen you learned | about the proble | m, inform | ation about the |
| Problem Summary | If you have additional details about any of the suspect p timely fashion. If you do not have any details at this tim | | | | | resolve the | problem in a |
| □ Products | Your organization's internal identifier correspond | ling to | | | | | |
| □ Distribution Information | this report (Case ID) | ing to | | | | | |
| □ Supplier Information | *Date the article of food was determined to be a | | | | 3 | | |
| □ Attachments | Reportable Food | | | | | | |
| My Report History | *How did your site first learn about the Reportab | le Food? | Please s | elect | | | • |
| OMB Approval Number: 0910-0645 | *Reason this food is reportable (agent) | | Salmonel | la | | | • |
| OMB Expiration 09/30/2012 Date: OMB Burden Statement | *What did your investigation identify as the root of the problem (if you were required to conduct an in tion under section 417(d)(1)(B) of the FD&C Act)? | | Please | select | | | ¥ |
| | *To the best of your knowledge, has all of the rep- food been removed from commerce? | ortable | ⊘ Yes | ⊕ No | Unknown | Other | e. |
| | What corrective actions have been taken to preve occurrences? | nt future | | | | | lè |
| | *Is a Bacterial Isolate Available for collection? | | Yes | ⊕ No | Unknown | Othe | r |
| | *Do you believe the Reportable Food issue was intentionally caused? | | Please s | elect | | | • |
| | For the following questions, to protect privacy, do not information; instead, the responsible party should as code will permit the responsible party to cross-refere event that the responsible party needs to follow-up. | sign a code | (e.g, the | patient's initials) | to each adverse | event. The | ne assigned |
| | *Has a human adverse event been reported? | | Please s | elect | | | v |
| | *Has an animal adverse event been reported? | | Please s | elect | | | • |
| | *You are required to give a full account of the Re progress or results to date, and any other releval it happened, any contributing factors, and how los involves biological, physical, radiological or chemother than the progression of the pro | nt details ng this pro | as to the | cause. If know | n, include wha | t the pro | blem is, how |
| | Save Draft Exit Submit Report | | | | | < B: | ack Next > |

| | #Posture Name (Value Abordance and Abordance | | | | |
|--|---|--------|-----------------------------|--------|--------------------|
| | *Product Name (Include the brand name and the pro name, as printed on the product label or the product itself.) | | | A | |
| Welcome B. Red | | | | | LOGOUT |
| Name: Manda Food R | *Product Type | | Please select | ▼ | |
| 1005 o 110-85 | Package Category | | Bulk Institutional Retail | | |
| ID: 9470 (Created: 04/13/ | Container Type (please describe the smallest contain available for retail sale or further distribution) | ner | Please select | • | en the |
| ☐ Contact Inf | Container Size (please describe the smallest container available for retail sale or further distribution) | | Select Unit of Measure | • | |
| • Products | Universal Product Code (UPC) from label | | | | Back Next > |
| □ Distribution | *Manufacturing/Production Date(s) | Start | TE End | 13 | |
| □ Supplier Inf | | | | | iminal penalties.] |
| □ Attachment | *Product Commodity Type | Please | select | ▼ | |
| My Report His | | | | | |
| OMB Approval | *How did you determine which products/lots/batches affected? | were | | | |
| Number: OMB Expiration | | | | li | |
| Date: OMB Burden Stat | *Use-by dates, if any, or approximate Shelf Life | | 12 | | |
| | | | | | |
| | *Was product treated to reduce microorganisms? | | • Yes No Unknown Other | | |
| | *Microbial Reduction Treatment Details | | | l. | |
| | *Intended Product Use | | Please select | • | |
| | *Did you receive the reportable food from an outsid source? | de | Please select | • | |
| | *Was the product recalled? | | Please select | • | |
| | *Was the product distributed in any form to anothe location? | er | Please select | • | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | Save | Cancel | |
| A CONTRACTOR OF THE PARTY OF TH | | | | | |

