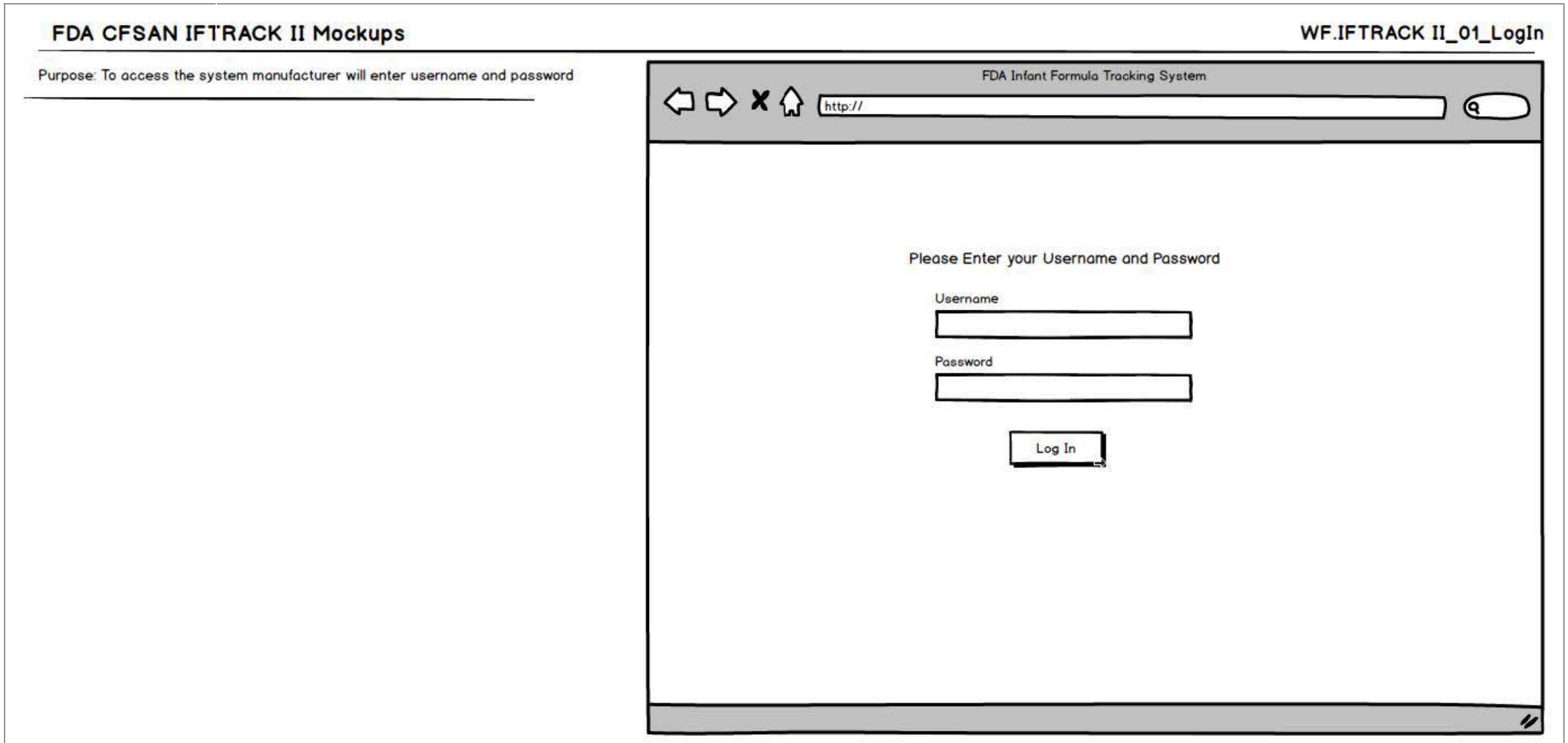
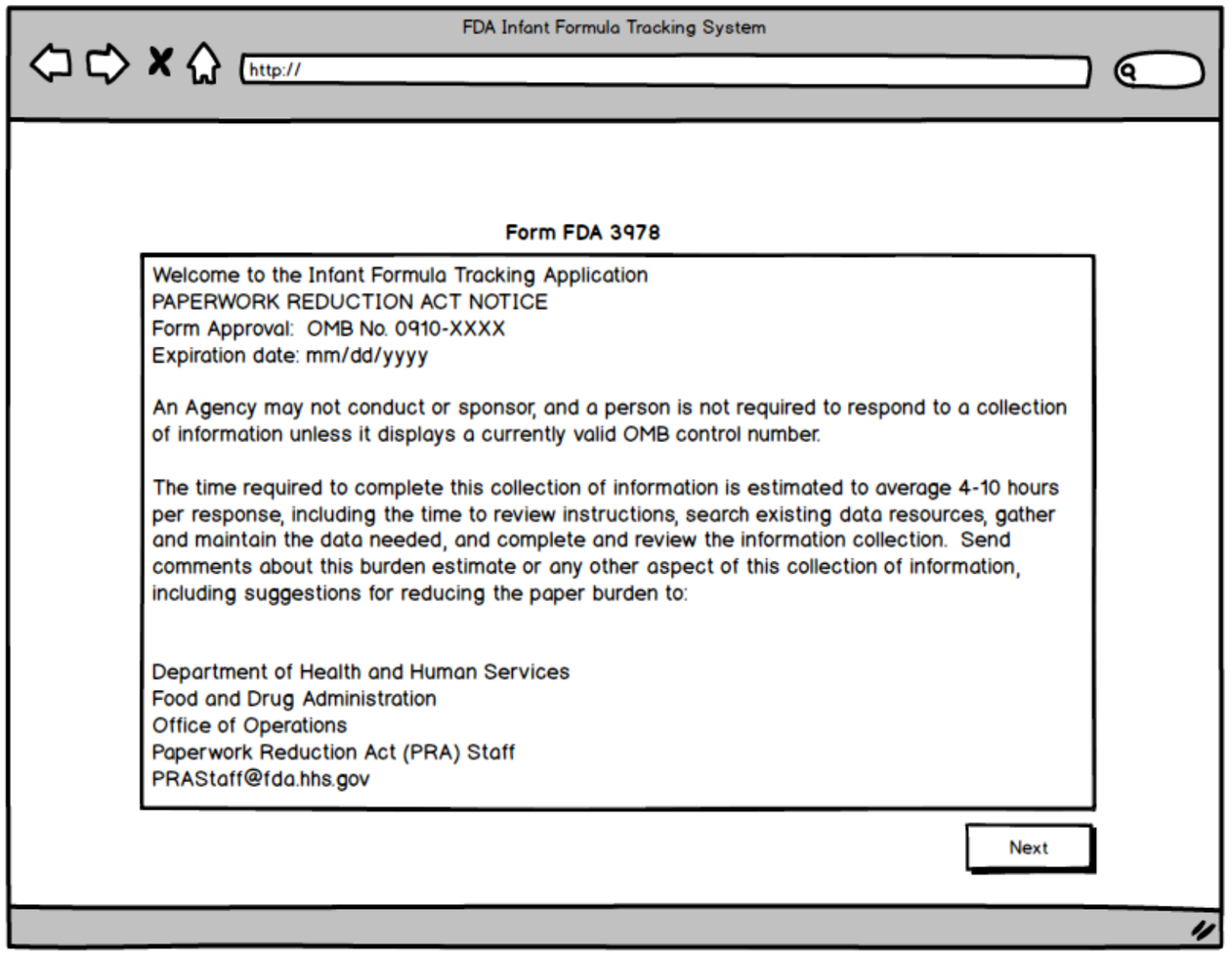
1.1 90 DAYS EXEMPT SUBMISSION



