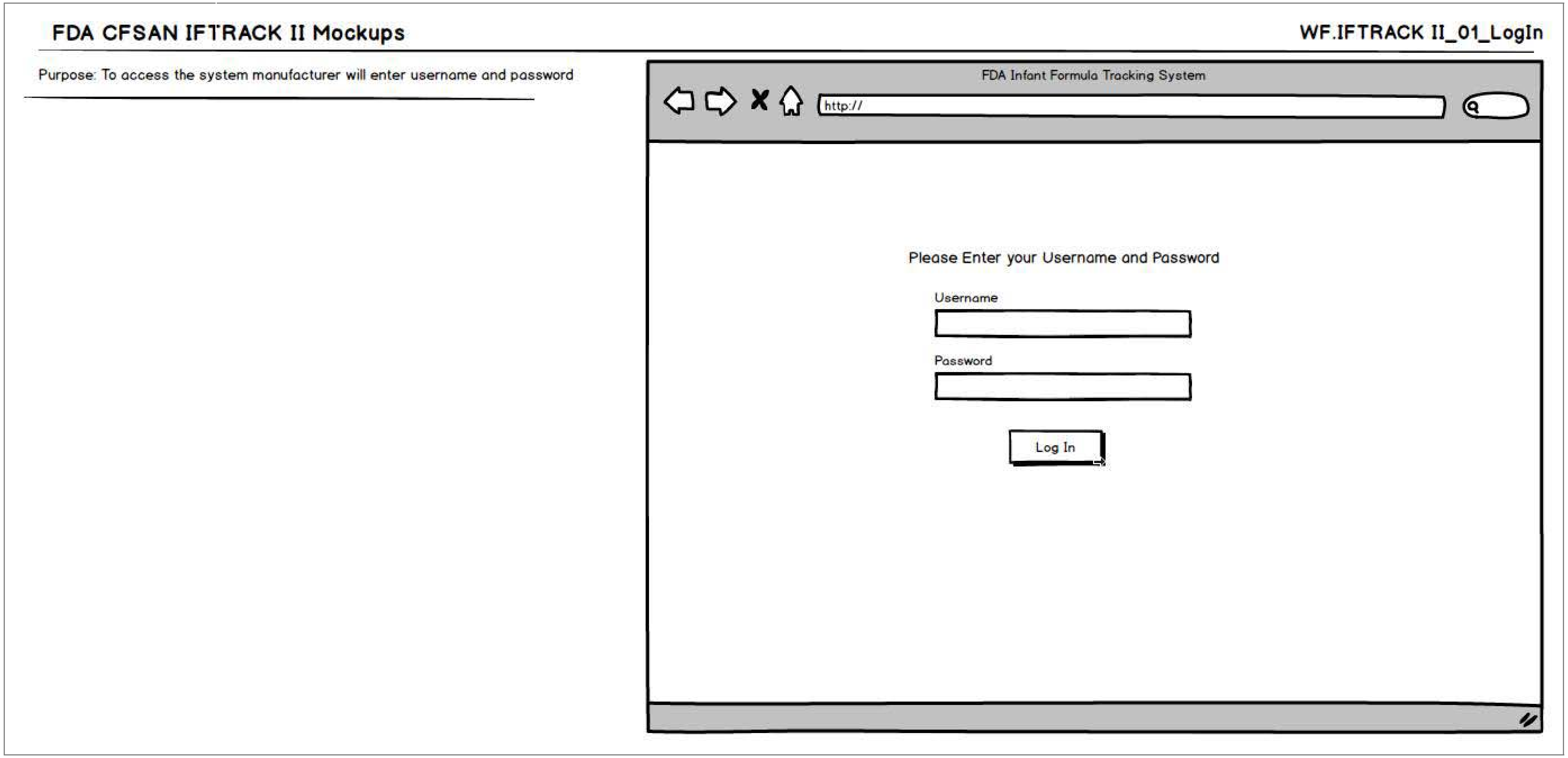
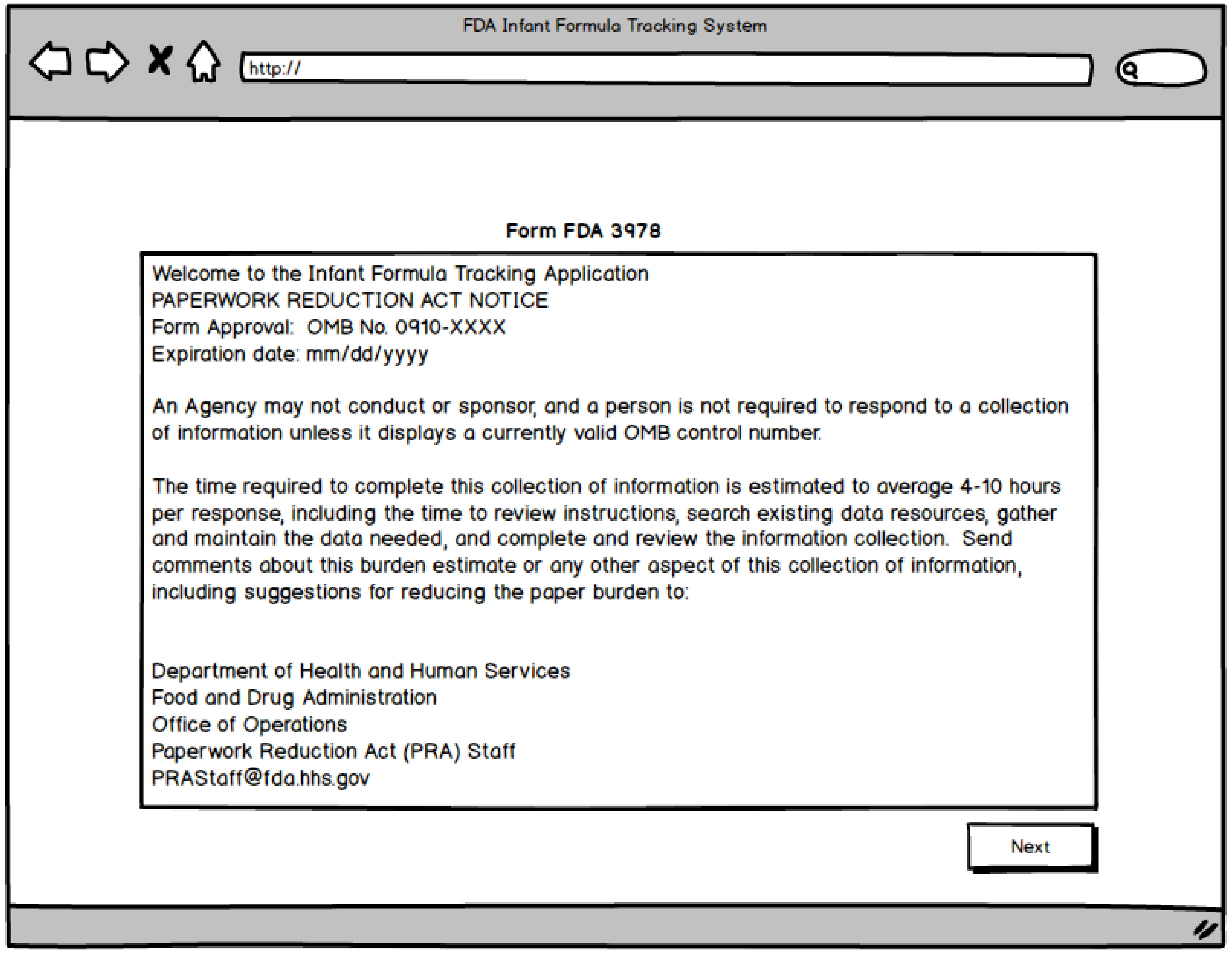
## 1.1 90 DAYS EXEMPT SUBMISSION


FDA CFSAN IFTRACK II Mockups
WF.IFTRACK II_01_LogIn
FDA Infant Formula Tracking System
http://
Please Enter your Username and Password
Username
Password
Log In

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

**FDA CFSAN IFTRACK II Mockups** **WF.IFTRACK II_001_Welcome**



**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:

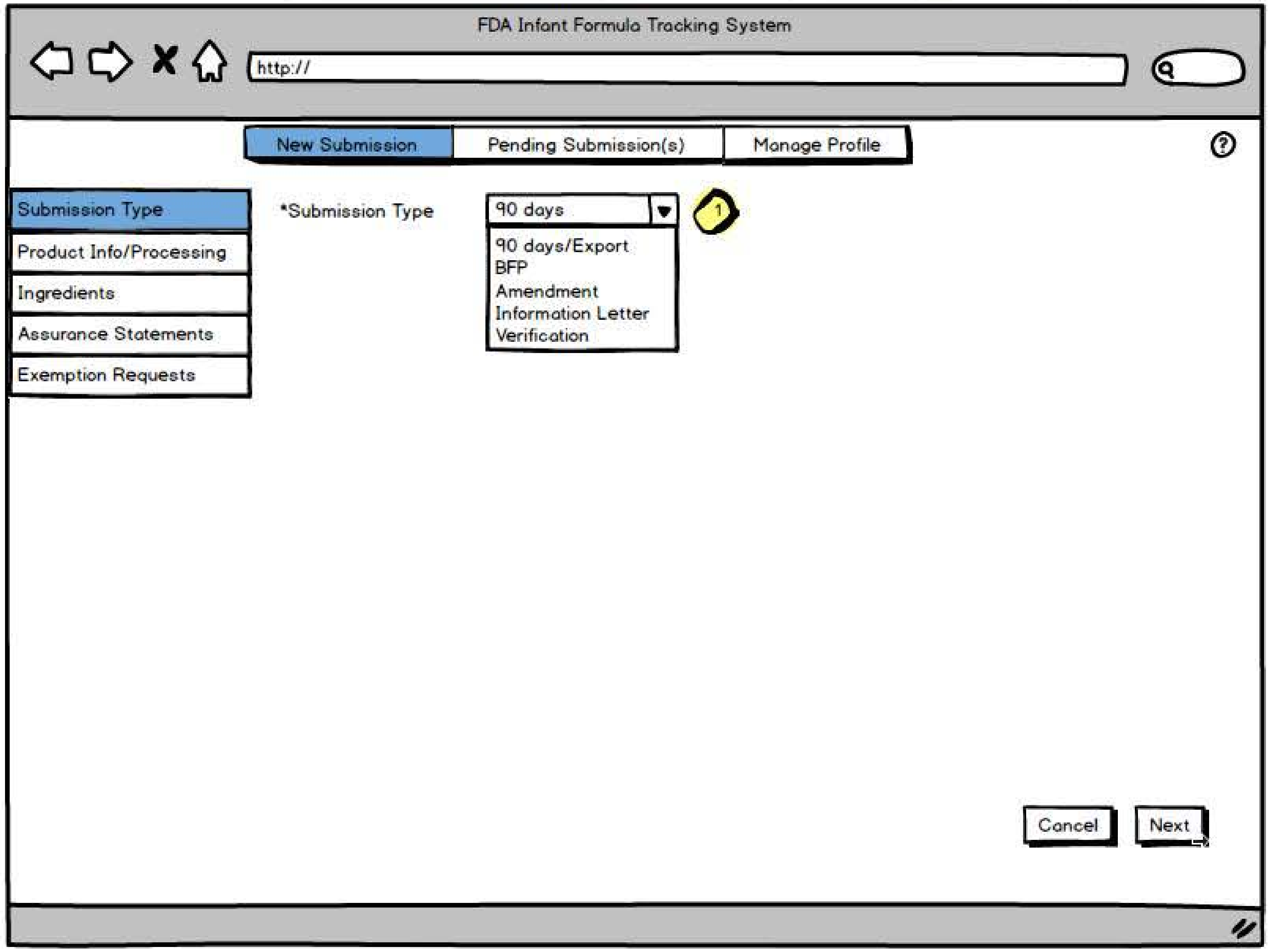
Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

**FDA CFSAN IFTRACK II Wireframes**

**WF.IFTRACK II.1A_90Days SubmissionType**

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

① 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
Assurance Statements
Exemption Requests
90 days/Export
BFP
Amendment
Information Letter
Verification
1
Cancel
Next

*Submission Type: 90 days

**FDA CFSAN IFTRACK II Wireframes** **WF.IFTRACK II.2B_90 days_Exempt_Processing**

Purpose: To enter product and ingredients 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 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

3. IF Explanation/Other will only be displayed as a selection if any other/ primary value for IF Explanation has been selected.

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.

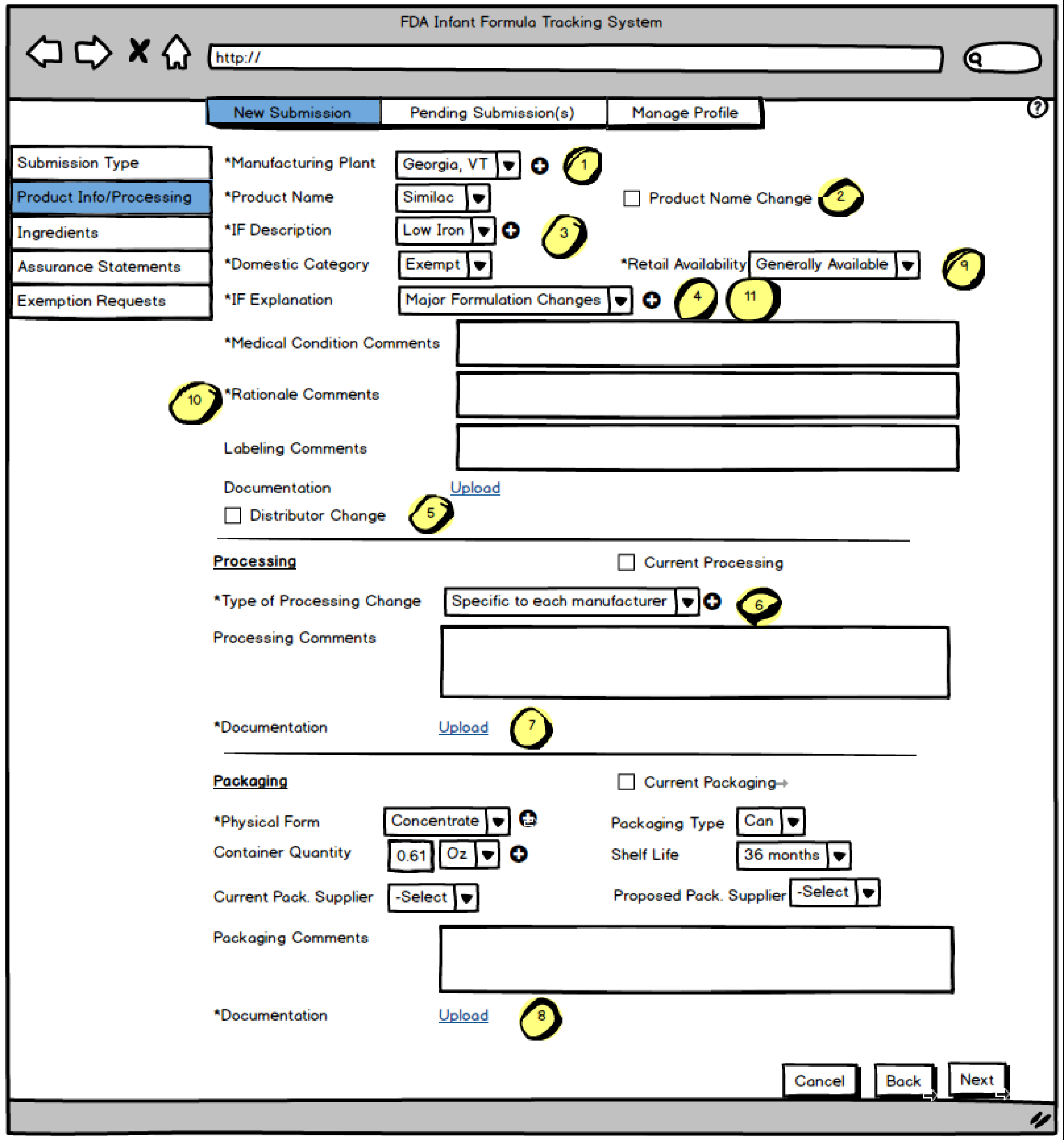
⑦ The user will be required to add either Processing comments or Processing documentation if Major processing change and/or Non Major processing change is selected for all submission types.

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.
4. The user will be able to attach multiple documents under each category of documents: Medical Condition, Rationale, Labeling

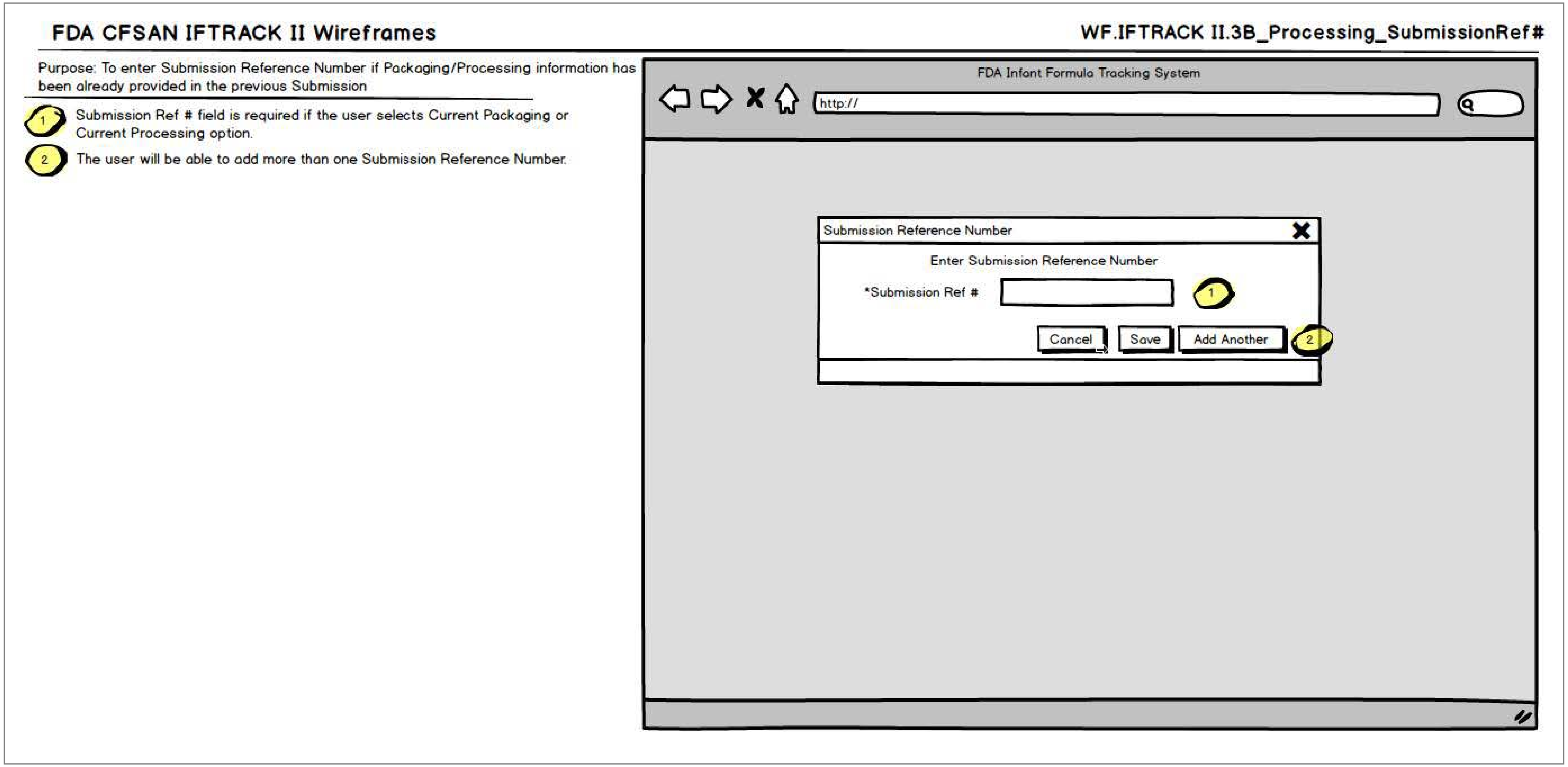
⑪ The user will be required to enter processing, packaging information and quantitative formulation if New infant formula (new to market) or New form are selected for IF Explanation.
The user will be required to enter processing information if New manufacturer , New plant, New Contractor Plant are selected for IF Explanation.



*Manufacturing Plant Georgia, VT ①
*Product Name Similac ☐ Product Name Change ②
*IF Description Low Iron ③
*Domestic Category Exempt *Retail Availability Generally Available ⑨
*IF Explanation Major Formulation Changes ④ ⑪
*Medical Condition Comments
⑩ *Rationale Comments
Labeling Comments
Documentation Upload
☐ Distributor Change ⑤

**Processing** ☐ Current Processing
*Type of Processing Change Specific to each manufacturer ⑥
Processing Comments
*Documentation Upload ⑦

**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 -Select
Packaging Comments
*Documentation Upload ⑧



**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

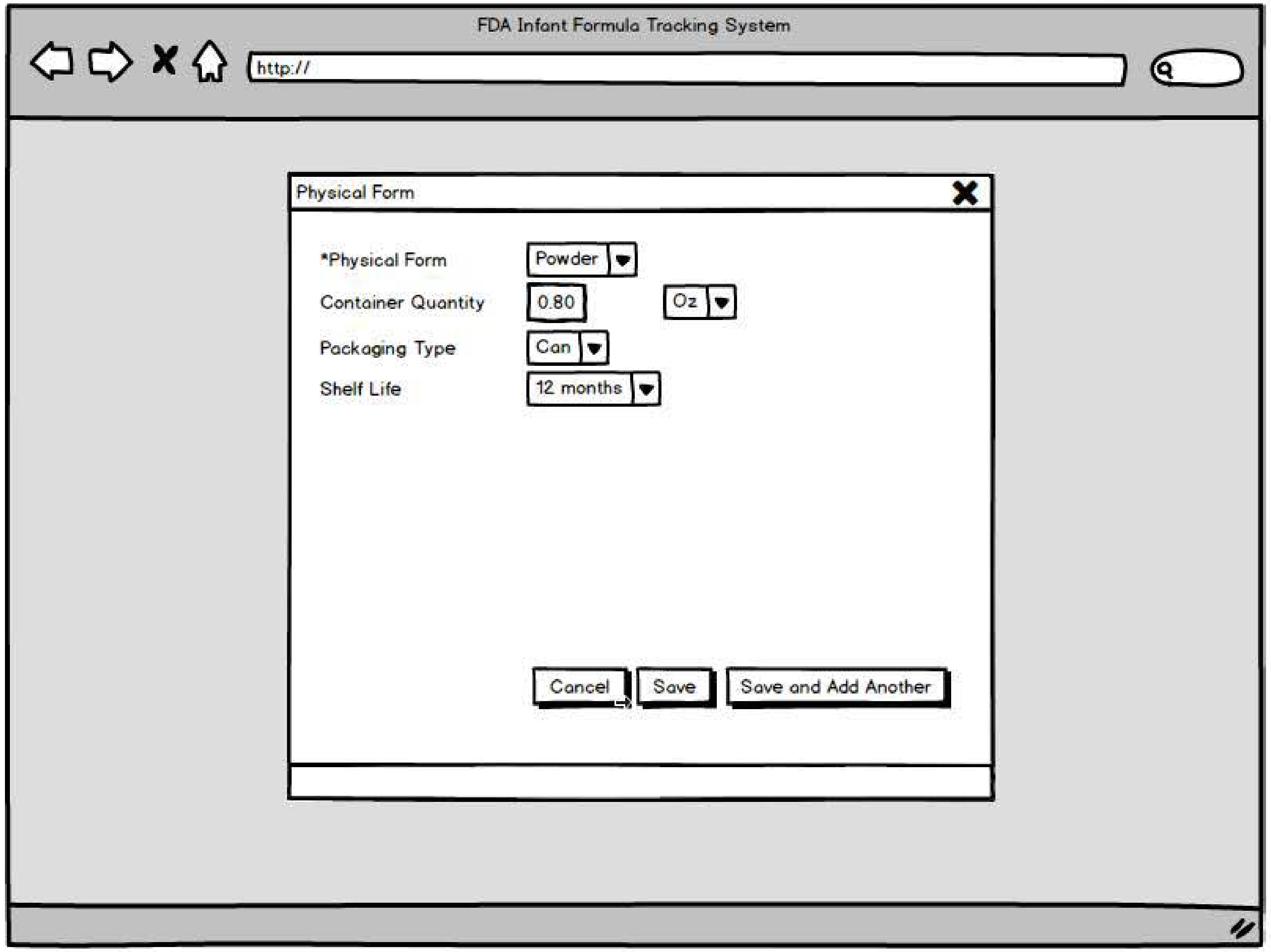
1. Submission Ref # field is required if the user selects Current Packaging or Current Processing option.
2. The user will be able to add more than one Submission Reference Number.

FDA Infant Formula Tracking System
http://
Submission Reference Number
Enter Submission Reference Number
*Submission Ref #
1
Cancel
Save
Add Another
2

**FDA CFSAN IFTRACK II Wireframes**

**WF.IFTRACK II.3A_Processing_AddNewPhysicalForm**

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


FDA Infant Formula Tracking System
http://
Physical Form
Cancel
Save
Save and Add Another

| | | |
|---|---|---|
| *Physical Form | Powder ▼ | |
| Container Quantity | 0.80 | Oz ▼ |
| Packaging Type | Can ▼ | |
| Shelf Life | 12 months ▼ | |

**FDA CFSAN IFTRACK II Wireframes** **WF.IFTRACK II.4B_90 days_Exempt_Ingredients**

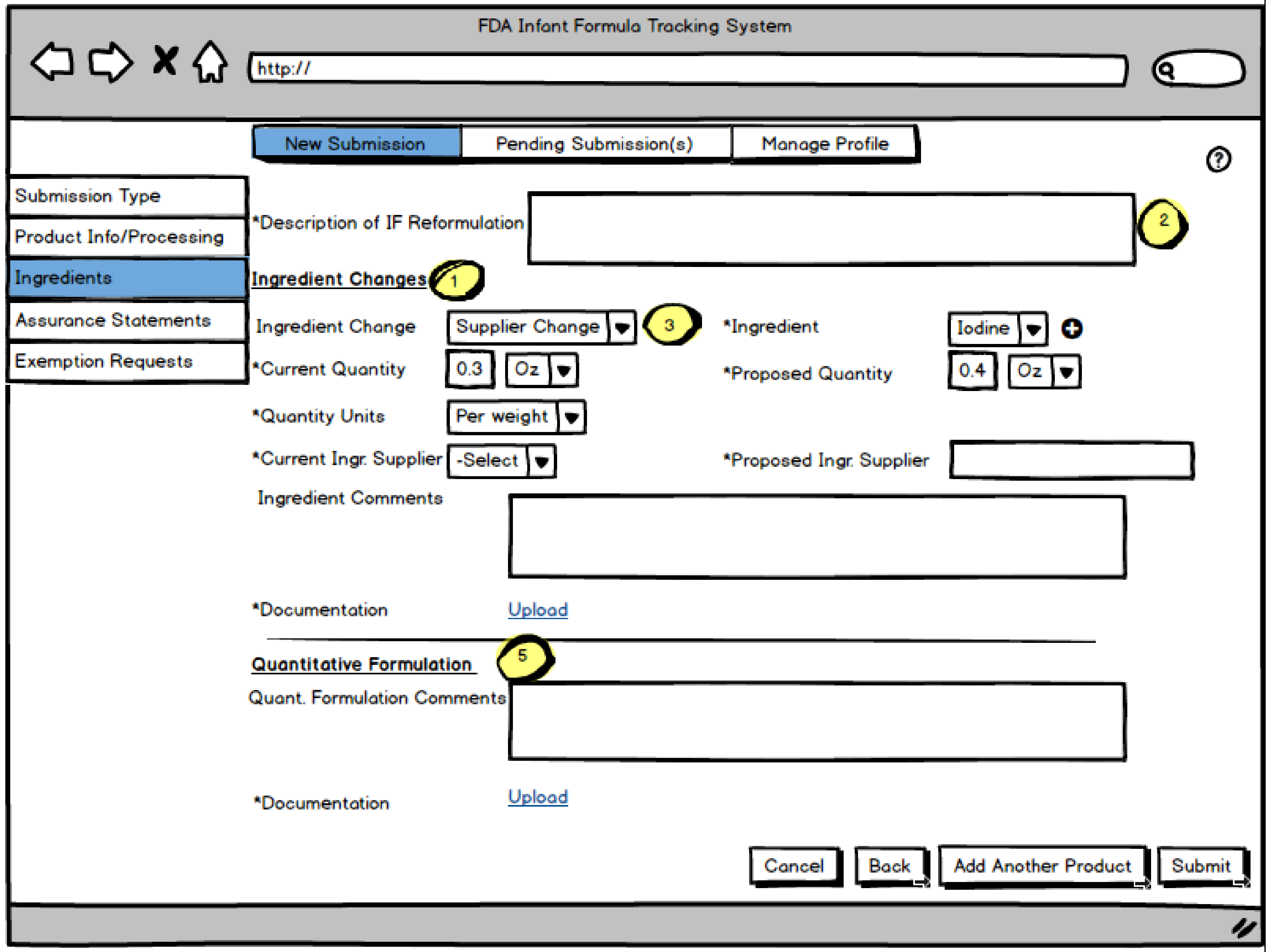
Purpose: To enter ingredients information.