Scenario 3 -> Foreign object in hazard

| Welcome B. Reddington | HOME FA | QS RELATED | LINKS CONTACT US | FEEDBACK | HELP LOGOUT |
|---|--|--|--|---------------------------------|--------------------------|
| Name: Mandatory Reportable Food Report (Section 1005 of Public Law 110-85) | Problem Summary | | | | |
| ID: 9470 (I) Created: 04/13/2012 | *=Required | | | | |
| ☐ Introduction | Problem Summary | | | | |
| □ Contact Information | This section asks for a summary of the product pro suspect product(s) and a description of the problem | | ow and when you learned | about the problem | n, information about the |
| Problem Summary | If you have additional details about any of the susptimely fashion. If you do not have any details at the | ect products, ple is time, you can | ase provide them so that v submit them in an amende | we can move to re ed report. | solve the problem in a |
| □ Products | | | | | |
| □ Distribution Information | Your organization's internal identifier corres this report (Case ID) | sponding to | | | |
| ☐ Supplier Information | *Date the article of food was determined to | he a | | na _n | |
| □ Attachments | Reportable Food | DC u | - A | 12 | |
| My Report History | *How did your site first learn about the Rep | ortable Food? | Please select | | • |
| OMB Approval Number: 0910-0645 | *Reason this food is reportable (agent) | | Foreign Object | | • |
| OMB Expiration 09/30/2012 OMB Burden Statement | *What did your investigation identify as the r the problem (if you were required to conduct tion under section 417(d)(1)(B) of the FD&C A | an investiga- | Please select | | ▼ |
| | *To the best of your knowledge, has all of the food been removed from commerce? | e reportable | | O Unknown | Other |
| | What corrective actions have been taken to poccurrences? | prevent future | | | h |
| | *Do you believe the Reportable Food issue intentionally caused? | was | Please select | | ▼ |
| | For the following questions, to protect privacy, of information; instead, the responsible party shot code will permit the responsible party to cross-revent that the responsible party needs to follow | ild assign a code eference identify | (e.g, the patient's initials) | to each adverse e | event. The assigned |
| | *Has a human adverse event been reported | !? | Please select | | Ţ |
| | *Has an animal adverse event been reporte | ed? | Please select | | |
| | | | | | • |
| | *You are required to give a full account of the progress or results to date, and any other re it happened, any contributing factors, and ho | levant details a | s to the cause. If know | n, include what | the problem is, how |
| | involves biological, physical, radiological or | | | . | |
| | ABC 🥝 | | | | |
| | Save Draft Exit Submit Report |) | | | < Back Next > |





| Welcome B. Red | | | | LOGOUT |
|-------------------------------|---|---------------------------|----------|--------------------|
| Name: Manda | *Product Type | Please select | - | COGOOT |
| Food R 1005 o 110-85 | Package Category | Bulk Institutional Retail | | |
| ID: 9470 (Created: 04/13/ | Container Type (please describe the smallest container available for retail sale or further distribution) | Please select | v | |
| ☐ Introduction | available for retail sale or further distribution) | | | en the |
| ☑ Contact Inf | Container Size (please describe the smallest container available for retail sale or further distribution) | Select Unit of Measure | • | |
| ☑ Problem Sur | | | | |
| Products | Universal Product Code (UPC) from label | | | Back Next > |
| □ Distribution | *Manufacturing/Production Date(s) Start | 12 End | 13 | |
| □ Supplier Inf | | | | iminal penalties.] |
| □ Attachment | *Product Commodity Type Please | select 🔻 | | |
| My Report His | | | | |
| OMB Approval | *How did you determine which products/lots/batches were affected? | | | |
| Number: OMB Expiration | | | 10 | |
| Date: OMB Burden Stat | *Use-by dates, if any, or approximate Shelf Life | (Tig) | | |
| | oss by actos, it any, or approximate orien and | 14 | | |
| | *Intended Product Use | Please select | - | |
| | | | | |
| | *Did you receive the reportable food from an outside source? | Please select | • | |
| | *Was the product recalled? | Please select | • | |
| | *Was the product distributed in any form to another location? | Please select | T | |
| | | | | |
| The second second | | | | |
| | | Save | Cancel | |
| | | | | |

