

1.1 90 DAYS EXEMPT SUBMISSION

**FDA CFSAN IFTRACK II Mockups** WF.IFTRACK II\_01\_LogIn

Purpose: To access the system manufacturer will enter username and password

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FDA Infant Formula Tracking System

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Please Enter your Username and Password

Username

Password

FDA Infant Formula Tracking System

http://

**Form FDA 3978**

Welcome to the Infant Formula Tracking Application  
PAPERWORK REDUCTION ACT NOTICE  
Form Approval: OMB No. 0910-XXXX  
Expiration date: mm/dd/yyyy

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The time required to complete this collection of information is estimated to average 4-10 hours per response, including the time to review instructions, search existing data resources, gather and maintain the data needed, and complete and review the information collection. Send comments about this burden estimate or any other aspect of this collection of information, including suggestions for reducing the paper burden to:


Department of Health and Human Services  
Food and Drug Administration  
Office of Operations  
Paperwork Reduction Act (PRA) Staff  
PRASStaff@fda.hhs.gov

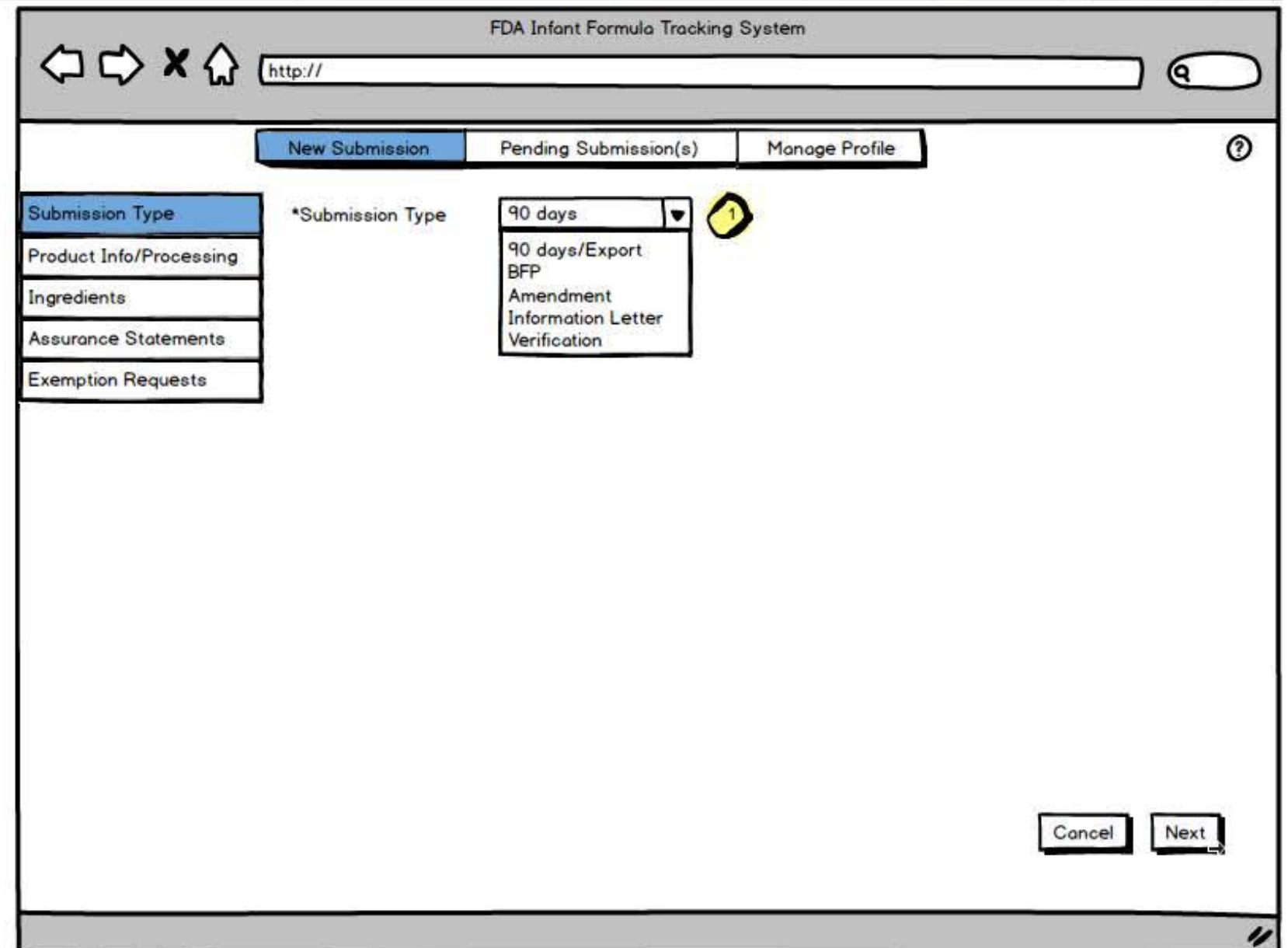
Next

### FDA CFSAN IFTRACK II Wireframes


### WF.IFTRACK II.1A\_90Days SubmissionType

Purpose: To initiate a new Submission , manufacturer will select Submission Type first

 Different fields will be displayed based on the Submission type selected.



The wireframe shows a web browser window titled "FDA Infant Formula Tracking System". The address bar contains "http://". Below the browser window is a navigation bar with three tabs: "New Submission" (highlighted in blue), "Pending Submission(s)", and "Manage Profile". A help icon (?) is located on the right side of the navigation bar. The main content area features a table with the following rows:

Submission Type	*Submission Type	90 days 
Product Info/Processing		90 days/Export
Ingredients		BFP
Assurance Statements		Amendment
Exemption Requests		Information Letter
		Verification

At the bottom right of the main content area, there are two buttons: "Cancel" and "Next". A small icon is visible in the bottom right corner of the browser window frame.

FDA CFSAN IFTRACK II Wireframes

WF.IFTRACK II.2B\_90 days\_Exempt\_Processing

Purpose: To enter product and ingredients information.

- 1. The user will be able to add multiple Manufacturing Plants
- 2. The user will be able to add multiple Products for each Manufacturing Plant.
- 3. The user will be able to add multiple Physical forms for each Product.
- 4. The user will be able to add multiple Containers for each Physical Form.
- 5. The user will be required to enter Proposed Product Name if Product Name Change is selected.
- 6. 1. The following values for IF Description are hidden if Non-Exempt is selected for Domestic Category :  
Amino Acid  
Carbohydrate free  
Human Milk Supplement  
Hypoallergenic  
In-hospital preterm  
Metabolic  
Post -hospital preterm
- 7. 2. The user will be able to add more than one value under IF Description field.
- 8. 1. The user will be able to add more than one value under IF Explanation field.  
2. The user will be able to select the following values for 90 Days (Exempt) IF Explanation:  
New Infant formula (new to market)  
New Form  
Major Formulation Changes  
New manufacturer  
New plant  
New contractor plant  
Major processing change  
Major packaging change  
Medical condition changes  
Other
  - Non major processing change
  - Non-major packaging change
  - Non-major reformulation
  - Label/labeling changes
- 9. 3. IF Explanation/Other will only be displayed as a selection if any other/primary value for IF Explanation has been selected.
- 10. The user will be required to enter Distributor Name if Distributor Change has been selected.
- 11. 1. Type of Processing Change is only required if Major processing change and/or Non Major processing change are selected for 90 days/IF Explanation.  
2. The user will be able to add more than one value under Type of Processing Change field.
- 12. The user will be required to add either Processing comments or Processing documentation if Major processing change and/or Non Major processing change is selected for all submission types.
- 13. The user will be required to add either Packaging comments or Packaging documentation if Major or Non-major packaging change is selected for IF Explanation. For other IF Explanation types the selection will be optional.
- 14. Retail Availability field is required if Exempt is selected for Domestic Category.
- 15. 1. The user will be required to add Medical Condition comment or documentation for Exempt IF.  
2. The user will be required to add Rationale comment or documentation for Exempt IF.  
3. The user will be required to add Labeling comment or attachment for Exempt IF.  
4. The user will be able to attach multiple documents under each category of documents: Medical Condition, Rationale, Labeling
- 16. The user will be required to enter processing, packaging information and quantitative formulation if New infant formula (new to market) or New form are selected for IF Explanation.  
The user will be required to enter processing information if New manufacturer , New plant, New Contractor Plant are selected for IF Explanation.

FDA Infant Formula Tracking System

http://

Submission Type	*Manufacturing Plant <input type="text" value="Georgia, VT"/> <input type="button" value="+"/>		
<b>Product Info/Processing</b>	*Product Name	<input type="text" value="Similac"/>	<input type="checkbox"/> Product Name Change
Ingredients	*IF Description	<input type="text" value="Low Iron"/> <input type="button" value="+"/>	
Assurance Statements	*Domestic Category	<input type="text" value="Exempt"/>	*Retail Availability <input type="text" value="Generally Available"/>
Exemption Requests	*IF Explanation	<input type="text" value="Major Formulation Changes"/> <input type="button" value="+"/>	
	*Medical Condition Comments	<input type="text"/>	
	*Rationale Comments	<input type="text"/>	
	Labeling Comments	<input type="text"/>	
	Documentation	<input type="button" value="Upload"/>	
	<input type="checkbox"/> Distributor Change		
	<b>Processing</b>	<input type="checkbox"/> Current Processing	
	*Type of Processing Change	<input type="text" value="Specific to each manufacturer"/> <input type="button" value="+"/>	
	Processing Comments	<input type="text"/>	
	*Documentation	<input type="button" value="Upload"/>	
	<b>Packaging</b>	<input type="checkbox"/> Current Packaging	
	*Physical Form	<input type="text" value="Concentrate"/> <input type="button" value="+"/>	Packaging Type <input type="text" value="Can"/>
	Container Quantity	<input type="text" value="0.61"/> <input type="text" value="Oz"/> <input type="button" value="+"/>	Shelf Life <input type="text" value="36 months"/>
	Current Pack. Supplier	<input type="text" value="-Select"/>	
	Proposed Pack. Supplier	<input type="text" value="-Select"/>	
	Packaging Comments	<input type="text"/>	
	*Documentation	<input type="button" value="Upload"/>	

### FDA CFSAN IFTRACK II Wireframes

### WF.IFTRACK II.3B\_Processing\_SubmissionRef#

Purpose: To enter Submission Reference Number if Packaging/Processing information has been already provided in the previous Submission

- 1 Submission Ref # field is required if the user selects Current Packaging or Current Processing option.
- 2 The user will be able to add more than one Submission Reference Number.

The wireframe depicts a web browser window titled "FDA Infont Formula Tracking System". The address bar shows "http://". A modal dialog box titled "Submission Reference Number" is centered on the screen. The dialog box contains the text "Enter Submission Reference Number" and a required field labeled "\*Submission Ref #". Below the input field are three buttons: "Cancel", "Save", and "Add Another". A callout circle with the number "1" points to the input field, and another callout circle with the number "2" points to the "Add Another" button.

### FDA CFSAN IFTRACK II Wireframes

### WF.IFTRACK II.3A\_Processing\_AddNewPhysicalForm

Purpose: To enter additional Physical form(s) for the same product

The wireframe shows a browser window titled "FDA Infant Formula Tracking System" with a search bar. A modal dialog box titled "Physical Form" is open, containing the following fields and controls:

- \*Physical Form:
- Container Quantity:
- Packaging Type:
- Shelf Life:

At the bottom of the dialog box are three buttons: , , and .

**FDA CFSAN IFTRACK II Wireframes**

**WF.IFTRACK II.4B\_90 days\_Exempt\_Ingredients**

Purpose: To enter ingredients information.

- 1. Ingredient Changes section will be required if Major Reformulation or Non major reformulation has been selected for IF Explanation on 90 days Non-Exempts, BFP Non-Exempts or Exports submissions.
- 2. Ingredient Changes section will be optional if Major Reformulation or Non major reformulation has been selected for IF Explanation on 90 days Exempts or BFP Exempts submissions.
- 3. The user will be required to add Description of IF Reformulation if major or non-major reformulation is selected for IF explanation for all 90 days Exempt/Non-exempt and BFP Exempt/Non-exempt submissions.
- 4. The user will be required to select Ingredient, Current and Proposed Quantity if Increase or Decrease are selected for Ingredient Change.
- 5. The user will be required to select Ingredient and Proposed Quantity if New is selected for Ingredient Change.
- 6. The user will be required to select Ingredient and Current Quantity if Removed is selected for Ingredient Change.
- 7. The user will be required to select Ingredient, Current and Proposed Quantity, Current and Proposed Ingr. Supplier if Supplier Change is selected for Ingredient Change.
- 8. The user will be required to upload Quantitative Formulation for all Exempt, 90 days Non-Exempt and Export submissions.
- 9. For BFP Non-Exempt submissions the user will be required to upload Quantitative Formulation or enter Submission Ref # .