① 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 optoinal 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
Assurance Statements
Exemption Requests
Upload
Upload
Cancel
Back
Add Another Product
Submit
1
2
3
5

*Description of IF Reformulation

**Ingredient Changes**

Ingredient Change: Supplier Change
*Ingredient: Iodine
*Current Quantity: 0.3 Oz
*Proposed Quantity: 0.4 Oz
*Quantity Units: Per weight
*Current Ingr. Supplier: -Select
*Proposed Ingr. Supplier
Ingredient Comments
*Documentation: Upload

**Quantitative Formulation**

Quant. Formulation Comments
*Documentation: Upload

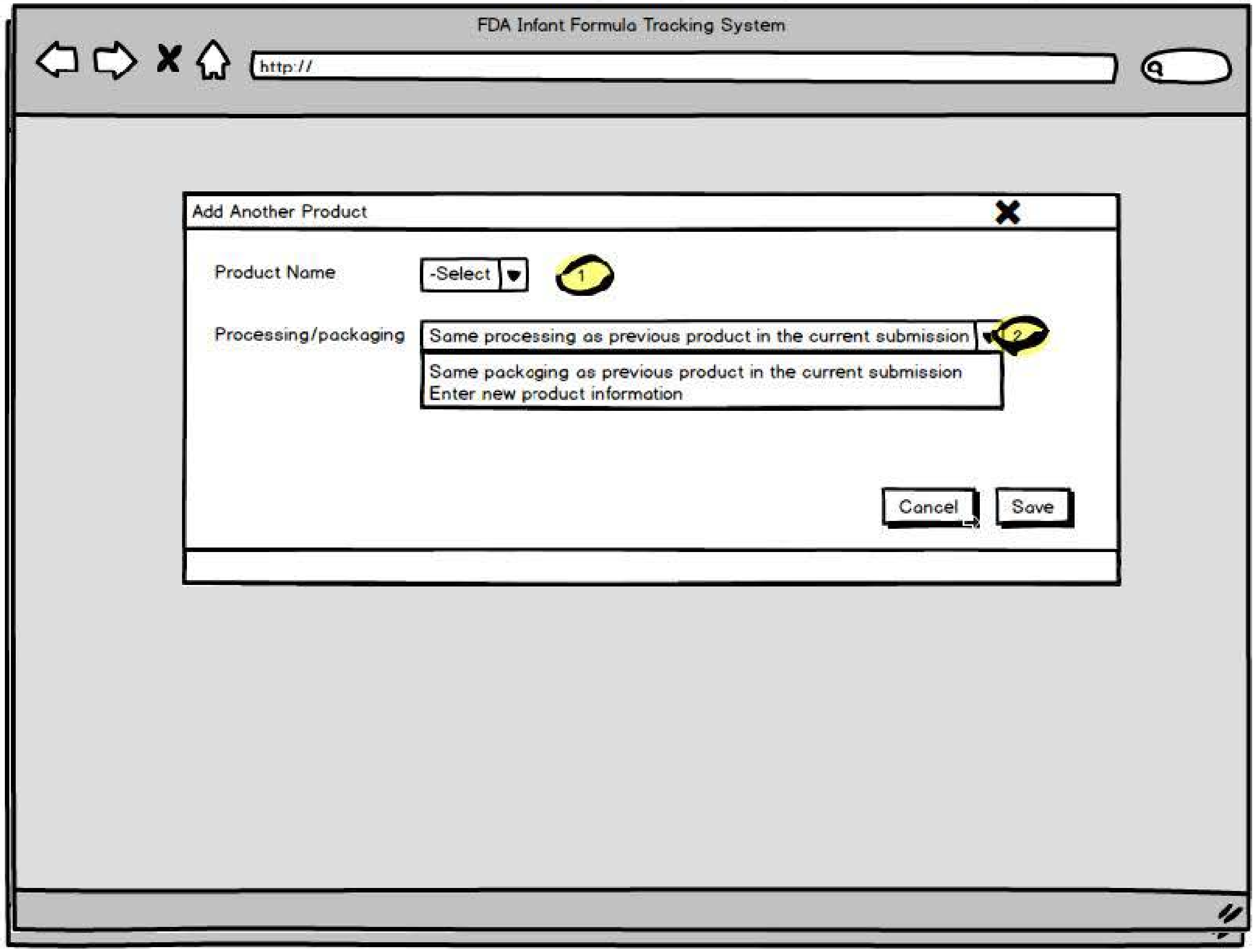
## FDA CFSAN IFTRACK II Wireframes

## 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 enetered.

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.



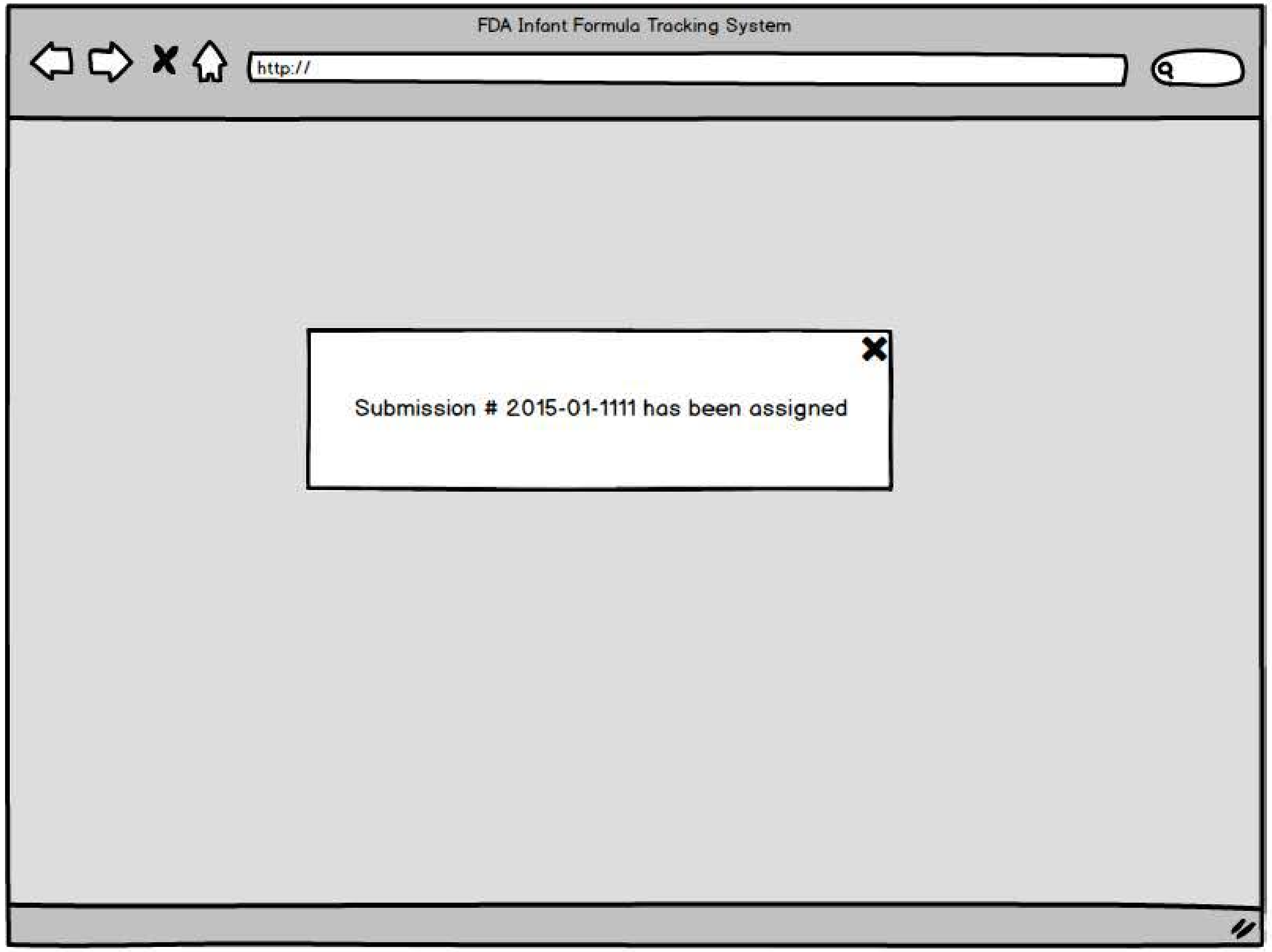
Product Name -Select

Processing/packaging Same processing as previous product in the current submission
Same packaging as previous product in the current submission
Enter new product information

**FDA CFSAN IFTRACK II Wireframes**

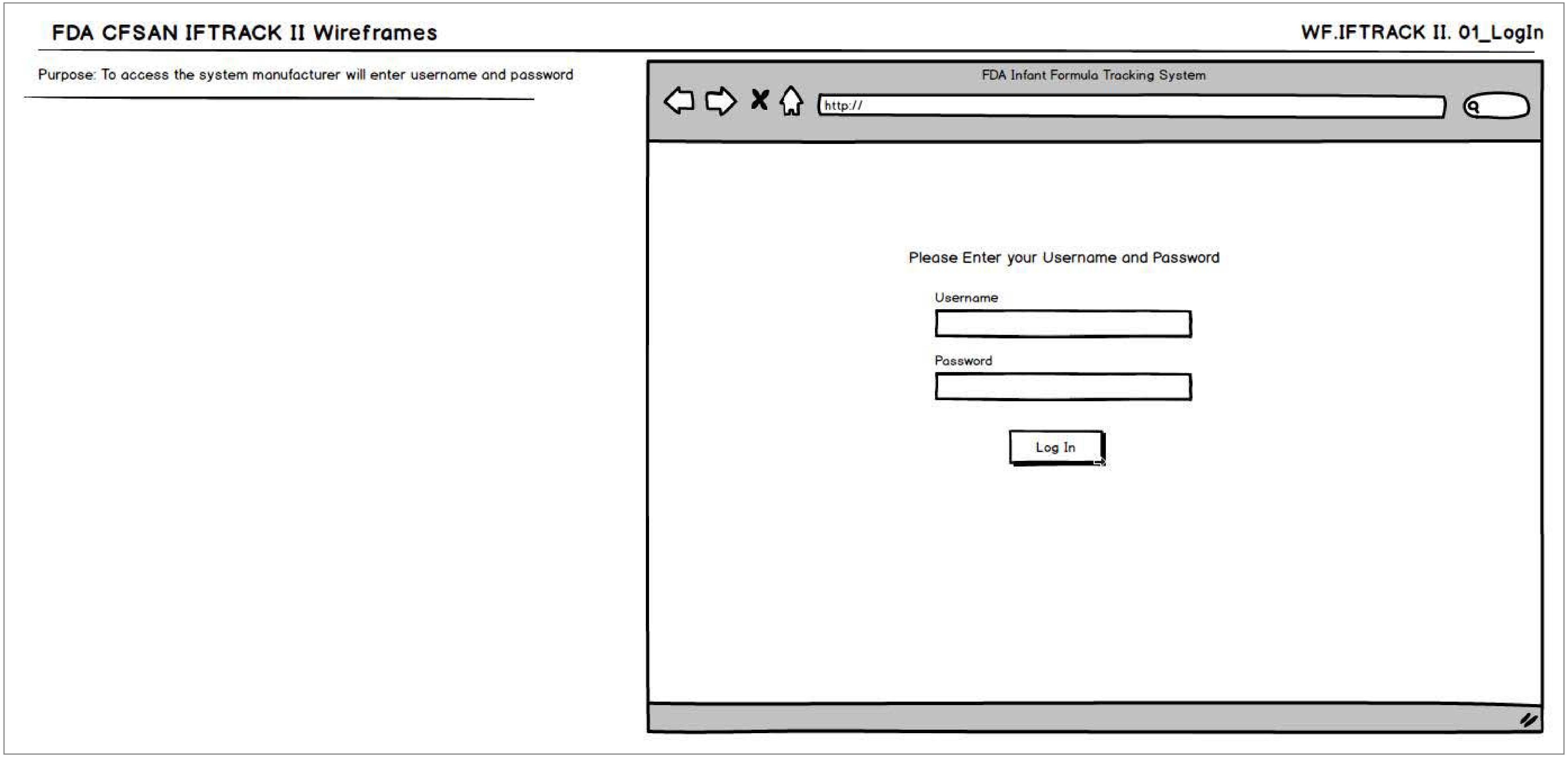
**WF.IFTRACK II.8A_AssignedSubmissionRef#**

Purpose: To view assigned Submission Reference Number


FDA Infant Formula Tracking System
http://

Submission # 2015-01-1111 has been assigned

### 1.2 90 DAYS NON-EXEMPT SUBMISSION



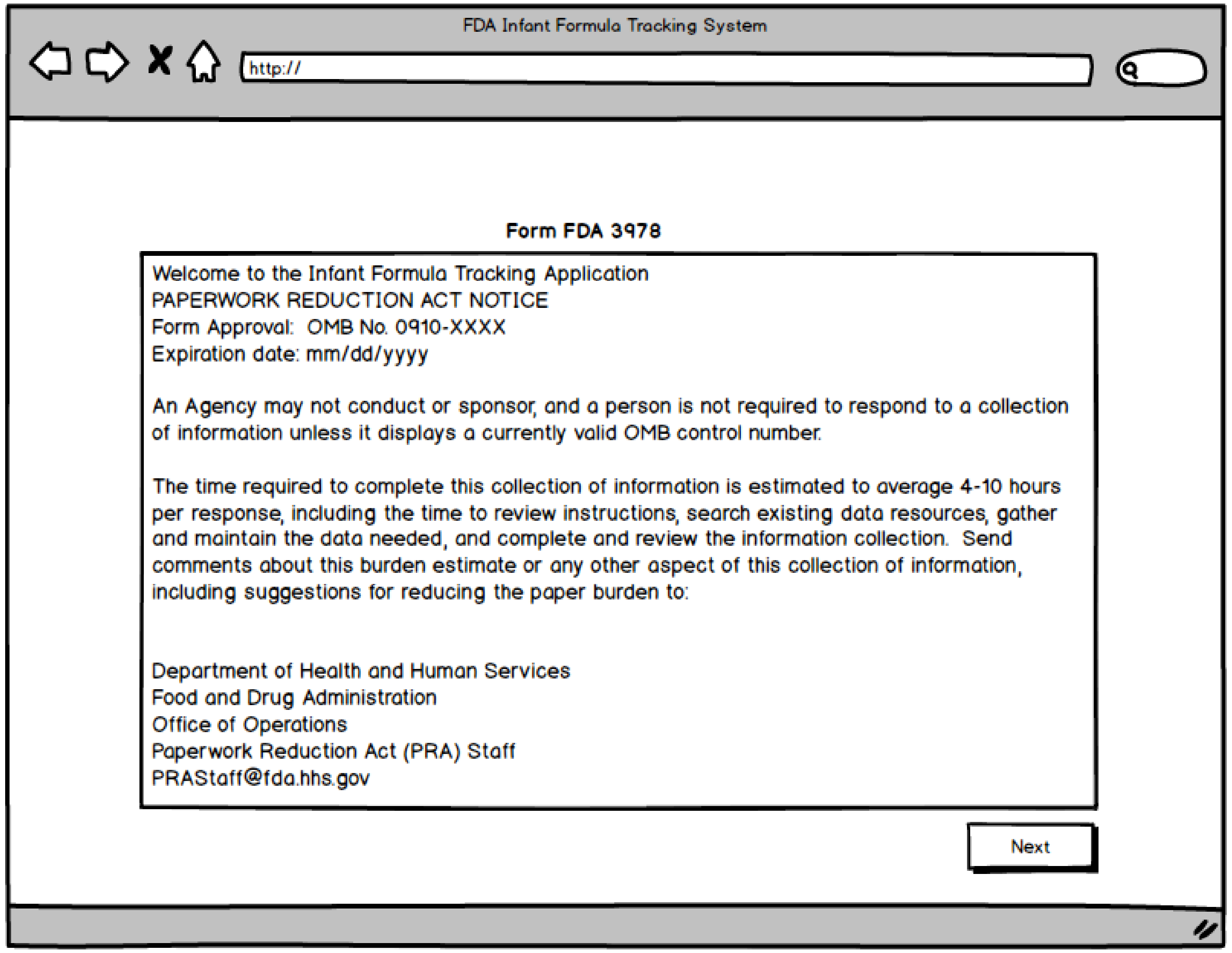
**FDA CFSAN IFTRACK II Wireframes**

**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

**FDA CFSAN IFTRACK II Mockups** **WF.IFTRACK II_001_Welcome**



**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:

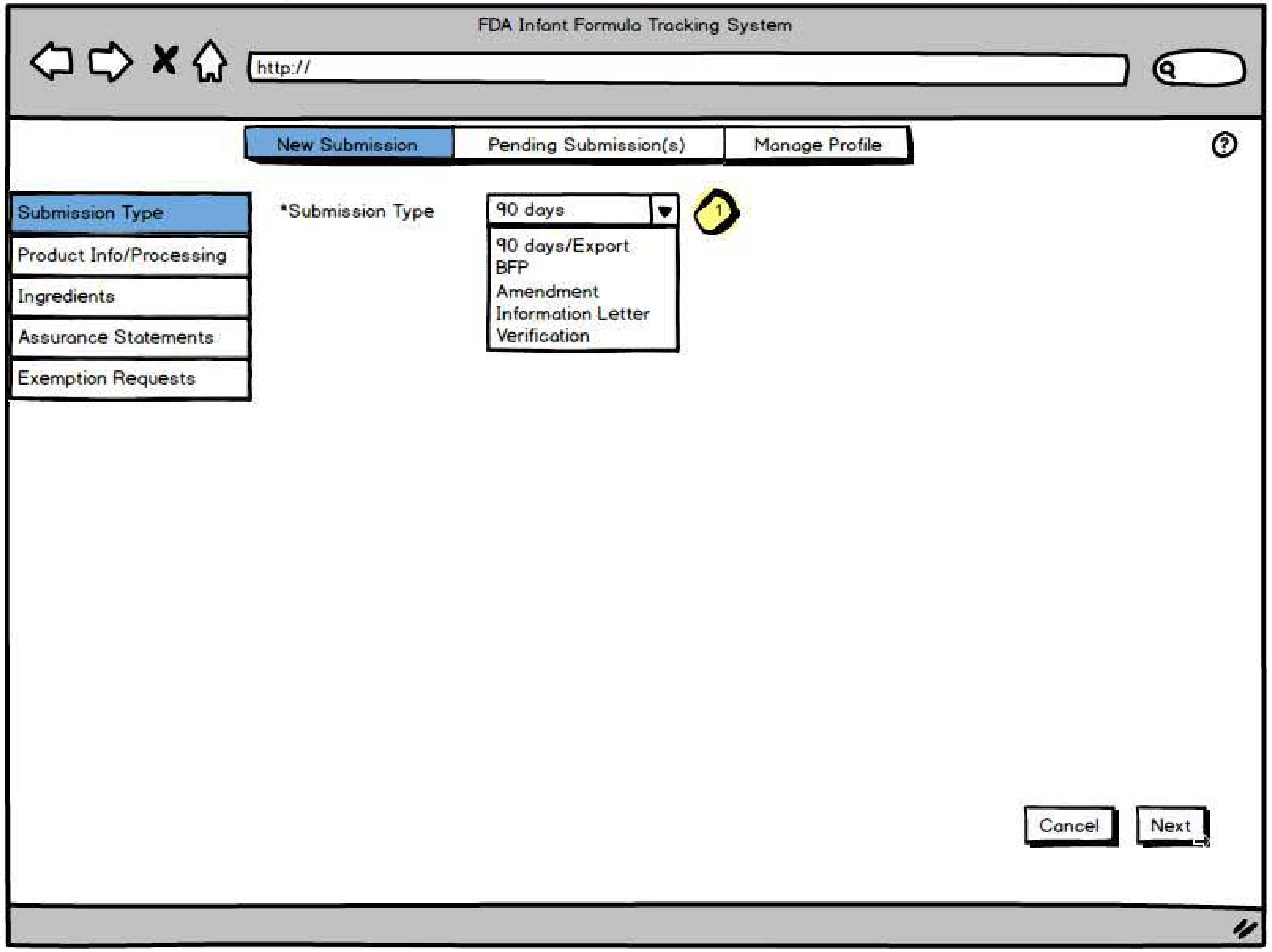
Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

## FDA CFSAN IFTRACK II Wireframes

## WF.IFTRACK II.1A_90Days SubmissionType

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

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


*Submission Type: 90 days ①

FDA Infant Formula Tracking System
http://
New Submission
Pending Submission(s)
Manage Profile
Submission Type
Product Info/Processing
Ingredients
Assurance Statements
Exemption Requests
90 days/Export
BFP
Amendment
Information Letter
Verification
Cancel
Next

**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
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 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

3. IF Explanation/Other will only be displayed as a selection if any other/ primary value for IF Explanation has been selected.
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.

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

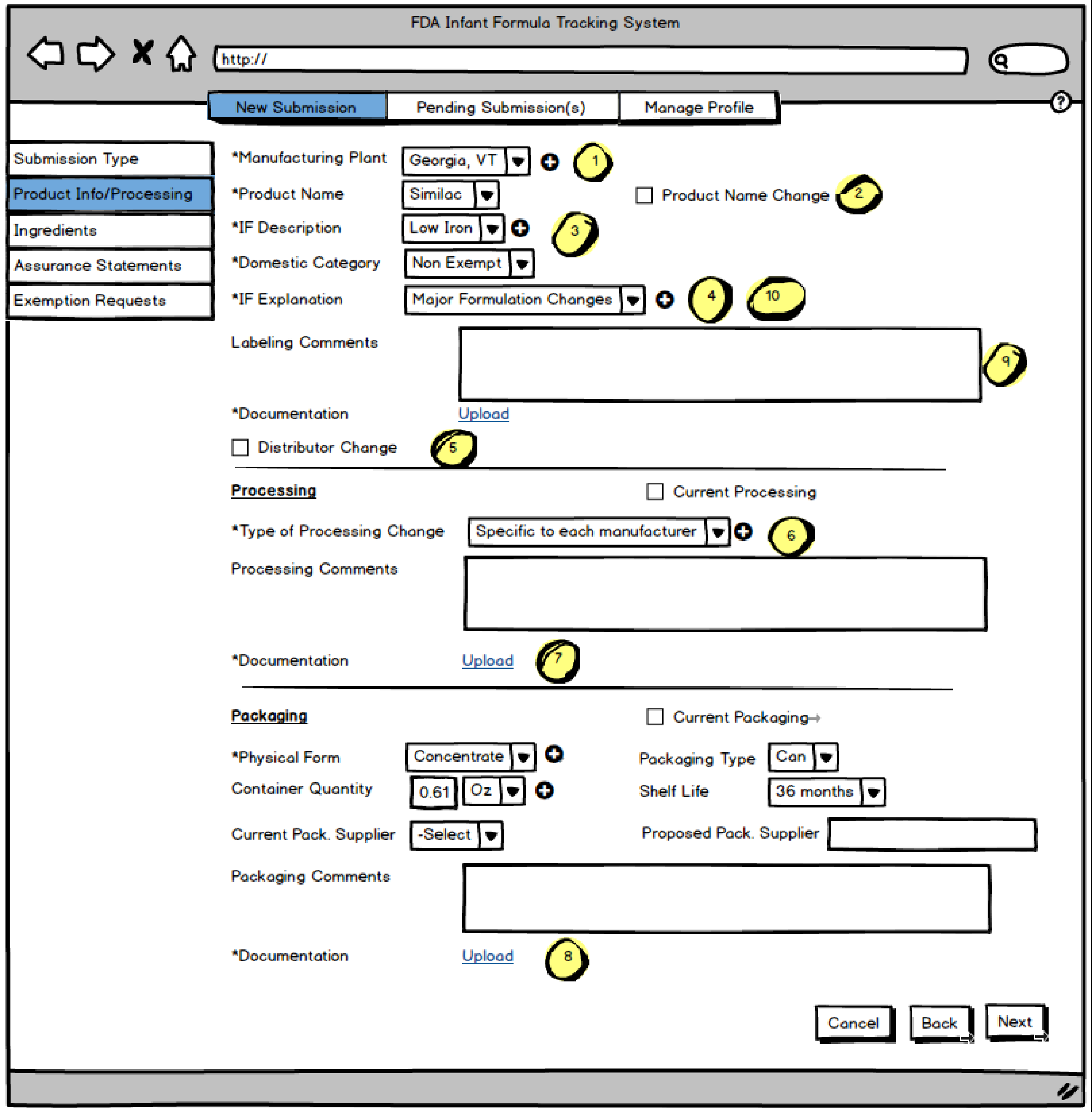
⑥ 1. Type of Processing Change is only required if Major processing change and/or Non Major processing change are selected for 90 days/IF Explanation.
2.The user will be able to add more than one value under Type of Processing Change field.

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 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.



*Manufacturing Plant: Georgia, VT
*Product Name: Similac
☐ Product Name Change
*IF Description: Low Iron
*Domestic Category: Non Exempt
*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

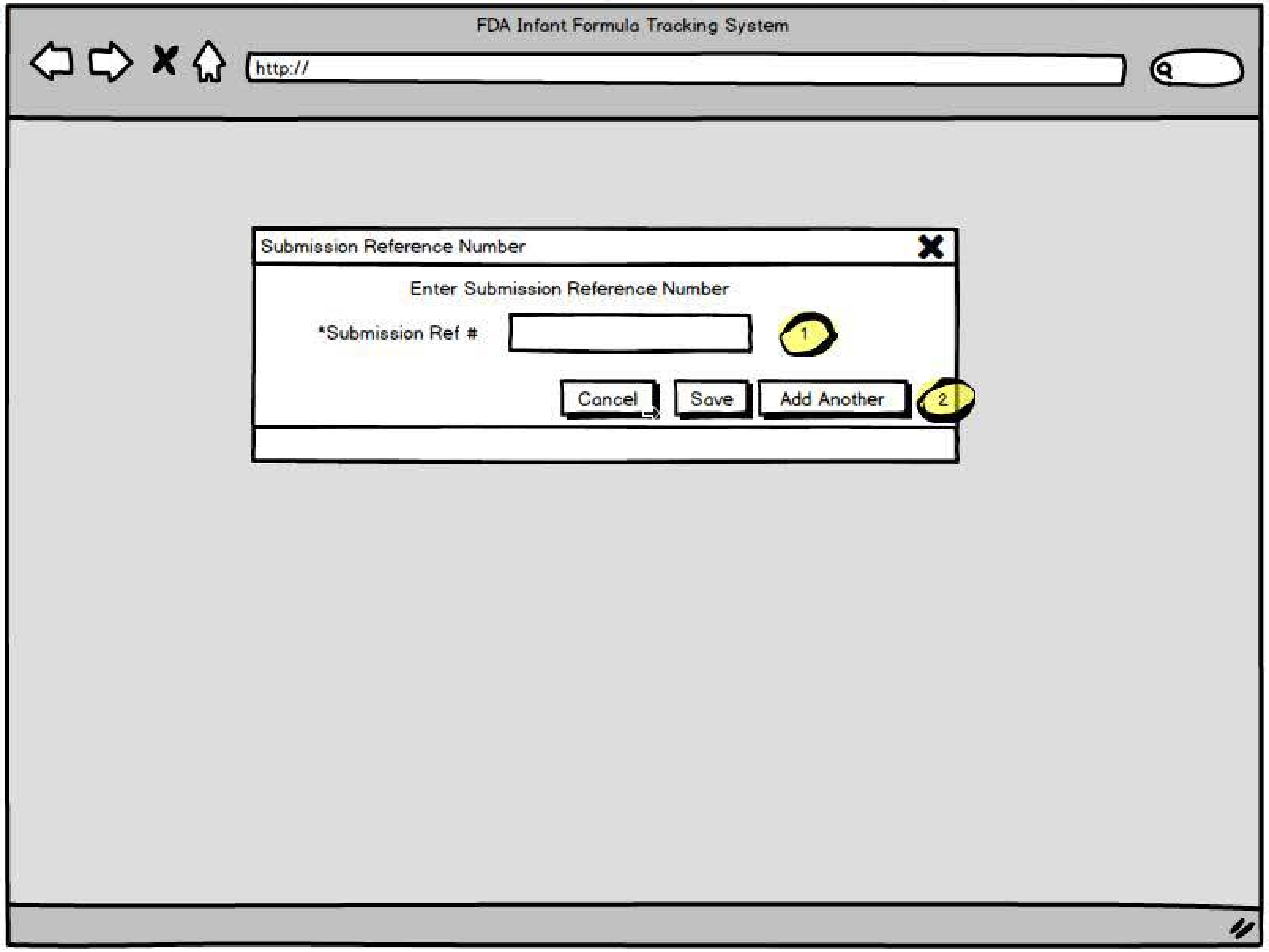
**Packaging**
☐ Current Packaging
*Physical Form: Concentrate
Packaging Type: Can
Container Quantity: 0.61 Oz
Shelf Life: 36 months
Current Pack. Supplier: -Select
Proposed Pack. Supplier:
Packaging Comments:
*Documentation: Upload

## 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

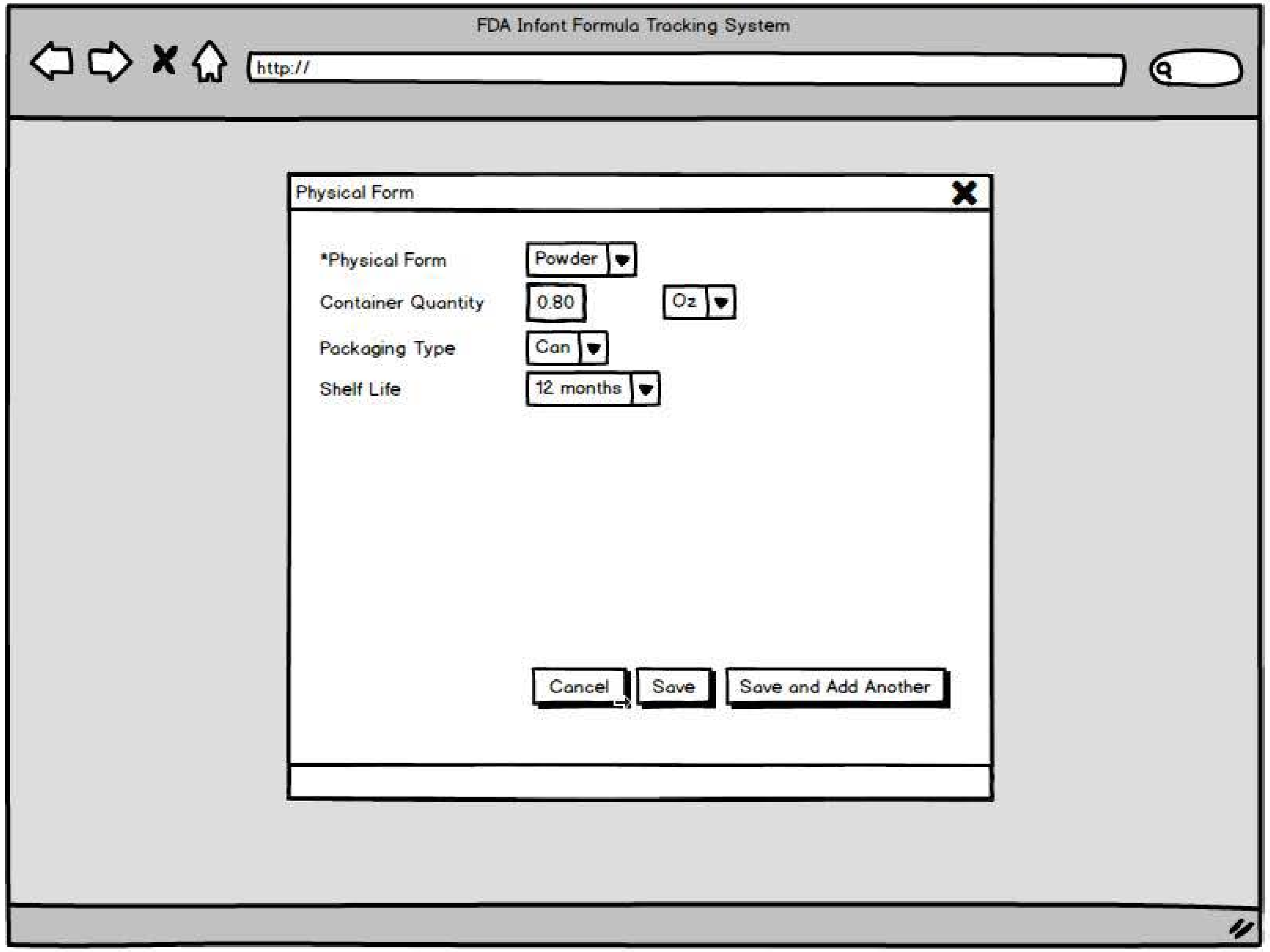
1. Submission Ref # field is required if the user selects Current Packaging or Current Processing option.
2. The user will be able to add more than one Submission Reference Number.


