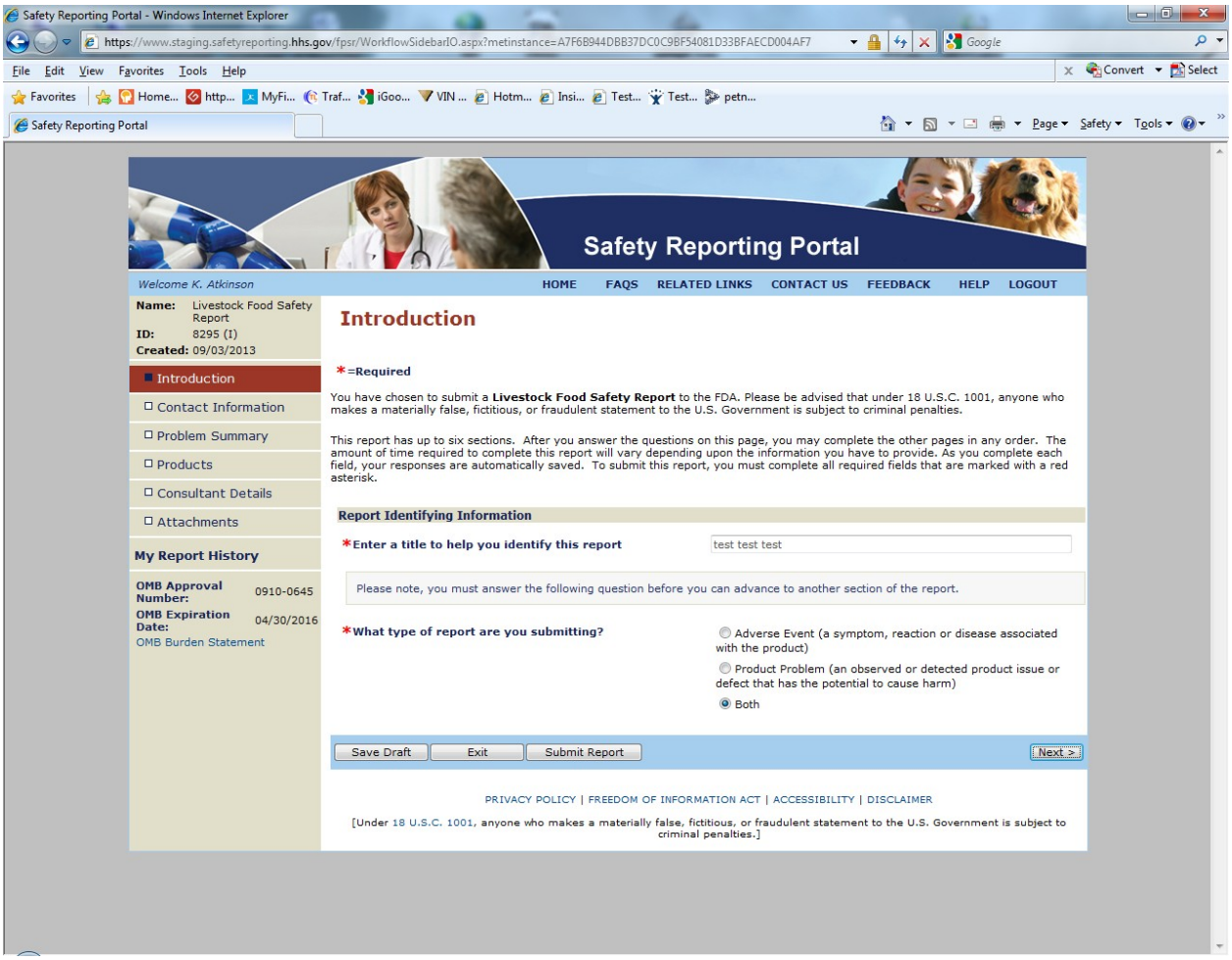
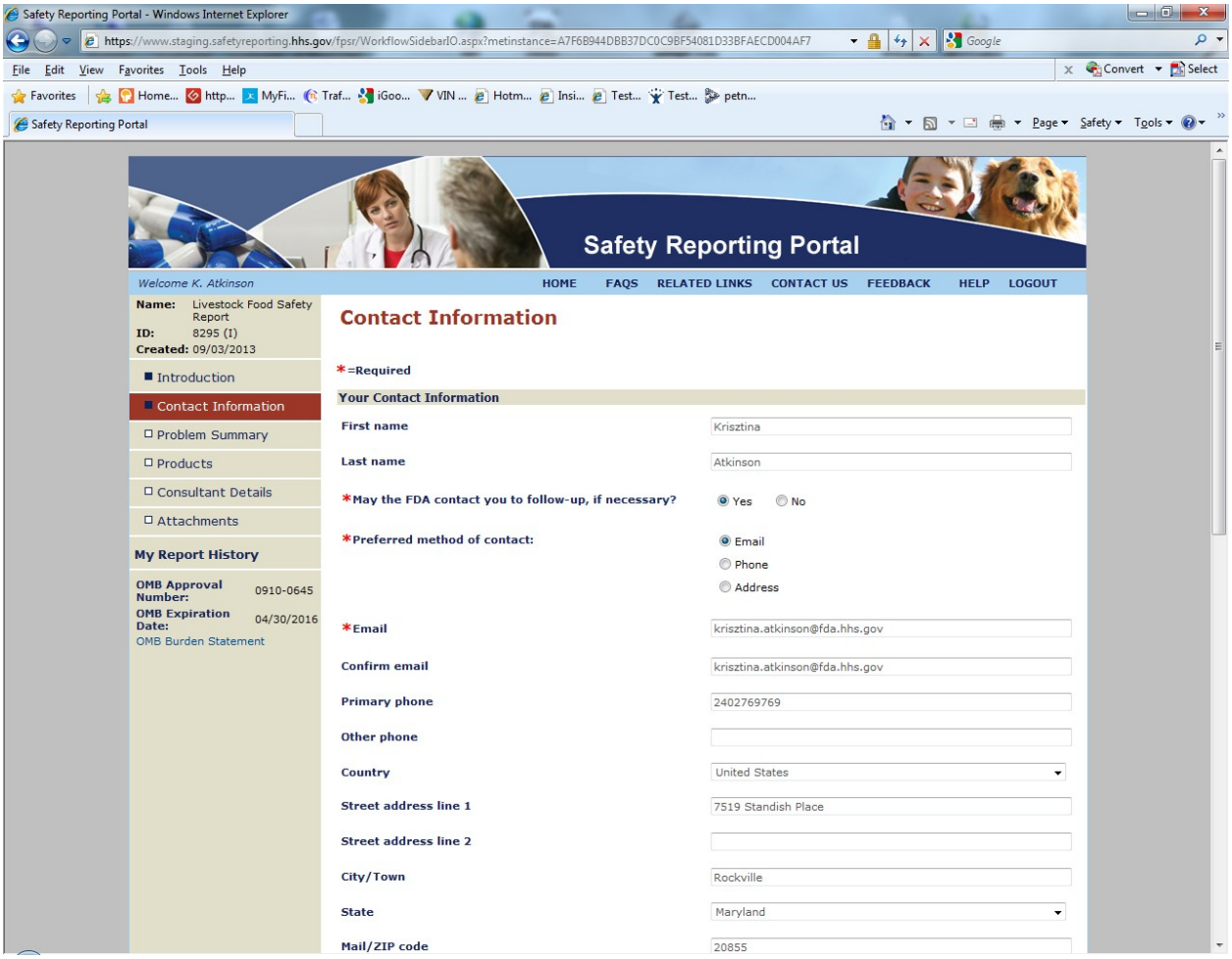
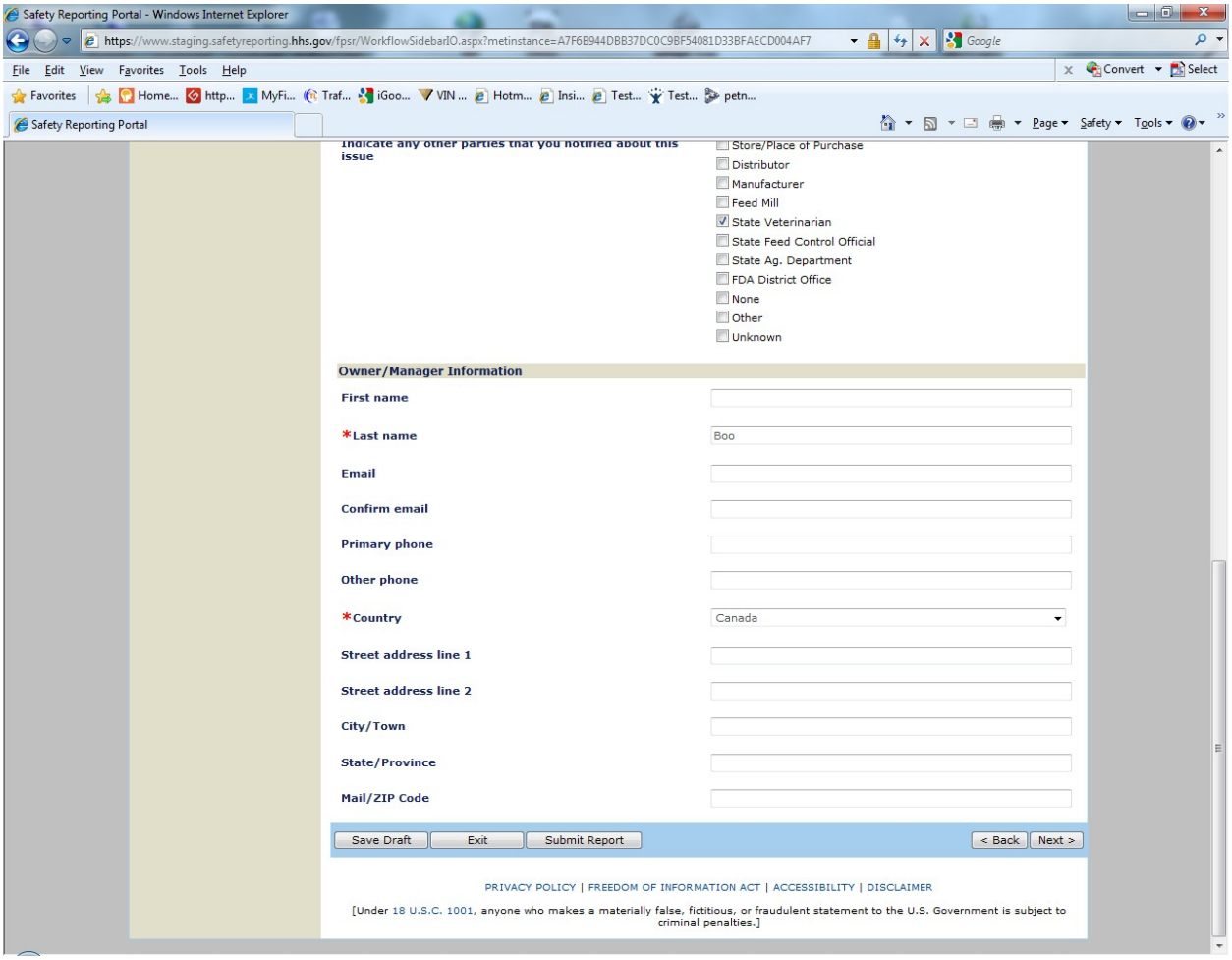
Electronic Submission of Food and Drug Administration Adverse Event Reports and Other Safety Information Using the Electronic Submission Gateway and the Safety Reporting Portal - Control No. 0910-0645

Sample Screen Shots for Livestock Food Reports




Safety Reporting Portal - Windows Internet Explorer
https://www.staging.safetyreporting.hhs.gov/fpsr/WorkflowSidebarIO.aspx?metinstance=A7F6B944DBB37DC0C9BF54081D33BFAECD004AF7
File Edit View Favorites Tools Help
Favorites
Safety Reporting Portal
Safety Reporting Portal
Welcome K. Atkinson
HOME FAQS RELATED LINKS CONTACT US FEEDBACK HELP LOGOUT
Name: Livestock Food Safety Report
ID: 8295 (I)
Created: 09/03/2013