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http://
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New Submission
Pending Submission(s)
Manage Profile
?

Submission Type			
Product Info/Processing	*Description of IF Reformulation <input style="width: 90%;" type="text"/>		
Ingredients	Ingredient Changes <span style="border: 1px solid black; border-radius: 50%; padding: 2px;">1</span>		
Assurance Statements	Ingredient Change	Supplier Change <span style="border: 1px solid black; border-radius: 50%; padding: 2px;">3</span>	*Ingredient <input style="width: 80%;" type="text" value="Iodine"/>
Exemption Requests	*Current Quantity	0.3 <input style="width: 20px;" type="text"/> Oz <span style="border: 1px solid black; border-radius: 50%; padding: 2px;">2</span>	*Proposed Quantity
		*Quantity Units	0.4 <input style="width: 20px;" type="text"/> Oz
		*Current Ingr. Supplier	*Proposed Ingr. Supplier
		-Select <span style="border: 1px solid black; border-radius: 50%; padding: 2px;">5</span>	<input style="width: 80%;" type="text"/>
Ingredient Comments <input style="width: 95%;" type="text"/>			
*Documentation <a href="#">Upload</a>			
Quantitative Formulation <span style="border: 1px solid black; border-radius: 50%; padding: 2px;">5</span>			
Quant. Formulation Comments <input style="width: 95%;" type="text"/>			
*Documentation <a href="#">Upload</a>			

Cancel Back Add Another Product Submit

## FDA CFSAN IFTRACK II Wireframes

## WF.IFTRACK II.7A\_AddAnotherProduct

Purpose: To enter additional product name.

- 1 The user will be allowed to add Another product after all information for the first product has been entered.
- 2 If the user selects "Same processing as previous product in the current submission" for Processing/packaging field, processing information will be automatically populated for the next product.  
If the user selects "Same packaging as previous product in the current submission" for Processing/packaging field, packaging information will be automatically populated for the next product.

The wireframe shows a browser window titled "FDA Infant Formula Tracking System" with a search bar containing "http://". Inside the browser is a dialog box titled "Add Another Product" with a close button (X). The dialog contains the following elements:

- Product Name:** A dropdown menu with the text "-Select" and a callout bubble labeled "1".
- Processing/packaging:** A dropdown menu with the text "Same processing as previous product in the current submission" and a callout bubble labeled "2". Below the dropdown are two options: "Same packaging as previous product in the current submission" and "Enter new product information".
- Buttons:** "Cancel" and "Save" buttons at the bottom right.



### FDA CFSAN IFTRACK II Wireframes

### WF.IFTRACK II.8A\_AssignedSubmissionRef#

Purpose: To view assigned Submission Reference Number



1.2 90 DAYS NON-EXEMPT SUBMISSION

### FDA CFSAN IFTRACK II Wireframes

WF.IFTRACK II. 01\_LogIn

Purpose: To access the system manufacturer will enter username and password

FDA Infant Formula Tracking System

http://

Please Enter your Username and Password

Username

Password

Log In

The screenshot shows a web browser window titled "FDA Infant Formula Tracking System". The address bar contains "http://". The main content area displays the following text:

**Form FDA 3978**

Welcome to the Infant Formula Tracking Application  
PAPERWORK REDUCTION ACT NOTICE  
Form Approval: OMB No. 0910-XXXX  
Expiration date: mm/dd/yyyy

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.


The time required to complete this collection of information is estimated to average 4-10 hours per response, including the time to review instructions, search existing data resources, gather and maintain the data needed, and complete and review the information collection. Send comments about this burden estimate or any other aspect of this collection of information, including suggestions for reducing the paper burden to:

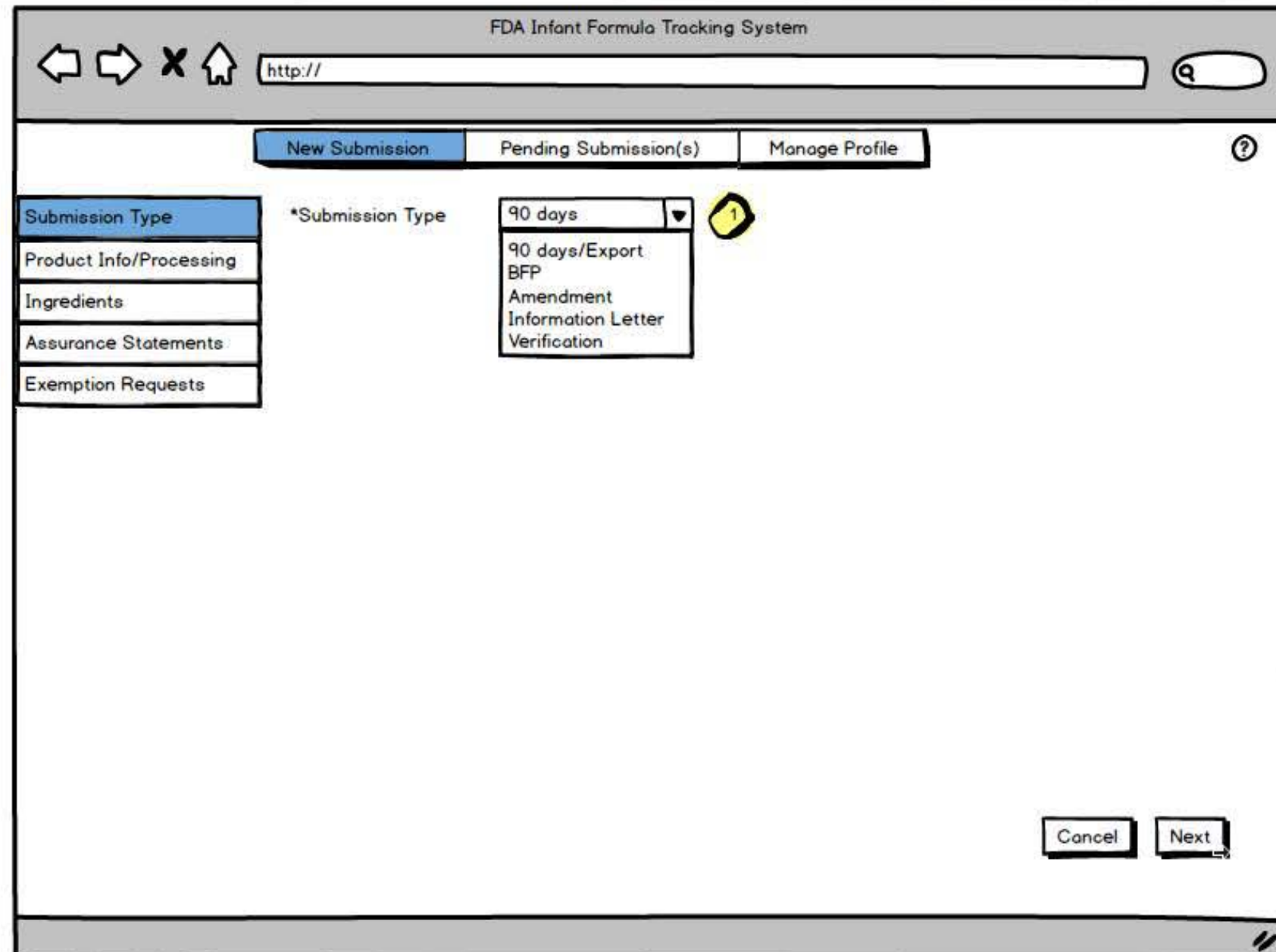
Department of Health and Human Services  
Food and Drug Administration  
Office of Operations  
Paperwork Reduction Act (PRA) Staff  
PRASStaff@fda.hhs.gov

### FDA CFSAN IFTRACK II Wireframes

### WF.IFTRACK II.1A\_90Days SubmissionType

Purpose: To initiate a new Submission , manufacturer will select Submission Type first

 Different fields will be displayed based on the Submission type selected.



The wireframe shows a web browser window titled "FDA Infant Formula Tracking System". The address bar contains "http://". Below the address bar are three tabs: "New Submission" (selected), "Pending Submission(s)", and "Manage Profile". A sidebar on the left lists "Submission Type" with options: "Product Info/Processing", "Ingredients", "Assurance Statements", and "Exemption Requests". The main content area has a label "\*Submission Type" followed by a dropdown menu. The dropdown menu is open, showing options: "90 days", "90 days/Export BFP", "Amendment", "Information Letter", and "Verification". A yellow callout bubble with the number "1" is positioned next to the dropdown menu. At the bottom right of the window are "Cancel" and "Next" buttons.

FDA CFSAN IFTRACK II Wireframes

WF.IFTRACK II.2A\_90 days\_Non Exempt\_Processing

Purpose: To enter product and ingredients information.

- 1 The user will be able to add multiple Manufacturing Plants
- 2 The user will be able to add multiple Products for each Manufacturing Plant.
- 3 The user will be able to add multiple Physical forms for each Product.
- 4 The user will be able to add multiple Containers for each Physical Form.
- 5 The user will be required to enter Proposed Product Name if Product Name Change is selected.
- 6 1. The following values for IF Description are hidden if Non-Exempt is selected for Domestic Category :  
Amino Acid  
Carbohydrate free  
Human Milk Supplement  
Hypoallergenic  
In-hospital preterm  
Metabolic  
Post -hospital preterm
- 7 2. The user will be able to add more than one value under IF Description field.
- 8 1. The user will be able to add more than one value under IF Explanation field.  
2. The user will be able to select the following values for 90 Days (non-exempt) IF Explanation:  
New Infant formula (new to market)  
New Form  
Major Formulation Changes  
New manufacturer  
New plant  
New contractor plant  
Major processing change  
Major packaging change  
Other
  - Non major processing change
  - Non-major packaging change
  - Non-major reformulation
- 9 3. IF Explanation/Other will only be displayed as a selection if any other/primary value for IF Explanation has been selected.
- 10 4. The user will be required to add the name of the plant and the address of the plant if New Plant or New Contractor Plant is selected.
- 11 The user will be required to enter Distributor Name if Distributor Change has been selected.
- 12 1. Type of Processing Change is only required if Major processing change and/or Non Major processing change are selected for 90 days/IF Explanation.  
2. The user will be able to add more than one value under Type of Processing Change field.
- 13 The user will be required to add either Processing comments or Processing documentation if Major processing change and/or Non Major processing change is selected for all submission types.
- 14 The user will be required to add either Packaging comments or Packaging documentation if Major or Non-major packaging change is selected for IF Explanation. For other IF Explanation types the selection will be optional.
- 15 The user will be allowed to add Labeling comment and attachment for Non- Exempt IF.
- 16 The user will be required to enter processing, packaging information and quantitative formulation if New infant formula (new to market) or New form are selected for IF Explanation.  
The user will be required to enter processing information if New manufacturer , New plant, New Contractor Plant are selected for IF Explanation.

FDA Infant Formula Tracking System

http://

New Submission Pending Submission(s) Manage Profile

Submission Type \*Manufacturing Plant Georgia, VT

Product Info/Processing \*Product Name Similac  Product Name Change

Ingredients \*IF Description Low Iron

Assurance Statements \*Domestic Category Non Exempt

Exemption Requests \*IF Explanation Major Formulation Changes

Labeling Comments

\*Documentation Upload

Distributor Change

Processing  Current Processing

\*Type of Processing Change Specific to each manufacturer

Processing Comments

\*Documentation Upload

Packaging  Current Packaging→

\*Physical Form Concentrate Packaging Type Can

Container Quantity 0.61 Oz Shelf Life 36 months

Current Pack. Supplier -Select Proposed Pack. Supplier

Packaging Comments

\*Documentation Upload

Cancel Back Next

### FDA CFSAN IFTRACK II Wireframes

### WF.IFTRACK II.3B\_Processing\_SubmissionRef#

Purpose: To enter Submission Reference Number if Packaging/Processing information has been already provided in the previous Submission

- 1 Submission Ref # field is required if the user selects Current Packaging or Current Processing option.
- 2 The user will be able to add more than one Submission Reference Number.

The wireframe depicts a web browser window titled "FDA Infant Formula Tracking System". The address bar shows "http://". A modal dialog box titled "Submission Reference Number" is open, containing the text "Enter Submission Reference Number" and a required field "\*Submission Ref #" with an input box. Below the input box are "Cancel", "Save", and "Add Another" buttons. Callout circles 1 and 2 highlight the input field and the "Add Another" button.