FDA Infant Formula Tracking System
http://
Submission Reference Number
Enter Submission Reference Number
*Submission Ref #
1
Cancel
Save
Add Another
2

**FDA CFSAN IFTRACK II Wireframes**

**WF.IFTRACK II. 3A_Processing_AddNewPhysicalForm**

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



FDA Infant Formula Tracking System
http://
Physical Form
Cancel
Save
Save and Add Another

| | |
|---|---|
| *Physical Form | Powder |
| Container Quantity | 0.80 Oz |
| Packaging Type | Can |
| Shelf Life | 12 months |

**FDA CFSAN IFTRACK II Wireframes** **WF.IFTRACK II.4A_90 days_Non Exempt_Ingredients**

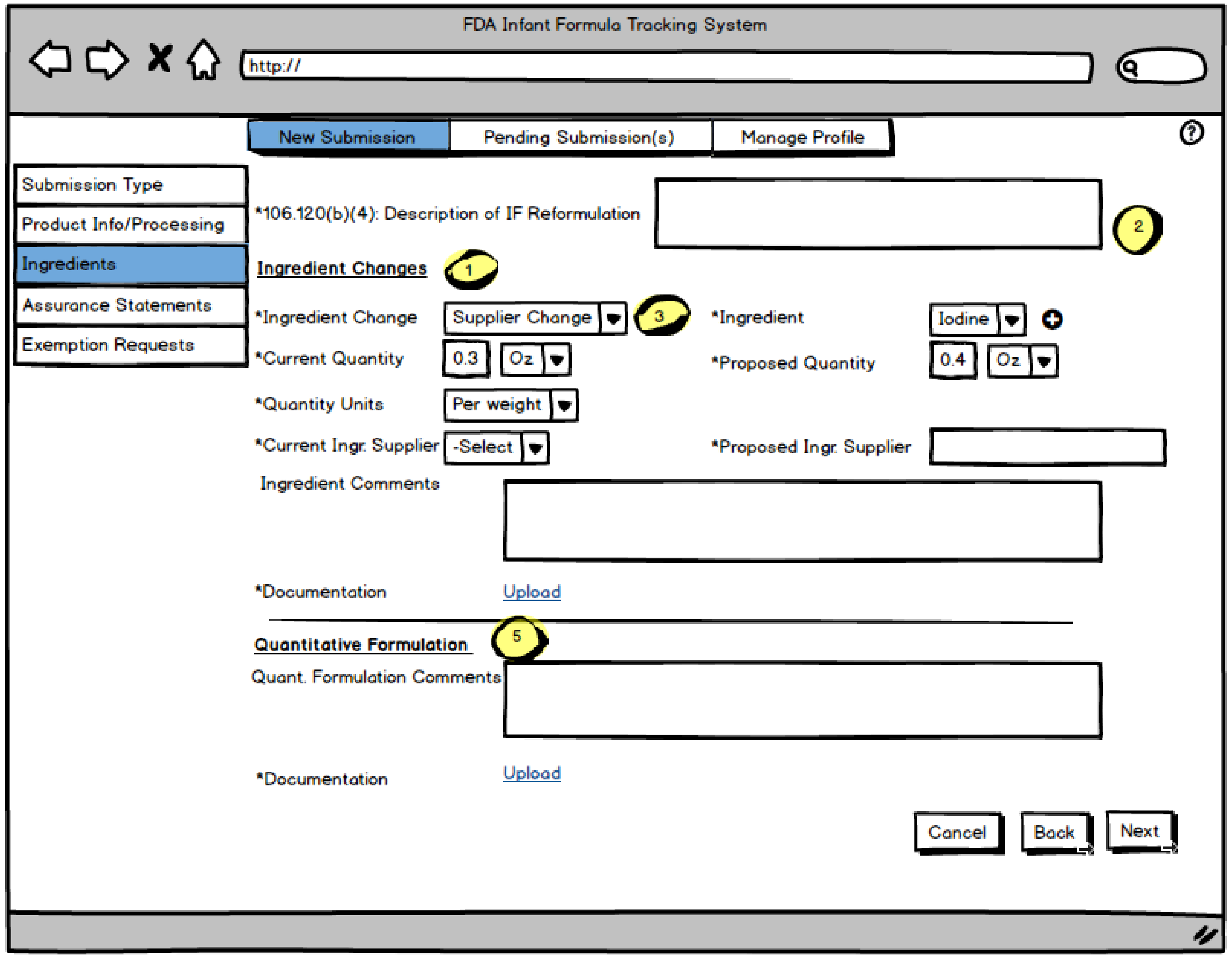
Purpose: To enter ingredients information.

① 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 optoinal 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
Assurance Statements
Exemption Requests
*106.120(b)(4): Description of IF Reformulation
②
Ingredient Changes
①
③
Ingredient Comments
*Documentation
Upload
Quantitative Formulation
⑤
Quant. Formulation Comments
*Documentation
Upload
Cancel
Back
Next

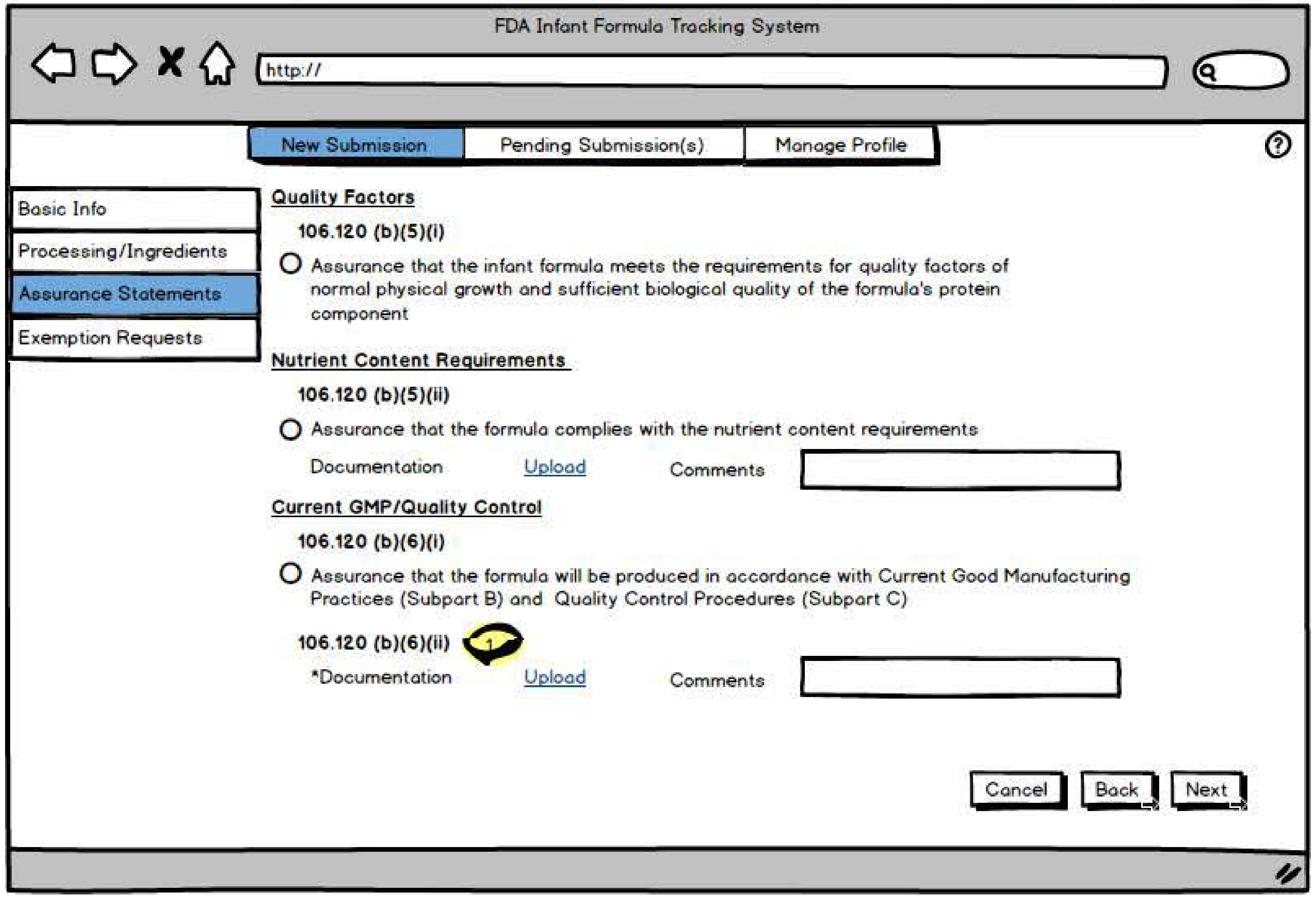
*Ingredient Change: Supplier Change
*Ingredient: Iodine
*Current Quantity: 0.3 Oz
*Proposed Quantity: 0.4 Oz
*Quantity Units: Per weight
*Current Ingr. Supplier: -Select
*Proposed Ingr. Supplier:

## FDA CFSAN IFTRACK II Wireframes

## WF.IFTRACK II.5A_90Days_Non Exempt_QualityFactors

Purpose: To select Quality Factors and enter Quaility Factors information

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


FDA Infant Formula Tracking System
http://
New Submission
Pending Submission(s)
Manage Profile
Basic Info
Processing/Ingredients
Assurance Statements
Exemption Requests
Cancel
Back
Next

**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)

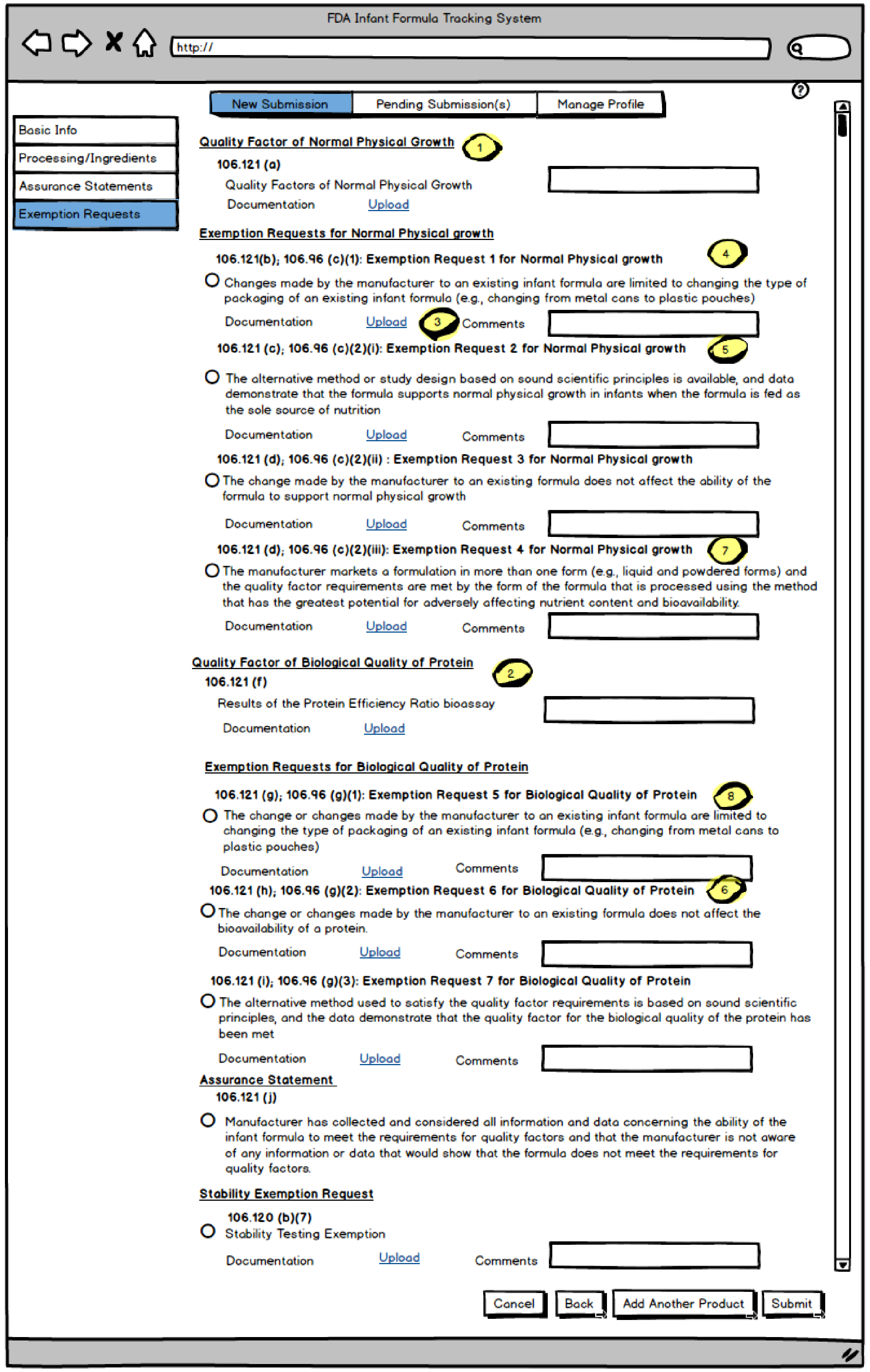
**106.120 (b)(6)(ii)** 1

*Documentation Upload Comments

**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.



**Quality Factor of Normal Physical Growth**

**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**

○ 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 (c); 106.96 (c)(2)(i): Exemption Request 2 for Normal Physical growth**

○ 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**

○ 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**

**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**

○ 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**

○ 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

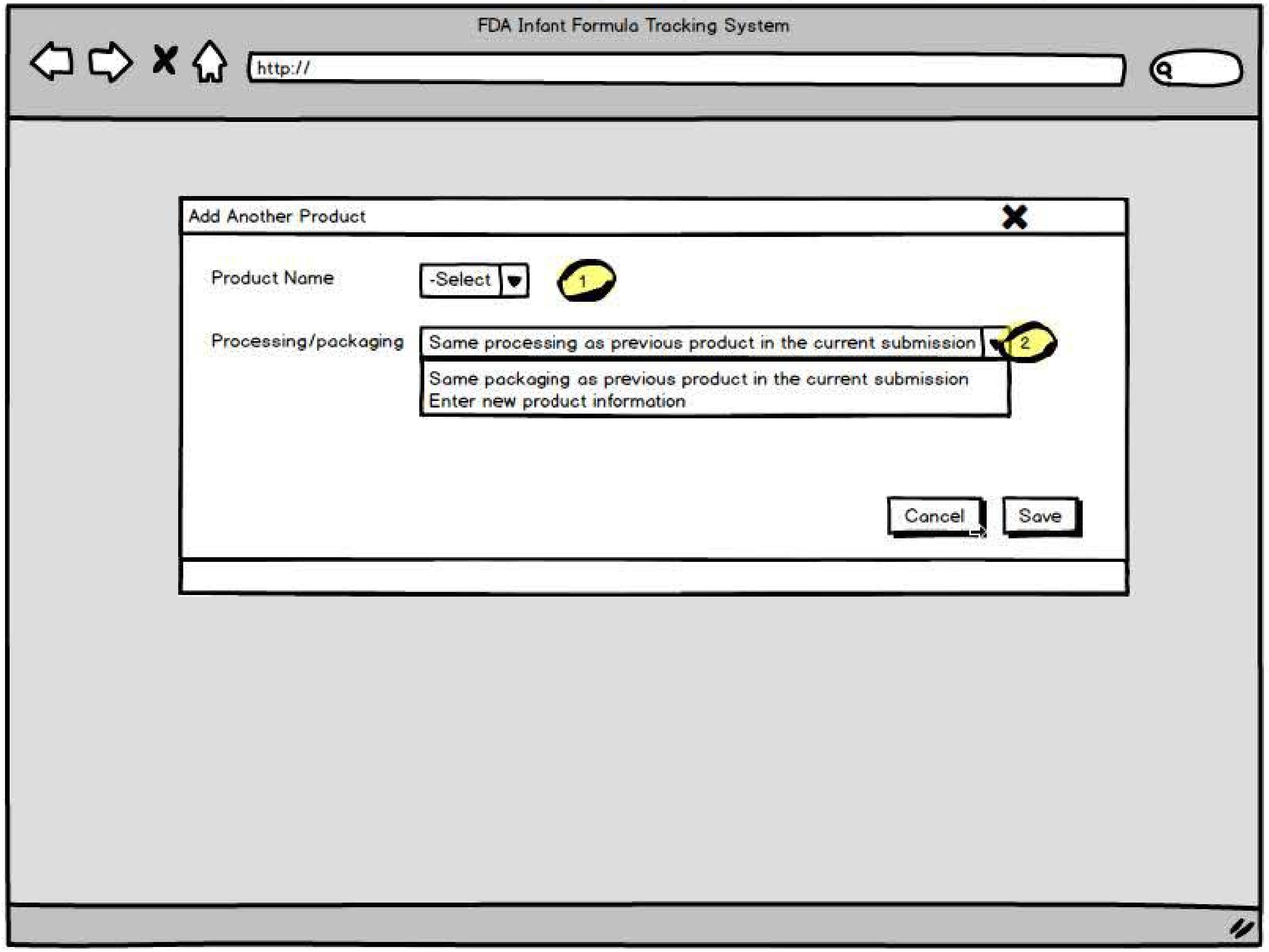
## FDA CFSAN IFTRACK II Wireframes

## 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 enetered.

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.



Add Another Product

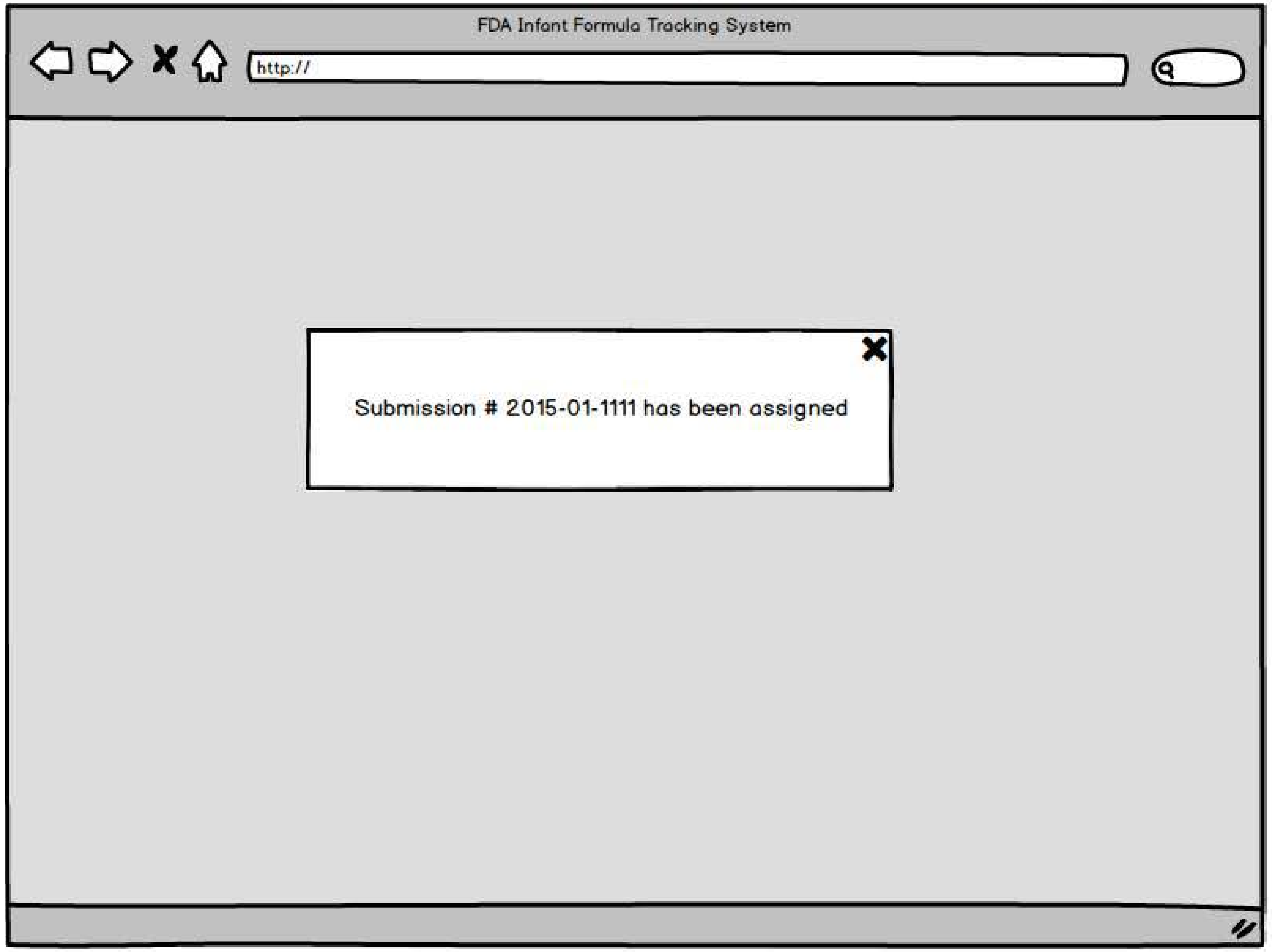
Product Name: -Select ①

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

**FDA CFSAN IFTRACK II Wireframes**

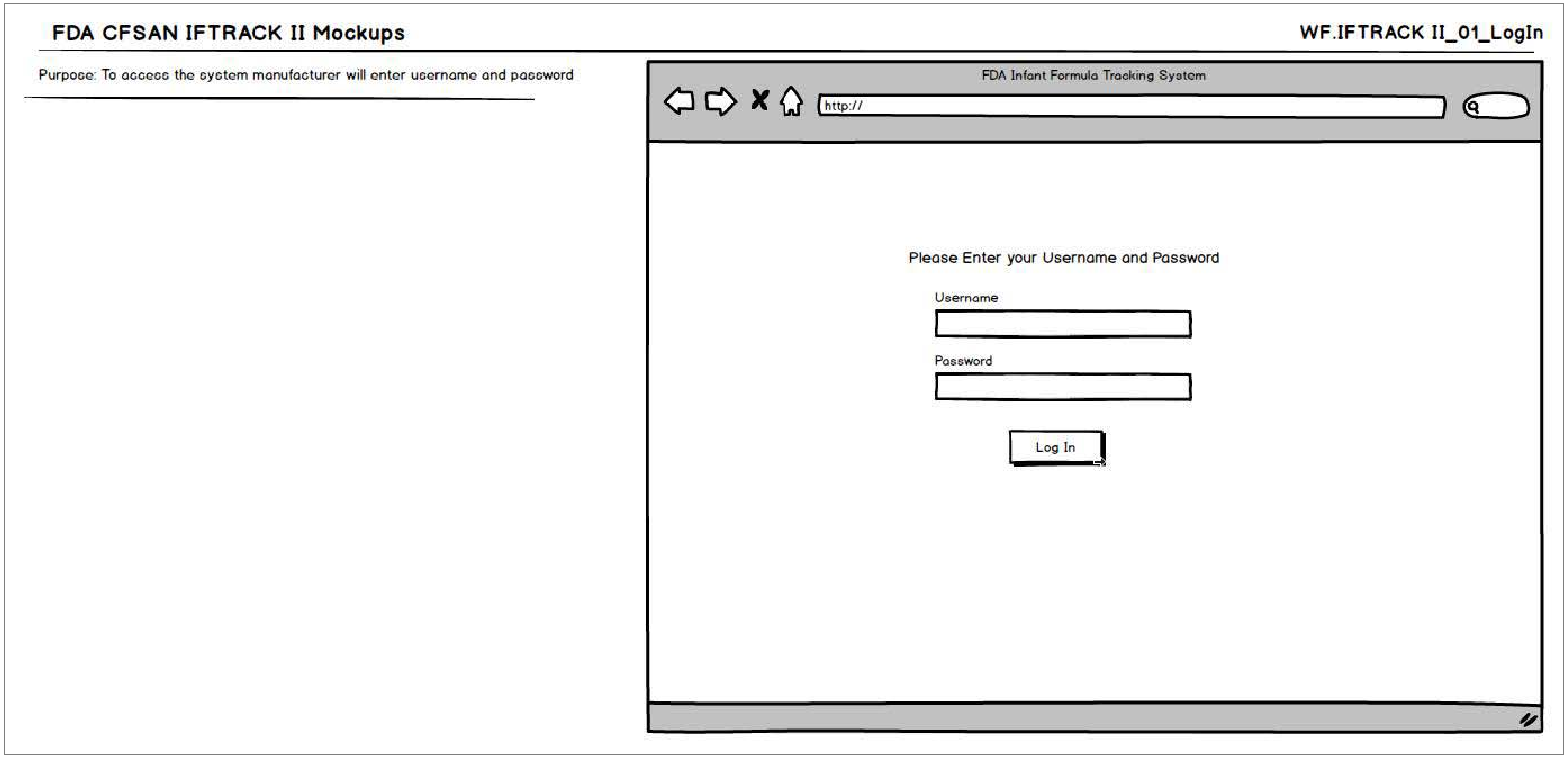
**WF.IFTRACK II.8A_AssignedSubmissionRef#**

Purpose: To view assigned Submission Reference Number


FDA Infant Formula Tracking System
http://

Submission # 2015-01-1111 has been assigned

## 1.3 90 DAYS EXPORT SUBMISSION



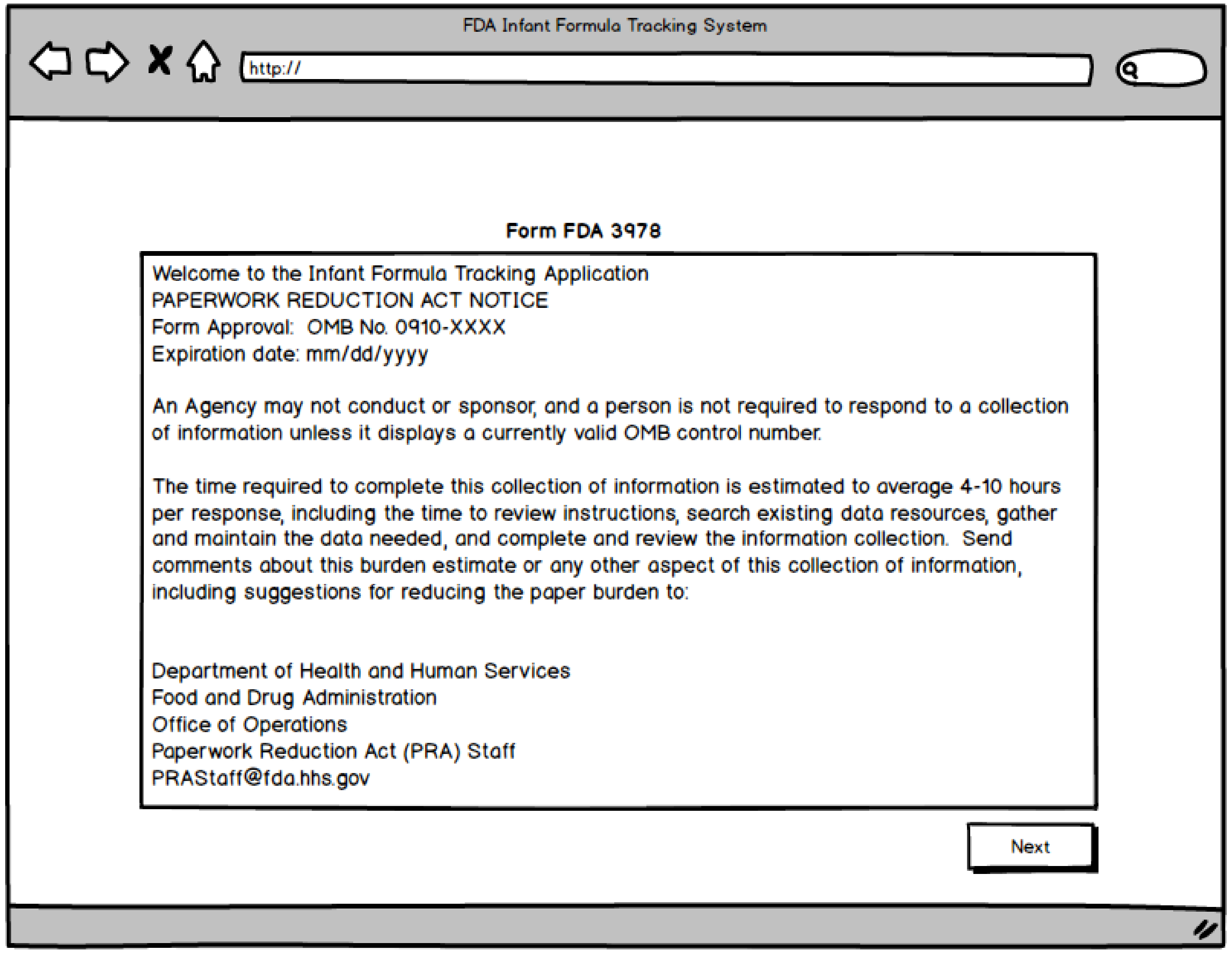
FDA CFSAN IFTRACK II Mockups

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
Log In

**FDA CFSAN IFTRACK II Mockups** **WF.IFTRACK II_001_Welcome**



**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:

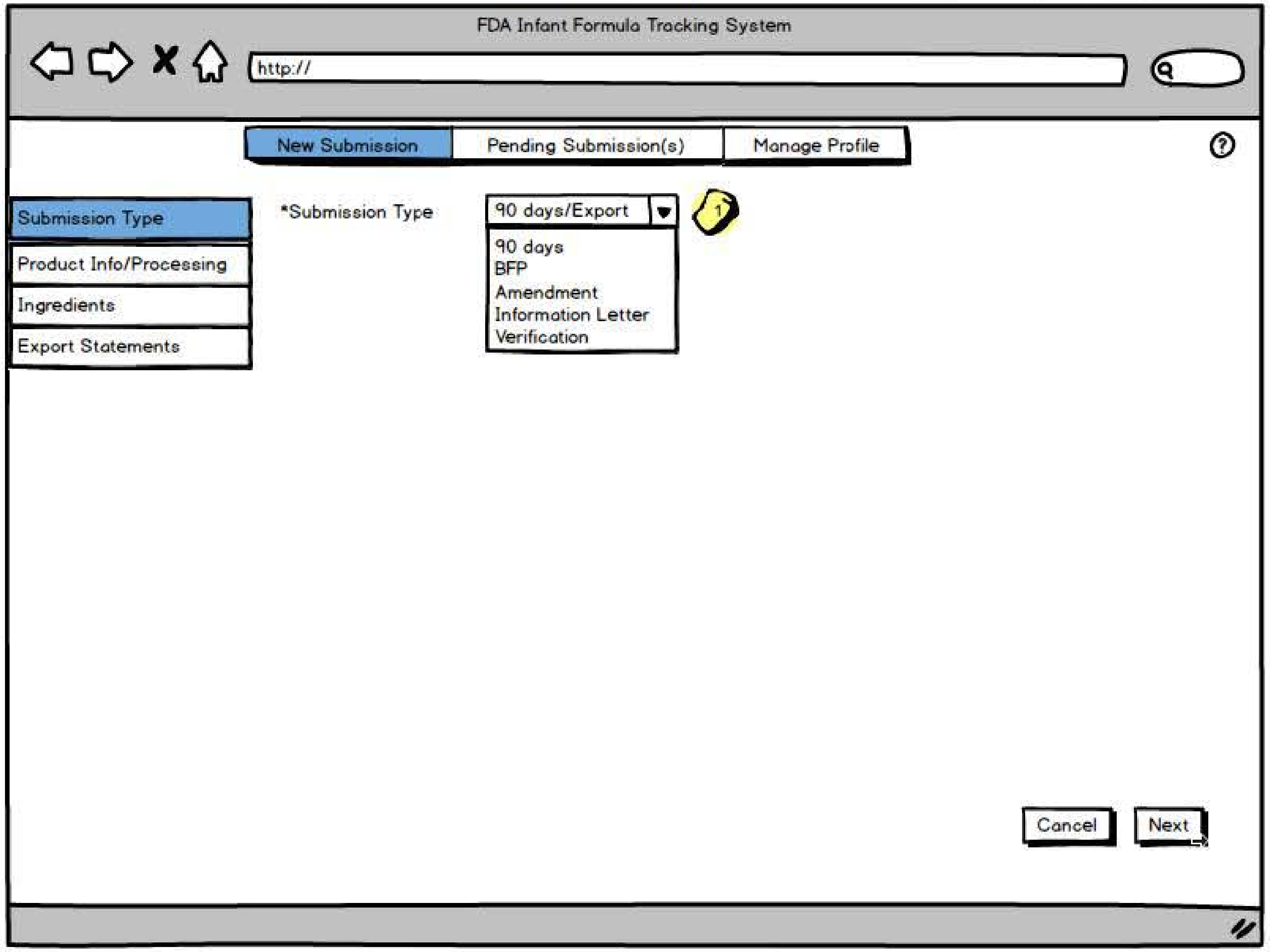
Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

**FDA CFSAN IFTRACK II Mockups**

**WF.IFTRACK II.1C_90Days_Export_SubmissionType**

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

① 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
90 days
BFP
Amendment
Information Letter
Verification
1
Cancel
Next

*Submission Type: 90 days/Export

## WF.IFTRACK II.2E_90Days_Export_Processing

Purpose: To enter product, processing and packaging information.