Introduction
Contact Information
Problem Summary
Products
Consultant Details
Attachments
My Report History
OMB Approval Number: 0910-0645
OMB Expiration Date: 04/30/2016
OMB Burden Statement
Contact Information
*=Required
Your Contact Information
First name Krisztina
Last name Atkinson
*May the FDA contact you to follow-up, if necessary? Yes No
*Preferred method of contact: Email Phone Address
*Email krisztina.atkinson@fda.hhs.gov
Confirm email krisztina.atkinson@fda.hhs.gov
Primary phone 2402769769
Other phone
Country United States
Street address line 1 7519 Standish Place
Street address line 2
City/Town Rockville
State Maryland
Mail/ZIP code 20855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File Edit View Favorites Tools Help
Safety Reporting Portal
Indicate any other parties that you notified about this issue
Store/Place of Purchase
Distributor
Manufacturer
Feed Mill
State Veterinarian
State Feed Control Official
State Ag. Department
FDA District Office
None
Other
Unknown
Owner/Manager Information
First name
*Last name
Boo
Email
Confirm email
Primary phone
Other phone
*Country
Canada
Street address line 1
Street address line 2
City/Town
State/Province
Mail/ZIP Code
Save Draft
Exit
Submit Report
< Back
Next >
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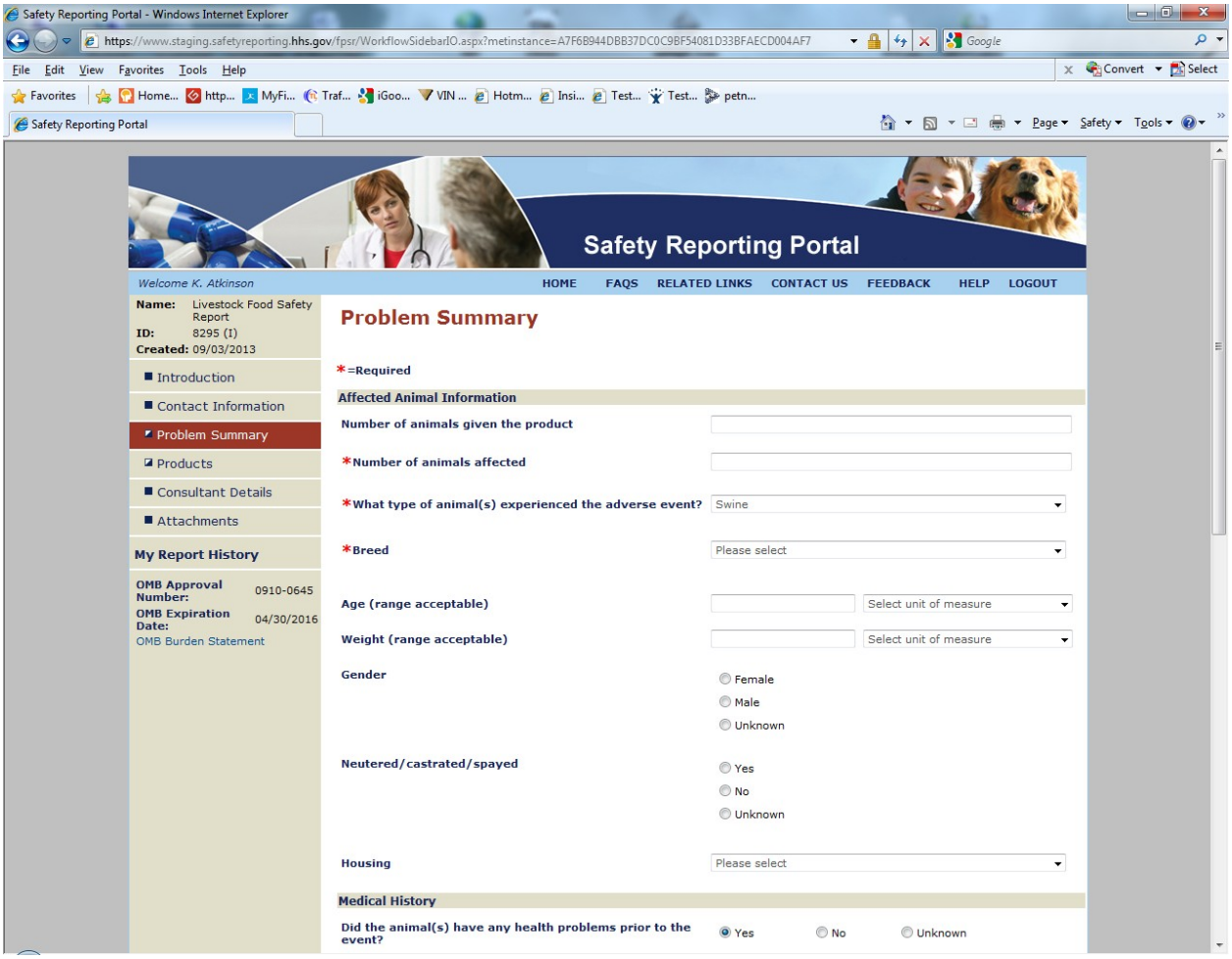
[Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.]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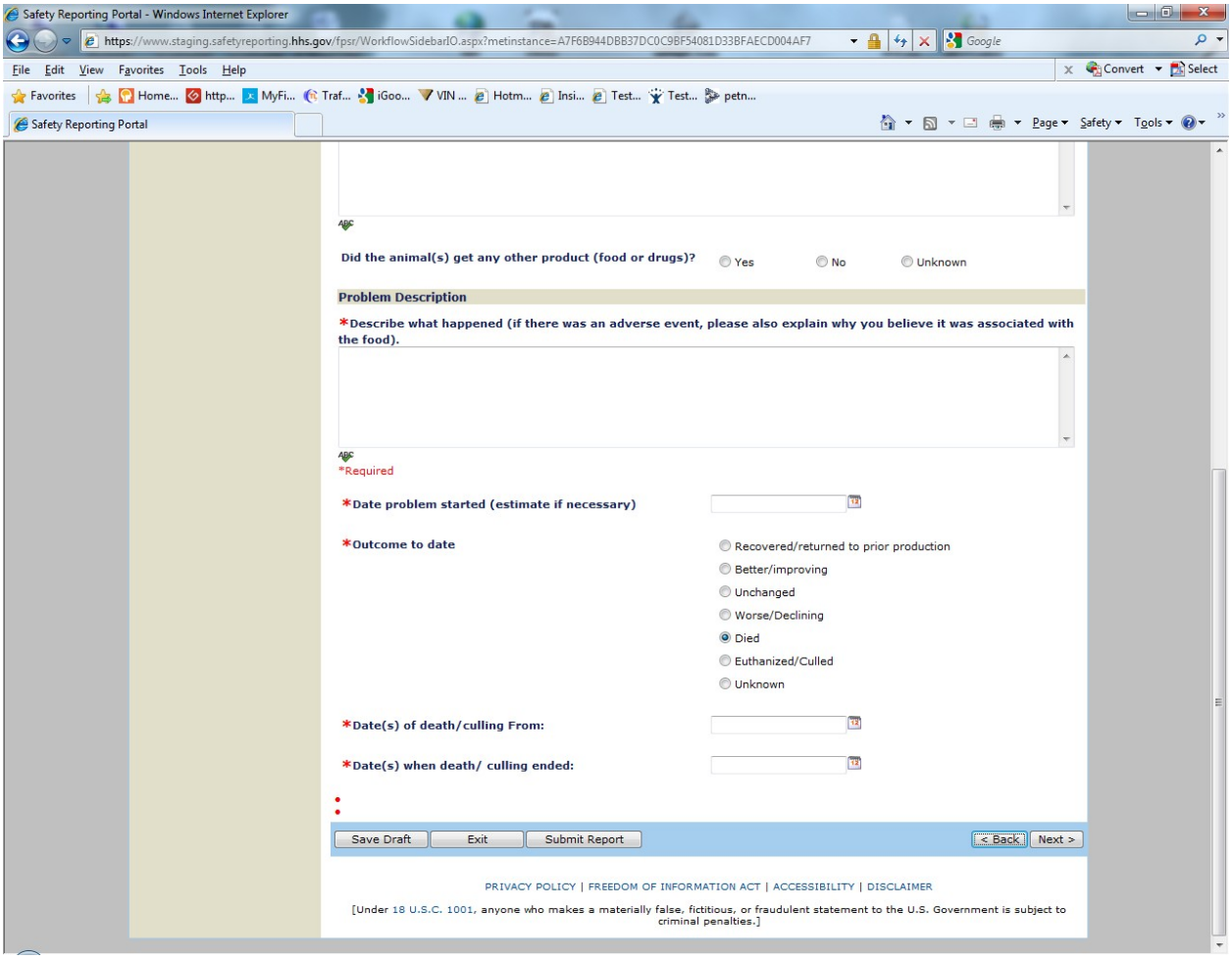
OMB Approval Number: 0910-0645
OMB Expiration Date: 04/30/2016
OMB Burden Statement
Problem Summary
*=Required
Affected Animal Information
Number of animals given the product
*Number of animals affected
*What type of animal(s) experienced the adverse event? Swine
*Breed Please select
Age (range acceptable) Select unit of measure
Weight (range acceptable) Select unit of measure
Gender Female Male Unknown
Neutered/castrated/spayed Yes No Unknown
Housing Please select
Medical History
Did the animal(s) have any health problems prior to the event? Yes No Unknown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Safety Reporting Portal
Did the animal(s) get any other product (food or drugs)?
Yes
No
Unknown
Problem Description
*Describe what happened (if there was an adverse event, please also explain why you believe it was associated with the food).