### FDA CFSAN IFTRACK II Wireframes

### WF.IFTRACK II. 3A\_Processing\_AddNewPhysicalForm

Purpose: To enter additional Physical form(s) for the same product

The screenshot shows a web browser window titled "FDA Infant Formula Tracking System". The browser's address bar contains "http://". A modal dialog box titled "Physical Form" is open, containing the following fields and controls:

- \*Physical Form: Powder (dropdown menu)
- Container Quantity: 0.80 (text input) and Oz (dropdown menu)
- Packaging Type: Can (dropdown menu)
- Shelf Life: 12 months (dropdown menu)

At the bottom of the dialog box, there are three buttons: "Cancel", "Save", and "Save and Add Another".

### FDA CFSAN IFTRACK II Wireframes

### WF.IFTRACK II.4A\_90 days\_Non Exempt\_Ingredients

Purpose: To enter ingredients information.

- 1. Ingredient Changes section will be required if Major Reformulation or Non major reformulation has been selected for IF Explanation on 90 days Non-Exempts, BFP Non-Exempts or Exports submissions.
- 2. Ingredient Changes section will be optional if Major Reformulation or Non major reformulation has been selected for IF Explanation on 90 days Exempts or BFP Exempts submissions.
- 3. The user will be required to add Description of IF Reformulation if major or non-major reformulation is selected for IF explanation for all 90 days Exempt/Non-exempt and BFP Exempt/Non-exempt submissions.
- 4. The user will be required to select Ingredient, Current and Proposed Quantity if Increase or Decrease are selected for Ingredient Change.
- 5. The user will be required to select Ingredient and Proposed Quantity if New is selected for Ingredient Change.
- 6. The user will be required to select Ingredient and Current Quantity if Removed is selected for Ingredient Change.
- 7. The user will be required to select Ingredient, Current and Proposed Quantity, Current and Proposed Ingr. Supplier if Supplier Change is selected for Ingredient Change.
- 8. The user will be required to upload Quantitative Formulation for all Exempt, 90 days Non-Exempt and Export submissions.
- 9. For BFP Non-Exempt submissions the user will be required to upload Quantitative Formulation or enter Submission Ref # .

FDA Infant Formula Tracking System

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New Submission Pending Submission(s) Manage Profile ?

Submission Type
Product Info/Processing
Ingredients
Assurance Statements
Exemption Requests

\*106.120(b)(4): Description of IF Reformulation

Ingredient Changes

<span style="font-weight: bold;">*Ingredient Change</span> <span style="border: 1px solid black; padding: 2px;">Supplier Change</span>	<span style="font-weight: bold;">*Ingredient</span> <span style="border: 1px solid black; padding: 2px;">Iodine</span> <span style="font-size: 10px;">▼</span> <span style="font-size: 10px;">+</span>
<span style="font-weight: bold;">*Current Quantity</span> <span style="border: 1px solid black; padding: 2px;">0.3</span> <span style="border: 1px solid black; padding: 2px;">Oz</span> <span style="font-size: 10px;">▼</span>	<span style="font-weight: bold;">*Proposed Quantity</span> <span style="border: 1px solid black; padding: 2px;">0.4</span> <span style="border: 1px solid black; padding: 2px;">Oz</span> <span style="font-size: 10px;">▼</span>
<span style="font-weight: bold;">*Quantity Units</span> <span style="border: 1px solid black; padding: 2px;">Per weight</span> <span style="font-size: 10px;">▼</span>	<span style="font-weight: bold;">*Proposed Ingr. Supplier</span> <input style="width: 80px;" type="text"/>
<span style="font-weight: bold;">*Current Ingr. Supplier</span> <span style="border: 1px solid black; padding: 2px;">-Select</span> <span style="font-size: 10px;">▼</span>	

Ingredient Comments

\*Documentation [Upload](#)

Quantitative Formulation

Quant. Formulation Comments

\*Documentation [Upload](#)

Cancel Back Next



**FDA CFSAN IFTRACK II Wireframes**

**WF.IFTRACK II.5A\_90Days\_Non Exempt\_QualityFactors**

Purpose: To select Quality Factors and enter Quality Factors information



Either doc or comments are required for 106.120 (b)(6)(ii)

FDA Infant Formula Tracking System

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New Submission
Pending Submission(s)
Manage Profile
?

Basic Info

Processing/Ingredients

Assurance Statements

Exemption Requests

**Quality Factors**

**106.120 (b)(5)(i)**

Assurance that the infant formula meets the requirements for quality factors of normal physical growth and sufficient biological quality of the formula's protein component

**Nutrient Content Requirements**

**106.120 (b)(5)(ii)**

Assurance that the formula complies with the nutrient content requirements

Documentation [Upload](#)      Comments

**Current GMP/Quality Control**

**106.120 (b)(6)(i)**

Assurance that the formula will be produced in accordance with Current Good Manufacturing Practices (Subpart B) and Quality Control Procedures (Subpart C)

**106.120 (b)(6)(ii)**

\*Documentation [Upload](#)      Comments

Cancel
Back
Next

FDA CFSAN IFTRACK II Wireframes

WF.IFTRACK II.6A\_90Days\_Non Exempt\_Exemption Requests

Purpose: To select Exemption Requests (if applicable)

- 1 The user will be required to select Exemption Requests for Normal Physical growth if Documentation for Quality Factor of Normal Physical Growth hasn't been provided.
- 2 The user will be required to select Exemption Requests for Biological Quality of Protein if Documentation for Quality Factor of Biological Quality of Protein hasn't been provided.
- 3 The user will be required to upload documentation or enter comments if any Exemption request has been selected.
- 4 The user is not allowed to select any other Exemption request if 106.121(b); 106.96 (c)(1): Exemption Request 1 for Normal Physical growth has been selected.
- 5 The user is allowed to select 106.121 (d); 106.96 (c)(2)(ii) : Exemption Request 3 for Normal Physical growth and/or 106.121 (c); 106.96 (c)(2)(i): Exemption Request 2 for Normal Physical growth if one of them is selected.
- 6 The user is allowed to select 106.121 (h); 106.96 (g)(2): Exemption Request 6 for Biological Quality of Protein and/or 106.121 (i); 106.96 (g)(3): Exemption Request 7 for Biological Quality of Protein if one of them is selected.
- 7 The user is not allowed to select any other Exemption request if 106.121 (d); 106.96 (c)(2)(iii): Exemption Request 4 for Normal Physical growth has been selected.
- 8 The user is not allowed to select any other Exemption request if 106.121 (g); 106.96 (g)(1): Exemption Request 5 for Biological Quality of Protein has been selected.

FDA Infant Formula Tracking System

http://

New Submission
Pending Submission(s)
Manage Profile

Basic Info

Processing/Ingredients

Assurance Statements

Exemption Requests

**Quality Factor of Normal Physical Growth** 1

106.121 (a)  
Quality Factors of Normal Physical Growth  
Documentation [Upload](#)

**Exemption Requests for Normal Physical growth**

106.121(b); 106.96 (c)(1): Exemption Request 1 for Normal Physical growth 4  
 Changes made by the manufacturer to an existing infant formula are limited to changing the type of packaging of an existing infant formula (e.g., changing from metal cans to plastic pouches)  
 Documentation [Upload](#) 3 Comments

106.121 (c); 106.96 (c)(2)(i): Exemption Request 2 for Normal Physical growth 5  
 The alternative method or study design based on sound scientific principles is available, and data demonstrate that the formula supports normal physical growth in infants when the formula is fed as the sole source of nutrition  
 Documentation [Upload](#) Comments

106.121 (d); 106.96 (c)(2)(ii) : Exemption Request 3 for Normal Physical growth  
 The change made by the manufacturer to an existing formula does not affect the ability of the formula to support normal physical growth  
 Documentation [Upload](#) Comments

106.121 (d); 106.96 (c)(2)(iii): Exemption Request 4 for Normal Physical growth 7  
 The manufacturer markets a formulation in more than one form (e.g., liquid and powdered forms) and the quality factor requirements are met by the form of the formula that is processed using the method that has the greatest potential for adversely affecting nutrient content and bioavailability.  
 Documentation [Upload](#) Comments

**Quality Factor of Biological Quality of Protein** 2

106.121 (f)  
Results of the Protein Efficiency Ratio bioassay  
Documentation [Upload](#)

**Exemption Requests for Biological Quality of Protein**

106.121 (g); 106.96 (g)(1): Exemption Request 5 for Biological Quality of Protein 8  
 The change or changes made by the manufacturer to an existing infant formula are limited to changing the type of packaging of an existing infant formula (e.g., changing from metal cans to plastic pouches)  
 Documentation [Upload](#) Comments

106.121 (h); 106.96 (g)(2): Exemption Request 6 for Biological Quality of Protein 6  
 The change or changes made by the manufacturer to an existing formula does not affect the bioavailability of a protein.  
 Documentation [Upload](#) Comments

106.121 (i); 106.96 (g)(3): Exemption Request 7 for Biological Quality of Protein  
 The alternative method used to satisfy the quality factor requirements is based on sound scientific principles, and the data demonstrate that the quality factor for the biological quality of the protein has been met  
 Documentation [Upload](#) Comments

**Assurance Statement**

106.121 (j)  
 Manufacturer has collected and considered all information and data concerning the ability of the infant formula to meet the requirements for quality factors and that the manufacturer is not aware of any information or data that would show that the formula does not meet the requirements for quality factors.

**Stability Exemption Request**

106.120 (b)(7)  
 Stability Testing Exemption  
 Documentation [Upload](#) Comments

Cancel Back Add Another Product Submit

## FDA CFSAN IFTRACK II Wireframes

## WF.IFTRACK II.7A\_AddAnotherProduct

Purpose: To enter additional product name.

- 1 The user will be allowed to add Another product after all information for the first product has been entered.
- 2 If the user selects "Same processing as previous product in the current submission" for Processing/packaging field, processing information will be automatically populated for the next product.  
If the user selects "Same packaging as previous product in the current submission" for Processing/packaging field, packaging information will be automatically populated for the next product.

FDA Infant Formula Tracking System

http://

Add Another Product

Product Name -Select 1

Processing/packaging Same processing as previous product in the current submission 2

Same packaging as previous product in the current submission

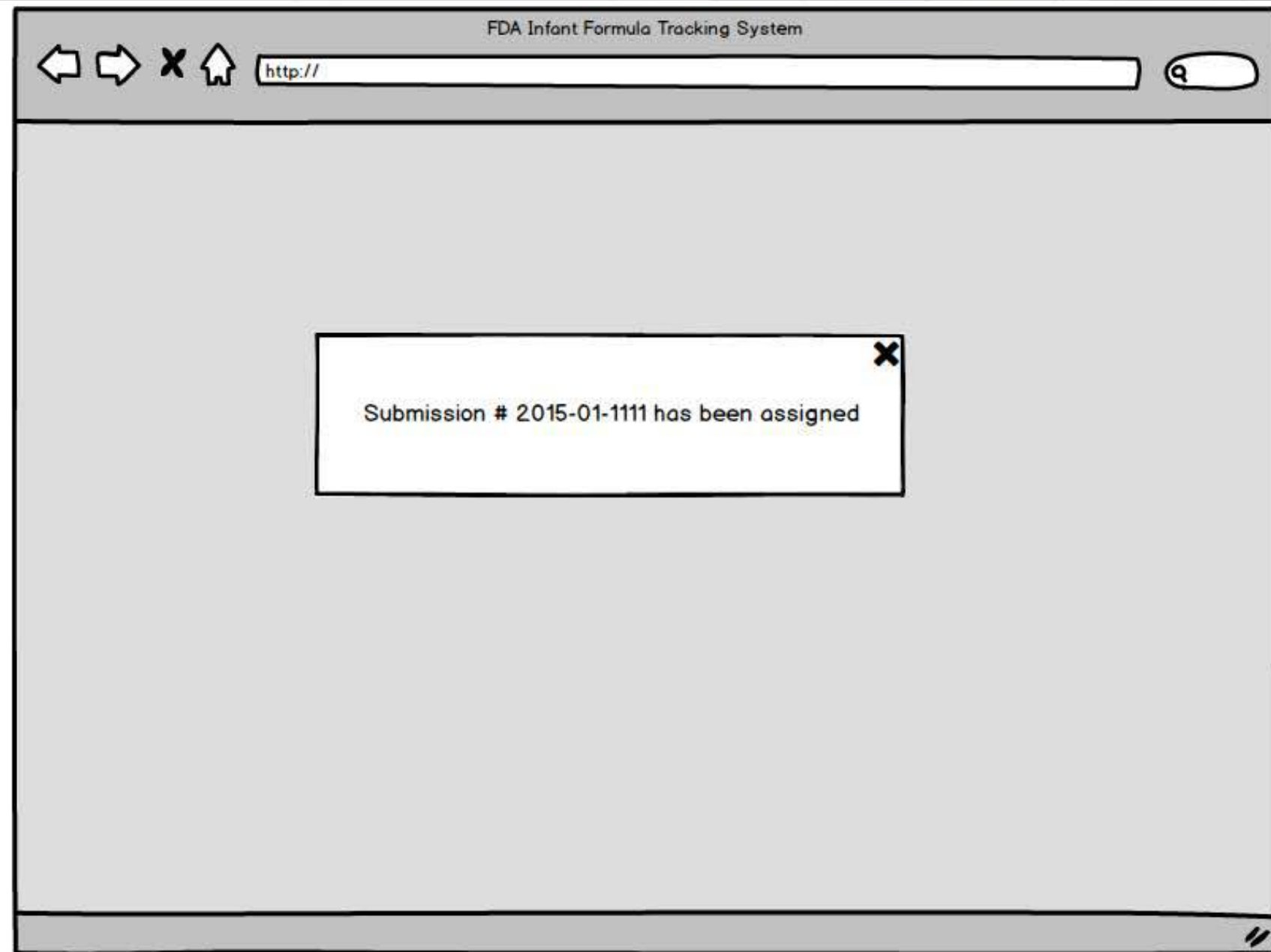
Enter new product information

Cancel Save

### FDA CFSAN IFTRACK II Wireframes

### WF.IFTRACK II.8A\_AssignedSubmissionRef#

Purpose: To view assigned Submission Reference Number



1.3 90 DAYS EXPORT SUBMISSION

**FDA CFSAN IFTRACK II Mockups** WF.IFTRACK II\_01\_LogIn

Purpose: To access the system manufacturer will enter username and password

---

FDA Infant Formula Tracking System

← → × ↶ http://

Please Enter your Username and Password

Username

Password

The screenshot shows a web browser window titled "FDA Infant Formula Tracking System". The address bar contains "http://". The main content area displays the following text:

**Form FDA 3978**

Welcome to the Infant Formula Tracking Application  
PAPERWORK REDUCTION ACT NOTICE  
Form Approval: OMB No. 0910-XXXX  
Expiration date: mm/dd/yyyy

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.


The time required to complete this collection of information is estimated to average 4-10 hours per response, including the time to review instructions, search existing data resources, gather and maintain the data needed, and complete and review the information collection. Send comments about this burden estimate or any other aspect of this collection of information, including suggestions for reducing the paper burden to:

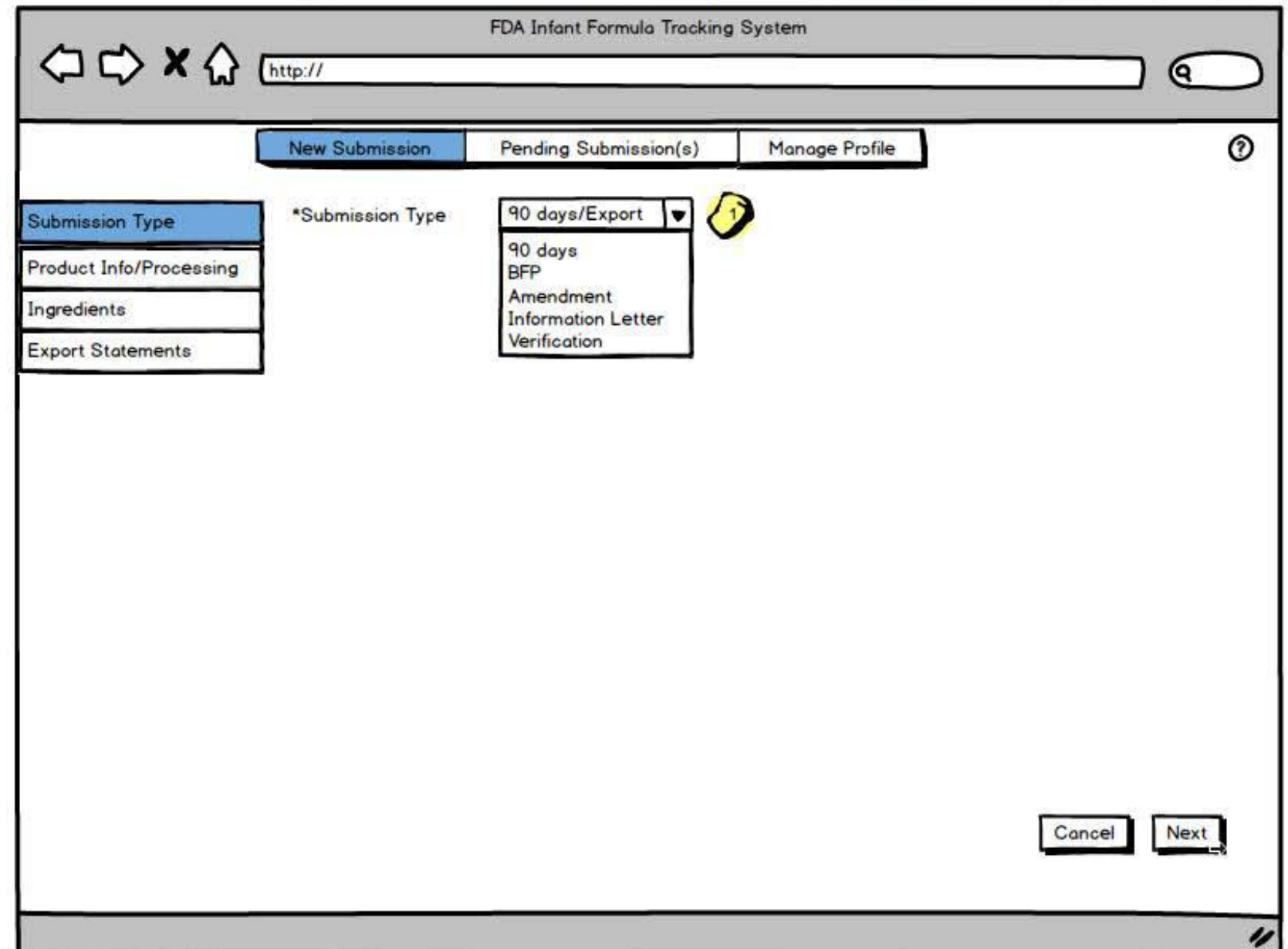
Department of Health and Human Services  
Food and Drug Administration  
Office of Operations  
Paperwork Reduction Act (PRA) Staff  
PRASStaff@fda.hhs.gov

### FDA CFSAN IFTRACK II Mockups

### WF.IFTRACK II.1C\_90Days\_Export\_SubmissionType

Purpose: To initiate a new Submission , manufacturer will select Submission Type first

 Different fields will be displayed based on the Submission type selected.



FDA Infant Formula Tracking System

http://

New Submission Pending Submission(s) Manage Profile

Submission Type

- Product Info/Processing
- Ingredients
- Export Statements

\*Submission Type

90 days/Export

- 90 days
- BFP
- Amendment
- Information Letter
- Verification

Cancel Next

WF.IFTRACK II.2E\_90Days\_Export\_Processing

Purpose: To enter product, processing and packaging information.

- The user will be able to add multiple Manufacturing Plants
- 1 The user will be able to add multiple Products for each Manufacturing Plant.  
The user will be able to add multiple Physical forms for each Product.
- 2 The user will be able to add multiple Containers for each Physical Form.  
The user will be required to enter Proposed Product Name if Product Name Change is selected.
- 3 1. The following values for IF Description are hidden if Non-Exempt is selected for Domestic Category :  
Amino Acid  
Carbohydrate free  
Human Milk Supplement  
Hypoallergenic  
In-hospital preterm  
Metabolic  
Post -hospital preterm  
2. The user will be able to add more than one value under IF Description field.
- 4 1. The user will be able to add more than one value under IF Explanation field.  
2. The user will be able to select the following values for 90 days/Export IF Explanation:  
  
New Infant formula (new to export)  
Major Formulation change  
Major Processing change
- 5 The user will be required to enter Distributor Name if Distributor Change has been selected.
- 6 1. Type of Processing Change is only required if Major processing change and/or Non Major processing change are selected for 90 days/IF Explanation.  
2. The user will be able to add more than one value under Type of Processing Change field.
- 7 The user will be required to add either Processing comments or Processing documentation if Major processing change and/or Non Major processing change is selected for all submission types.
- 8 The user will be required to add either Packaging comments or Packaging documentation if Major or Non-major packaging change is selected for IF Explanation. For other IF Explanation types the selection will be optional.
- 9 The user will be allowed to add Labeling comment and attachment for Non- Exempt IF.
- 10 The user will be able to add more than one value under Export Country field.

FDA Infant Formula Tracking System

http://

New Submission | Pending Submission(s) | Manage Profile

Submission Type: Product Info/Processing

\*Manufacturing Plant: Georgia, VT (+) 1

\*Product Name: Similac (+) 2  Product Name Change

\*IF Description: Low Iron (+) 3 Export Country: China (+) 10

\*IF Explanation: Major formulation change (+) 4

Labeling Comments: [Text Area] 9

\*Documentation: Upload

Distributor Change 5

**Processing**  Current Processing

\*Type of Processing Change: Specific to each manufacturer (+) 6

Processing Comments: [Text Area]

\*Documentation: Upload 7

**Packaging**  Current Packaging→

\*Physical Form: Concentrate (+)

Container Quantity: 0.61 Oz (+)

Current Pack. Supplier: -Select

Packaging Type: Can

Shelf Life: 36 months

Proposed Pack. Supplier: [Text Field]

Packaging Comments: [Text Area]

\*Documentation: Upload 8

Cancel Back Next



### FDA CFSAN IFTRACK II Mockups

### WF.IFTRACK II.3B\_Processing\_SubmissionRef#

Purpose: To enter Submission Reference Number if Packaging information has been already provided in the previous Submission

- 1 Submission Ref # field is required if the user selects Current Packaging option.
- 2 The user will be able to add more than one Submission Reference Number.

The mockup shows a browser window with the title 'FDA Infant Formula Tracking System'. The address bar contains 'http://'. A dialog box titled 'Submission Reference Number' is open, containing the text 'Enter Submission Reference Number'. Below this is a text input field labeled '\*Submission Ref #' with a callout '1' pointing to it. At the bottom of the dialog box are three buttons: 'Cancel', 'Save', and 'Add Another', with a callout '2' pointing to the 'Add Another' button.

### FDA CFSAN IFTRACK II Mockups

### WF.IFTRACK II.3A\_Processing\_AddNewPhysicalForm

Purpose: To enter additional Physical form(s) for the same product

The screenshot shows a web browser window titled "FDA Infant Formula Tracking System". The address bar contains "http://". A dialog box titled "Physical Form" is open, containing the following fields:

- \*Physical Form: Powder (dropdown menu)
- Container Quantity: 0.80 (text input) Oz (dropdown menu)
- Packaging Type: Can (dropdown menu)
- Shelf Life: 12 months (dropdown menu)

At the bottom of the dialog box are three buttons: "Cancel", "Save", and "Save and Add Another".

### FDA CFSAN IFTRACK II Mockups

### WF.IFTRACK II.4E\_90Days\_Export\_Ingredients

Purpose: To enter ingredients information.

- 1. Ingredient Changes section will be required if Major Reformulation or Non major reformulation has been selected for IF Explanation on 90 days Non-Exempts, BFP Non-Exempts or Exports submissions.
- 2. Ingredient Changes section will be optional if Major Reformulation or Non major reformulation has been selected for IF Explanation on 90 days Exempts or BFP Exempts submissions.
- 2. The user will be required to add Description of IF Reformulation if major or non-major reformulation is selected for IF explanation for all 90 days Exempt/Non-exempt and BFP Exempt/Non-exempt submissions.
- 3. 1. The user will be required to select Ingredient, Current and Proposed Quantity if Increase or Decrease are selected for Ingredient Change.  
2. The user will be required to select Ingredient and Proposed Quantity if New is selected for Ingredient Change.  
3. The user will be required to select Ingredient and Current Quantity if Removed is selected for Ingredient Change.  
4. The user will be required to select Ingredient, Current and Proposed Quantity, Current and Proposed Ingr. Supplier if Supplier Change is selected for Ingredient Change.
- 4. 1. The user will be required to upload Quantitative Formulation for all Exempt, 90 days Non-Exempt and Export submissions.  
2. For BFP Non-Exempt submissions the user will be required to upload Quantitative Formulation or enter Submission Ref # .

FDA Infant Formula Tracking System

http://

New Submission
Pending Submission(s)
Manage Profile ?