Scenario 4 - Foreign object harard and For Animal consumption conditions

| Welcome B. Reddington | номе | FAQS | RELATED | LINKS | CONTACT US | FEEDBACK | HELP | LOGOUT |
|---|---|-----------------------------|---------------------------|------------------|---------------------|------------------|------------|-----------------|
| Name: Mandatory Reportable Food Report (Section 1005 of Public Law 110-85) | Problem Summary | | | | | | | |
| ID: 9470 (I) Created: 04/13/2012 | *=Required | | | | | | | |
| ☑ Introduction | Problem Summary | | | | | | | |
| □ Contact Information | This section asks for a summary of the prod suspect product(s) and a description of the p | | , including h | now and w | hen you learned | about the proble | em, inform | ation about the |
| Problem Summary | If you have additional details about any of the timely fashion. If you do not have any deta | | | | | | resolve th | e problem in a |
| □ Products | 1. | | | | | | | |
| □ Distribution Information | Your organization's internal identifier this report (Case ID) | correspon | ding to | | | | | |
| ☐ Supplier Information | *Date the article of food was determine | ned to be a | , | | 1 | 2 | | |
| □ Attachments | Reportable Food | | | | L | <u></u> | | |
| My Report History | *How did your site first learn about th | e Reporta | ble Food? | Please s | elect | | | • |
| OMB Approval Number: 0910-0645 | *Reason this food is reportable (agent) | | | Foreign C | Dbject | | | • |
| OMB Expiration Date: 09/30/2012 OMB Burden Statement | *What did your investigation identify at the problem (if you were required to co tion under section 417(d)(1)(B) of the F | nduct an i | nvestiga- | Please | : select | | | |
| | *To the best of your knowledge, has al food been removed from commerce? | l of the rep | ortable | ⊕ Yes | ⊘ No | Unknown | ⊕ Othe | r |
| | What corrective actions have been tak occurrences? | en to preve | ent future | - Name to Assess | | | | ß |
| | *Do you believe the Reportable Food intentionally caused? | issue was | | Please s | elect | | | • |
| | For the following questions, to protect pri information; instead, the responsible par- code will permit the responsible party to event that the responsible party needs to | ty should as cross-refer | ssign a code | (e.g, the | patient's initials) | to each adverse | event. T | he assigned |
| | *Has a human adverse event been re | ported? | | Please s | elect | | | V |
| | *Has an animal adverse event been r | eported? | | Please s | elect | | | • |
| | *You are required to give a full accour progress or results to date, and any ot it happened, any contributing factors, involves biological, physical, radiological | her releva and how lo | nt details ng this pro | as to the | cause. If know | n, include wha | t the pro | blem is, how |
| | Save Draft Exit Submit F | Report | | | | | € E | Back Next > |

| | name, as printed on the product label or the product itself.) | | A | 144 |
|--|---|---|----------|--------------------|
| Welcome B. Red Name: Manda Food R | *Product Type | Please select | • | LOGOUT |
| 1005 c 110-85 1D: 9470 (| Package Category | Bulk Institutional Retail | | |
| Created: 04/13/ | Container Type (please describe the smallest container available for retail sale or further distribution) | Please select | V | ren the |
| ☑ Contact Inf | Container Size (please describe the smallest container available for retail sale or further distribution) | Select Unit of Measure | • | |
| Products | Universal Product Code (UPC) from label | | | Back Next > |
| □ Distribution □ Supplier Inf | *Manufacturing/Production Date(s) Start | 1 End | 13 | |
| □ Attachmen | *Product Commodity Type Please | e select 🔻 | | iminal penalties.] |
| My Report His OMB Approval Number: OMB Expiration | *How did you determine which products/lots/batches were affected? | | h | |
| Date: OMB Burden Stat | *Use-by dates, if any, or approximate Shelf Life | 2 | | |
| | *Intended Product Use | Animal | • | |
| | *Animal Species Intended For | <checkboxes for="" species="" various=""></checkboxes> | | |
| | *Lifestage of Animal Intended For | <checkboxes for="" lifestages="" various=""></checkboxes> | | |
| | *Did you receive the reportable food from an outside source? | Yes | • | |
| | *Was the product recalled? | Please select | · | The second |
| | *Was the product distributed in any form to another location? | Yes | + | |
| | | | | |
| | | Save | Cancel | |