*Required
*Date problem started (estimate if necessary)
*Outcome to date
Recovered/returned to prior production
Better/improving
Unchanged
Worse/Declining
Died
Euthanized/Culled
Unknown
*Date(s) of death/culling From:
*Date(s) when death/ culling ended:
Save Draft
Exit
Submit Report
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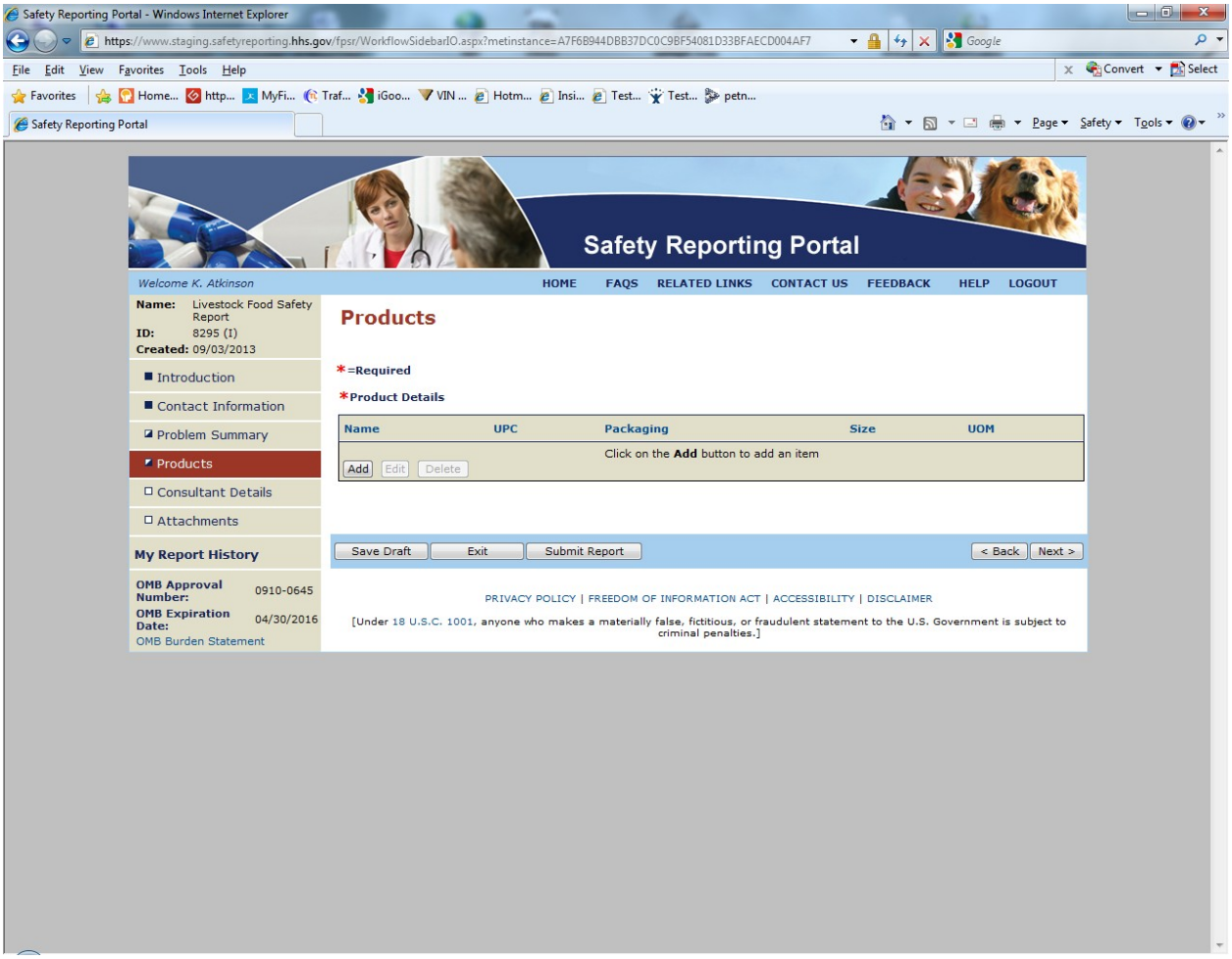
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OMB Expiration Date: 04/30/2016
OMB Burden Statement
Products
*=Required
*Product Details
Name UPC Packaging Size UOM
Click on the Add button to add an item
Add Edit Delete
Save Draft Exit Submit Report
< Back Next >