Submission Type

Product Info/Processing

Ingredients

Export Statements

Description of IF Reformulation

**Ingredient Changes** 1

Ingredient Change

\*Ingredient

\*Current Quantity

\*Proposed Quantity

\*Quantity Units

\*Current Ingr. Supplier

\*Proposed Ingr. Supplier

Ingredient Comments

\*Documentation [Upload](#)

**Quantitative Formulation** 4

Quant. Formulation Comments

Documentation [Upload](#)

### FDA CFSAN IFTRACK II Mockups

### WF.IFTRACK II.5C\_90Days\_Export Statements

Purpose: To select Export-Only Certifying Statements

1 Statements under 106.120 (c) regulations are applicable to Exports only.

FDA Infant Formula Tracking System

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New Submission
Pending Submission(s)
Manage Profile
?

Submission Type  
 Product Info/Processing  
 Ingredients  
Export Statements

**Export-Only Certifying Statements** 1

**106.120 (c)**

- Statement certifying the infant formula meets specifications of foreign purchaser
- Statement certifying that the infant formula doesn't conflict with the laws of the country to which it is intended for export
- Statement certifying that the infant formula is labeled on the outside of the shipping package to indicate that it is intended for export only
- Statement certifying that the infant formula will not be sold nor offered for sale in domestic commerce
- Statement certifying that it has adequate controls in place to ensure that such formula is actually exported

Cancel
Back
Add Another Product
Submit

### FDA CFSAN IFTRACK II Mockups

### WF.IFTRACK II.7A\_AddAnotherProduct

Purpose: To enter additional product name.

- 1 The user will be allowed to add Another product after all information for the first product has been entered.
- 2 If the user selects "Same processing as previous product in the current submission" for Processing/packaging field, processing information will be automatically populated for the next product.  
If the user selects "Same packaging as previous product in the current submission" for Processing/packaging field, packaging information will be automatically populated for the next product.

The screenshot shows a web browser window titled "FDA Infant Formula Tracking System". Inside the browser, a dialog box titled "Add Another Product" is open. The dialog box has a close button (X) in the top right corner. It contains two main input fields:

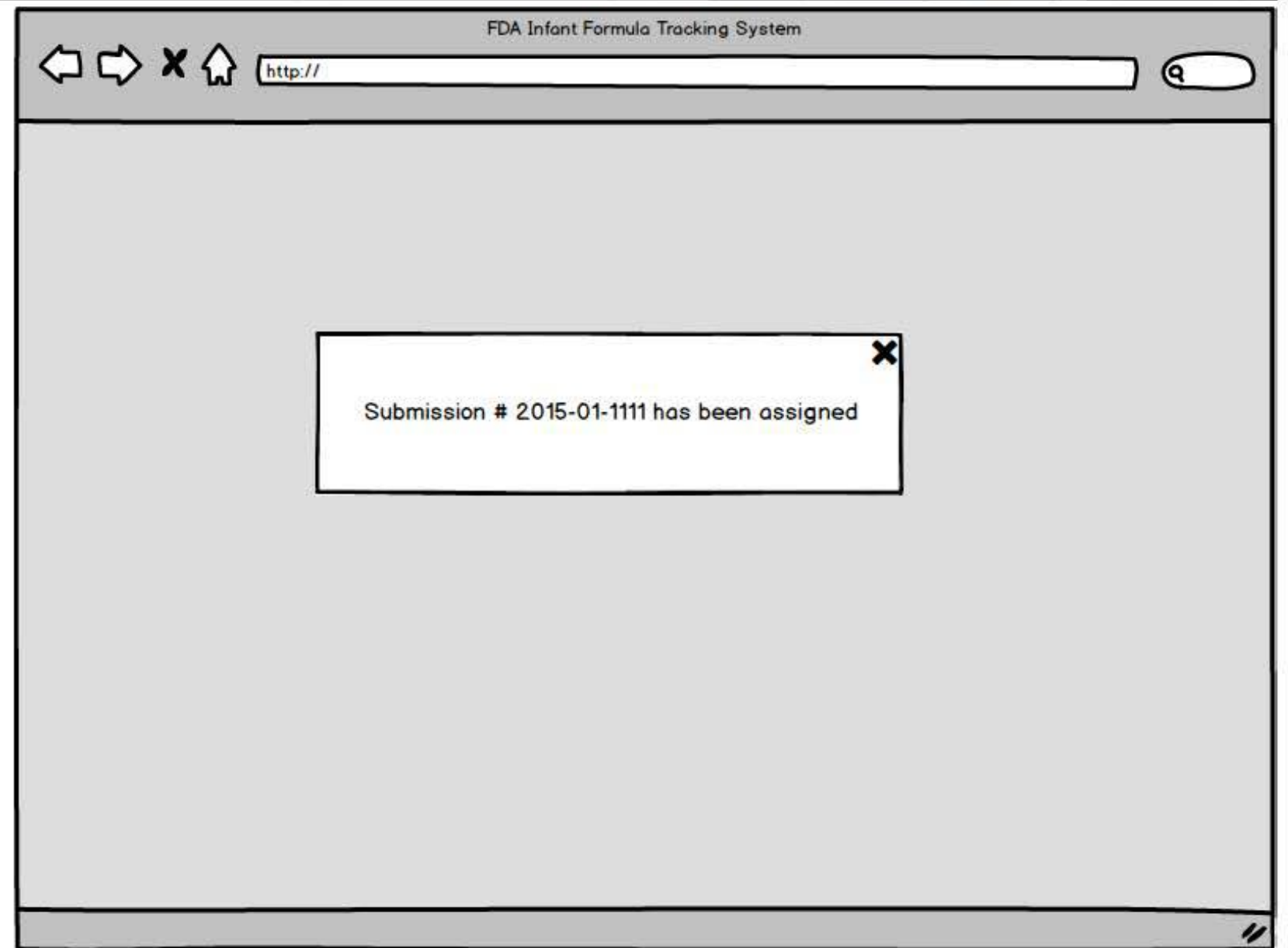
- Product Name:** A dropdown menu currently showing "-Select". A yellow callout bubble with the number "1" points to this dropdown.
- Processing/packaging:** A dropdown menu currently showing "Same processing as previous product in the current submission". A yellow callout bubble with the number "2" points to this dropdown. A list of options is visible below the dropdown, including "Same packaging as previous product in the current submission" and "Enter new product information".

At the bottom right of the dialog box, there are two buttons: "Cancel" and "Save".

### FDA CFSAN IFTRACK II Mockups

### WF.IFTRACK II.8A\_AssignedSubmissionRef #

Purpose: To view assigned Submission Reference Number



1.4 AMENDMENT SUBMISSION

**FDA CFSAN IFTRACK II Mockups** WF.IFTRACK II\_01\_LogIn

Purpose: To access the system manufacturer will enter username and password

---

FDA Infant Formula Tracking System

← → × 🏠 http://  🔍

Please Enter your Username and Password

Username

Password

The screenshot shows a web browser window titled "FDA Infant Formula Tracking System". The address bar contains "http://". The main content area displays the following text:

**Form FDA 3978**

Welcome to the Infant Formula Tracking Application  
PAPERWORK REDUCTION ACT NOTICE  
Form Approval: OMB No. 0910-XXXX  
Expiration date: mm/dd/yyyy

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The time required to complete this collection of information is estimated to average 4-10 hours per response, including the time to review instructions, search existing data resources, gather and maintain the data needed, and complete and review the information collection. Send comments about this burden estimate or any other aspect of this collection of information, including suggestions for reducing the paper burden to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Operations  
Paperwork Reduction Act (PRA) Staff  
PRASStaff@fda.hhs.gov



### FDA CFSAN IFTRACK II Mockups

### WF.IFTRACK II.1E\_Amendment\_SubmissionType

Purpose: To create Infant Formula Amendment submission

- 1 The user will be able to view Product, Processing and Ingredients information, but won't be able to update it if Amendment Submission type is selected.
- 2 The system will populate Filing date and Product Name when Submission Ref # is provided.

FDA Infant Formula Tracking System

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New Submission
Pending Submission(s)
Manage Profile
?

Submission Type 1

Product Info/Processing

Ingredients

\*Submission Type

\*Submission Ref #

🔍

Filing Date
10/10/2014
Product Name
Similac 2

\*Documentation
[Upload](#)

Comments

Cancel
Submit

### FDA CFSAN IFTRACK II Mockups

WF.IFTRACK II. 8A\_AssignedSubmissionRef #

Purpose: To view assigned Submission Reference Number



1.5 BFP EXEMPT SUBMISSION

**FDA CFSAN IFTRACK II Mockups** **WF.IFTRACK II\_01\_LogIn**

Purpose: To access the system manufacturer will enter username and password

---

FDA Infant Formula Tracking System

← → × 🏠 http://  🔍

Please Enter your Username and Password

Username

Password

FDA Infant Formula Tracking System

http://

**Form FDA 3978**

Welcome to the Infant Formula Tracking Application  
PAPERWORK REDUCTION ACT NOTICE  
Form Approval: OMB No. 0910-XXXX  
Expiration date: mm/dd/yyyy

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The time required to complete this collection of information is estimated to average 4-10 hours per response, including the time to review instructions, search existing data resources, gather and maintain the data needed, and complete and review the information collection. Send comments about this burden estimate or any other aspect of this collection of information, including suggestions for reducing the paper burden to:


Department of Health and Human Services  
Food and Drug Administration  
Office of Operations  
Paperwork Reduction Act (PRA) Staff  
PRASStaff@fda.hhs.gov

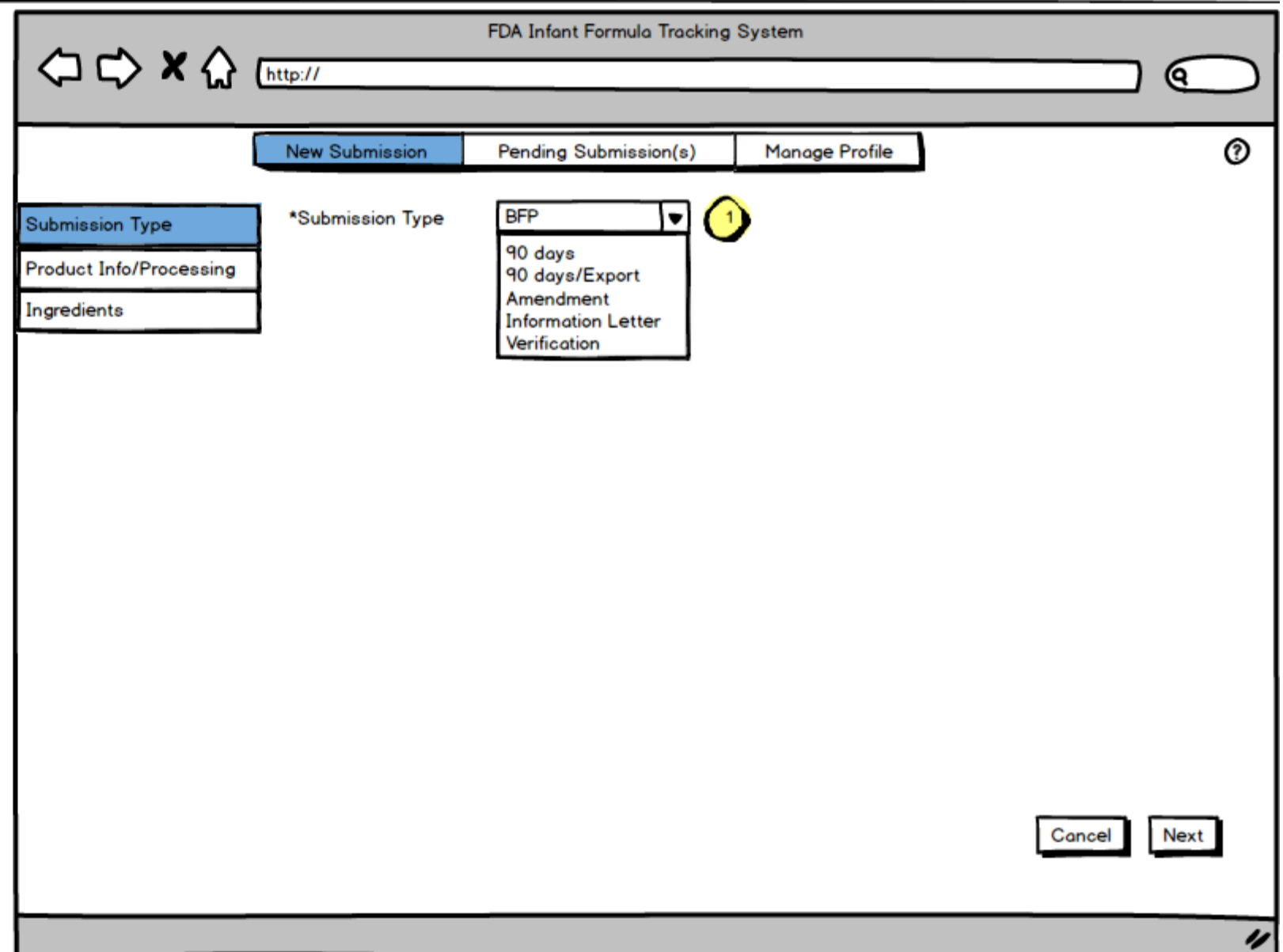
Next

### FDA CFSAN IFTRACK II Mockups

### WF.IFTRACK II.1B\_BFP\_SubmissionType

Purpose: To initiate a new Submission , manufacturer will select Submission Type first

 Different fields will be displayed based on the Submission type selected.