① The user will be able to add multiple Manufacturing Plants
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 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.

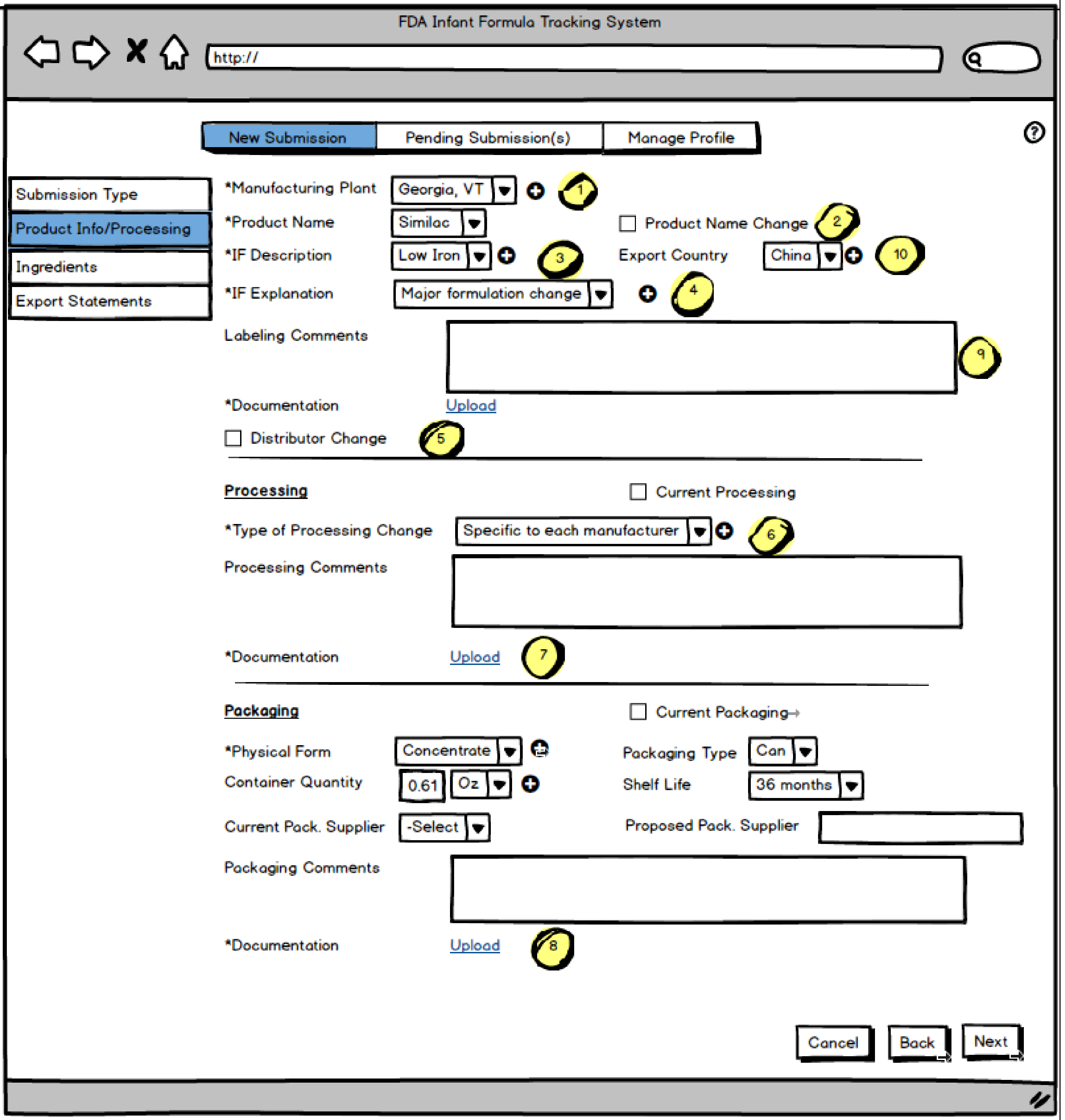
⑥ 1. Type of Processing Change is only required if Major processing change and/or Non Major processing change are selected for 90 days/IF Explanation.
2.The user will be able to add more than one value under Type of Processing Change field.

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.



*Manufacturing Plant: Georgia, VT ▾ ⊕ ①
*Product Name: Similac ▾
☐ Product Name Change ②
*IF Description: Low Iron ▾ ⊕ ③
Export Country: China ▾ ⊕ ⑩
*IF Explanation: Major formulation change ▾ ⊕ ④
Labeling Comments ⑨
*Documentation: Upload
☐ Distributor Change ⑤

**Processing**
☐ Current Processing
*Type of Processing Change: Specific to each manufacturer ▾ ⊕ ⑥
Processing Comments
*Documentation: Upload ⑦

**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 ⑧

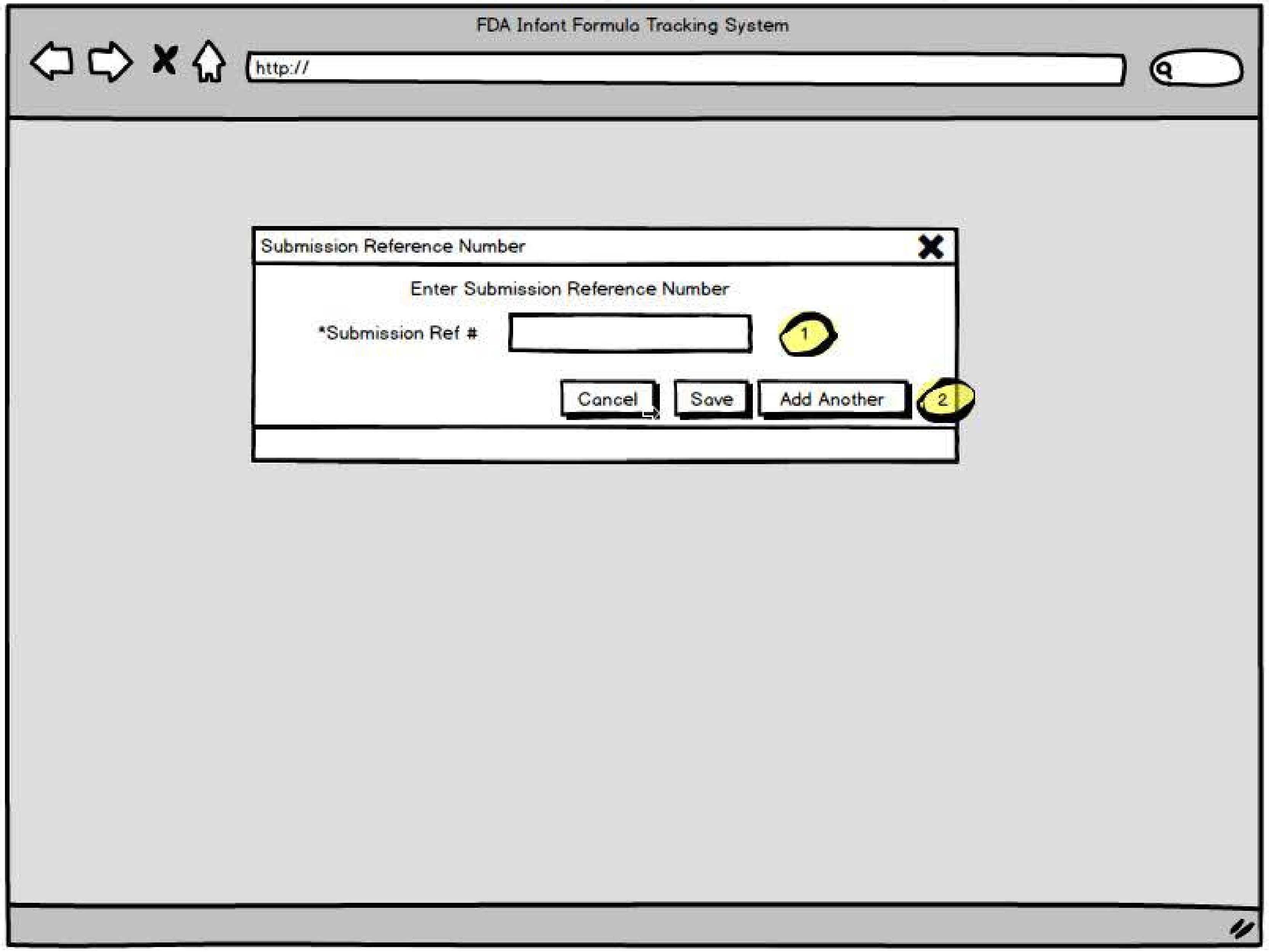
## FDA CFSAN IFTRACK II Mockups

## 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.

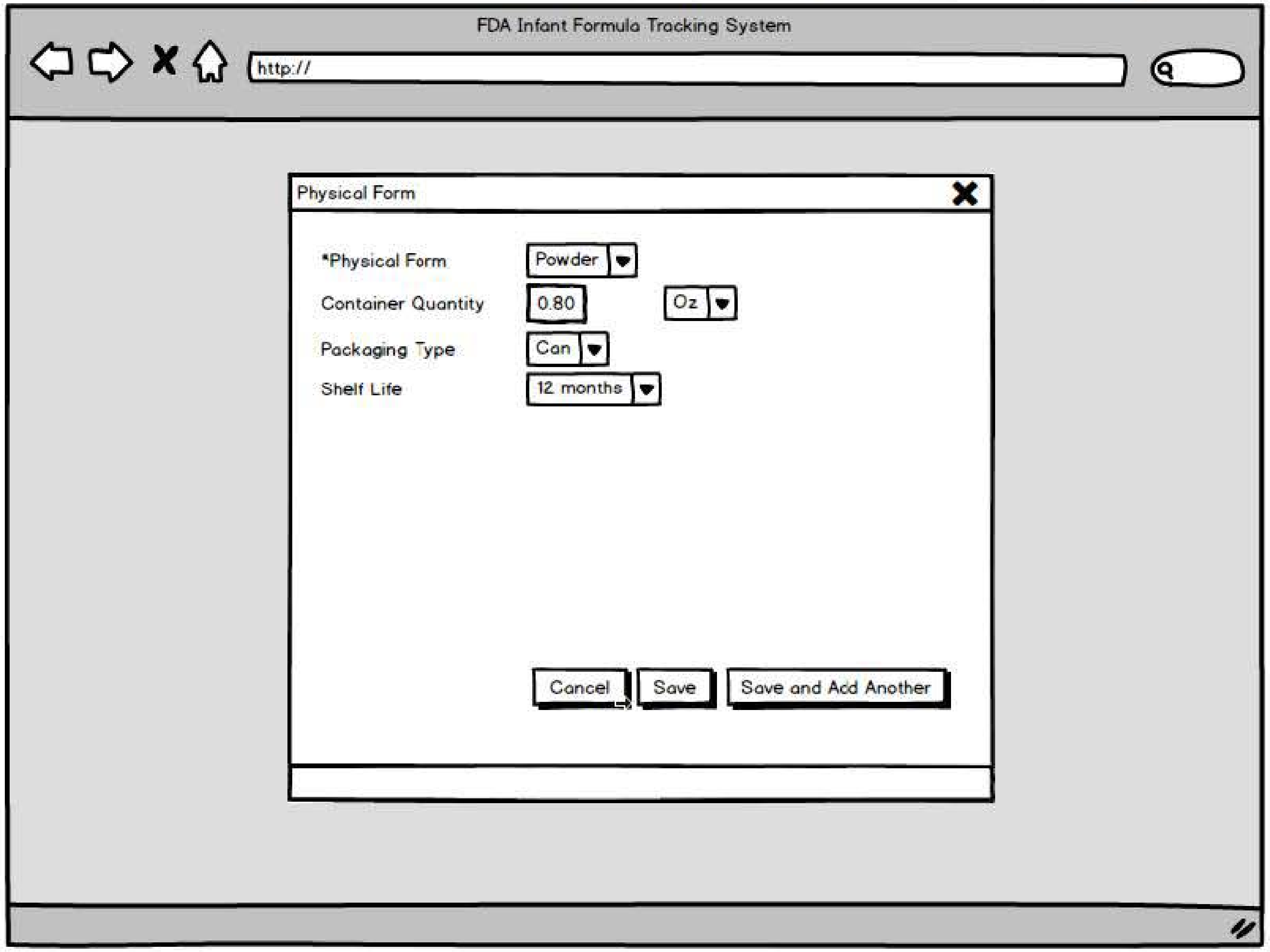
② The user will be able to add more than one Submission Reference Number.


FDA Infant Formula Tracking System
http://
Submission Reference Number
Enter Submission Reference Number
*Submission Ref #
1
Cancel
Save
Add Another
2

**FDA CFSAN IFTRACK II Mockups**

**WF.IFTRACK II.3A_Processing_AddNewPhysicalForm**

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


FDA Infant Formula Tracking System
http://
Physical Form
Cancel
Save
Save and Add Another

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

## FDA CFSAN IFTRACK II Mockups

## WF.IFTRACK II.4E_90Days_Export_Ingredients

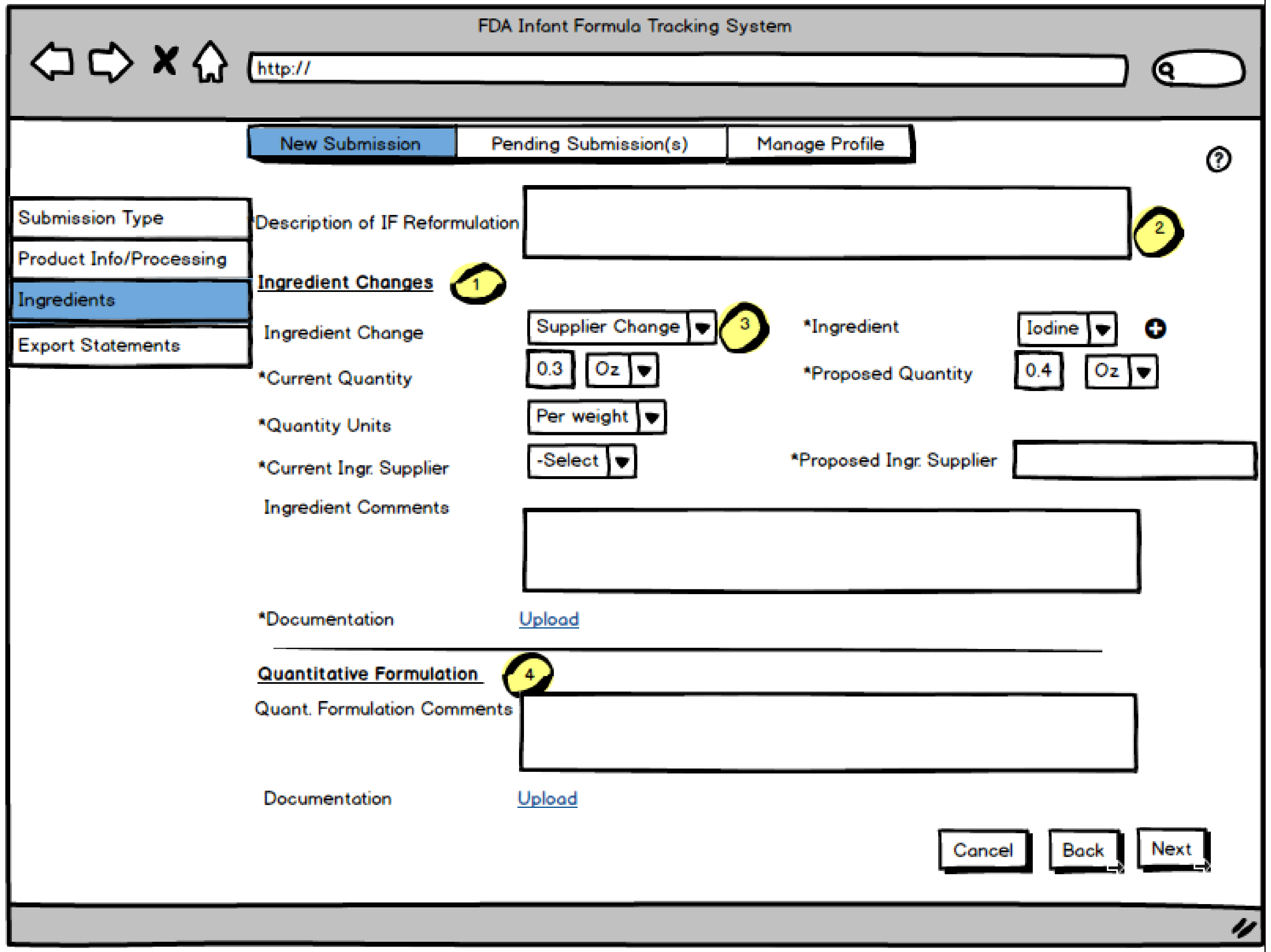
Purpose: To enter ingredients information.

① 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 optoinal 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 # .



Description of IF Reformulation

**Ingredient Changes**

Ingredient Change: Supplier Change

*Ingredient: Iodine

*Current Quantity: 0.3 Oz

*Proposed Quantity: 0.4 Oz

*Quantity Units: Per weight

*Current Ingr. Supplier: -Select

*Proposed Ingr. Supplier

Ingredient Comments

*Documentation: Upload

**Quantitative Formulation**

Quant. Formulation Comments

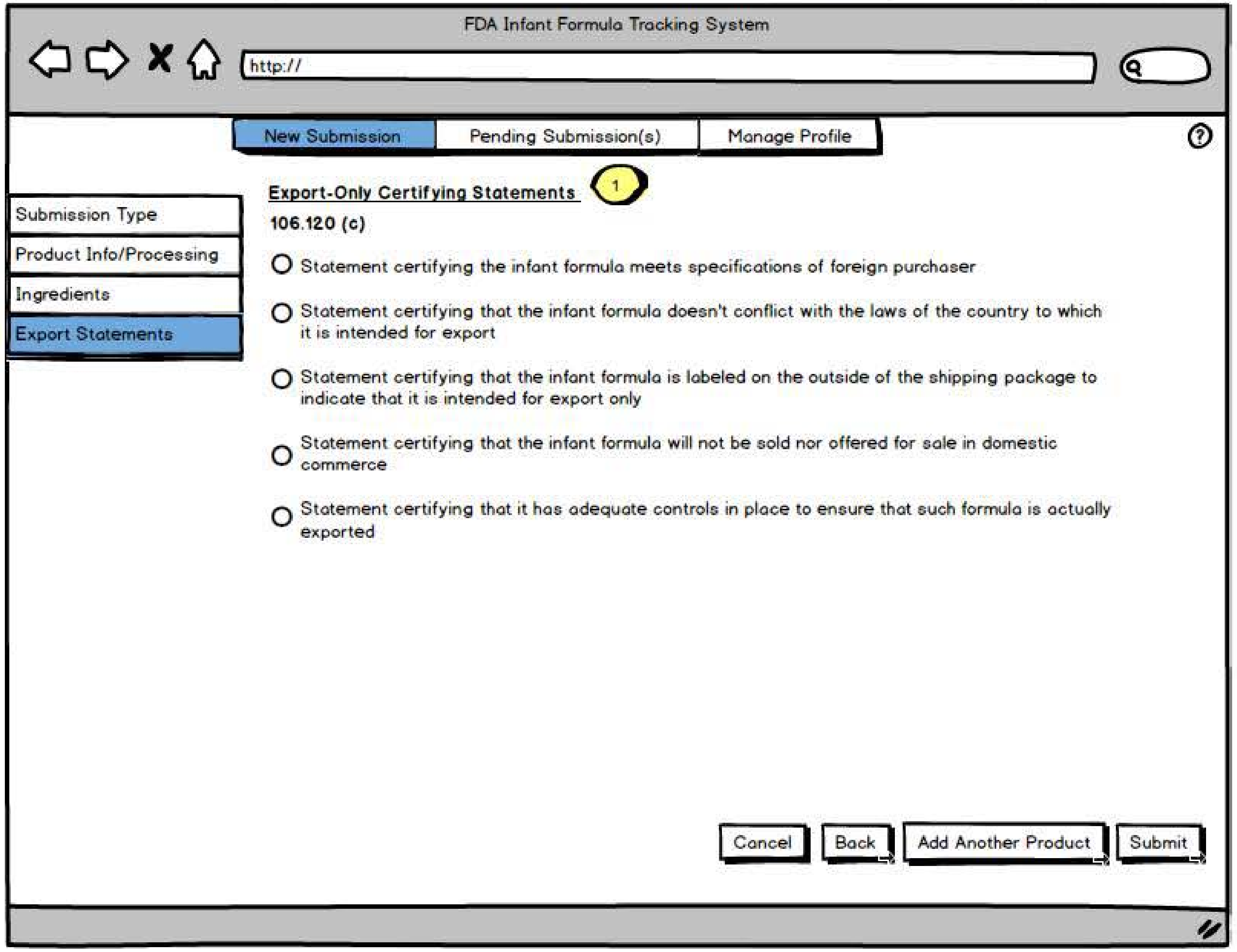
Documentation: Upload

## 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
http://
New Submission
Pending Submission(s)
Manage Profile
Submission Type
Product Info/Processing
Ingredients
Export Statements
Cancel
Back
Add Another Product
Submit

**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

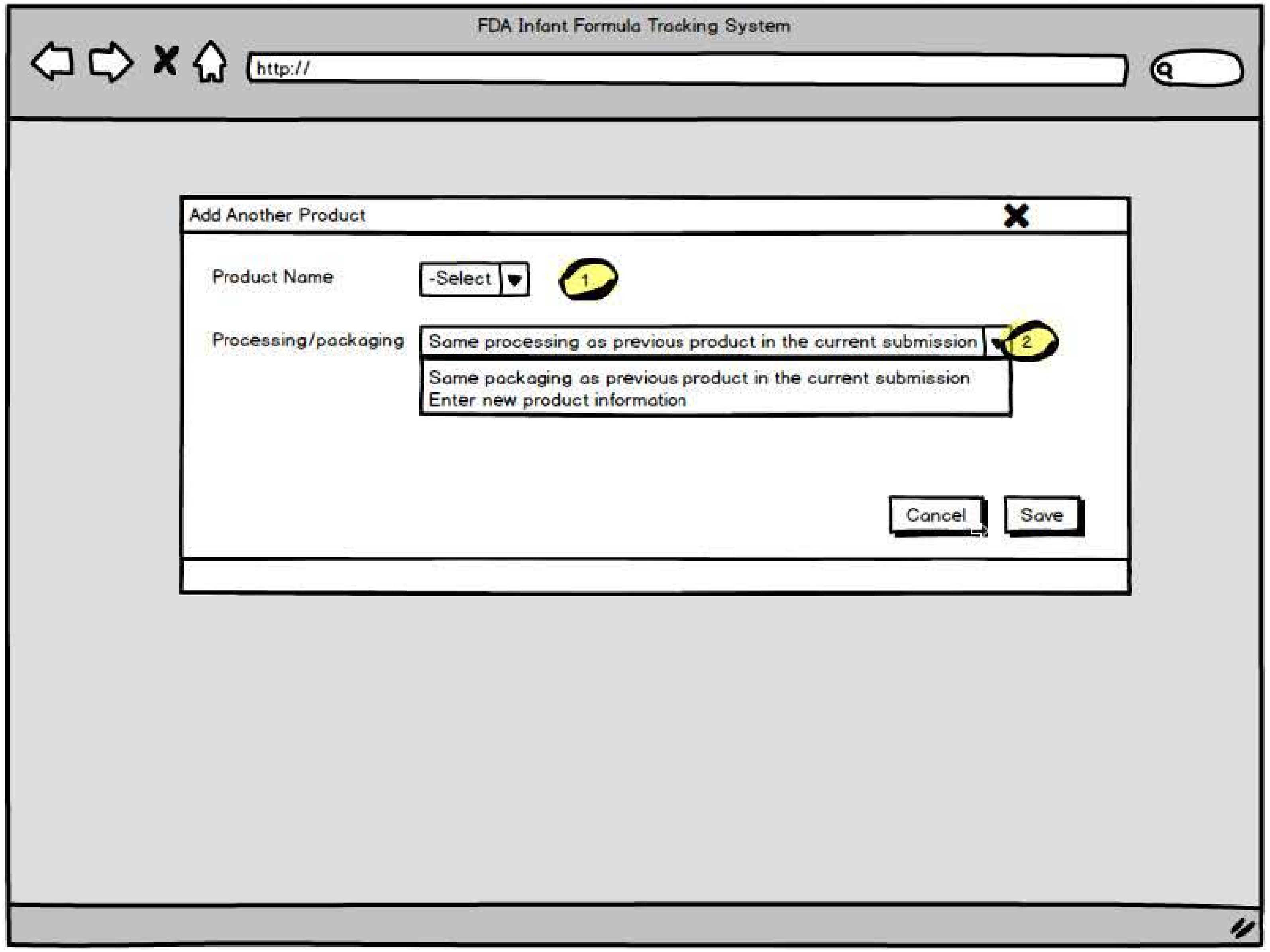
**FDA CFSAN IFTRACK II Mockups**

**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 enetered.

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.