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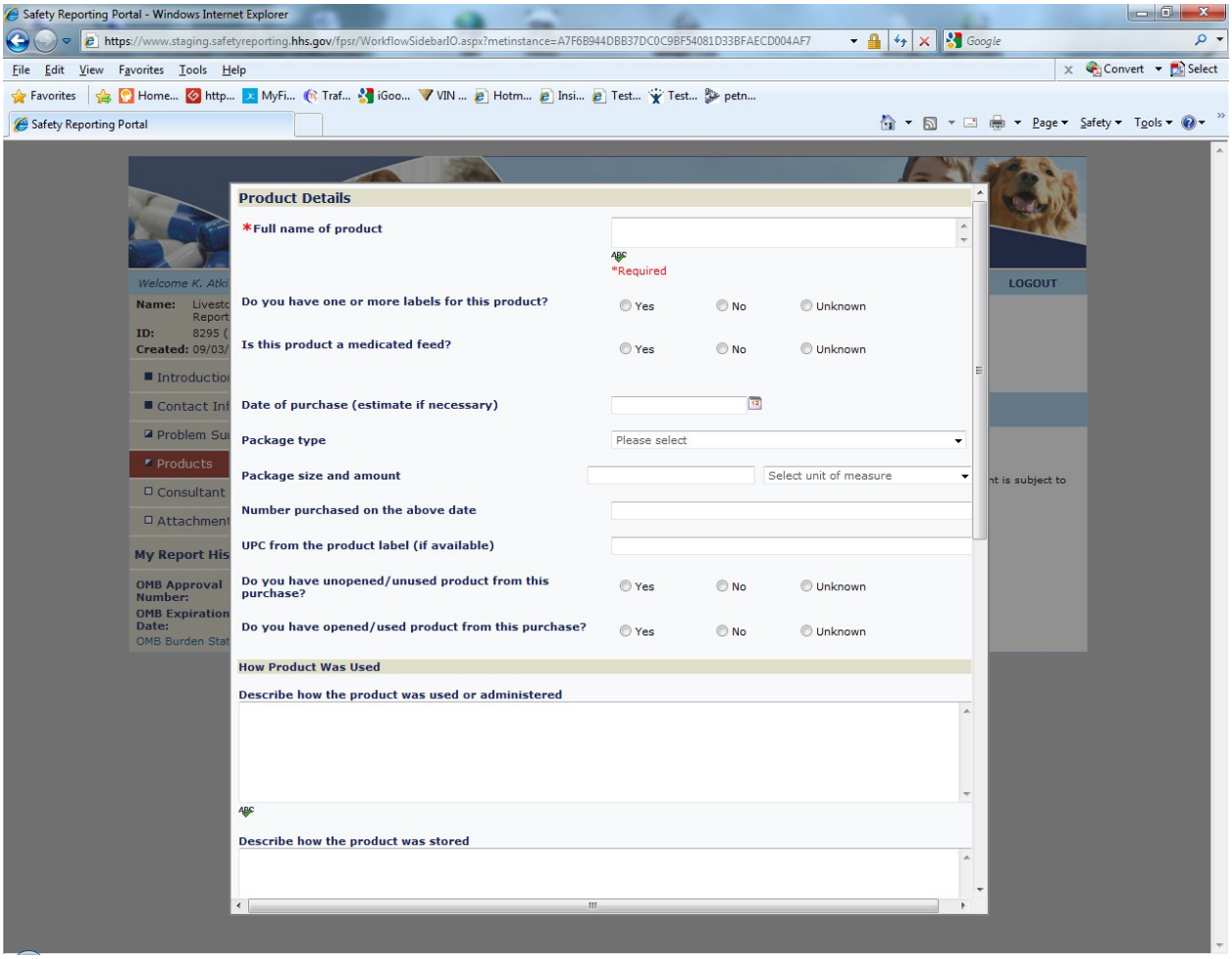
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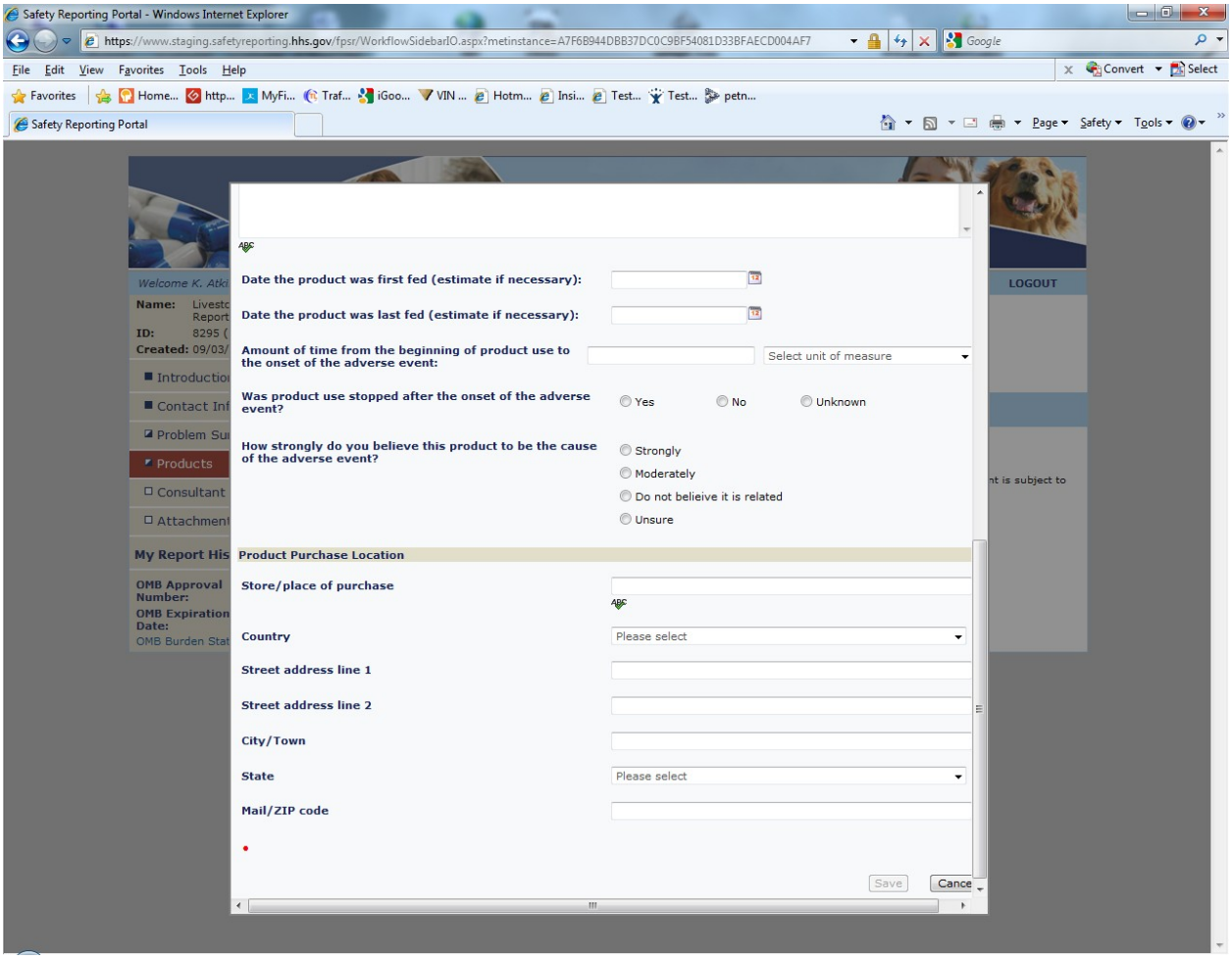
OMB Approval Number:
OMB Expiration Date:
OMB Burden Stat
Product Details
*Full name of product
*Required
Do you have one or more labels for this product?
Yes No Unknown
Is this product a medicated feed?
Yes No Unknown
Date of purchase (estimate if necessary)
Package type
Please select
Package size and amount
Select unit of measure
Number purchased on the above date
UPC from the product label (if available)
Do you have unopened/unused product from this purchase?
Yes No Unknown
Do you have opened/used product from this purchase?