The screenshot shows a web browser window titled "FDA Infant Formula Tracking System". The address bar contains "http://". The page has three tabs: "New Submission" (selected), "Pending Submission(s)", and "Manage Profile". On the left, there is a vertical menu with three items: "Submission Type" (highlighted in blue), "Product Info/Processing", and "Ingredients". In the main content area, there is a label "\*Submission Type" followed by a dropdown menu. The dropdown menu is open, showing the following options: "BFP", "90 days", "90 days/Export", "Amendment", "Information Letter", and "Verification". A yellow callout bubble with the number "1" is positioned to the right of the dropdown menu. At the bottom right of the page, there are two buttons: "Cancel" and "Next".

**FDA CFSAN IFTRACK II Mockups**
**WF.IFTRACK II.2D\_BFP\_Exempt\_Processing**

Purpose: To enter product, processing and packaging information.

---

The user will be able to add multiple Manufacturing Plants

1 The user will be able to add multiple Products for each Manufacturing Plant.  
The user will be able to add multiple Physical forms for each Product.  
The user will be able to add multiple Containers for each Physical Form.

2 The user will be required to enter Proposed Product Name if Product Name Change is selected.

3 1. The following values for IF Description are hidden if Non-Exempt is selected for Domestic Category :  
Amino Acid  
Carbohydrate free  
Human Milk Supplement  
Hypoallergenic  
In-hospital preterm  
Metabolic  
Post -hospital preterm  
2. The user will be able to add more than one value under IF Description field.

4 1. The user will be able to add more than one value under IF Explanation field.  
2. The user will be able to select the following values for BFP (Exempt) IF Explanation:  
  
Non-major reformulation  
Non major processing change  
Non-major packaging change  
Label/labeling changes

5 The user will be required to enter Distributor Name if Distributor Change has been selected.

6 1. Type of Processing Change is only required if Major processing change and/or Non Major processing change are selected for 90 days/IF Explanation.  
2. The user will be able to add more than one value under Type of Processing Change field.

7 The user will be required to add either Processing comments or Processing documentation if Major processing change and/or Non Major processing change is selected for all submission types.

8 The user will be required to add either Packaging comments or Packaging documentation if Major or Non-major packaging change is selected for IF Explanation. For other IF Explanation types the selection will be optional.

9 Retail Availability field is required if Exempt is selected for Domestic Category.

10 1. The user will be required to add Medical Condition comment or documentation for Exempt IF.  
2. The user will be required to add Rationale comment or documentation for Exempt IF.  
3. The user will be required to add Labeling comment or attachment for Exempt IF.

FDA Infant Formula Tracking System
http://

New Submission
Pending Submission(s)
Manage Profile

<div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">Submission Type</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">Product Info/Processing</div> <div style="border: 1px solid black; padding: 2px;">Ingredients</div>	<p>*Manufacturing Plant <span style="float: right;">+ 1</span>                  Georgia, VT</p> <p>*Product Name <span style="float: right;">+ 2</span>                  Similac <input type="checkbox"/> Product Name Change</p> <p>*IF Description <span style="float: right;">+ 3</span>                  Low Iron</p> <p>*Domestic Category <span style="float: right;">+ 4</span>                  Exempt <input type="checkbox"/> Retail Availability Generally Available</p> <p>*IF Explanation <span style="float: right;">+ 5</span>                  Non-major reformulation</p> <p>*Medical Condition Comments  <input style="width: 100%;" type="text"/></p> <p>*Rationale Comments <span style="float: right;">+ 10</span>  <input style="width: 100%;" type="text"/></p> <p>Labeling Comments  <input style="width: 100%;" type="text"/></p> <p>Documentation <a href="#">Upload</a></p> <p><input type="checkbox"/> Distributor Change <span style="float: right;">+ 5</span></p> <hr/> <p><b>Processing</b> <span style="float: right;"><input type="checkbox"/> Current Processing</span></p> <p>*Type of Processing Change <span style="float: right;">+ 6</span>                  Specific to each manufacturer</p> <p>Processing Comments  <input style="width: 100%;" type="text"/></p> <p>*Documentation <a href="#">Upload</a> <span style="float: right;">+ 7</span></p> <hr/> <p><b>Packaging</b> <span style="float: right;"><input type="checkbox"/> Current Packaging</span></p> <p>*Physical Form <span style="float: right;">+ 8</span>                  Concentrate</p> <p>Container Quantity <span style="float: right;">+ 9</span>                  0.61 Oz</p> <p>Current Pack. Supplier <span style="float: right;">+ 10</span>                  -Select</p> <p>Packaging Comments  <input style="width: 100%;" type="text"/></p> <p>*Documentation <a href="#">Upload</a></p>
---	---

Cancel Back Next

### FDA CFSAN IFTRACK II Mockups

Purpose: To enter Submission Reference Number if Packaging information has been already provided in the previous Submission

- 1 Submission Ref # field is required if the user selects Current Packaging option.
- 2 The user will be able to add more than one Submission Reference Number.

### WF.IFTRACK II.3B\_Processing\_SubmissionRef#

The screenshot shows a web browser window titled "FDA Infant Formula Tracking System". The address bar contains "http://". A modal dialog box titled "Submission Reference Number" is open in the center. The dialog box has a close button (X) in the top right corner. Inside the dialog, the text "Enter Submission Reference Number" is displayed. Below this, there is a label "\*Submission Ref #" followed by a text input field. A yellow callout marker with the number "1" points to the input field. Below the input field are three buttons: "Cancel", "Save", and "Add Another". A yellow callout marker with the number "2" points to the "Add Another" button.

### FDA CFSAN IFTRACK II Mockups

### WF.IFTRACK II.3A\_Processing\_AddNewPhysicalForm

Purpose: To enter additional Physical form(s) for the same product

The screenshot shows a web browser window titled "FDA Infant Formula Tracking System". Inside the browser, a "Physical Form" dialog box is open. The dialog box contains the following fields and values:

- \*Physical Form: Powder
- Container Quantity: 0.80
- Packaging Type: Can
- Shelf Life: 12 months

At the bottom of the dialog box, there are three buttons: "Cancel", "Save", and "Save and Add Another".



### FDA CFSAN IFTRACK II Mockups

Purpose: To enter ingredients information.

- 1. Ingredient Changes section will be required if Major Reformulation or Non major reformulation has been selected for IF Explanation on 90 days Non-Exempts, BFP Non-Exempts or Exports submissions.
- 2. Ingredient Changes section will be optional if Major Reformulation or Non major reformulation has been selected for IF Explanation on 90 days Exempts or BFP Exempts submissions.
- 2. The user will be required to add Description of IF Reformulation if major or non-major reformulation is selected for IF explanation for all 90 days Exempt/Non-exempt and BFP Exempt/Non-exempt submissions.
- 3. 1. The user will be required to select Ingredient, Current and Proposed Quantity if Increase or Decrease are selected for Ingredient Change.  
2. The user will be required to select Ingredient and Proposed Quantity if New is selected for Ingredient Change.  
3. The user will be required to select Ingredient and Current Quantity if Removed is selected for Ingredient Change.  
4. The user will be required to select Ingredient, Current and Proposed Quantity, Current and Proposed Ingr. Supplier if Supplier Change is selected for Ingredient Change.
- 4. 1. The user will be required to upload Quantitative Formulation for all Exempt, 90 days Non-Exempt and Export submissions.  
2. For BFP Non-Exempt submissions the user will be required to upload Quantitative Formulation or enter Submission Ref # .

### WF.IFTRACK II.4D\_BFP\_Exempt\_Ingredients

FDA Infant Formula Tracking System

http://

New Submission
Pending Submission(s)
Manage Profile
?

Submission Type

Product Info/Processing

Ingredients

**\*Description of IF Reformulation**

**Ingredient Changes** 1

Ingredient Change  3

\*Current Quantity

\*Quantity Units

\*Current Ingr. Supplier

Ingredient Comments

\*Documentation [Upload](#)

---

**Quantitative Formulation**

Quant. Formulation Comments

Documentation [Upload](#)      Submission Ref #  4

## FDA CFSAN IFTRACK II Mockups

## WF.IFTRACK II.7A\_AddAnotherProduct

Purpose: To enter additional product name.

- 1 The user will be allowed to add Another product after all information for the first product has been entered.
- 2 If the user selects "Same processing as previous product in the current submission" for Processing/packaging field, processing information will be automatically populated for the next product.  
If the user selects "Same packaging as previous product in the current submission" for Processing/packaging field, packaging information will be automatically populated for the next product.

FDA Infant Formula Tracking System

http://

Add Another Product

Product Name: -Select 1

Processing/packaging: Some processing as previous product in the current submission 2

Some packaging as previous product in the current submission

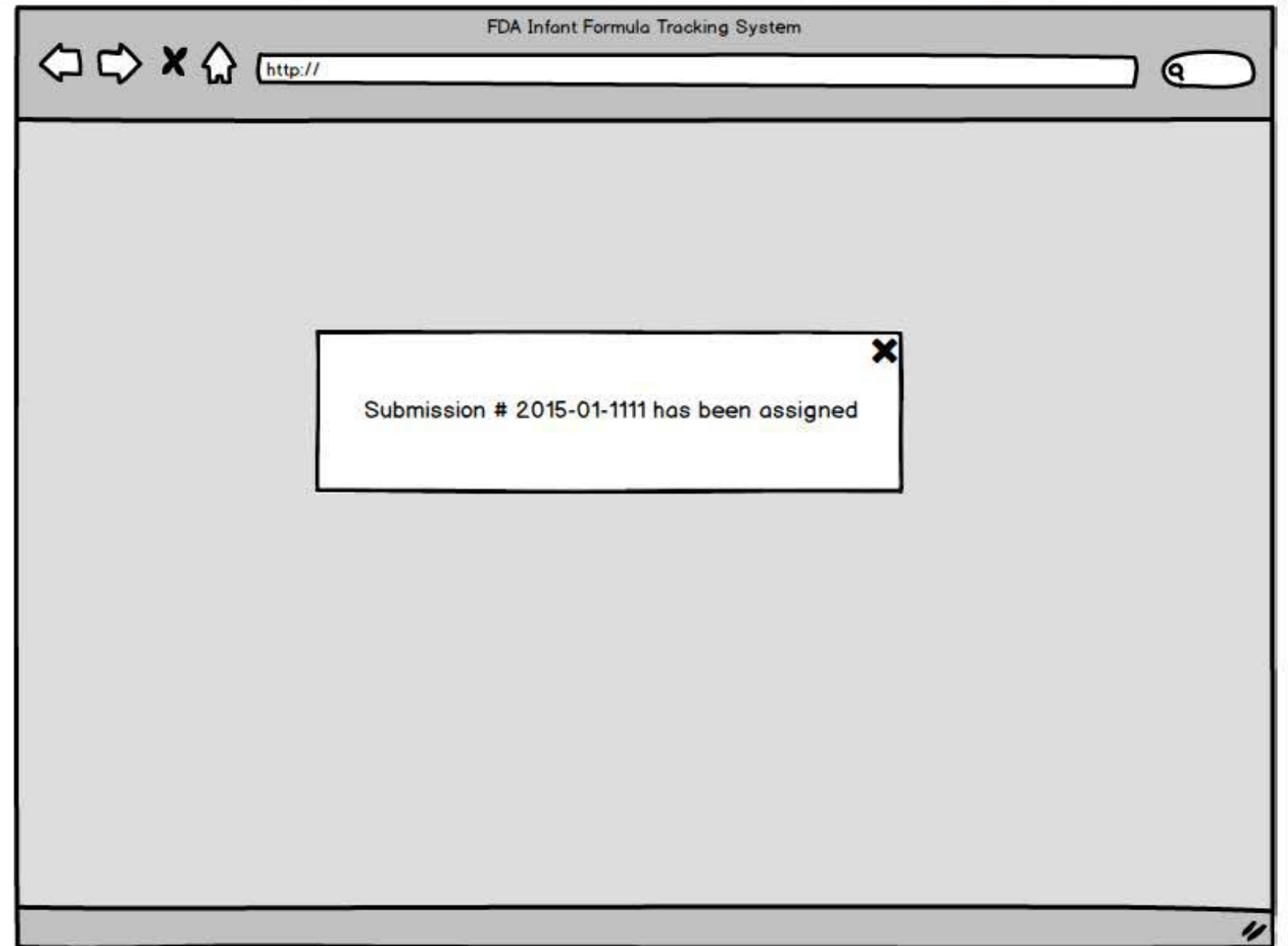
Enter new product information

Cancel Save

### FDA CFSAN IFTRACK II Mockups

### WF.IFTRACK II.8A\_AssignedSubmissionRef #

Purpose: To view assigned Submission Reference Number



1.6 BFP NON-EXEMPT SUBMISSION

**FDA CFSAN IFTRACK II Mockups** **WF.IFTRACK II\_01\_LogIn**

Purpose: To access the system manufacturer will enter username and password

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FDA Infant Formula Tracking System