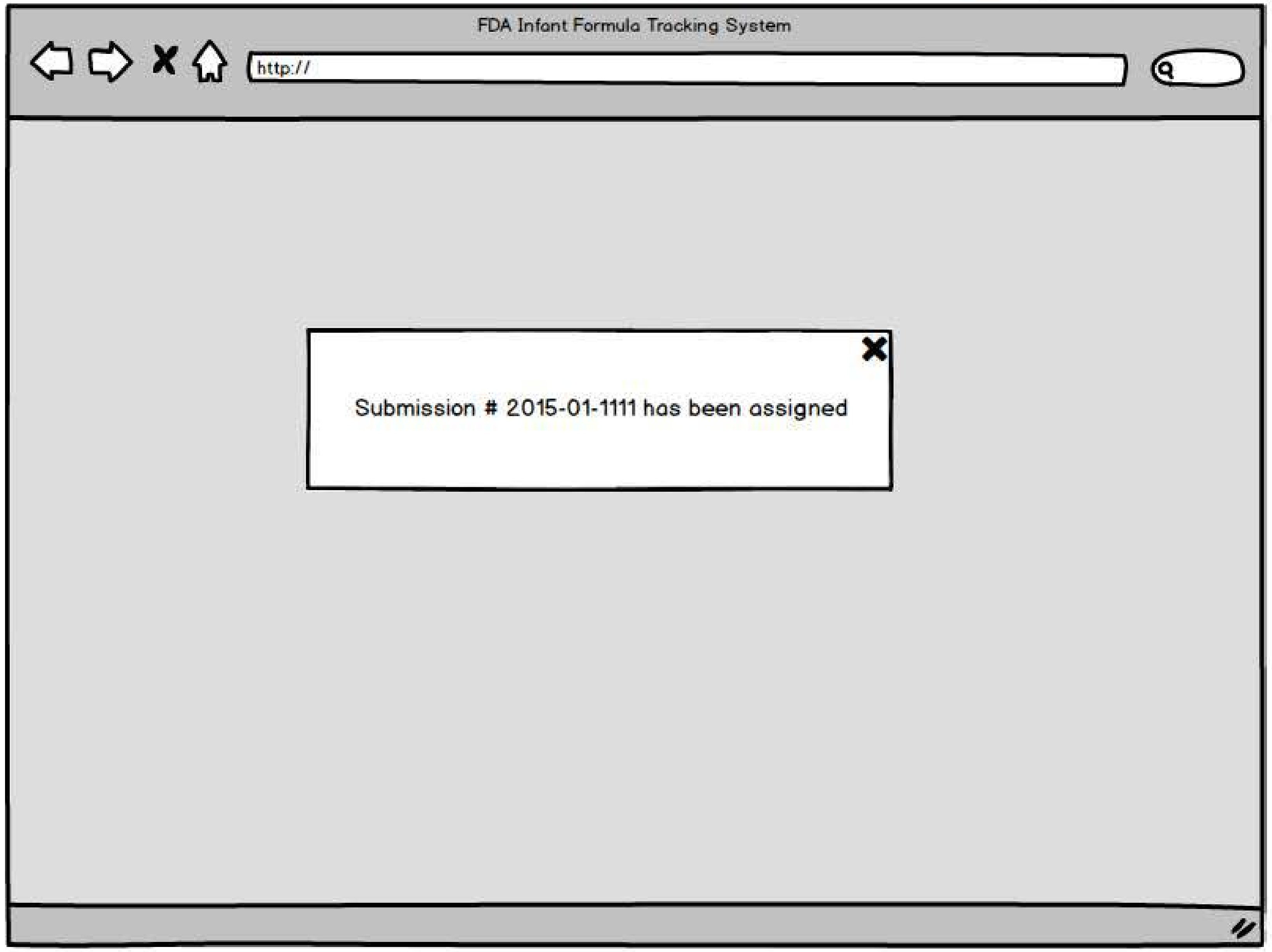
Product Name: -Select

Processing/packaging: Same processing as previous product in the current submission
- Same packaging as previous product in the current submission
- Enter new product information

**FDA CFSAN IFTRACK II Mockups**

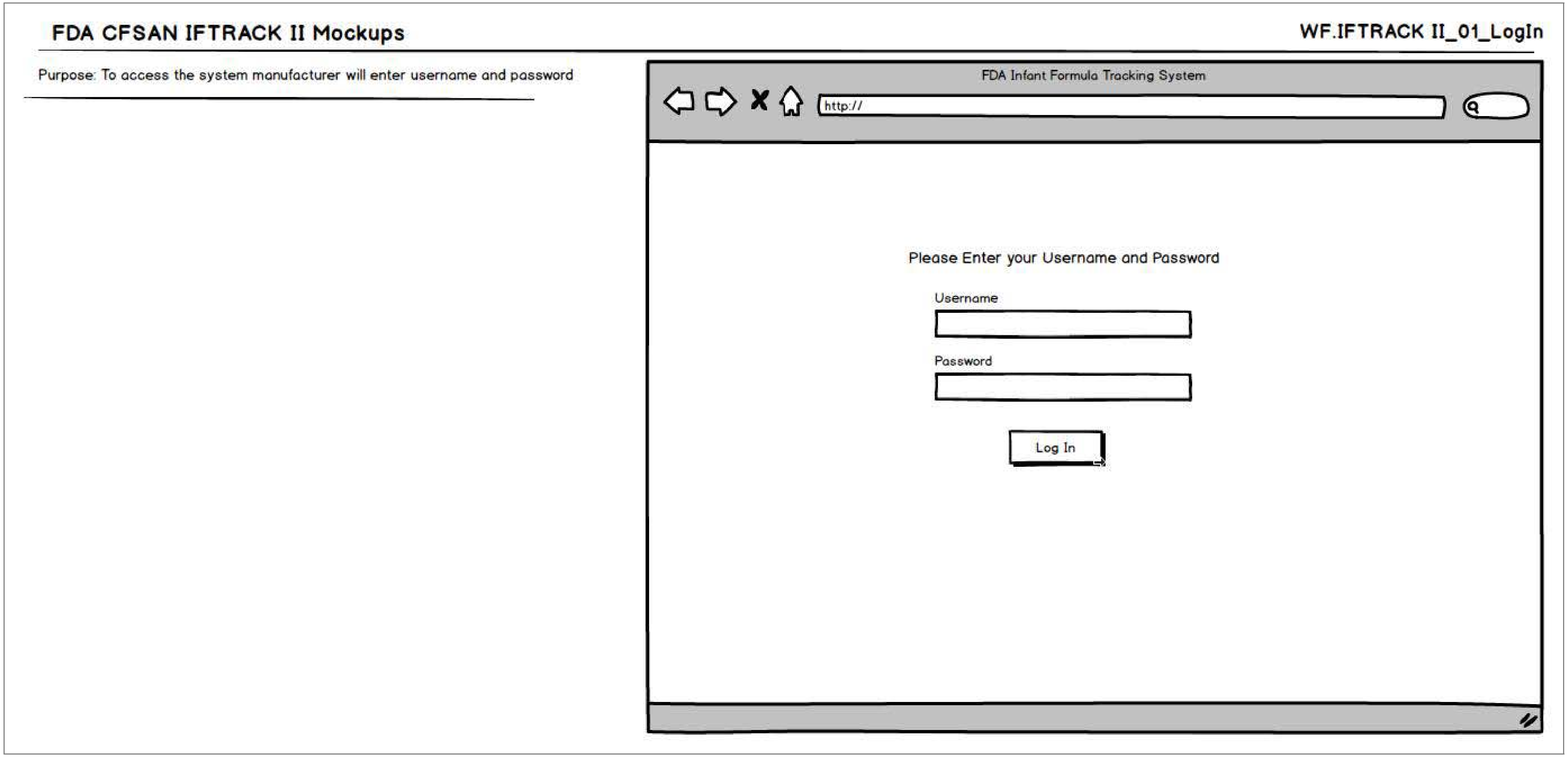
**WF.IFTRACK II.8A_AssignedSubmissionRef #**

Purpose: To view assigned Submission Reference Number


FDA Infant Formula Tracking System
http://

Submission # 2015-01-1111 has been assigned

## 1.4 AMENDMENT SUBMISSION



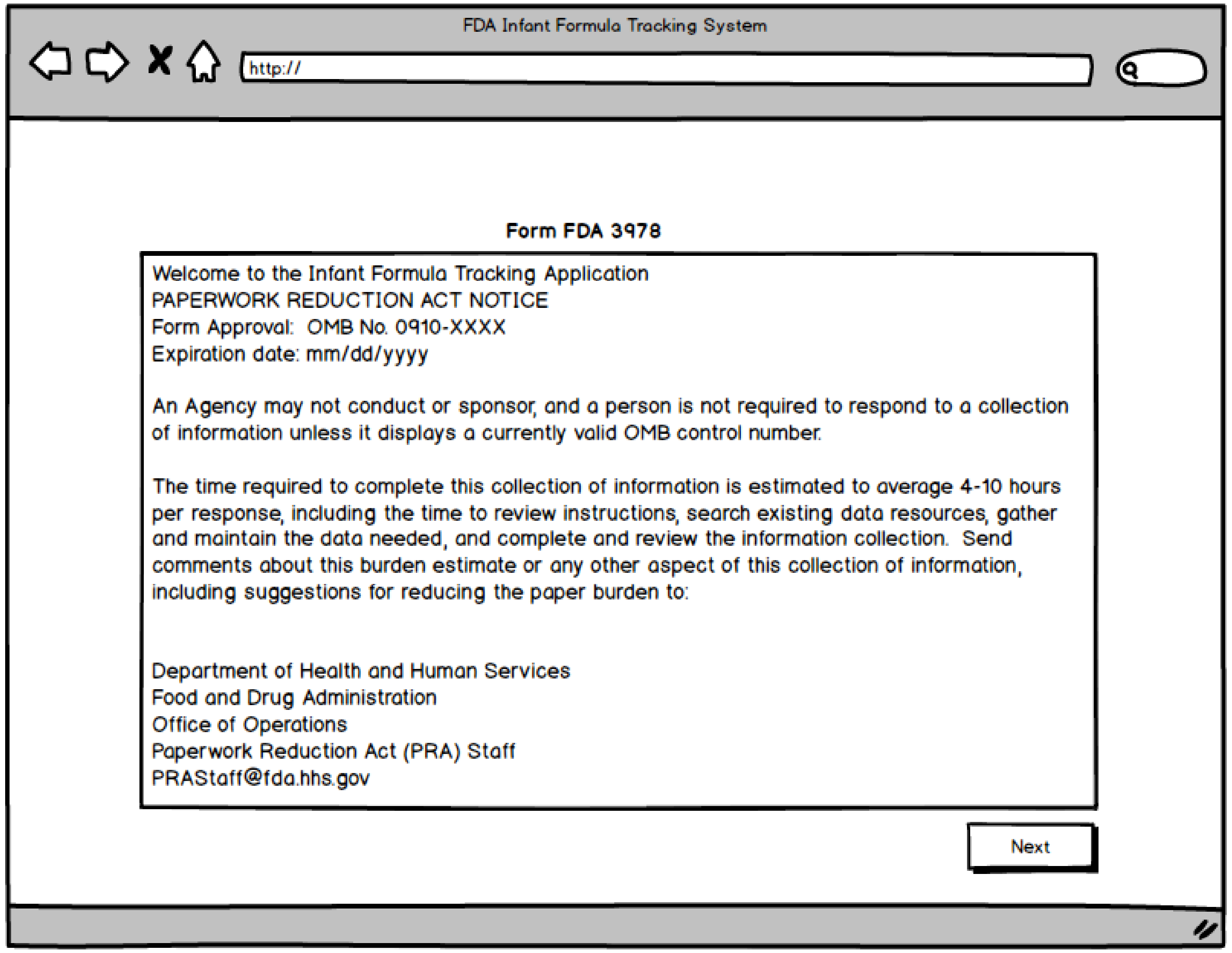
FDA CFSAN IFTRACK II Mockups

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
Log In

**FDA CFSAN IFTRACK II Mockups** **WF.IFTRACK II_001_Welcome**



**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
PRAStaff@fda.hhs.gov

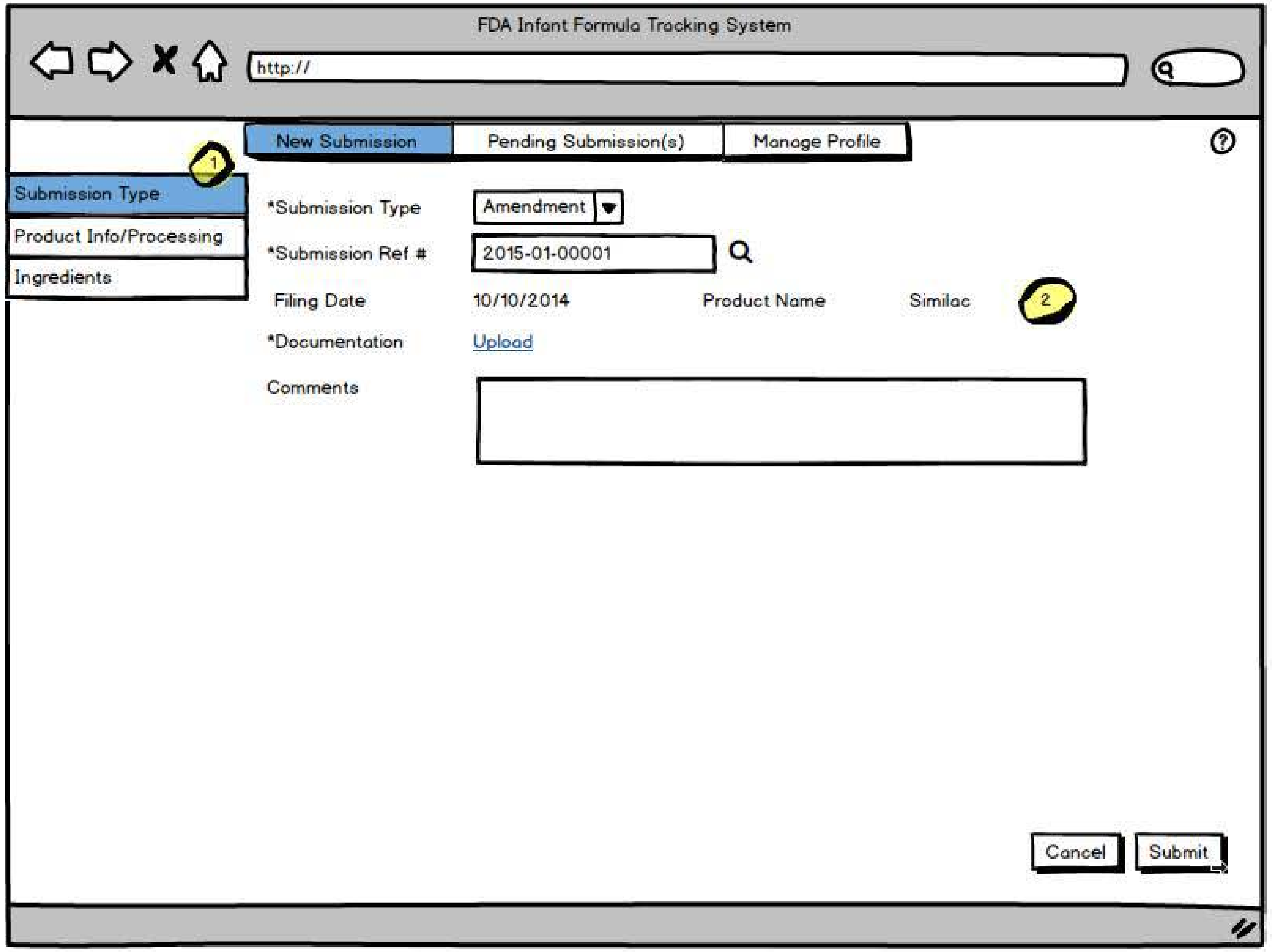
**FDA CFSAN IFTRACK II Mockups**

**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.

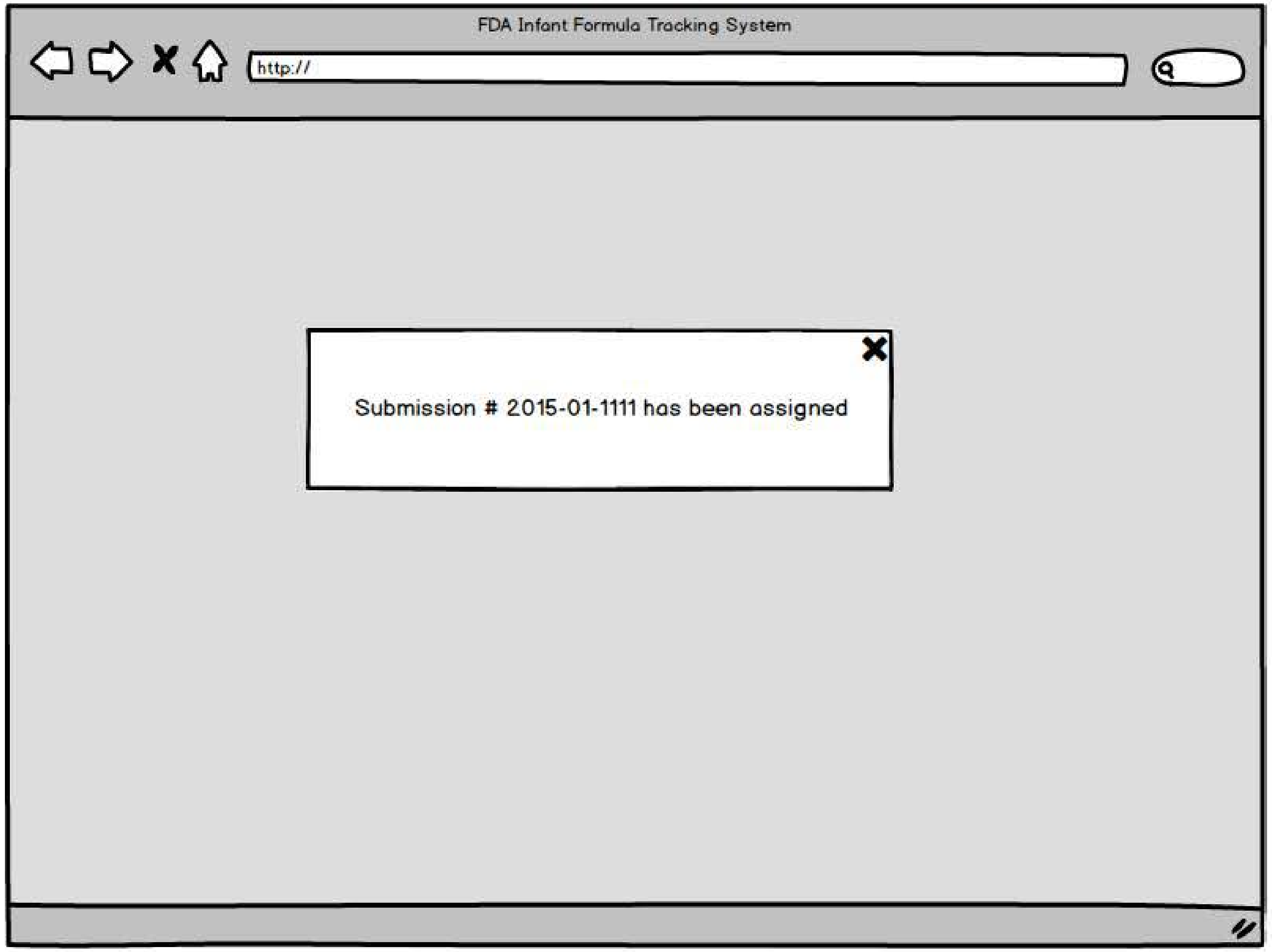

FDA Infant Formula Tracking System
http://
New Submission
Pending Submission(s)
Manage Profile
Submission Type
Product Info/Processing
Ingredients
1
2
Cancel
Submit

| | |
|---|---|
| *Submission Type | Amendment |
| *Submission Ref # | 2015-01-00001 |
| Filing Date | 10/10/2014 |
| Product Name | Similac |
| *Documentation | Upload |
| Comments | |

**FDA CFSAN IFTRACK II Mockups**

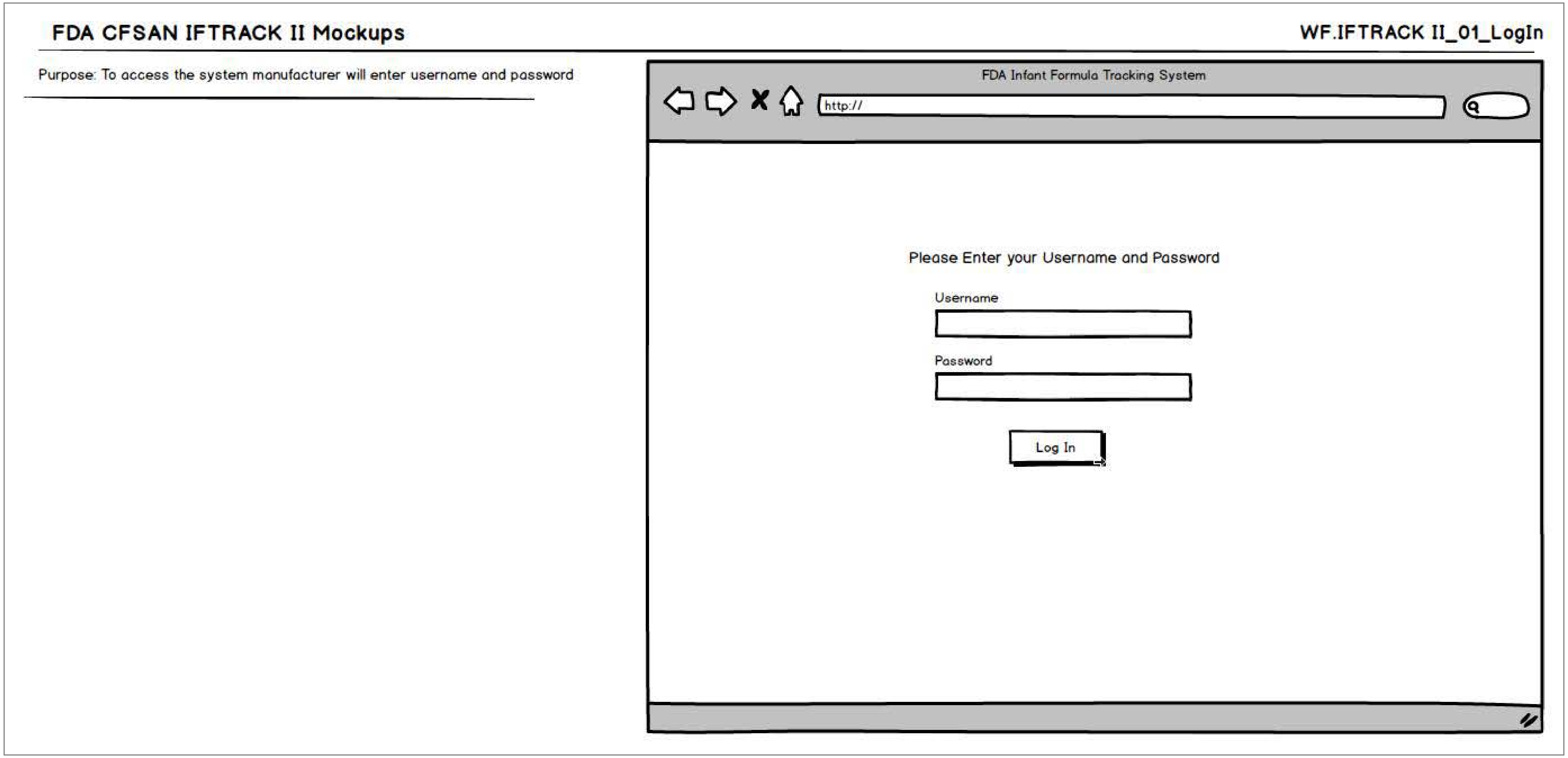
**WF.IFTRACK II. 8A_AssignedSubmissionRef #**

Purpose: To view assigned Submission Reference Number


FDA Infant Formula Tracking System
http://

Submission # 2015-01-1111 has been assigned

### 1.5 BFP EXEMPT SUBMISSION



FDA CFSAN IFTRACK II Mockups

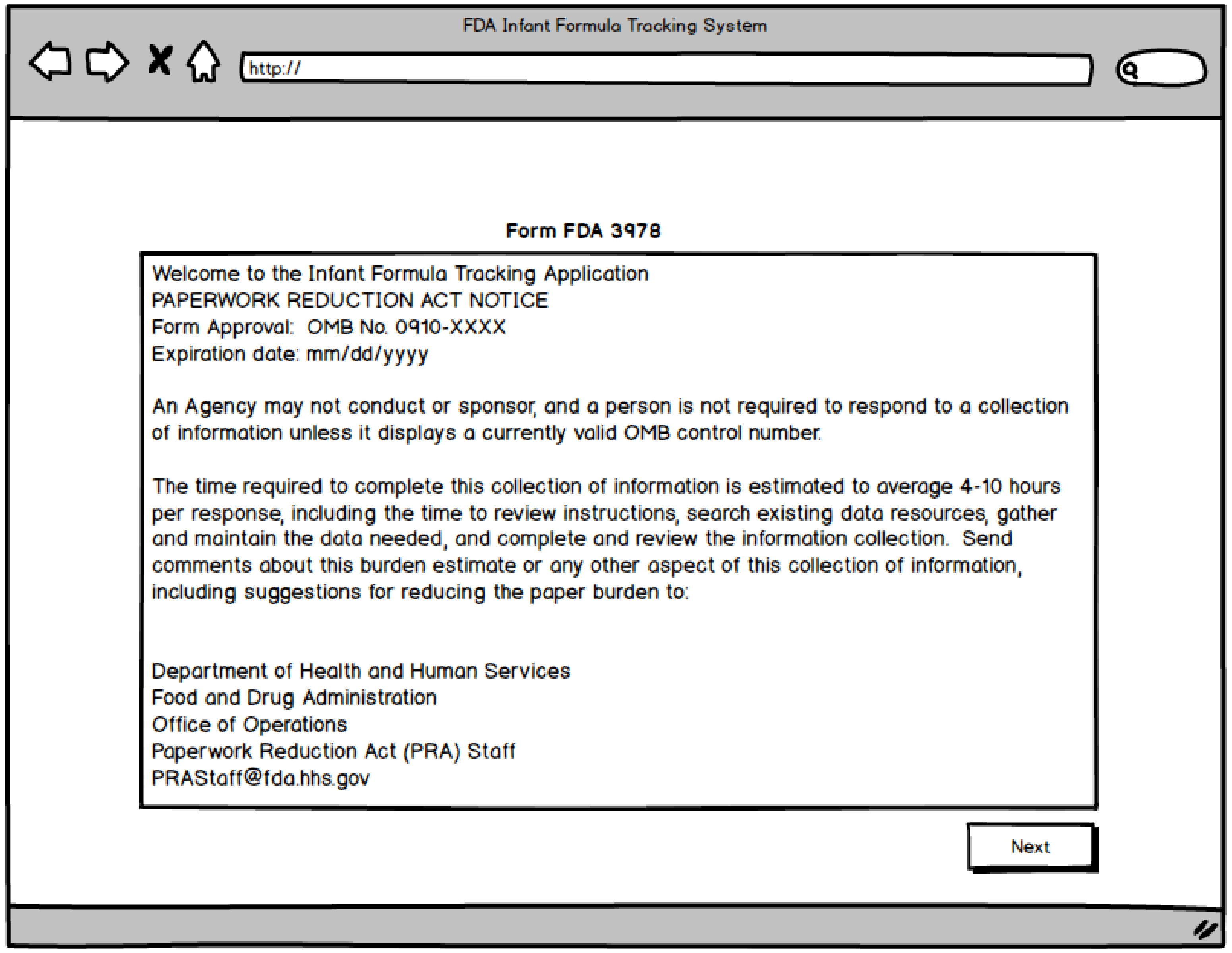
WF.IFTRACK II_01_LogIn

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

Please Enter your Username and Password

FDA Infant Formula Tracking System
http://
Username
Password
Log In

**FDA CFSAN IFTRACK II Mockups** **WF.IFTRACK II_001_Welcome**



**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:

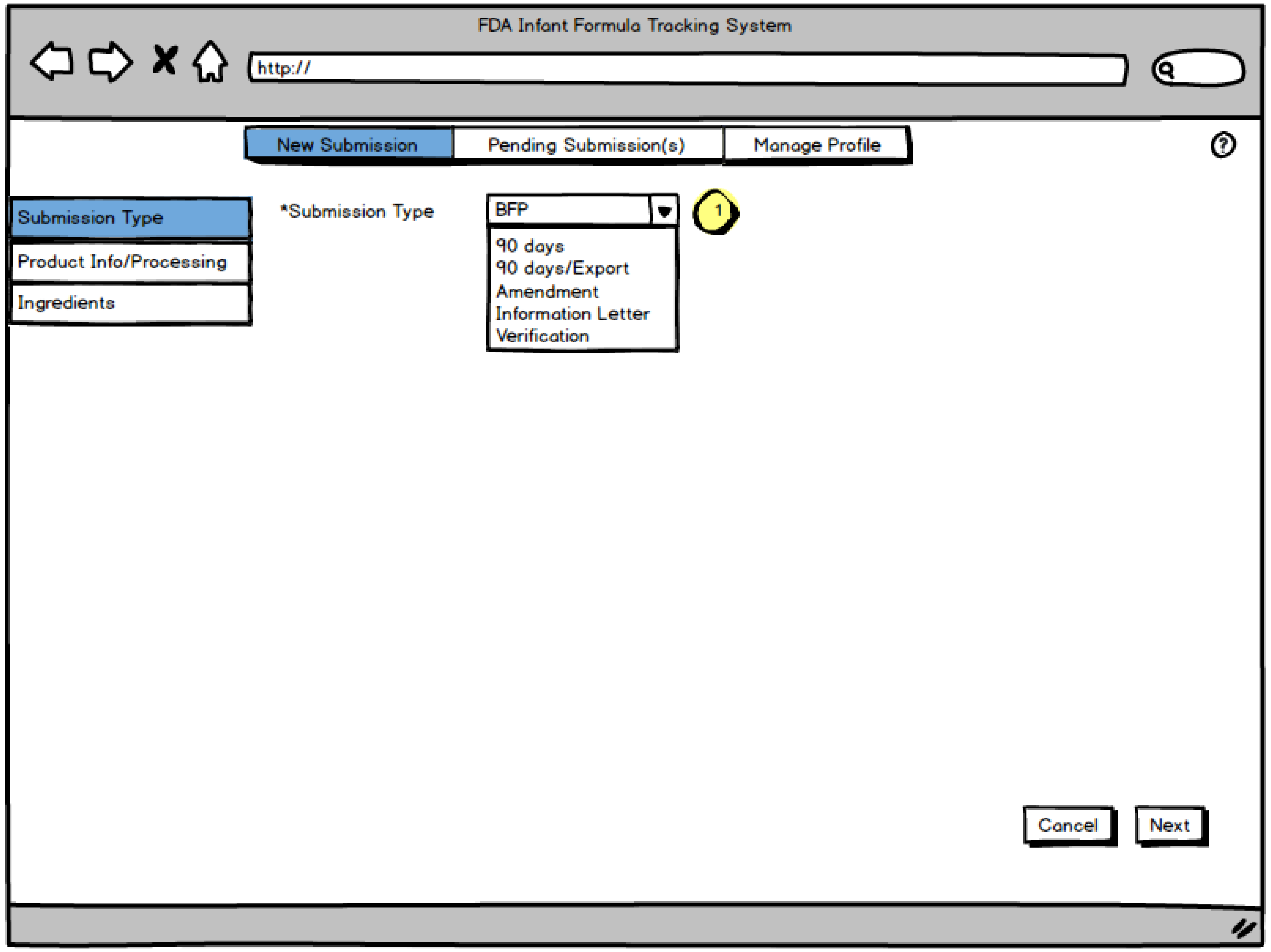
Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

## FDA CFSAN IFTRACK II Mockups

## WF.IFTRACK II.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.



*Submission Type: BFP ①

FDA Infant Formula Tracking System
http://
New Submission
Pending Submission(s)
Manage Profile
Submission Type
Product Info/Processing
Ingredients
90 days
90 days/Export
Amendment
Information Letter
Verification
Cancel
Next

**FDA CFSAN IFTRACK II Mockups** **WF.IFTRACK II.2D_BFP_Exempt_Processing**

Purpose: To enter product, processing and packaging information.