Yes No Unknown
How Product Was Used
Describe how the product was used or administered
Describe how the product was stored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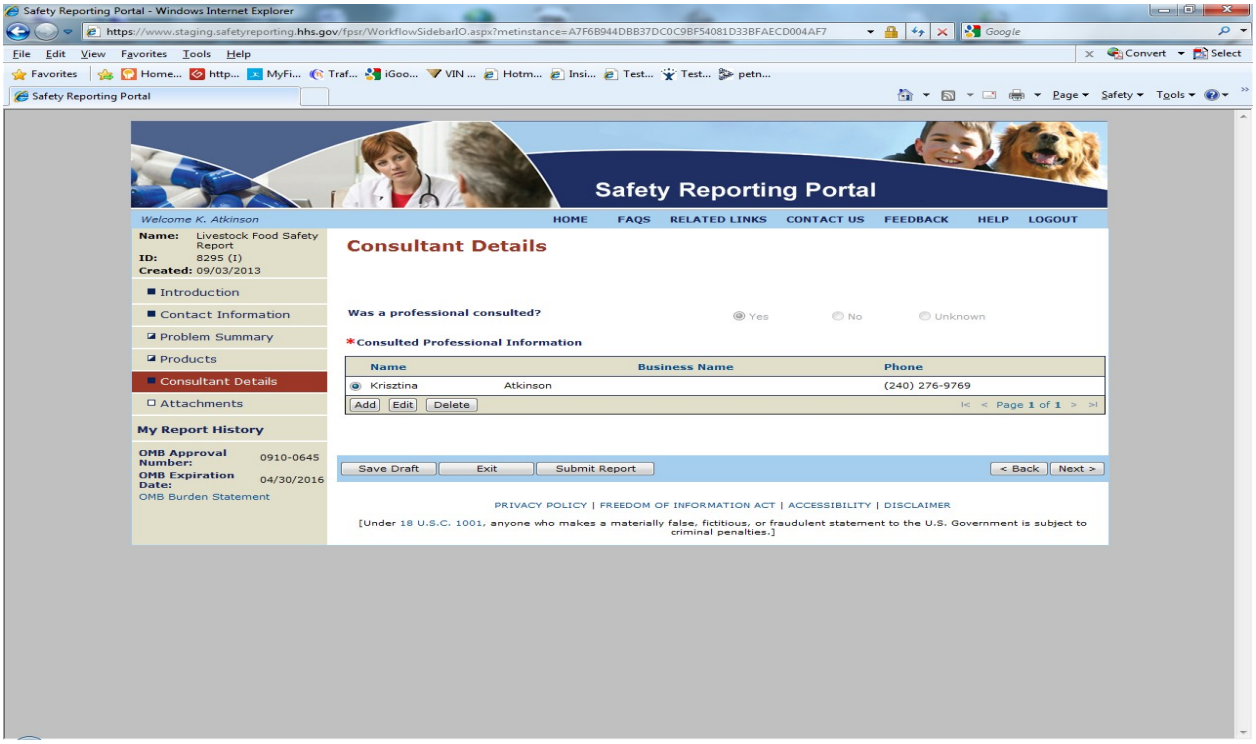
OMB Approval Number:
OMB Expiration Date:
OMB Burden Stat
Date the product was first fed (estimate if necessary):
Date the product was last fed (estimate if necessary):
Amount of time from the beginning of product use to the onset of the adverse event:
Select unit of measure
Was product use stopped after the onset of the adverse event?
Yes
No
Unknown
How strongly do you believe this product to be the cause of the adverse event?
Strongly
Moderately
Do not belieive it is related
Unsure
Product Purchase Location
Store/place of purchase
Country
Please select
Street address line 1
Street address line 2
City/Town
State
Please select
Mail/ZIP code
Save
Cance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OMB Expiration Date: 04/30/2016
OMB Burden Statement
Consultant Details
Was a professional consulted?
Yes No Unknown
*Consulted Professional Information