← → × 🏠 http://  🔍

Please Enter your Username and Password

Username

Password

FDA Infant Formula Tracking System

http://

**Form FDA 3978**

Welcome to the Infant Formula Tracking Application  
PAPERWORK REDUCTION ACT NOTICE  
Form Approval: OMB No. 0910-XXXX  
Expiration date: mm/dd/yyyy

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The time required to complete this collection of information is estimated to average 4-10 hours per response, including the time to review instructions, search existing data resources, gather and maintain the data needed, and complete and review the information collection. Send comments about this burden estimate or any other aspect of this collection of information, including suggestions for reducing the paper burden to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Operations  
Paperwork Reduction Act (PRA) Staff  
PRASStaff@fda.hhs.gov

Next

### FDA CFSAN IFTRACK II Mockups

WF.IFTRACK.1B\_BFP\_SubmissionType

Purpose: To initiate a new Submission , manufacturer will select Submission Type first

**1** Different fields will be displayed based on the Submission type selected.

The screenshot shows a web browser window titled "FDA Infant Formula Tracking System". The address bar contains "http://". Below the address bar is a navigation menu with three tabs: "New Submission" (highlighted in blue), "Pending Submission(s)", and "Manage Profile". A help icon (?) is located to the right of the "Manage Profile" tab.

On the left side of the main content area, there is a vertical menu with four items: "Submission Type" (highlighted in blue), "Product Info/Processing", "Ingredients", and "Assurance Statements".

To the right of this menu is a form field labeled "\*Submission Type". A dropdown menu is open, showing the following options: "BFP", "90 days", "90 days/Export", "Amendment", "Information Letter", and "Verification". A yellow callout bubble with the number "1" is positioned next to the dropdown menu.

At the bottom right of the page, there are two buttons: "Cancel" and "Next".

### FDA CFSAN IFTRACK II Mockups

### WF.IFTRACK.2C\_BFP\_Non Exempt\_Processing

Purpose: To enter product, processing and packaging information.

- 1 The user will be able to add multiple Manufacturing Plants
- 1 The user will be able to add multiple Products for each Manufacturing Plant.
- The user will be able to add multiple Physical forms for each Product.
- The user will be able to add multiple Containers for each Physical Form.
- 2 The user will be required to enter Proposed Product Name if Product Name Change is selected.
- 3 1. The following values for IF Description are hidden if Non-Exempt is selected for Domestic Category :  
Amino Acid  
Carbohydrate free  
Human Milk Supplement  
Hypoallergenic  
In-hospital preterm  
Metabolic  
Post -hospital preterm  
2. The user will be able to add more than one value under IF Description field.
- 4 1. The user will be able to add more than one value under IF Explanation field.  
2. The user will be able to select the following values for BFP (non-exempt) IF Explanation:  
  
Non-major reformulation  
Non major processing change  
Non-major packaging change
- 5 The user will be required to enter Distributor Comments if Distributor Change has been selected.
- 6 1. Type of Processing Change is only required if Major processing change and/or Non Major processing change are selected for 90 days/IF Explanation.  
2. The user will be able to add more than one value under Type of Processing Change field.
- 7 The user will be required to add either Processing comments or Processing documentation if Major processing change and/or Non Major processing change is selected for all submission types.
- 8 The user will be required to add either Packaging comments or Packaging documentation if Major or Non-major packaging change is selected for IF Explanation. For other IF Explanation types the selection will be optional.
- 9 The user will be allowed to add Labeling comment and attachment for Non- Exempt IF.
- 10 Eligible IF field is required if BFP is selected for Submission Type and Non-Exempt is selected for Domestic Category.

FDA Infant Formula Tracking System

← → × ↶

**New Submission**
Pending Submission(s)
Manage Profile ?

Submission Type  
 Product Info/Processing  
 Ingredients  
 Assurance Statements

\*Manufacturing Plant  + 1

\*Product Name

\*IF Description  + 3

\*Domestic Category

\*IF Explanation  + 4

Labeling Comments  9

\*Documentation [Upload](#)

Distributor Change 5

Product Name Change 2

\*Eligible IF  Yes  No 10

**Processing**  Current Processing

\*Type of Processing Change  + 6

Processing Comments

\*Documentation [Upload](#) 7

**Packaging**  Current Packaging→

\*Physical Form

Container Quantity   + 8

Current Pack. Supplier

Packaging Comments

\*Documentation [Upload](#)

### FDA CFSAN IFTRACK II Mockups

### WF.IFTRACK.3B\_Processing\_SubmissionRef#

Purpose: To enter Submission Reference Number if Packaging information has been already provided in the previous Submission

- 1 Submission Ref # field is required if the user selects Current Packaging option.
- 2 The user will be able to add more than one Submission Reference Number.

The screenshot shows a web browser window titled "FDA Infant Formula Tracking System". The address bar contains "http://". A modal dialog box titled "Submission Reference Number" is open. Inside the dialog, there is a text input field labeled "\*Submission Ref #" with a callout marker '1' pointing to it. Below the input field are three buttons: "Cancel", "Save", and "Add Another". A callout marker '2' points to the "Add Another" button. The dialog box has a close button (X) in the top right corner.



### FDA CFSAN IFTRACK II Mockups

### WF.IFTRACK.3A\_Processing\_AddNewPhysicalForm

Purpose: To enter additional Physical form(s) for the same product

The screenshot shows a web browser window titled "FDA Infant Formula Tracking System". The address bar contains "http://". A modal dialog box titled "Physical Form" is open, containing the following fields:

- \*Physical Form: Powder (dropdown menu)
- Container Quantity: 0.80 (text input) Oz (dropdown menu)
- Packaging Type: Can (dropdown menu)
- Shelf Life: 12 months (dropdown menu)

At the bottom of the dialog box are three buttons: "Cancel", "Save", and "Save and Add Another".

### FDA CFSAN IFTRACK II Mockups

Purpose: To enter ingredients information.

- 1. Ingredient Changes section will be required if Major Reformulation or Non major reformulation has been selected for IF Explanation on 90 days Non-Exempts, BFP Non-Exempts or Exports submissions.
- 2. Ingredient Changes section will be optional if Major Reformulation or Non major reformulation has been selected for IF Explanation on 90 days Exempts or BFP Exempts submissions.
- 2. The user will be required to add Description of IF Reformulation if major or non-major reformulation is selected for IF explanation for all 90 days Exempt/Non-exempt and BFP Exempt/Non-exempt submissions.
- 3. 1. The user will be required to select Ingredient, Current and Proposed Quantity if Increase or Decrease are selected for Ingredient Change.  
2. The user will be required to select Ingredient and Proposed Quantity if New is selected for Ingredient Change.  
3. The user will be required to select Ingredient and Current Quantity if Removed is selected for Ingredient Change.  
4. The user will be required to select Ingredient, Current and Proposed Quantity, Current and Proposed Ingr. Supplier if Supplier Change is selected for Ingredient Change.
- 4. 1. The user will be required to upload Quantitative Formulation for all Exempt, 90 days Non-Exempt and Export submissions.  
2. For BFP Non-Exempt submissions the user will be required to upload Quantitative Formulation or enter Submission Ref # .

### WF.IFTRACK.4C\_BFP\_Non Exempt\_Ingredients

FDA Infant Formula Tracking System

http://

New Submission
Pending Submission(s)
Manage Profile ?

Submission Type

Product Info/Processing

Ingredients

Assurance Statements

\*Description of IF Reformulation

**Ingredient Changes**

Ingredient Change

\*Current Quantity

\*Quantity Units

\*Current Ingr. Supplier

Ingredient Comments

\*Documentation [Upload](#)

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**Quantitative Formulation**

Quant. Formulation Comments

Documentation [Upload](#)      Submission Ref #

FDA CFSAN IFTRACK II Mockups

WF.IFTRACK.5B\_BFP\_Non Exempt\_Assurance Statements

Purpose: To select Submission compliances Concerning a Change in Infant Formula (BFP).

- 1 All Regulations under Submission Concerning a Change in Infant Formula (BFP) including Documentation and Comments apply only to BFP Non Exempt submissions.
- 2 If the user selects 106.140 (b)(3): Submission compliance with 106.120(b)(3) Statement 1, ingredients and quantitative formulation information will be required.
- 3 If the user selects 106.140 (b)(3): Submission compliance with 106.120(b)(4) Statement 2 and infant formula is non-eligible, processing and/or packaging information will be required.
- 4 If the user selects 106.140 (b)(3): Submission compliance with 106.120(b)(5) Statement 3, supporting documentation will be required.
- 5 If the user selects 106.140 (b)(3): Submission compliance with 106.120(b)(6) Statement 4, supporting documentation will be required.
- 6 If the user selects "previously submitted" for any of the BFP Non-Exempt assurance statements, submission reference number will be required. The user will be required to enter Submission Reference # only for non eligible Infant formulas.

FDA Infant Formula Tracking System

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New Submission
Pending Submission(s)
Manage Profile
?

**Submissions Concerning a Change in Infant Formula (BFP)**

Submission Type
Product Info/Processing
Ingredients
Assurance Statements

**\*106.140(b)(2)(ii)** 1

Explanation concerning adulteration prevention

\*Documentation [Upload](#)

---

**\*106.140 (b)(3): Submission compliance with 106.120(b)(3) Statement 1** 2

Submission complies with 106.120(b)(3)

\*Documentation [Upload](#)

Previously Supplied 6 Submission Ref#

Comments

---

**\*106.140 (b)(3): Submission compliance with 106.120(b)(4) Statement 2** 3

Submission complies with 106.120(b)(4)

\*Documentation [Upload](#)      Comments

Previously Supplied      Submission Ref#

Comments

---

**\*106.140 (b)(3): Submission compliance with 106.120(b)(5) Statement 3** 4

Submission complies with 106.120(b)(5)

\*Documentation [Upload](#)

Previously Supplied      Submission Ref#

Comments

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**\*106.140 (b)(3): Submission compliance with 106.120(b)(6) Statement 4** 5

Submission complies with 106.120(b)(6)

\*Documentation [Upload](#)

Previously Supplied      Submission Ref#

Comments

Cancel
Back
Add Another Product
Submit

## FDA CFSAN IFTRACK II Mockups

## WF.IFTRACK.7A\_AddAnotherProduct

Purpose: To enter additional product name.

- 1 The user will be allowed to add Another product after all information for the first product has been entered.
- 2 If the user selects "Same processing as previous product in the current submission" for Processing/packaging field, processing information will be automatically populated for the next product.  
If the user selects "Same packaging as previous product in the current submission" for Processing/packaging field, packaging information will be automatically populated for the next product.