① The user will be able to add multiple Manufacturing Plants
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.

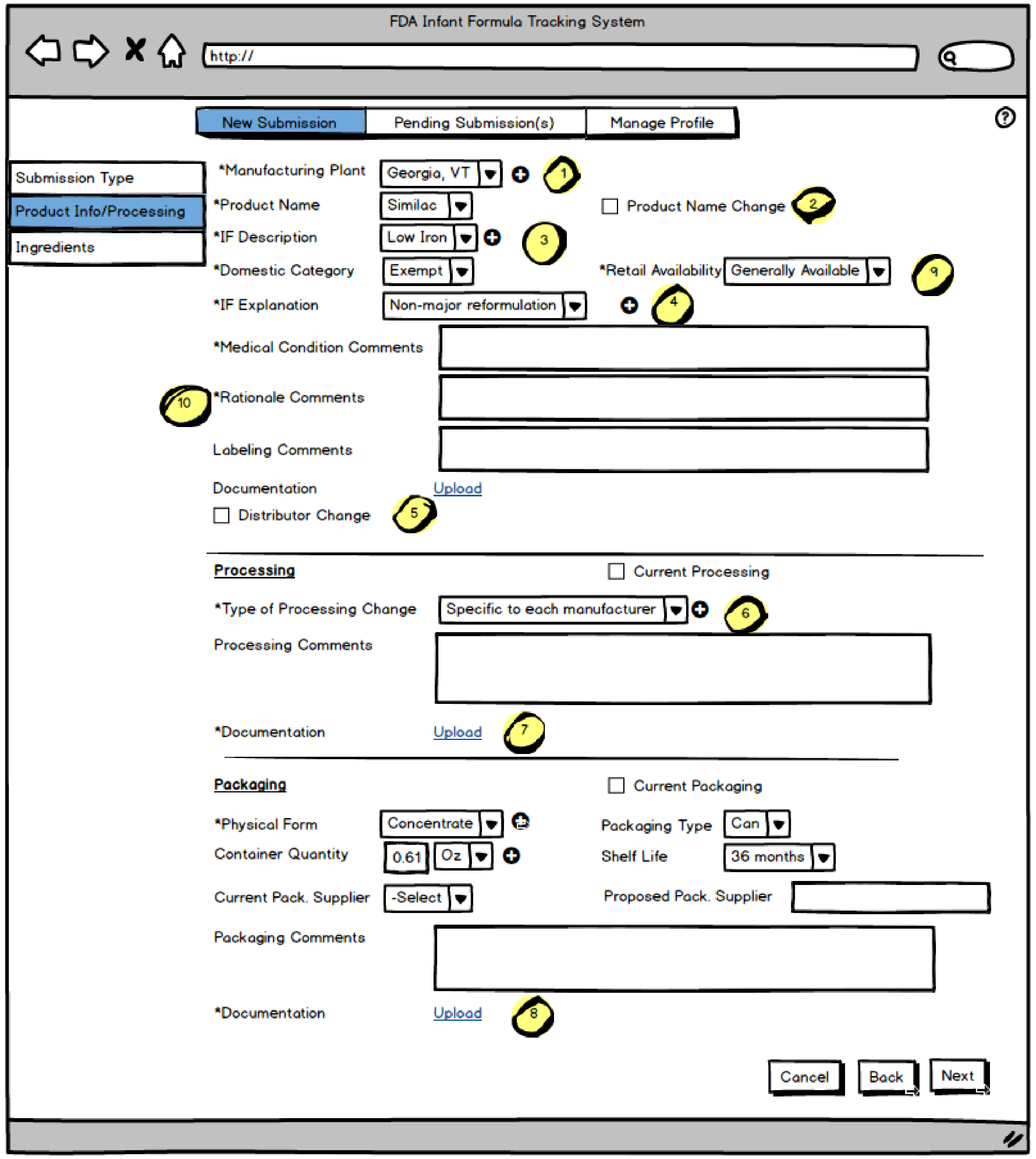
⑥ 1. Type of Processing Change is only required if Major processing change and/or Non Major processing change are selected for 90 days/IF Explanation.
2.The user will be able to add more than one value under Type of Processing Change field.

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.

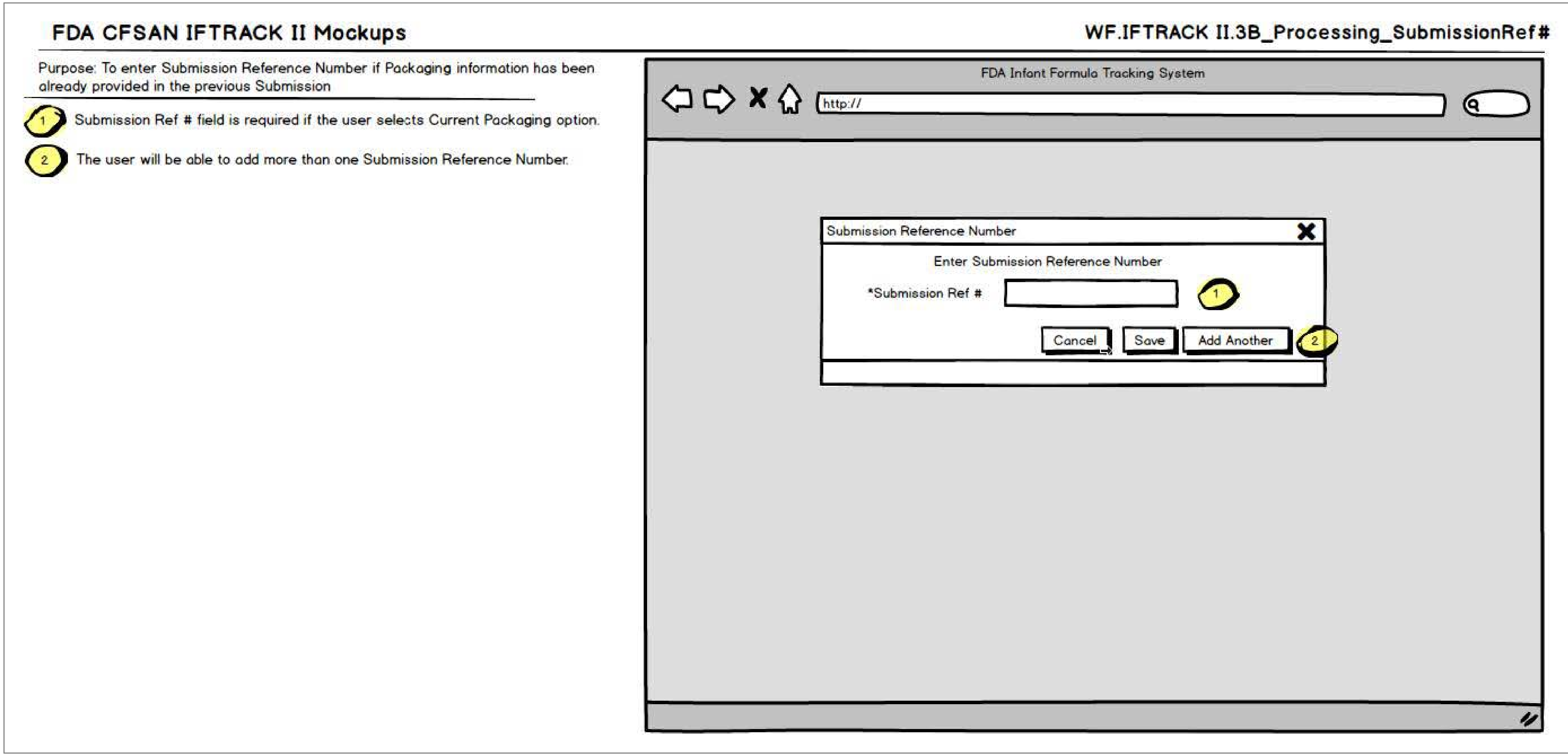
⑩ 1. The user will be required to add Medical Condition comment or documentation for Exempt IF.
2.The user will be required to add Rationale comment or documentation for Exempt IF.
3. The user will be required to add Labeling comment or attachment for Exempt IF.



*Manufacturing Plant: Georgia, VT
*Product Name: Similac
☐ Product Name Change
*IF Description: Low Iron
*Domestic Category: Exempt
*Retail Availability: Generally Available
*IF Explanation: Non-major reformulation
*Medical Condition Comments
*Rationale Comments
Labeling Comments
Documentation
☐ Distributor Change

**Processing**
☐ Current Processing
*Type of Processing Change: Specific to each manufacturer
Processing Comments
*Documentation

**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



**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

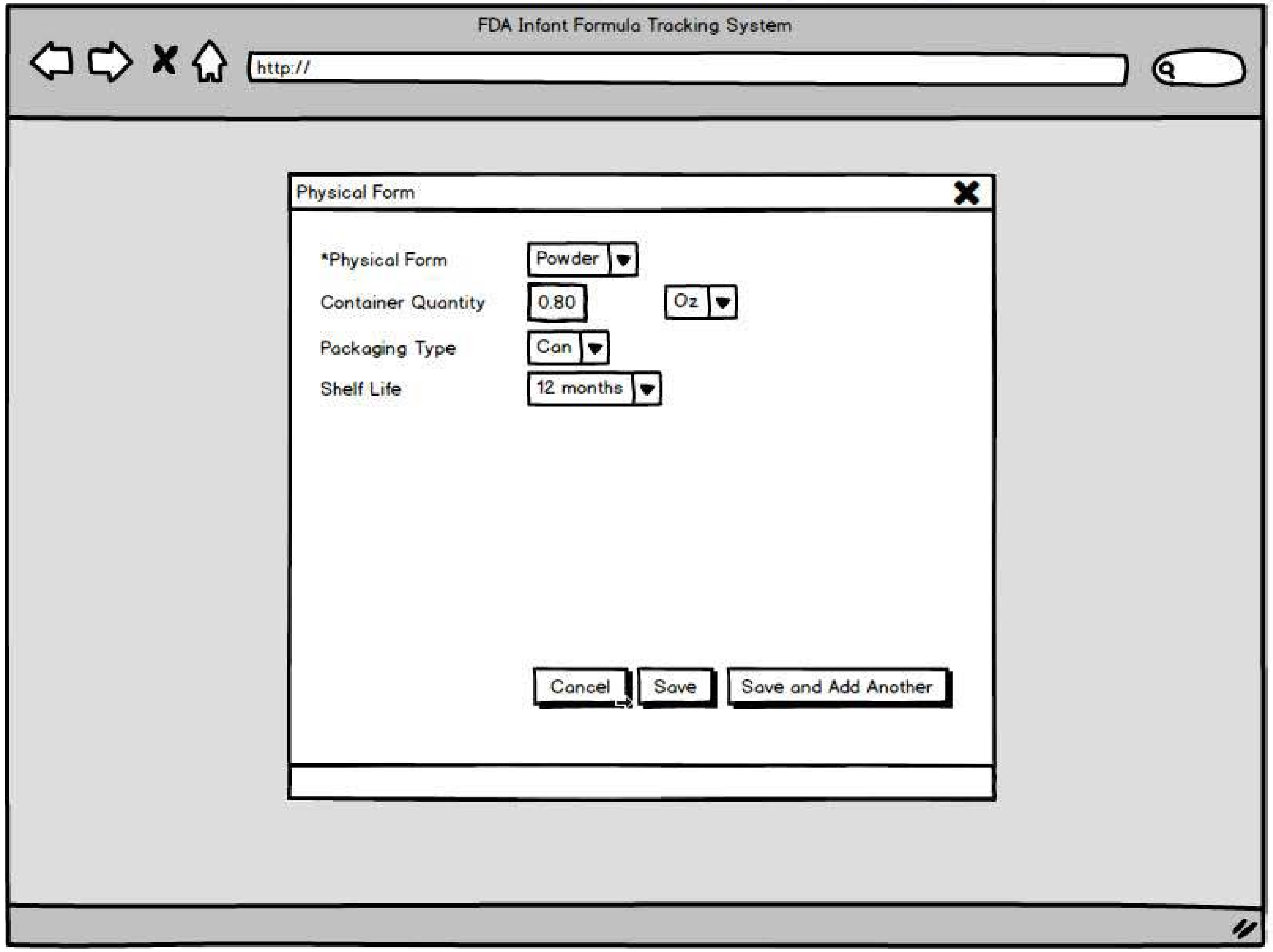
1. Submission Ref # field is required if the user selects Current Packaging option.
2. The user will be able to add more than one Submission Reference Number.

FDA Infant Formula Tracking System
http://
Submission Reference Number
Enter Submission Reference Number
*Submission Ref #
1
Cancel
Save
Add Another
2

## FDA CFSAN IFTRACK II Mockups

## WF.IFTRACK II.3A_Processing_AddNewPhysicalForm

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


FDA Infant Formula Tracking System
http://
Physical Form
Cancel
Save
Save and Add Another

| | |
|---|---|
| *Physical Form | Powder |
| Container Quantity | 0.80 Oz |
| Packaging Type | Can |
| Shelf Life | 12 months |

**FDA CFSAN IFTRACK II Mockups** **WF.IFTRACK II.4D_BFP_Exempt_Ingredients**

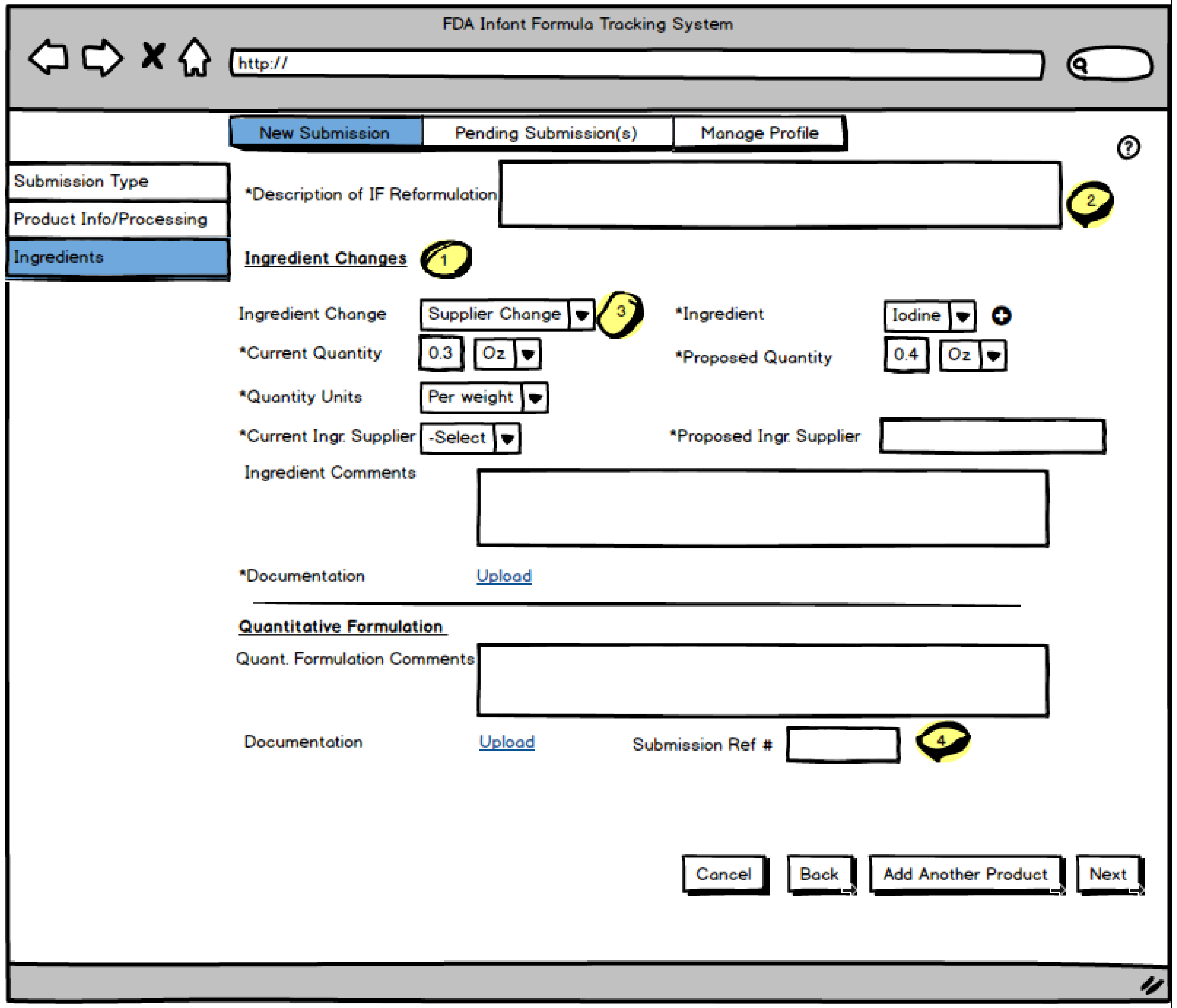
Purpose: To enter ingredients information.

① 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 optoinal 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 # .



*Description of IF Reformulation

**Ingredient Changes**

Ingredient Change: Supplier Change
*Ingredient: Iodine
*Current Quantity: 0.3 Oz
*Proposed Quantity: 0.4 Oz
*Quantity Units: Per weight
*Current Ingr. Supplier: -Select
*Proposed Ingr. Supplier
Ingredient Comments
*Documentation: Upload

**Quantitative Formulation**

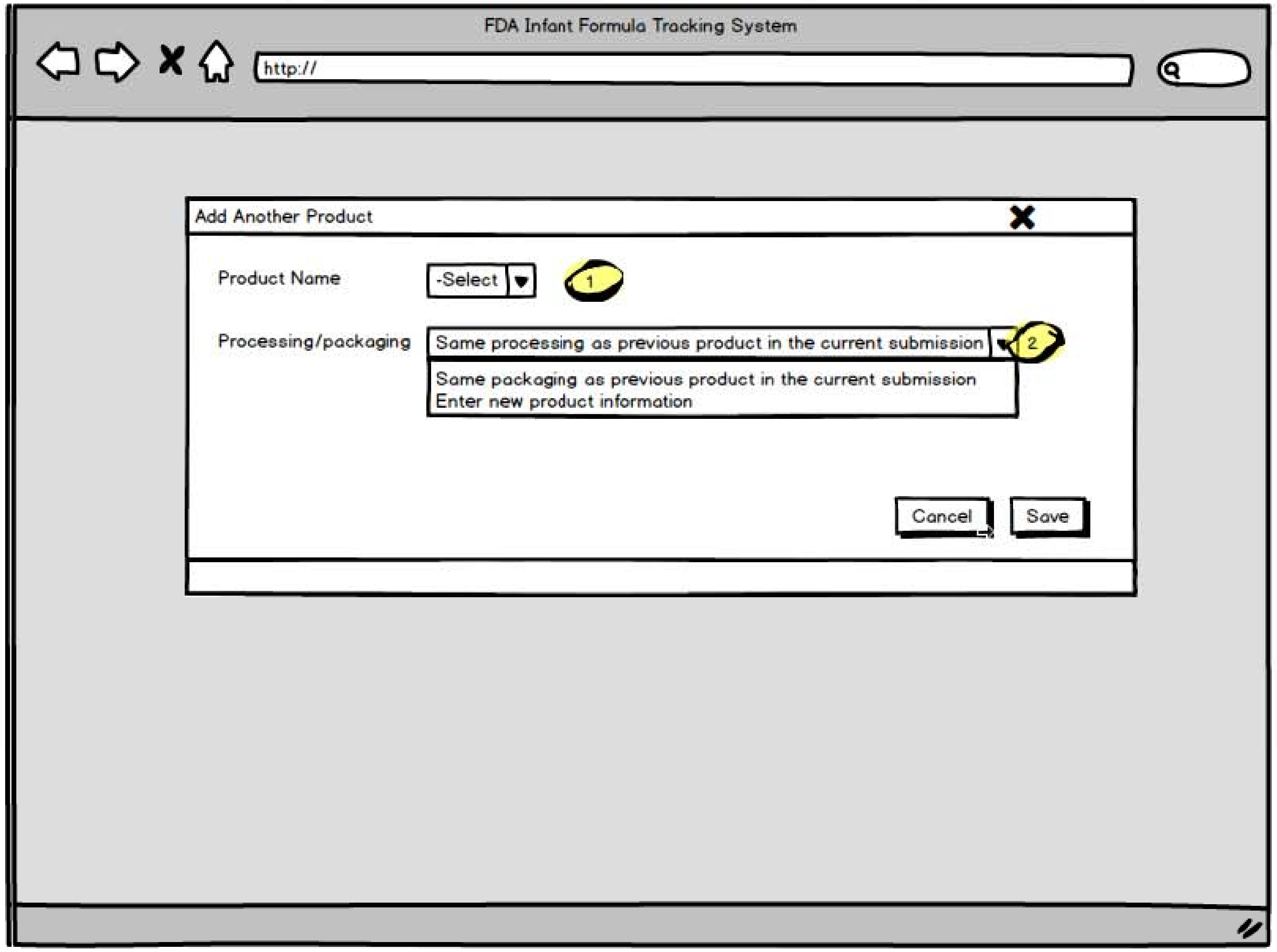
Quant. Formulation Comments
Documentation: Upload
Submission Ref #

## FDA CFSAN IFTRACK II Mockups

## WF.IFTRACK II.7A_AddAnotherProduct

Purpose: To enter additional product name.

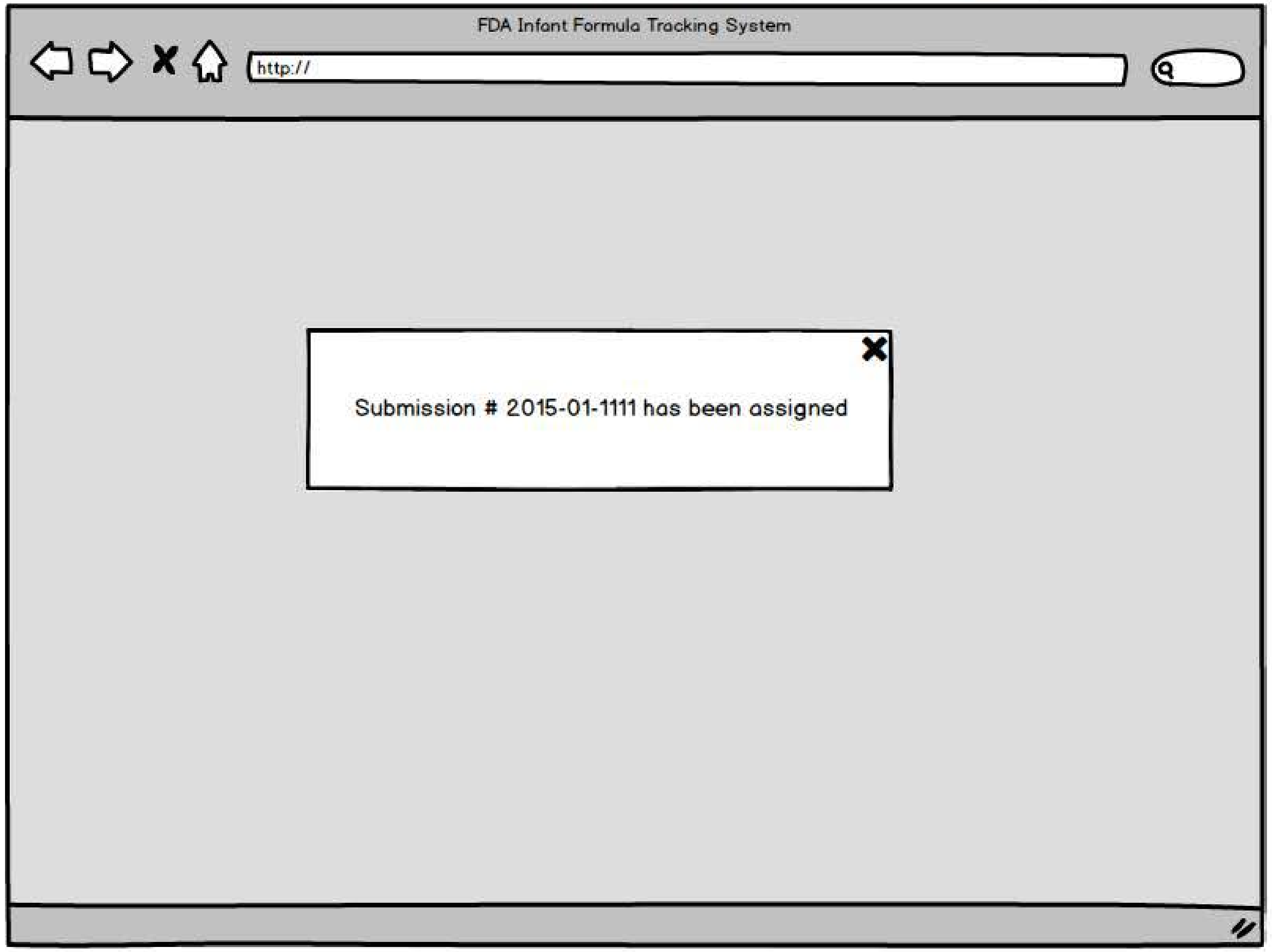
1. The user will be allowed to add Another product after all information for the first product has been enetered.
2. If the user selects "Same processing as previous product in the current submission" for Processing/packaging field, processing information will be automatically populated for the next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

**FDA CFSAN IFTRACK II Mockups**

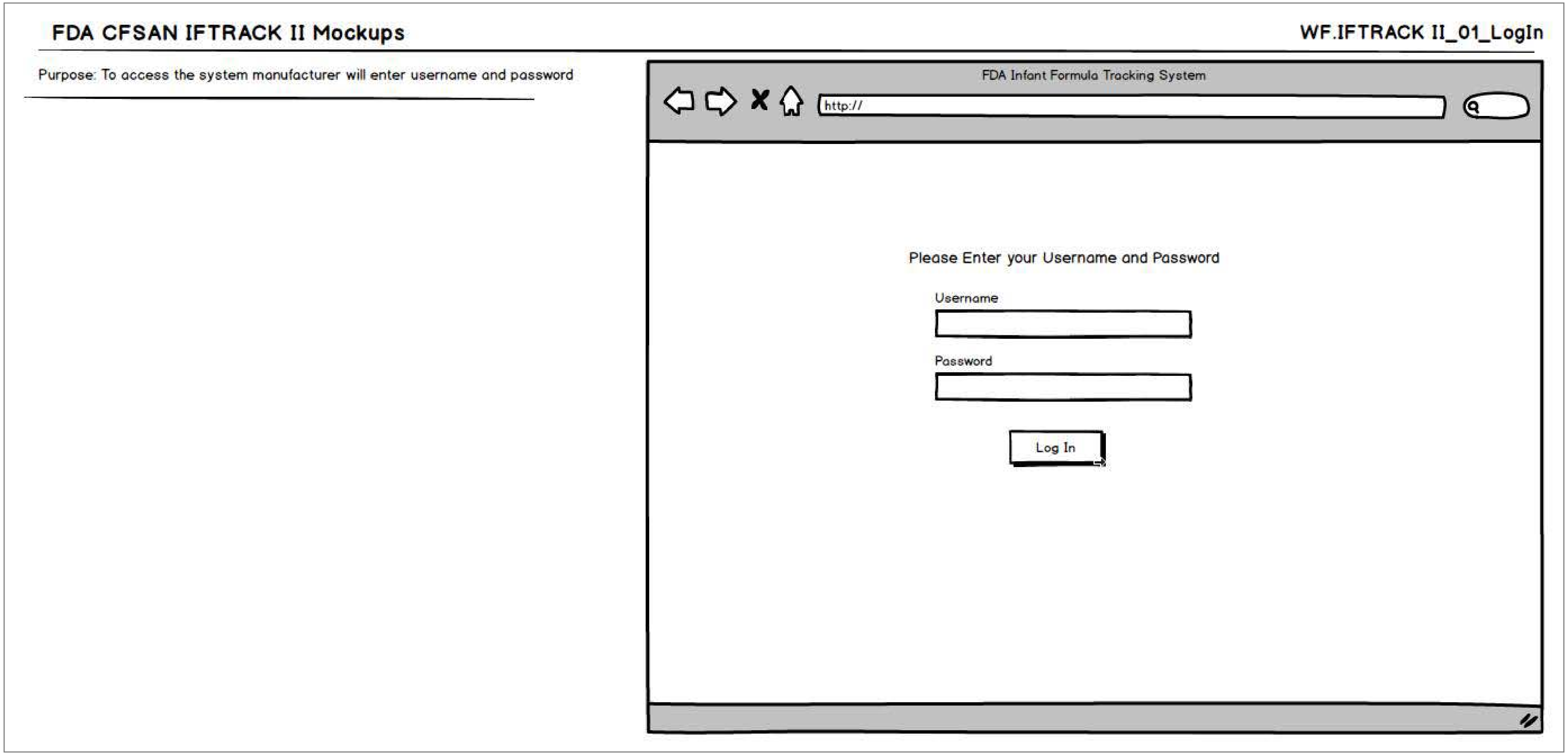
**WF.IFTRACK II.8A_AssignedSubmissionRef #**