Scenario 5 > toreign object

For Animal Consumption

Lots of product distributed

Lots of product (ecieved)

Ly conditions)

| Name: Mendetery Reportable Food Seport (Seation 10-997 (I) Created: 04/13/2012 In: 9970 (I) Created: 04/13/2012 Introduction Problem Summary This section asks for a summary of the product problem, including how and when you learned about the problem in a summary of the product problem. Including how and when you learned about the problem in a summary of the product problem. Including how and when you learned about the problem in a summary of the product problem, including how and when you learned about the problem in a summary of the product problem, including how and when you learned about the problem in a summary of the problem in a | Welcome B. Reddington | HOME FAQS RELATE | D LINKS CONTACT US FEEL | DBACK HELP LOGOUT |
|--|--|--|--|---|
| ### Problem Summary | Food Report (Section 1005 of Public Law | Problem Summary | | |
| ☐ Introduction ☐ Contact Information ☐ Contact Information ☐ Products ☐ Distribution Information ☐ Supplier Information ☐ Reportable Food ☐ Without Information ☐ Reportable Food ☐ Without Information ☐ Supplier Information ☐ Reportable Food ☐ Without Information ☐ Supplier Information ☐ Reportable Food ☐ Without Information ☐ Supplier Information ☐ Supplier Information ☐ Supplier Information ☐ Products ☐ Please select ☐ Proving Object ☐ Proving Object ☐ Please select ☐ Please sel | | *=Required | | |
| Contact Information | | Problem Summary | | |
| □ Products □ Products □ Distribution Information □ Supplier Information □ Attachments My Report History OHE Approval Sumbary **How did your site first learn about the Reportable Food? Please select **What did your investigation identify as the root cause of the problem (if you were required to conduct an investigation under section 477(q)(19) of the PBaC select **To the best of your knowledge, has all of the reportable food been removed from commerce? What corrective actions have been taken to prevent future occurrences? **Do you believe the Reportable Food issue was intentionally caused? **To the following questions, to protect privacy, do not identify individuals by name or address or other personally-identifiable information; instead, the responsible party to roose-reference identifying information and contact information for the patient in the event that the responsible party needs to follow-up. **Has an animal adverse event been reported? **Has an animal adverse event been reported? **You are required to give a full account of the Reportable Food is the cause. If known, include what the problem involves biological, physical, rediological or chemical adulteration. | | | how and when you learned about t | he problem, information about th |
| Obstribution Information □ Supplier Information □ Attachments My Report History Attachments My Report History Attachments # How did your site first learn about the Reportable Food? # Reason this food is reportable (agent) * What did your investigation identify as the root cause of the problem (if you were required to conduct an investigation under section 417(g)(1)(g) (f) (f) (f) (f) (f) (f) (f) (f) (f) (f | Problem Summary | If you have additional details about any of the suspect products, pl timely fashion. If you do not have any details at this time, you car | ease provide them so that we can submit them in an amended repo | move to resolve the problem in a rt. |
| Uniformation Supplier Information Attachments Wy Report History My | □ Products | Non-constant of the second the Million of the Ac- | | |
| My Report History *How did your site first learn about the Reportable Food? *How did your site first learn about the Reportable Food? *Mapproval Number: OMB Expiration Doste: O9/30/2012 OMB Surden Statement *To the best of your knowledge, has all of the reportable food been removed from commerce? What corrective actions have been taken to prevent future occurrences? *Do you believe the Reportable Food issue was intentionally caused? For the following questions, to protect privacy, do not identify individuals by name or address or other personally-identifiable information; impact, the responsible party should assign a side (e.g. the patient's initials) to each adverse event. The assigned event that the responsible party needs to follow-up. *Has a human adverse event been reported? *Has a naminal adverse event been reported? Please select *Has an animal adverse event been reported? Please select *You are required to give a full account of the Reportable Food issue including the current status, investigation progress or results to date, and any other relevant details as to the cause. If known, include what the problem is, how it happened, any contributing factors, and how long this problem has been occurring. If known, specify if the problem involves biological, physical, radiological or chemical adulteration. | □ Distribution Information | | | |