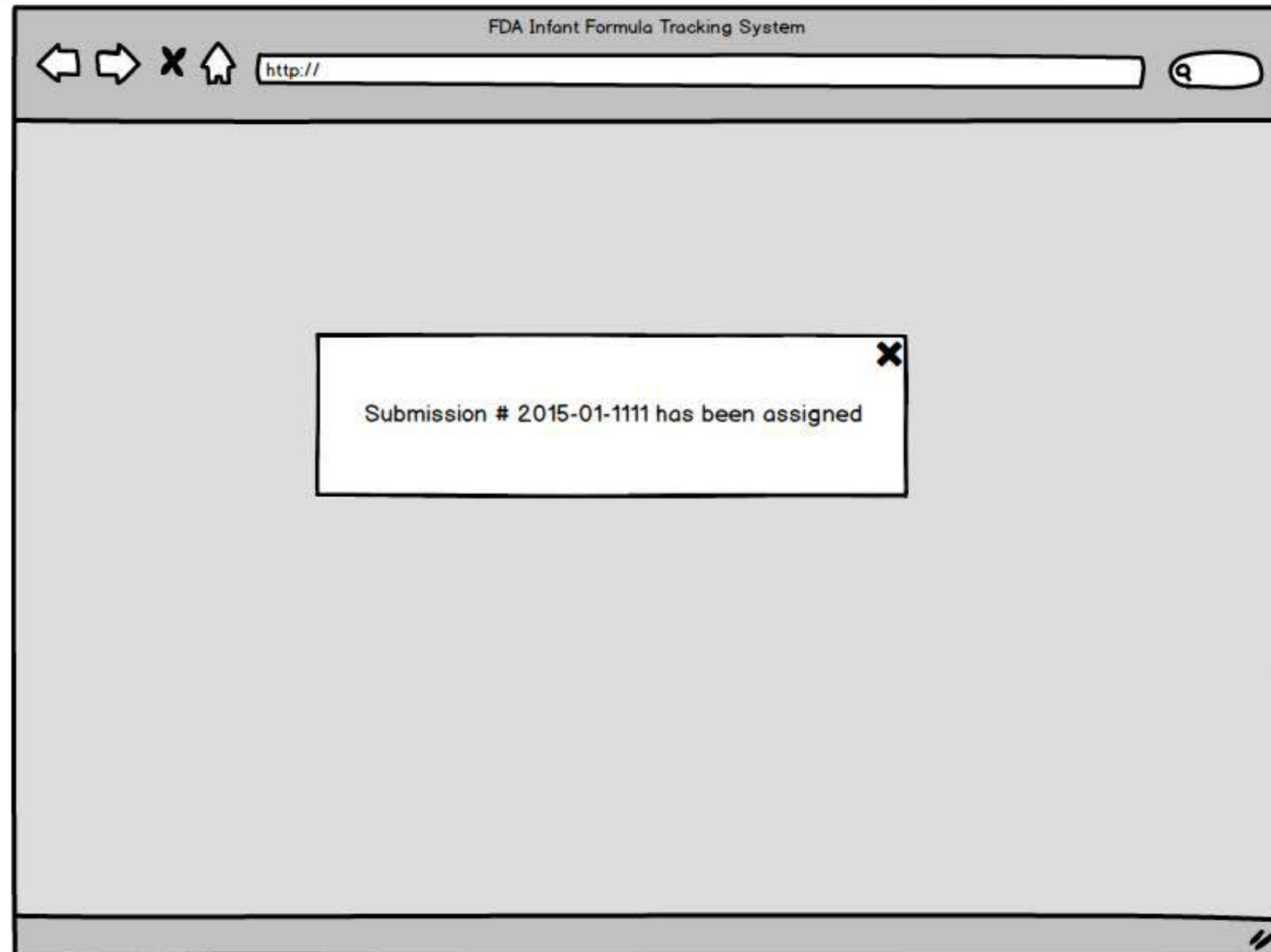
The screenshot shows a web browser window titled "FDA Infant Formula Tracking System" with a search bar. A modal dialog box titled "Add Another Product" is open. The dialog contains the following elements:

- Product Name:** A dropdown menu with the text "-Select" and a downward arrow. A yellow circle with the number "1" is placed over the dropdown.
- Processing/packaging:** A dropdown menu with three options: "Same processing as previous product in the current submission", "Same packaging as previous product in the current submission", and "Enter new product information". A yellow circle with the number "2" is placed over the first option.
- Buttons:** "Cancel" and "Save" buttons are located at the bottom right of the dialog.

### FDA CFSAN IFTRACK II Mockups

WF.IFTRACK.8A\_AssignedSubmissionRef #

Purpose: To view assigned Submission Reference Number



1.7 VERIFICATION SUBMISSION

**FDA CFSAN IFTRACK II Mockups** WF.IFTRACK II\_01\_LogIn

Purpose: To access the system manufacturer will enter username and password

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FDA Infant Formula Tracking System

⏪ ⏩ ✕ 🏠 http://  🔍

Please Enter your Username and Password

Username

Password

The screenshot shows a web browser window titled "FDA Infant Formula Tracking System". The address bar contains "http://". The main content area displays the following text:

**Form FDA 3978**

Welcome to the Infant Formula Tracking Application  
PAPERWORK REDUCTION ACT NOTICE  
Form Approval: OMB No. 0910-XXXX  
Expiration date: mm/dd/yyyy

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The time required to complete this collection of information is estimated to average 4-10 hours per response, including the time to review instructions, search existing data resources, gather and maintain the data needed, and complete and review the information collection. Send comments about this burden estimate or any other aspect of this collection of information, including suggestions for reducing the paper burden to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Operations  
Paperwork Reduction Act (PRA) Staff  
PRASStaff@fda.hhs.gov

### FDA CFSAN IFTRACK II Mockups

### WF.IFTRACK II.1D\_Verification\_SubmissionType

Purpose: To create Infant Formula Verification submission

1 The user will be able to view Product, Processing and Ingredients information, but won't be able to update it if Verification Submission type is selected.

2 The system will populate Filing date and Product Name when Submission Ref # is provided.

FDA Infant Formula Tracking System

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New Submission
Pending Submission(s)
Manage Profile ?

Submission Type <span style="float: right; font-size: 0.8em;">1</span>	*Submission Type	<input style="width: 100%;" type="text" value="Verification"/>	
Product Info/Processing	*Submission Ref #	<input style="width: 150px;" type="text" value="2015-01-00001"/>	🔍
Ingredients	Filing Date	<input style="width: 100px;" type="text" value="10/10/2014"/>	Product Name
Verification Statements	*Documentation	<a href="#">Upload</a>	
	Comments	<div style="border: 1px solid black; height: 40px; width: 100%;"></div>	

Product Name
Similar 2



### FDA CFSAN IFTRACK II Mockups

### WF.IFTRACK II.5D\_VerificationStatements

Purpose: To select Verification Statements. Verification Statements are only applicable for Verification Submission type.

1 The user will be able to view Product/Processing or Ingredients information, but won't be able to update it if Verification Submission type is selected.

2 Verification Statements are only applicable to Verification Submission type.

FDA Infant Formula Tracking System

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New Submission
Pending Submission(s)
Manage Profile ?

Submission Type

Verification Statements 2

Product Info/Processing

106.130 (a)

Ingredients

Verification that the infant formula complies with the requirements of the Federal Food, Drug, and Cosmetic Act and is not adulterated

Verification Statements

106.130 (b)(2)
   
 The infant formula to be introduced into interstate commerce is the same as the infant formula that was the subject of the new infant formula notification and for which the manufacturer provided assurances in accordance with the requirements of §106.120

106.130 (b)(3)
   
 \*Documentation

[Upload](#)

Comments

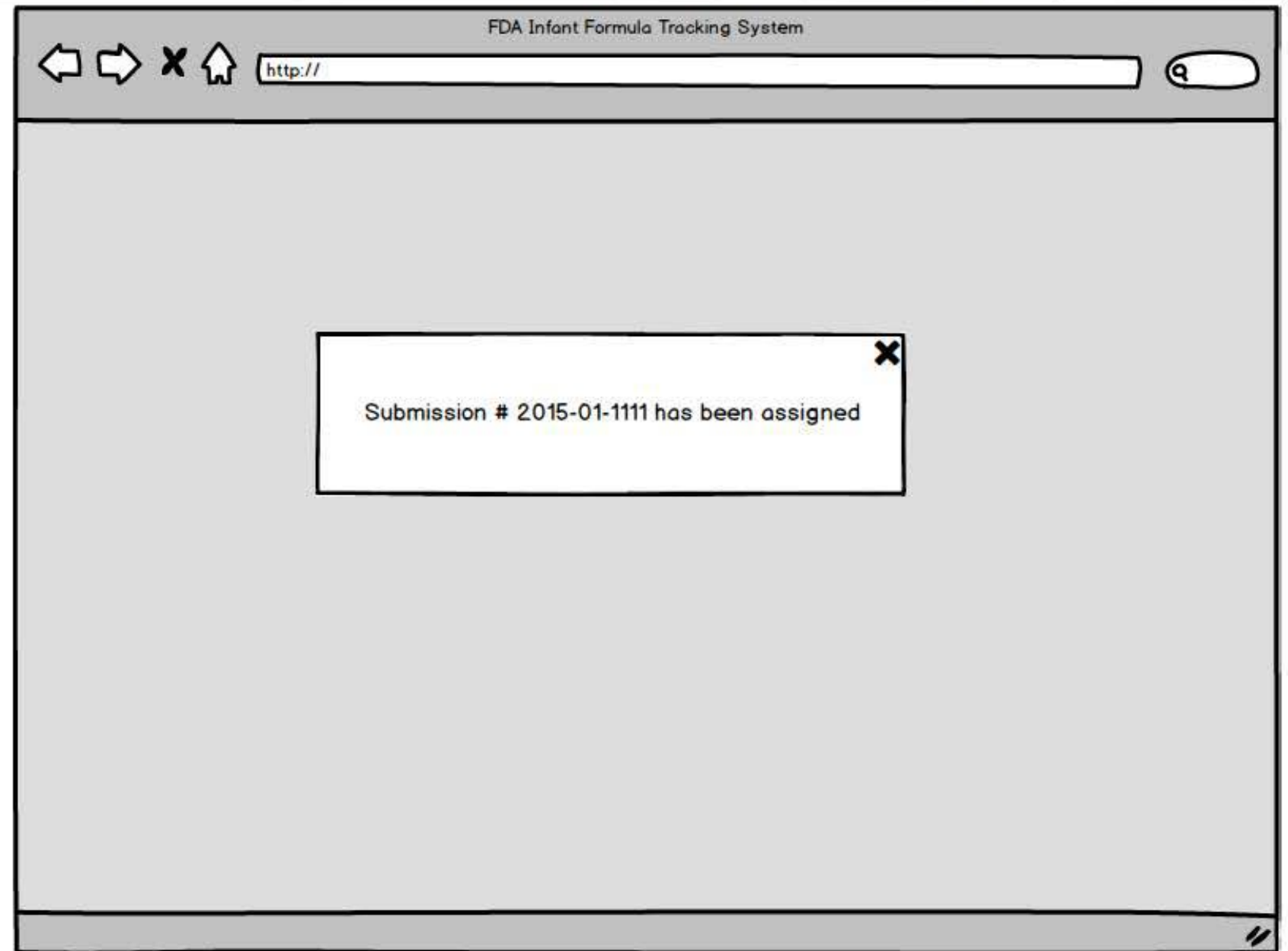
106.130 (b)(4)
   
 Good manufacturing practices, including quality control procedures and in-process controls, and testing required by current good manufacturing practice, designed to prevent adulteration of the formula in accordance with Current Good Manufacturing Practices (Subpart B) and Quality Control Procedures (Subpart C) have been established.

Cancel
Back
Submit

### FDA CFSAN IFTRACK II Mockups

WF.IFTRACK II.8A\_AssignedSubmissionRef #

Purpose: To view assigned Submission Reference Number



1.8 MANUFACTURER PROFILE

**FDA CFSAN IFTRACK II Mockups**
**WF.IFTRACK II.9A\_ManageProfile**

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Purpose: To manage manufacturer's profile information

**1** The user will be able to add multiple Contacts and Establishments

**2** The user will verify that manufacturer profile is correct prior to submitting notification.

**3** Contacts and Establishments will be manufacturer specific.

**4** 1. The following fields will be manufacturer specific:  
 Current/Proposed Supplier  
 Product Name  
 Processing Plant  
 Ingredients  
 Type of Processing Change

2. Any field that is added as a notification change will be automatically added to the appropriate dropdown list.

FDA Infant Formula Tracking System
http://

New Submission
Pending Submission(s)
Manage Profile
?

**Manufacturer Information**

\*Manufacturer ID xxx-xxxx-xxxxx

\*Manufacturer Name Abbot

\*Address 123 Main Street \*State Ohio

\*City Columbus \*Zip/Postal Code 43215-1724

**Contact Information**

\*First Name John \*Last Name Smith [Add New](#) **1**

\*Phone Number 564-111-1111 \*E-mail Johnsmith@abbot.com

**Establishment Information**

\*Establishment Name  **3**  Contractor [Add New](#)

\*Address  \*State -Select

\*City  \*Zip/Postal Code 43215-1724

**Manufacturer-Managed Lists** **4**

Current Supplier	-Select	<a href="#">Add New</a> <a href="#">Edit</a>
Product Name	-Select	<a href="#">Add New</a> <a href="#">Edit</a>
Processing Plant	-Select	<a href="#">Add New</a> <a href="#">Edit</a>
Ingredient	-Select	<a href="#">Add New</a> <a href="#">Edit</a>
Type of Processing Change	-Select	<a href="#">Add New</a> <a href="#">Edit</a>

Cancel Save **2**