Purpose: To view assigned Submission Reference Number


FDA Infant Formula Tracking System
http://

Submission # 2015-01-1111 has been assigned

## 1.6 BFP NON-EXEMPT SUBMISSION



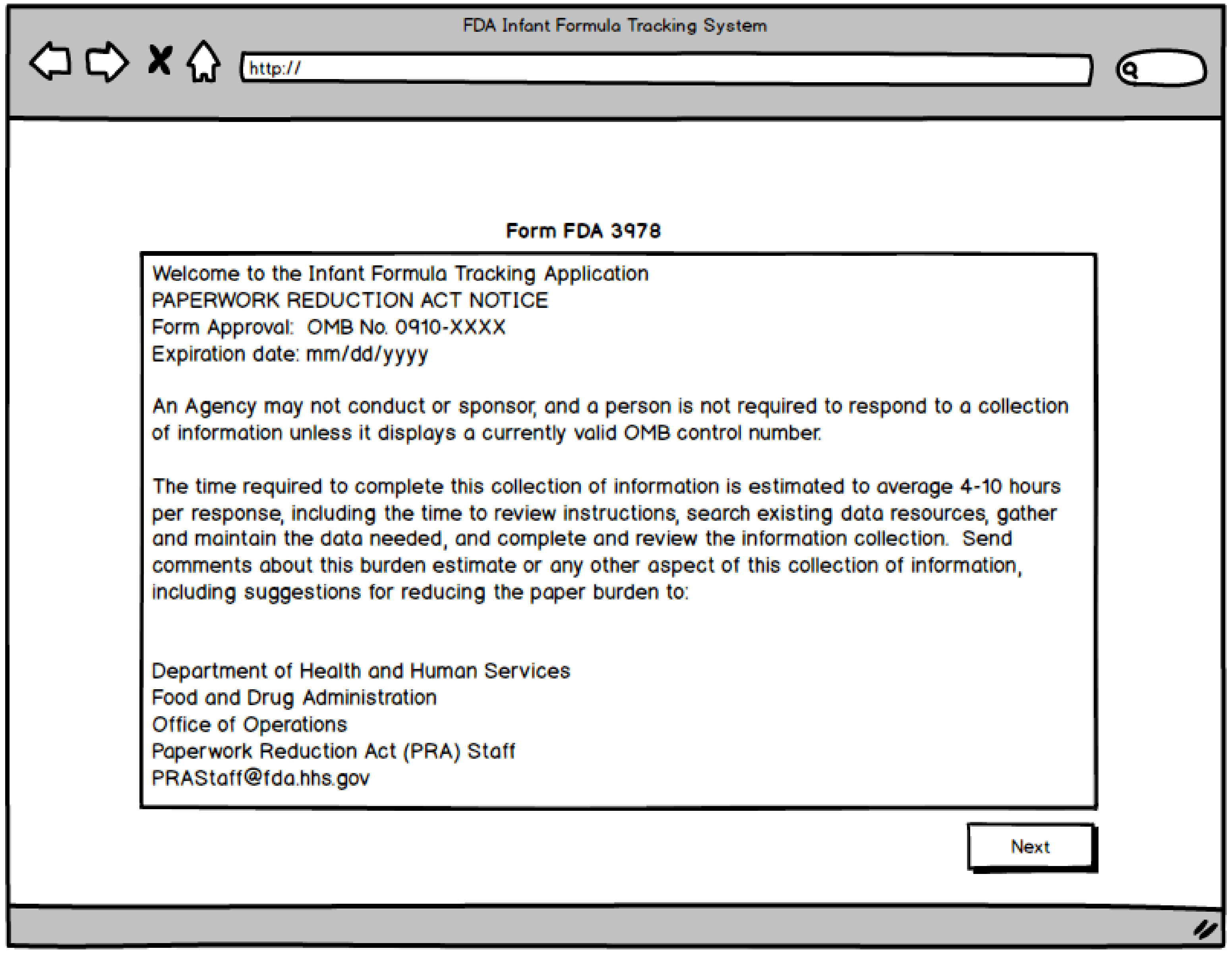
FDA CFSAN IFTRACK II Mockups

WF.IFTRACK II_01_LogIn

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

FDA Infant Formula Tracking System
http://
Please Enter your Username and Password
Username
Password
Log In

**FDA CFSAN IFTRACK II Mockups** **WF.IFTRACK II_001_Welcome**



**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:

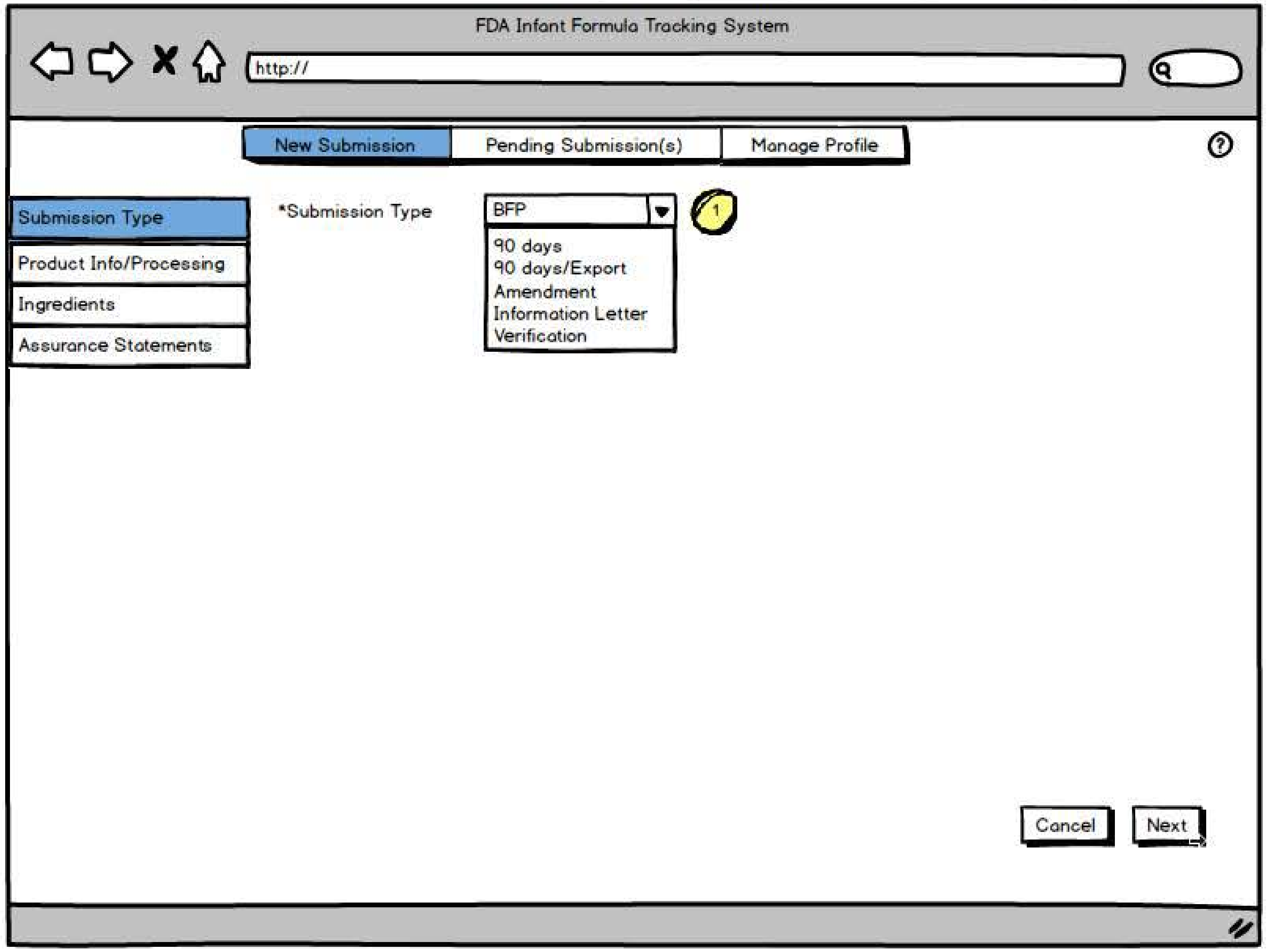
Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

**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.


FDA Infant Formula Tracking System
http://
New Submission
Pending Submission(s)
Manage Profile
Submission Type
Product Info/Processing
Ingredients
Assurance Statements
90 days
90 days/Export
Amendment
Information Letter
Verification
①
Cancel
Next

*Submission Type: BFP

## 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
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.

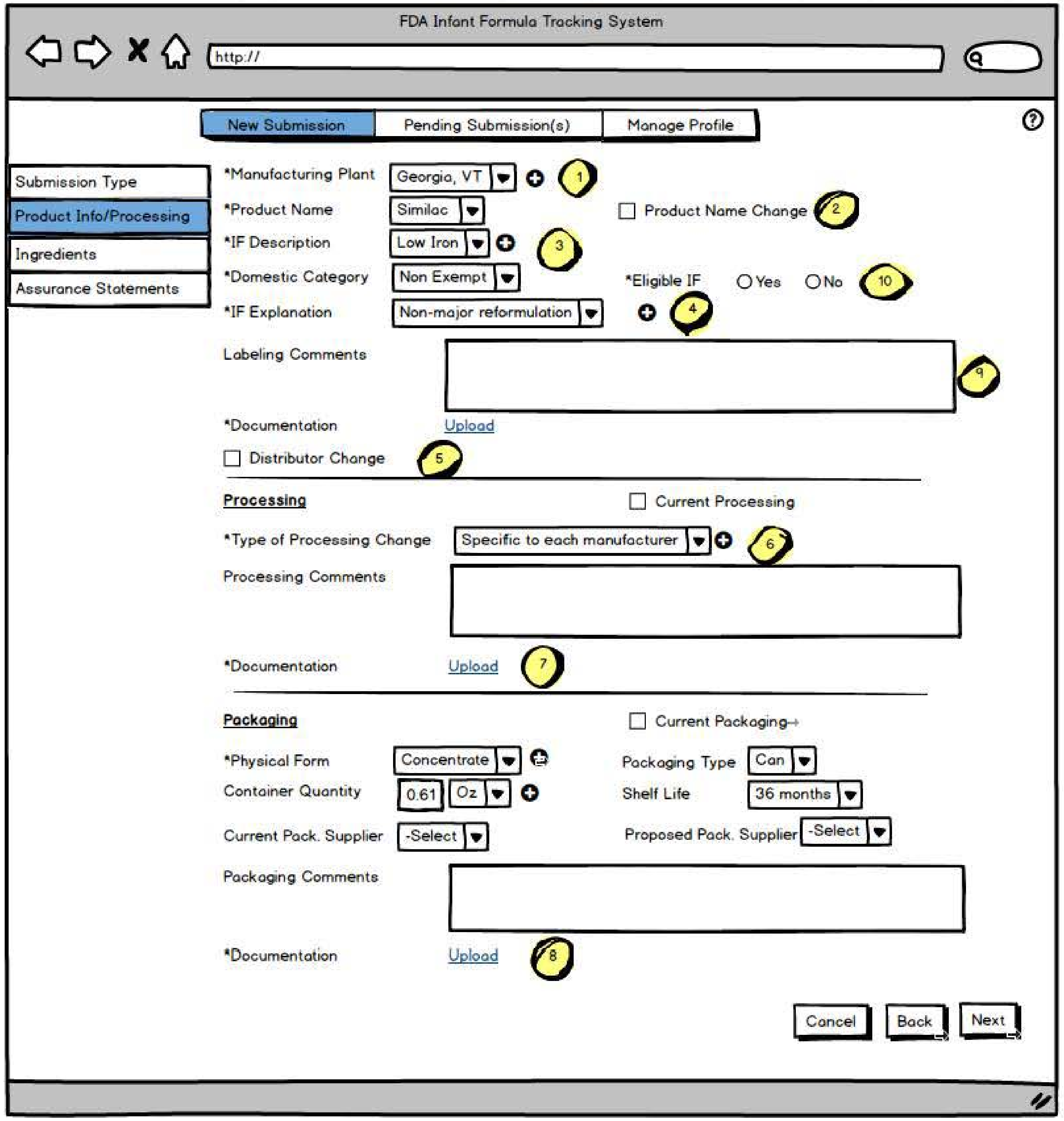
⑥ 1. Type of Processing Change is only required if Major processing change and/or Non Major processing change are selected for 90 days/IF Explanation.
2.The user will be able to add more than one value under Type of Processing Change field.

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.



*Manufacturing Plant: Georgia, VT ①

*Product Name: Similac

☐ Product Name Change ②

*IF Description: Low Iron ③

*Domestic Category: Non Exempt

*Eligible IF ○ Yes ○ No ⑩

*IF Explanation: Non-major reformulation ④

Labeling Comments ⑨

*Documentation Upload

☐ Distributor Change ⑤

**Processing**

☐ Current Processing

*Type of Processing Change: Specific to each manufacturer ⑥

Processing Comments

*Documentation Upload ⑦

**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: -Select

Packaging Comments

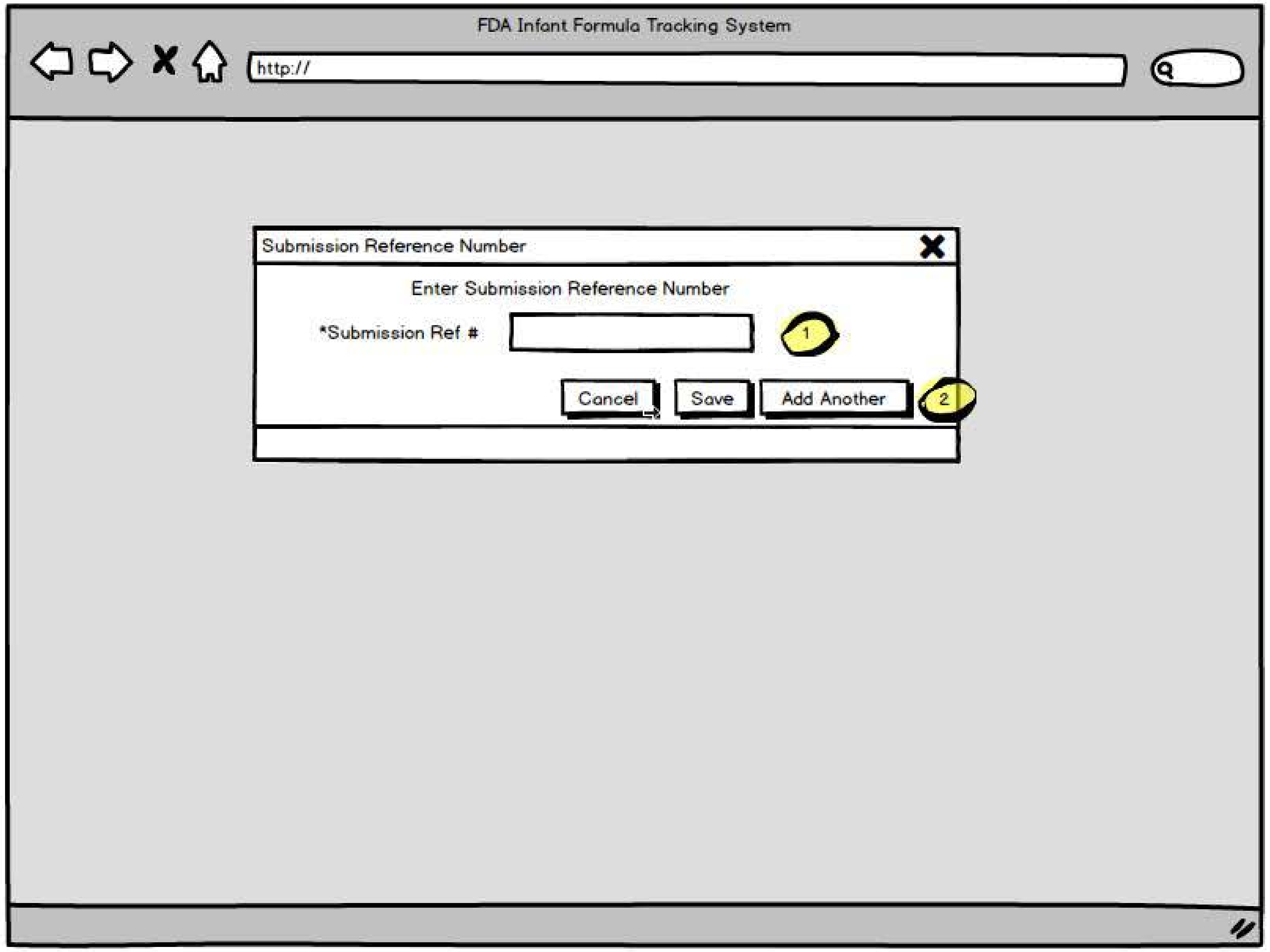
*Documentation Upload ⑧

## 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.



FDA Infant Formula Tracking System

Submission Reference Number

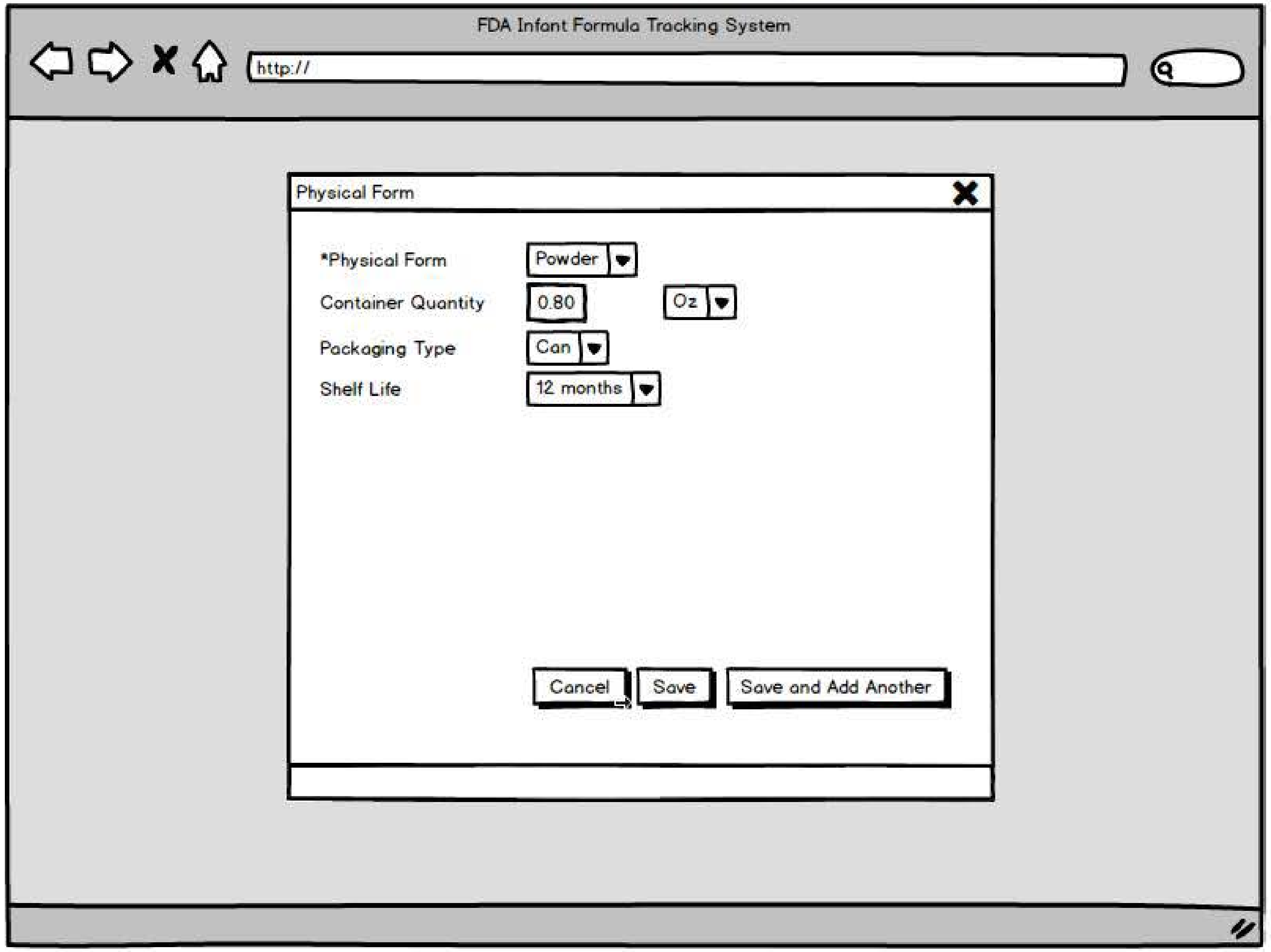
Enter Submission Reference Number

*Submission Ref #

**FDA CFSAN IFTRACK II Mockups**

**WF.IFTRACK.3A_Processing_AddNewPhysicalForm**

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


FDA Infant Formula Tracking System
http://
Physical Form
Cancel
Save
Save and Add Another

| | |
|---|---|
| *Physical Form | Powder |
| Container Quantity | 0.80 Oz |
| Packaging Type | Can |
| Shelf Life | 12 months |

**FDA CFSAN IFTRACK II Mockups** **WF.IFTRACK.4C_BFP_Non Exempt_Ingredients**

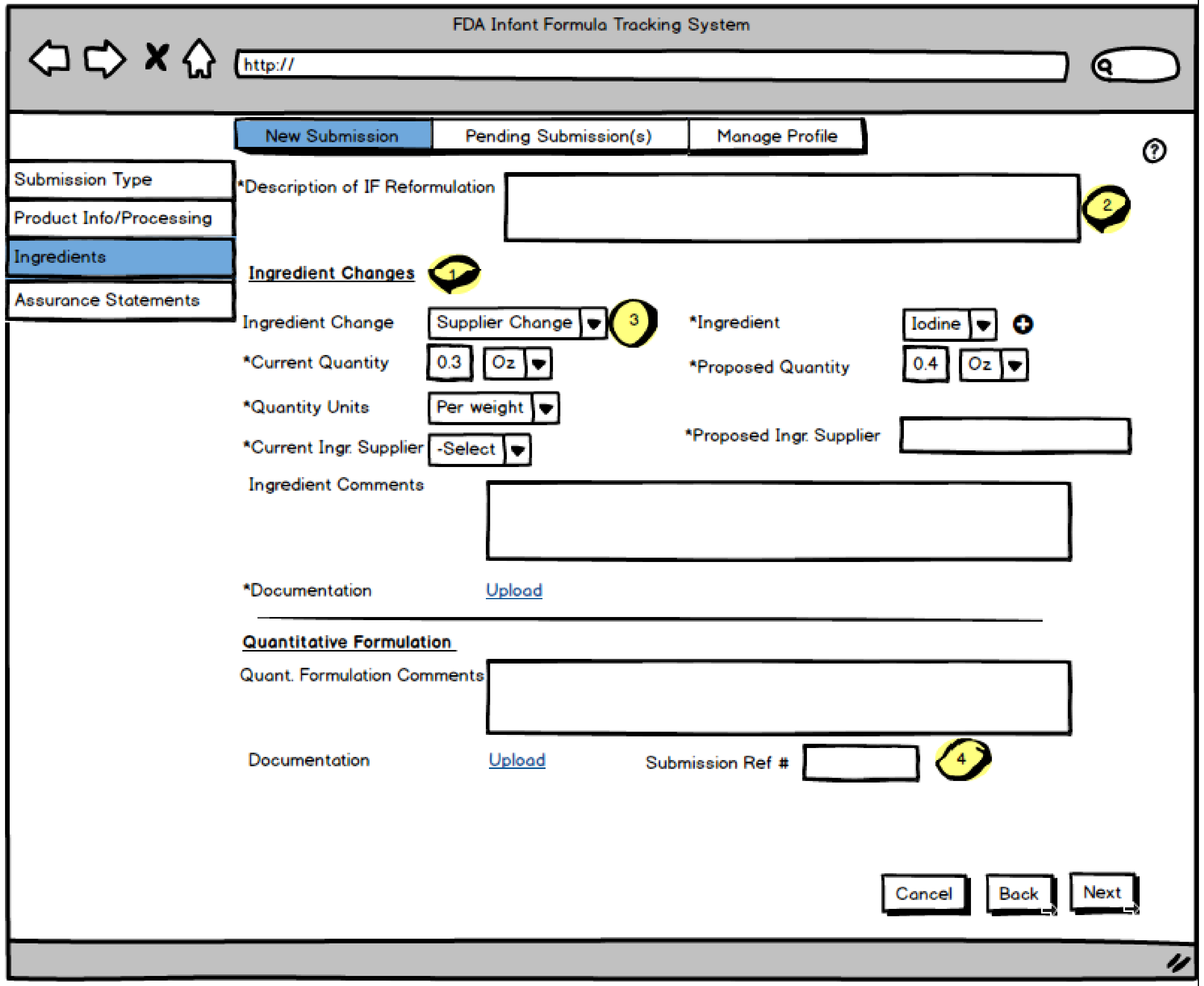
Purpose: To enter ingredients information.

① 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 optoinal 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 # .

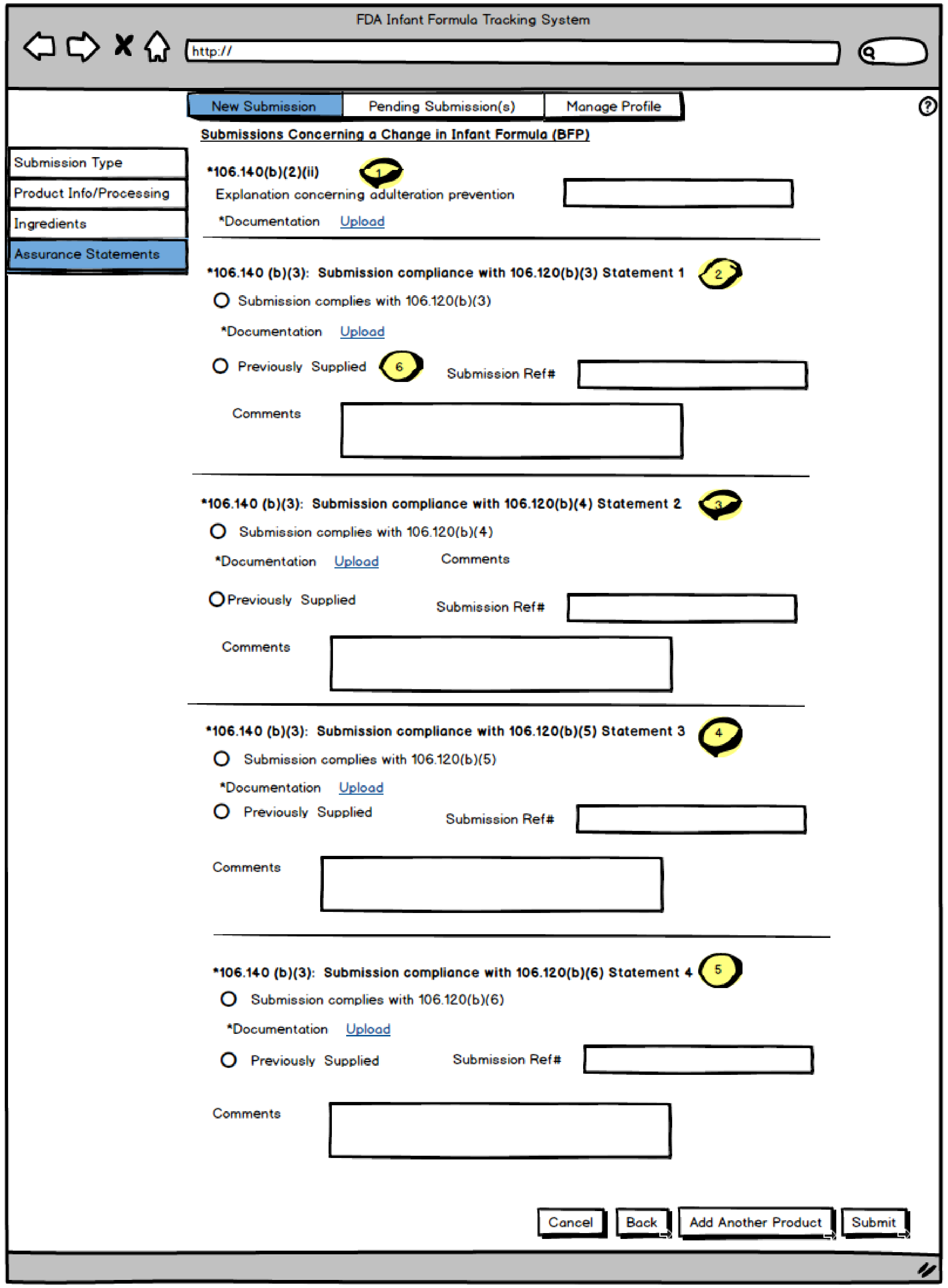

FDA Infant Formula Tracking System
http://
New Submission
Pending Submission(s)
Manage Profile
Submission Type
Product Info/Processing
Ingredients
Assurance Statements
*Description of IF Reformulation
2
Ingredient Changes
1
3
Ingredient Comments
*Documentation
Upload
Quantitative Formulation
Quant. Formulation Comments
Documentation
Upload
Submission Ref #
4
Cancel
Back
Next

Ingredient Change: Supplier Change
*Current Quantity: 0.3 Oz
*Quantity Units: Per weight
*Current Ingr. Supplier: -Select
*Ingredient: Iodine
*Proposed Quantity: 0.4 Oz
*Proposed Ingr. Supplier:

**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.



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

***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

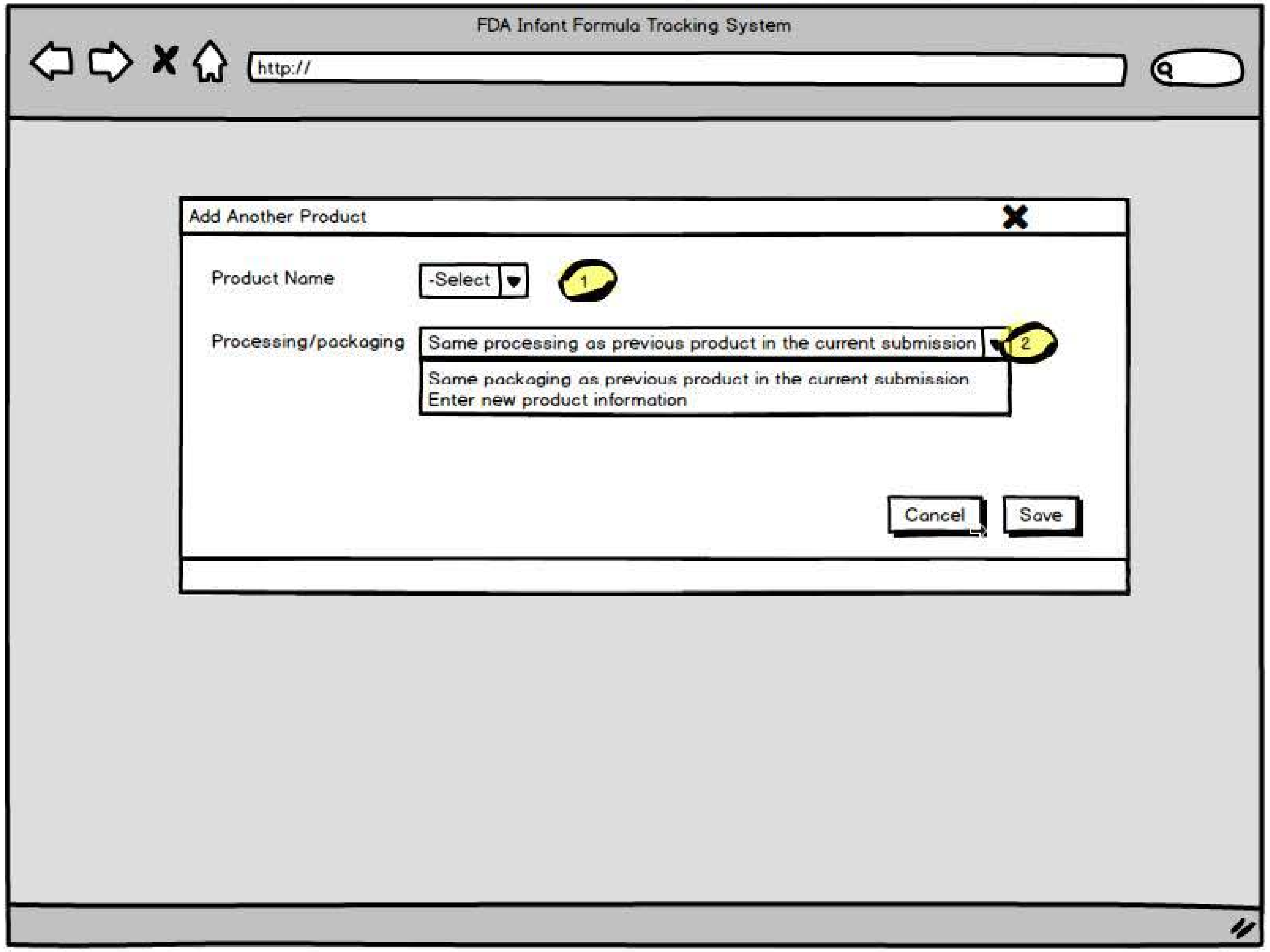
***106.140 (b)(3): Submission compliance with 106.120(b)(6) Statement 4** ⑤
○ Submission complies with 106.120(b)(6)
*Documentation Upload
○ Previously Supplied Submission Ref#
Comments

## 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 enetered.
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.