Name Business Name Phone
Krisztina Atkinson (240) 276-9769
Add Edit Delete
Page 1 of 1
Save Draft Exit Submit Report < Back Next >
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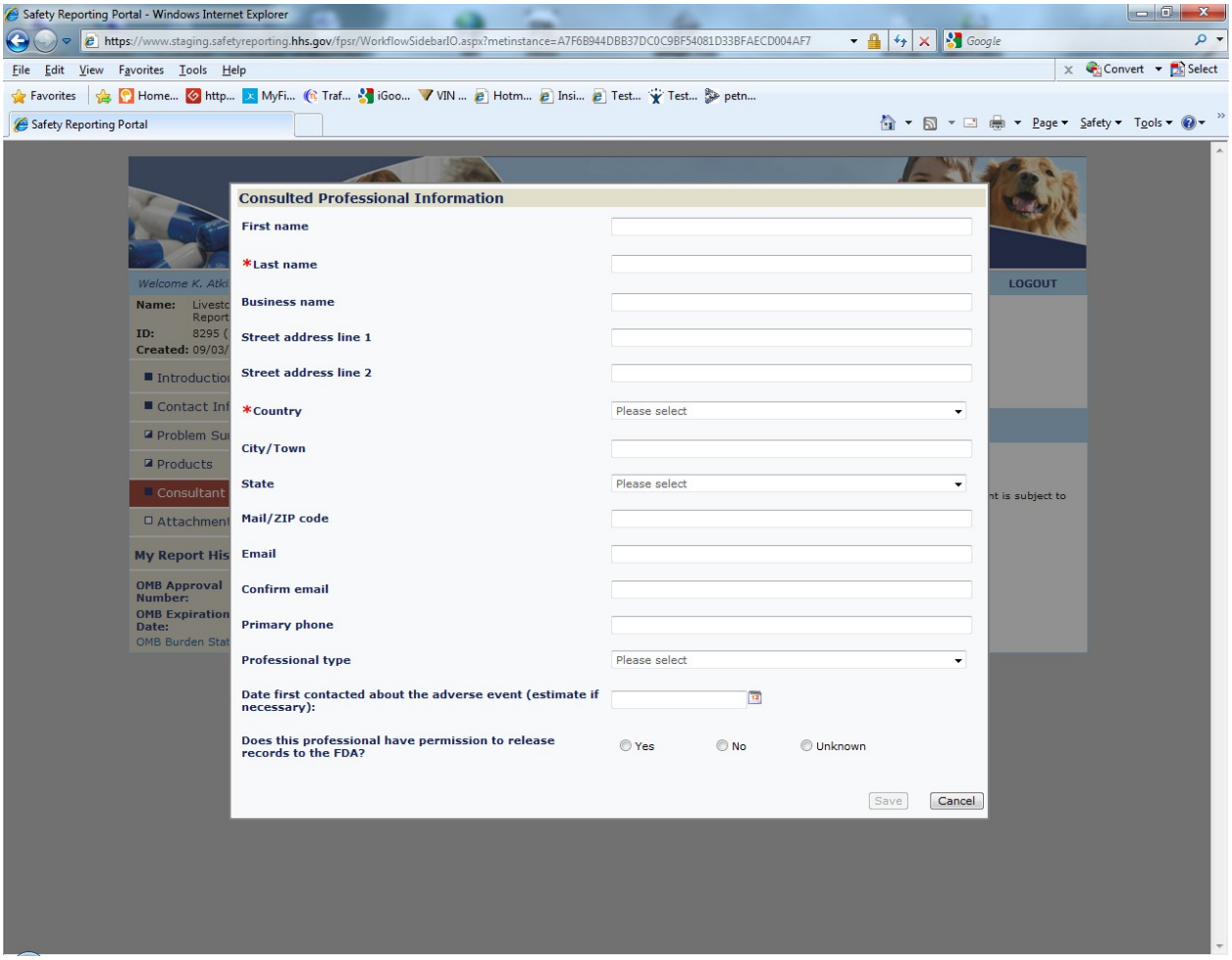
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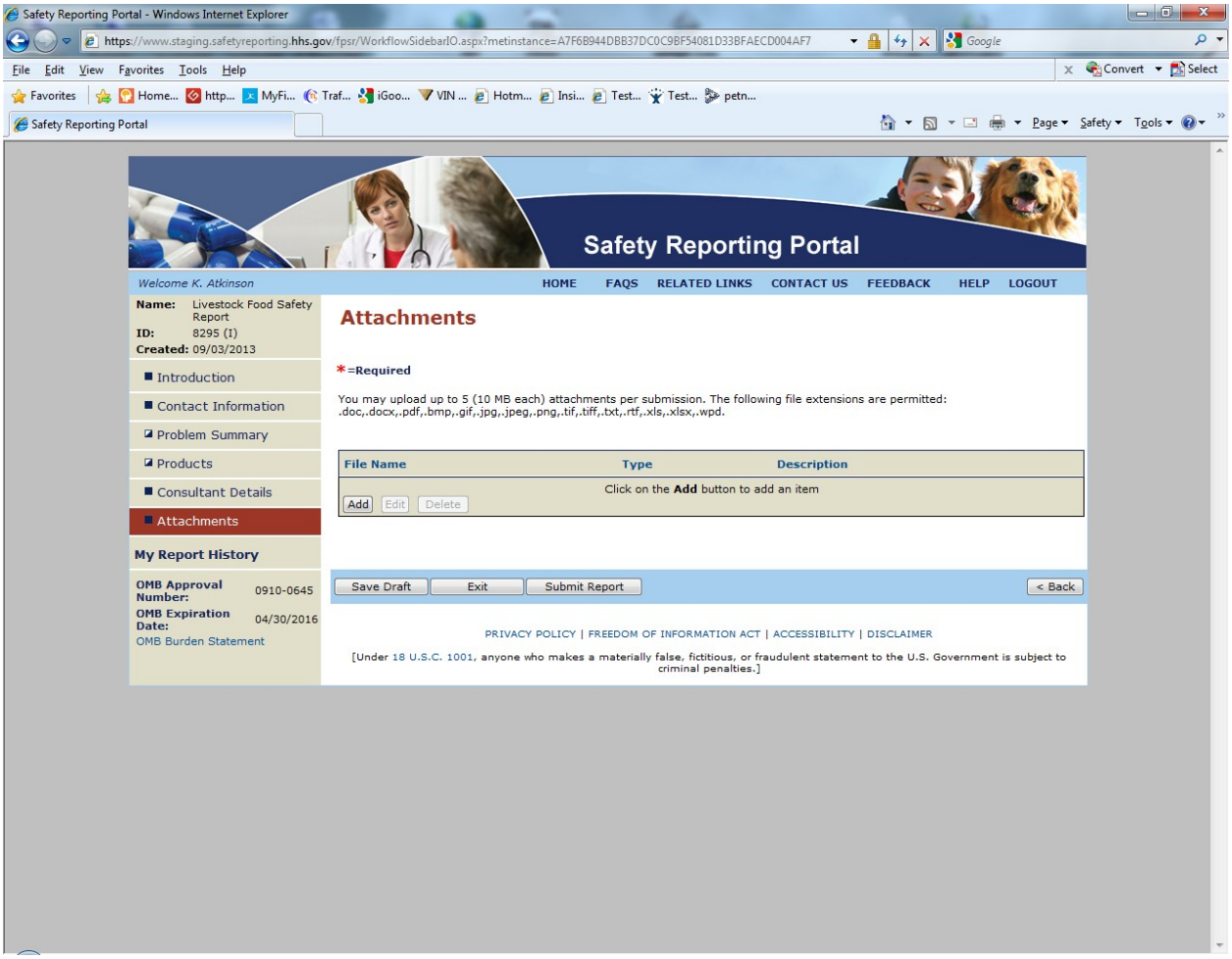
Consulted Professional Information
First name
*Last name
Business name
Street address line 1
Street address line 2
*Country
Please select
City/Town
State
Please select
Mail/ZIP code
Email
Confirm email
Primary phone
Professional type
Please select
Date first contacted about the adverse event (estimate if necessary):
Does this professional have permission to release records to the FDA?
Yes No Unknown
Save Cancel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OMB Burden Statement
Attachments
*=Required
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File Name
Type
Description
Click on the Add button to add an item
Add
Edit
Delete
Save Draft
Exit
Submit Report
< Back
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