| My Report History *How did your site first learn about the Reportable Food? Please select *How did your site first learn about the Reportable Food? Please select *Reason this food is reportable (agent) ONB Expiration 09/30/2012 *What did your investigation identify as the root cause of the problem (if you were required to conduct an investigation under section 417(d)(1)(8) of the FD&C Act)? *To the best of your knowledge, has all of the reportable food been removed from commerce? What corrective actions have been taken to prevent future occurrences? *Do you believe the Reportable Food issue was intentionally caused? *To the following questions, to protect privacy, do not identify individuals by name or address or other personally-identifiable information; instead, the responsible party should assign a code (e.g., the patients' initials) to each adverse event. The assigned code will permit the responsible party hould assign a code (e.g., the patients' initials) to each adverse event. The assigned code will permit the responsible party needs to follow-up. *Has an human adverse event been reported? Please select *You are required to give a full account of the Reportable Food issue including the current status, investigation progress or results to date, and any other relevant details as to the cause. If known, include what the problem is, how it happened, any contributing factors, and how long this problem has been occurring. If known, specify if the problem involves biological, physical, radiological or chemical adulteration. | ☐ Supplier Information | *Date the article of food was determined to be a | 1 | |
| OMB Approval Number: OMB Expiration Date: To the best of your knowledge, has all of the reportable food been removed from commerce? What corrective actions have been taken to prevent future occurrences? What corrective actions have been taken to prevent future occurrences? **Do you believe the Reportable Food Issue was intentionally caused? For the following questions, to protect privacy, do not identify individuals by name or address or other personally-identifiable information; instead, the responsible party should assign a code (e.g., the patient's initials) to each adverse event. The assigned code will permit the responsible party or corse-reference identifying information and contact information for the patient in the event that the responsible party needs to follow-up. *Has a human adverse event been reported? Please select *You are required to give a full account of the Reportable Food Issue including the current status, investigation progress or results to date, and any other relevant details as to the cause. If known, include what the problem is, how it happened, any contributing factors, and how long this problem has been occurring. If known, specify if the problem involves biological, physical, radiological or chemical adulteration. | □ Attachments | Reportable Food | | |
| Number: OMB Expiration Date: *What did your investigation identify as the root cause of the problem (if you were required to conduct an investiga- tion under section 417(d)(1)(B) of the FD&C Act)? *To the best of your knowledge, has all of the reportable food been removed from commerce? What corrective actions have been taken to prevent future occurrences? *Do you believe the Reportable Food issue was intentionally caused? For the following questions, to protect privacy, do not identify individuals by name or address or other personally-identifiable information; instead, the responsible party should assign a code (e.g., the patient's initials) to each adverse event. The assigned code in the personal party needs to follow-up. *Has a human adverse event been reported? Please select *Has an animal adverse event been reported? Please select *You are required to give a full account of the Reportable Food issue including the current status, investigation progress or results to date, and any other relevant details as to the cause. If known, include what the problem is, how it happened, any contributing factors, and how long this problem has been occurring. If known, specify if the problem involves biological, physical, radiological or chemical adulteration. | My Report History | *How did your site first learn about the Reportable Food? | Please select | • |
| DABE Expiration Date: OMB Burden Statement *What did your investigation identify as the root cause of the problem (if you were required to conduct an investigation under section 417(d)(f)(B) of the FD&C Act)? *To the best of your knowledge, has all of the reportable food been removed from commerce? What corrective actions have been taken to prevent future occurrences? *Do you believe the Reportable Food issue was intentionally caused? For the following questions, to protect privacy, do not identify individuals by name or address or other personally-identifiable information; instead, the responsible party should assign a code (e.g., the patient's initials) to each adverse event. The assigned code will permit the responsible party needs to follow-up. *Has a human adverse event been reported? Please select *Has an animal adverse event been reported? Please select *You are required to give a full account of the Reportable Food issue including the current status, investigation progress or results to date, and any other relevant details as to the cause. If known, include what the problem is, how it happened, any contributing factors, and how long this problem has been occurring. If known, specify if the problem involves biological, physical, radiological or chemical adulteration. | | *Reason this food is reportable (agent) | Foreign Object | v |