Product Name: -Select

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

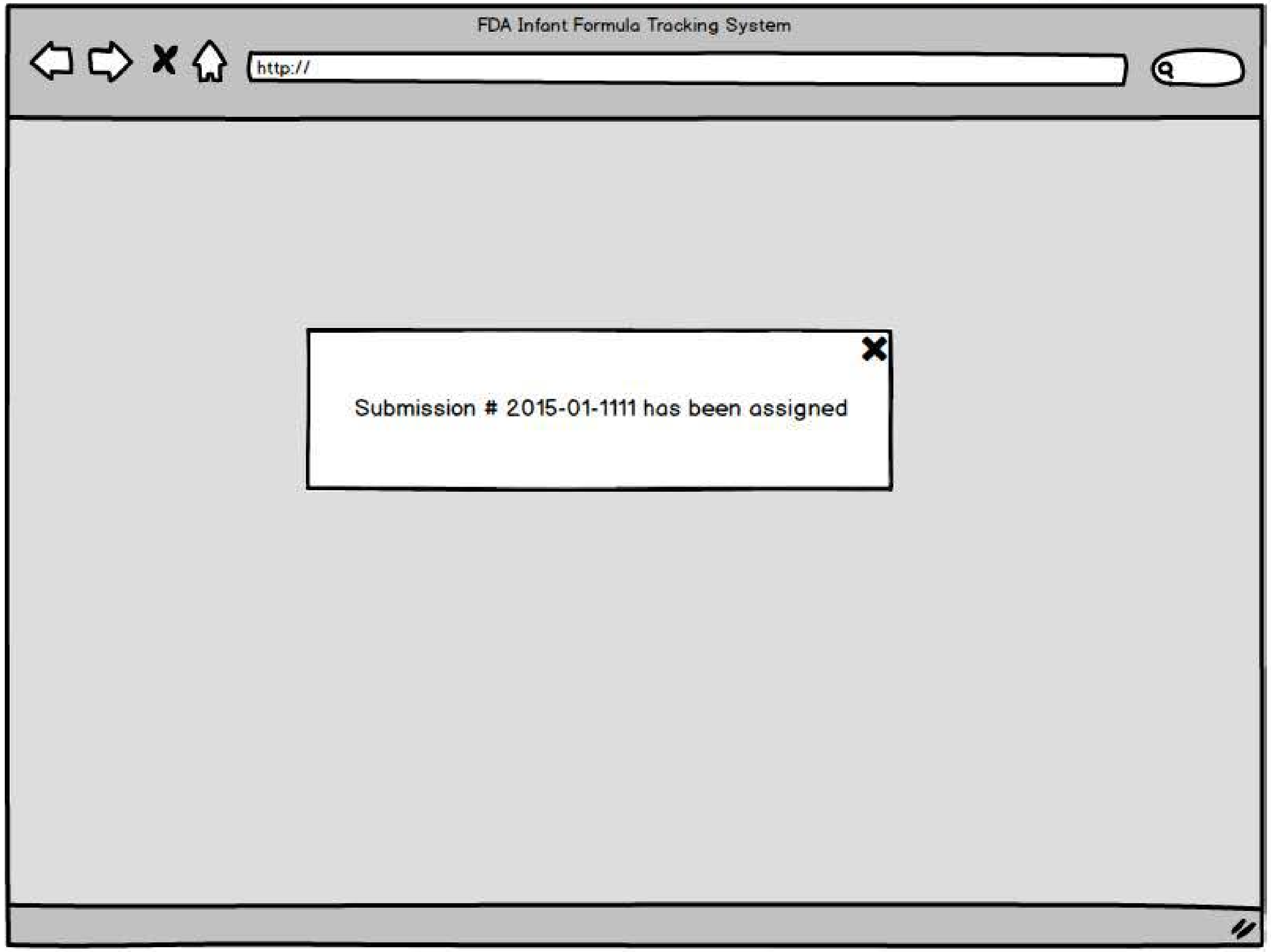
Same packaging as previous product in the current submission

Enter new product information

**FDA CFSAN IFTRACK II Mockups**

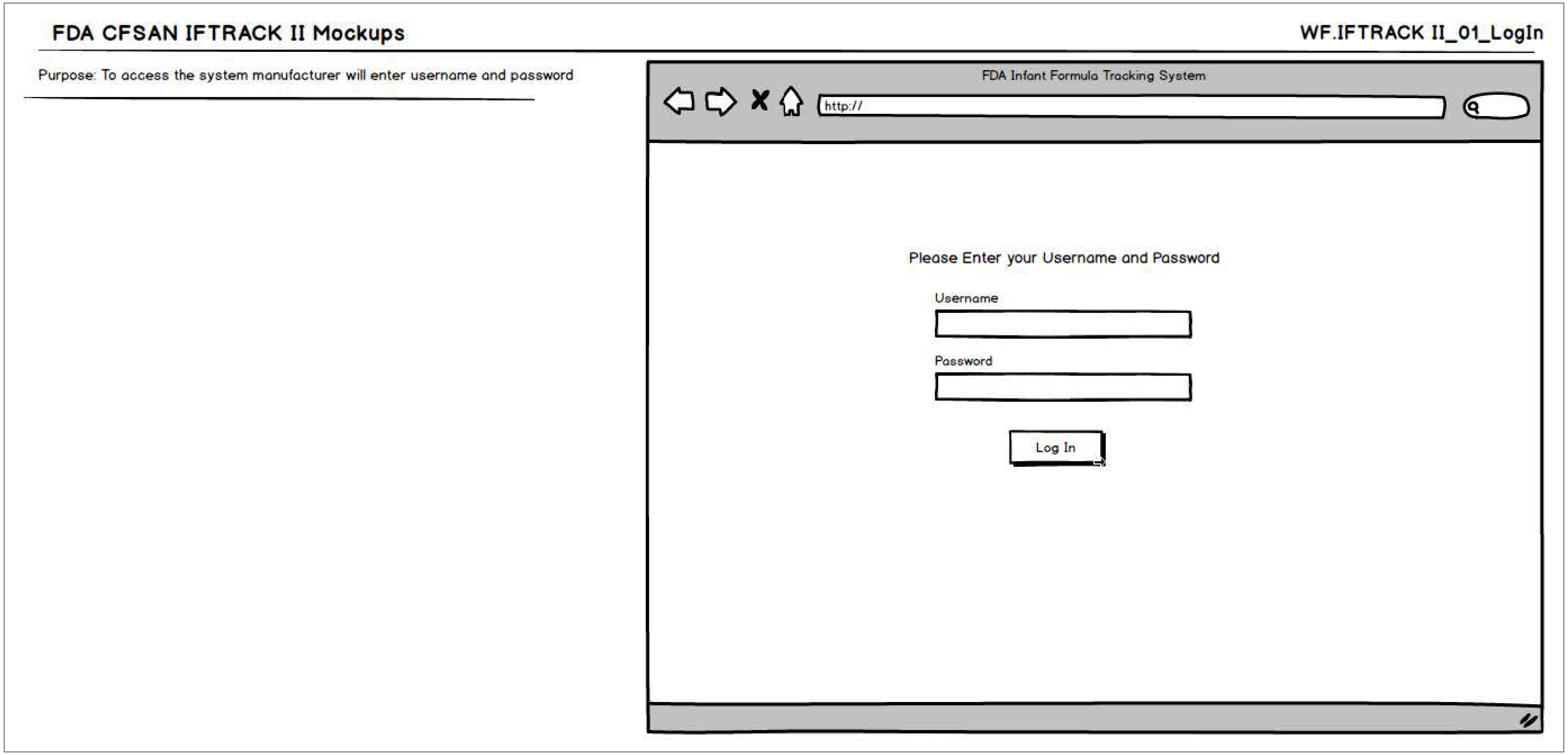
**WF.IFTRACK.8A_AssignedSubmissionRef #**

Purpose: To view assigned Submission Reference Number


FDA Infant Formula Tracking System
http://

Submission # 2015-01-1111 has been assigned

### 1.7 VERIFICATION SUBMISSION



FDA CFSAN IFTRACK II Mockups

WF.IFTRACK II_01_LogIn

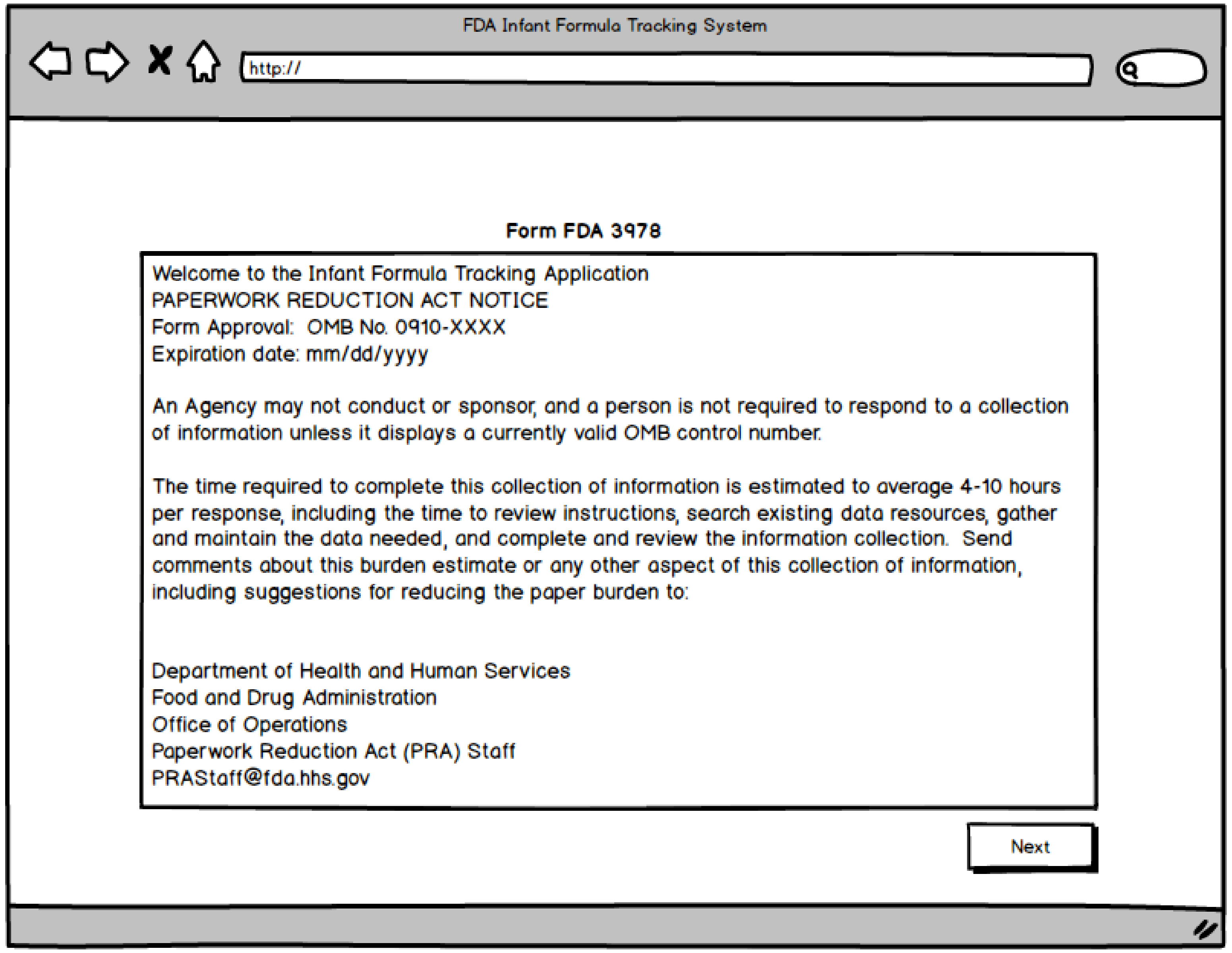
Purpose: To access the system manufacturer will enter username and password

Please Enter your Username and Password

FDA Infant Formula Tracking System
http://
Username
Password
Log In

**FDA CFSAN IFTRACK II Mockups**

**WF.IFTRACK II_001_Welcome**



**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
PRAStaff@fda.hhs.gov

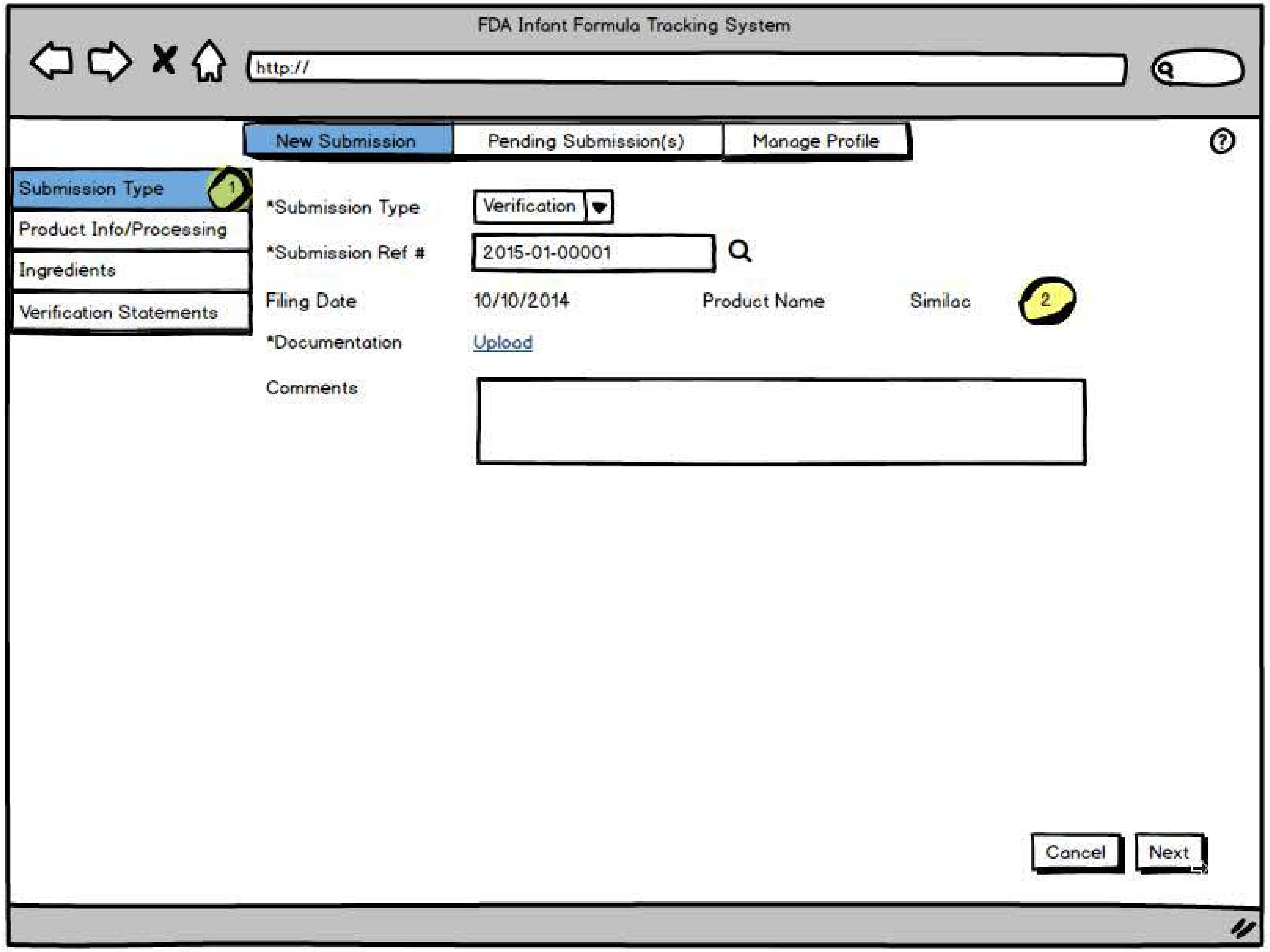
**FDA CFSAN IFTRACK II Mockups**

**WF.IFTRACK II.1D_Verification_SubmissionType**

Purpose: To create Infant Formula Verification submission

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
http://
New Submission
Pending Submission(s)
Manage Profile
Submission Type
1
Product Info/Processing
Ingredients
Verification Statements
2
Cancel
Next

*Submission Type: Verification

*Submission Ref #: 2015-01-00001

Filing Date: 10/10/2014

Product Name: Similac

*Documentation: Upload

Comments:

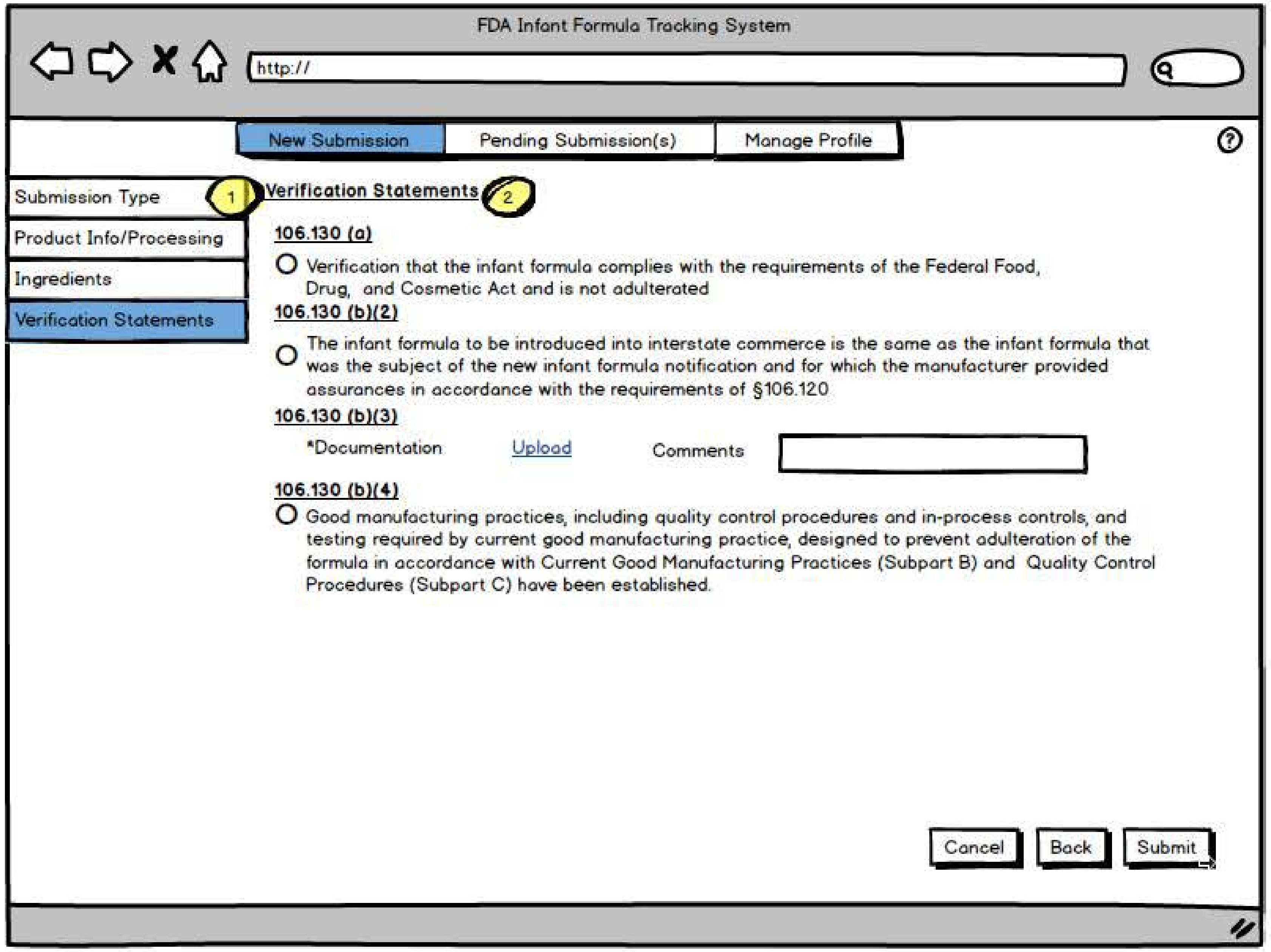
## FDA CFSAN IFTRACK II Mockups

## 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
http://
New Submission
Pending Submission(s)
Manage Profile
Submission Type
Product Info/Processing
Ingredients
Verification Statements
①
②
Cancel
Back
Submit

**Verification Statements**

**106.130 (a)**

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

**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

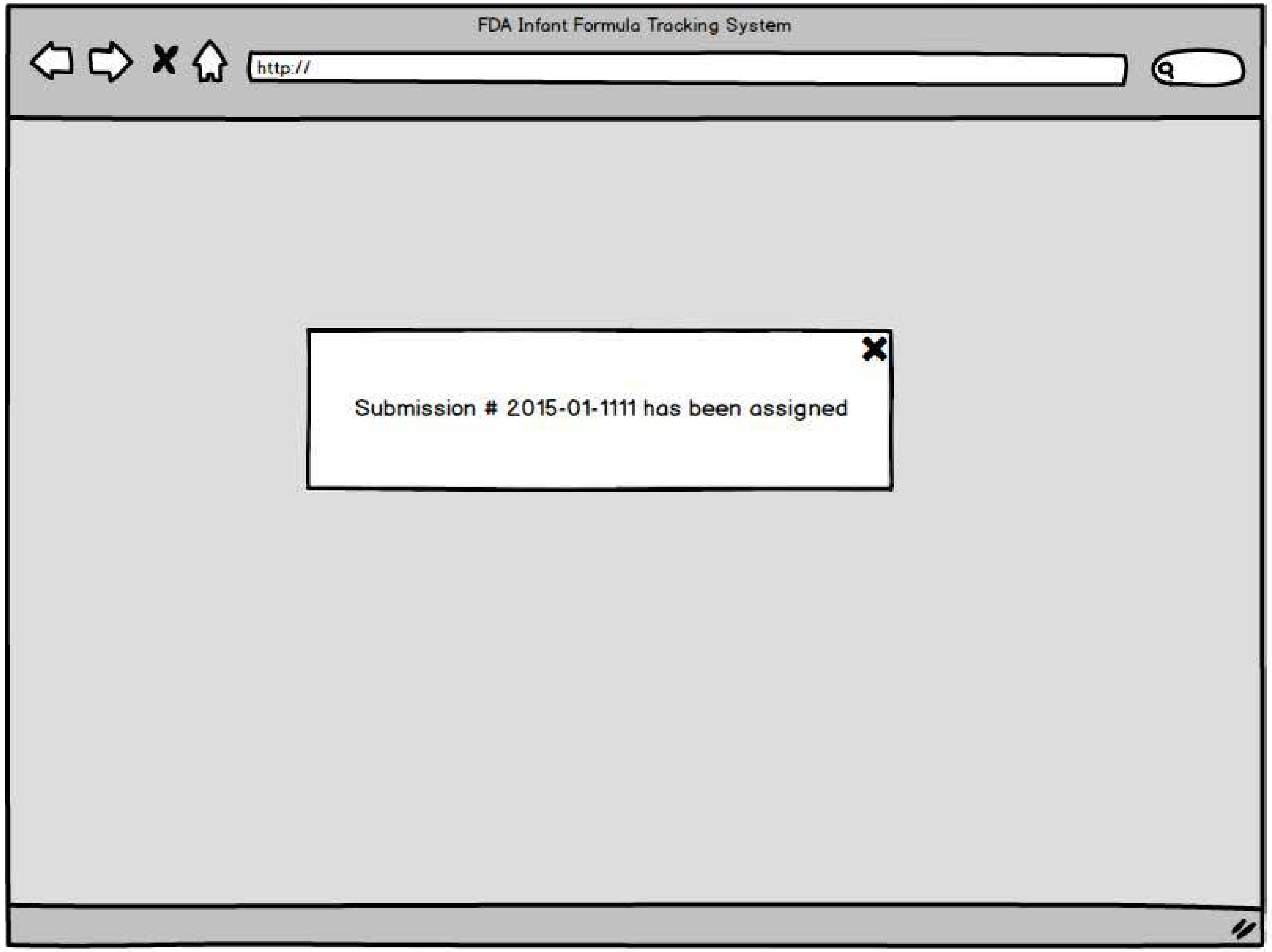
**106.130 (b)(4)**

○ 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.

**FDA CFSAN IFTRACK II Mockups**

**WF.IFTRACK II.8A_AssignedSubmissionRef #**

Purpose: To view assigned Submission Reference Number


FDA Infant Formula Tracking System
http://

Submission # 2015-01-1111 has been assigned

## 1.8 MANUFACTURER PROFILE

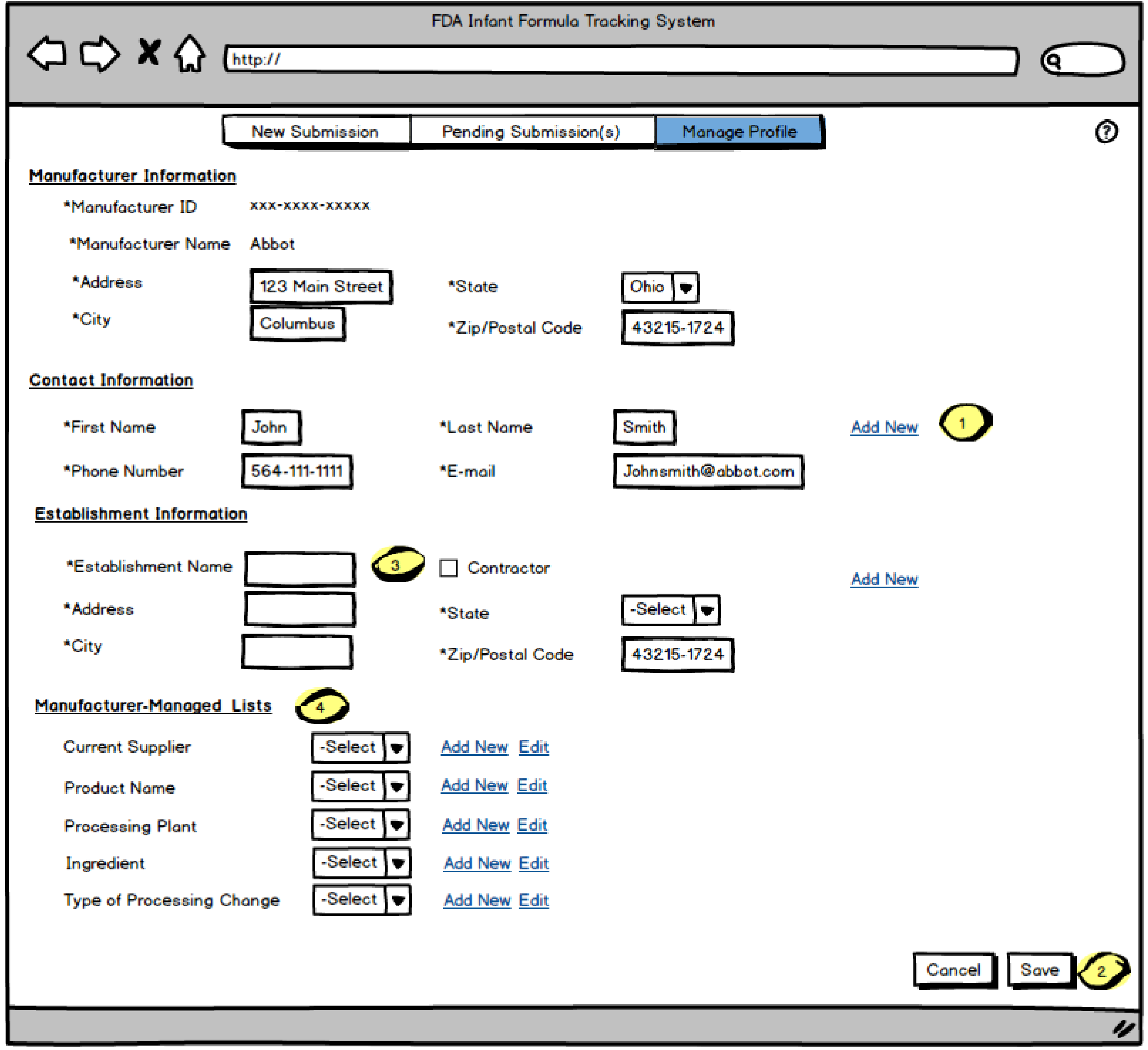
**FDA CFSAN IFTRACK II Mockups** **WF.IFTRACK II.9A_ManageProfile**

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

*Phone Number 564-111-1111

*E-mail Johnsmith@abbot.com

Add New
1

**Establishment Information**

*Establishment Name

3

☐ Contractor

Add New

*Address

*State -Select

*City

*Zip/Postal Code 43215-1724

**Manufacturer-Managed Lists**

Current Supplier -Select

Product Name -Select

Processing Plant -Select

Ingredient -Select

Type of Processing Change -Select

Add New Edit
Add New Edit
Add New Edit
Add New Edit
Add New Edit
Cancel
Save
2