| the problem (if you were required to conduct an investigation under section 417(d)(1)(B) of the FD&C Act)? *To the best of your knowledge, has all of the reportable food been removed from commerce? What corrective actions have been taken to prevent future occurrences? *Do you believe the Reportable Food issue was intentionally caused? For the following questions, to protect privacy, do not identify individuals by name or address or other personally-identifiable information; instead, the responsible party should assign a code (e.g., the patient's initials) to each adverse event. The assigned code will permit the responsible party to cross-reference identifying information and contact information for the patient in the event that the responsible party needs to follow-up. *Has a human adverse event been reported? Please select *You are required to give a full account of the Reportable Food issue including the current status, investigation progress or results to date, and any other relevant details as to the cause. If known, include what the problem is, how it happened, any contributing factors, and how long this problem has been occurring. If known, specify if the problem involves biological, physical, radiological or chemical adulteration. | OMB Expiration 09/30/2013 | *What did your investigation identify as the root cause of | | |
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| information; instead, the responsible party should assign a code (e.g., the patient's initials) to each adverse event. The assigned code will permit the responsible party to cross-reference identifying information and contact information for the patient in the event that the responsible party needs to follow-up. *Has a human adverse event been reported? Please select *You are required to give a full account of the Reportable Food issue including the current status, investigation progress or results to date, and any other relevant details as to the cause. If known, include what the problem is, how it happened, any contributing factors, and how long this problem has been occurring. If known, specify if the problem involves biological, physical, radiological or chemical adulteration. | | The second secon | Please select | • |
| *Has an animal adverse event been reported? Please select *You are required to give a full account of the Reportable Food issue including the current status, investigation progress or results to date, and any other relevant details as to the cause. If known, include what the problem is, how it happened, any contributing factors, and how long this problem has been occurring. If known, specify if the problem involves biological, physical, radiological or chemical adulteration. | | information; instead, the responsible party should assign a code code will permit the responsible party to cross-reference identif | e (e.g, the patient's initials) to each | n adverse event. The assigned |
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| | | progress or results to date, and any other relevant details it happened, any contributing factors, and how long this pr | as to the cause. If known, included the cause of the caus | lude what the problem is, how |
| | | ABC @ | | A |
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| | name, as printed on the product label or the product itself.) | t | | 4 | |
|---|---|--------|---|----------|--------------------|
| Welcome B. Red Name: Manda Food R | *Product Type | | Please select | ¥ | LOGOUT |
| 1005 o 110-85 ID: 9470 (| Package Category | | Bulk Institutional Retail | | |
| Created: 04/13/ | Container Type (please describe the smallest contain available for retail sale or further distribution) | iner | Please select | • | ren the |
| ☑ Contact Inf | Container Size (please describe the smallest container available for retail sale or further distribution) | | Select Unit of Measure | • | |
| Problem Sur | Universal Product Code (UPC) from label | | | | Back Next > |
| ☐ Distribution☐ Supplier Inf | *Manufacturing/Production Date(s) | Start | End | 13 | |
| □ Attachment | *Product Commodity Type | Please | e select 🔻 | | iminal penalties.) |
| My Report His OMB Approval Number: OMB Expiration | *How did you determine which products/lots/batchesaffected? | s were | | lo | |
| OMB Burden Stat | *Use-by dates, if any, or approximate Shelf Life | | 12 | | |
| | *Intended Product Use | | Animal | • | |
| | *Animal Species Intended For | | <checkboxes for="" species="" various=""></checkboxes> | | |
| | *Lifestage of Animal Intended For | | <checkboxes for="" lifestages="" various=""></checkboxes> | | |
| | *Did you receive the reportable food from an outsid source? | le | Yes | V | |
| | Have you notified all immediate previous sources of this reportable food? | | ○ Yes ○ No ○ Unknown ○ Other | | |
| | *Was the product recalled? | | Please select | • | |
| | *Was the product distributed in any other form to another location? | | Yes | V | |
| | *Have you notified all immediate subsequent recipients of this reportable food? | | ○ Yes ○ No ○ Unknown ○ Other | | |
| | | | Save | Cancel | |