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

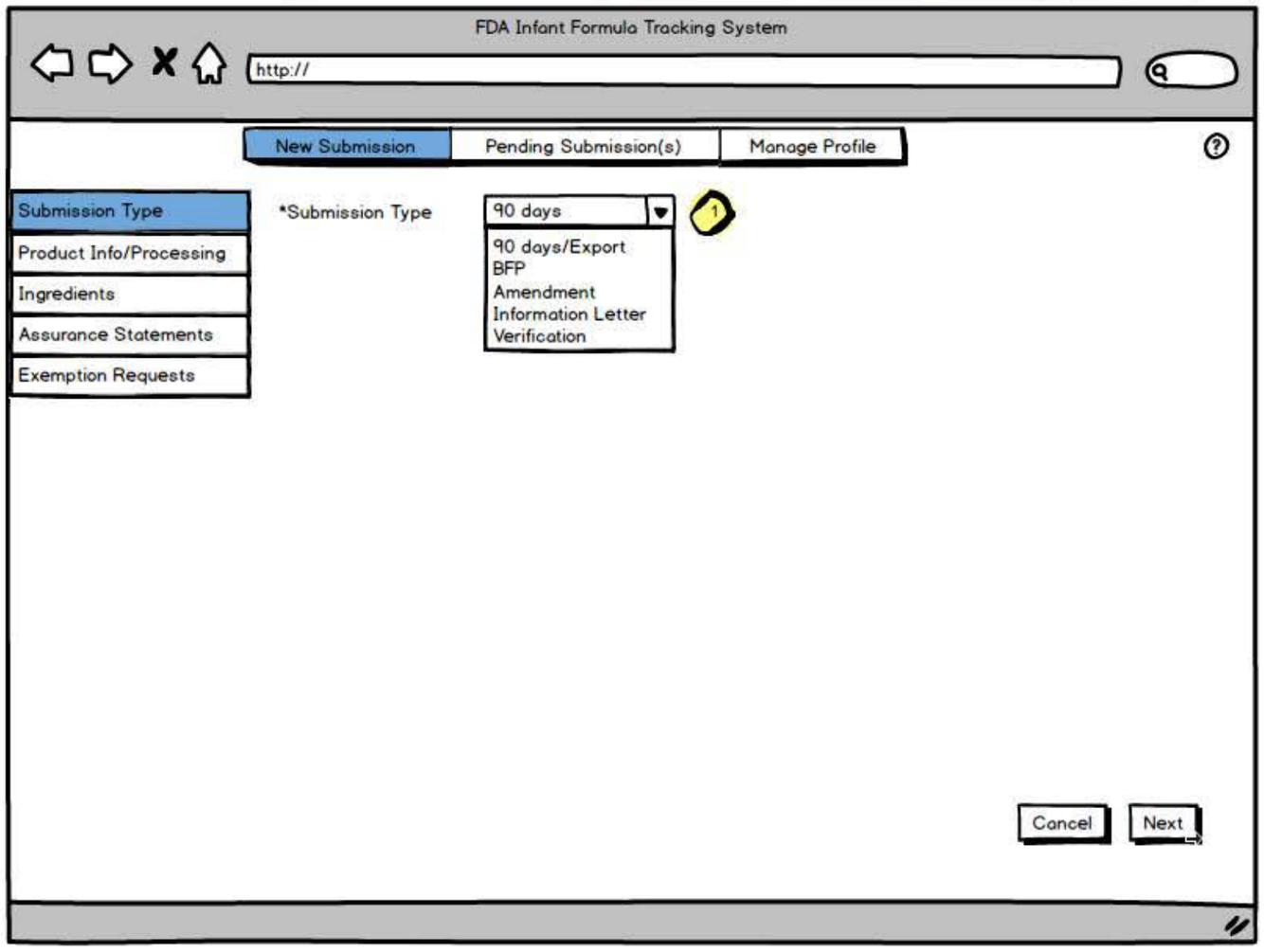


FDA CFSAN IFTRACK II Wireframes

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 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
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.

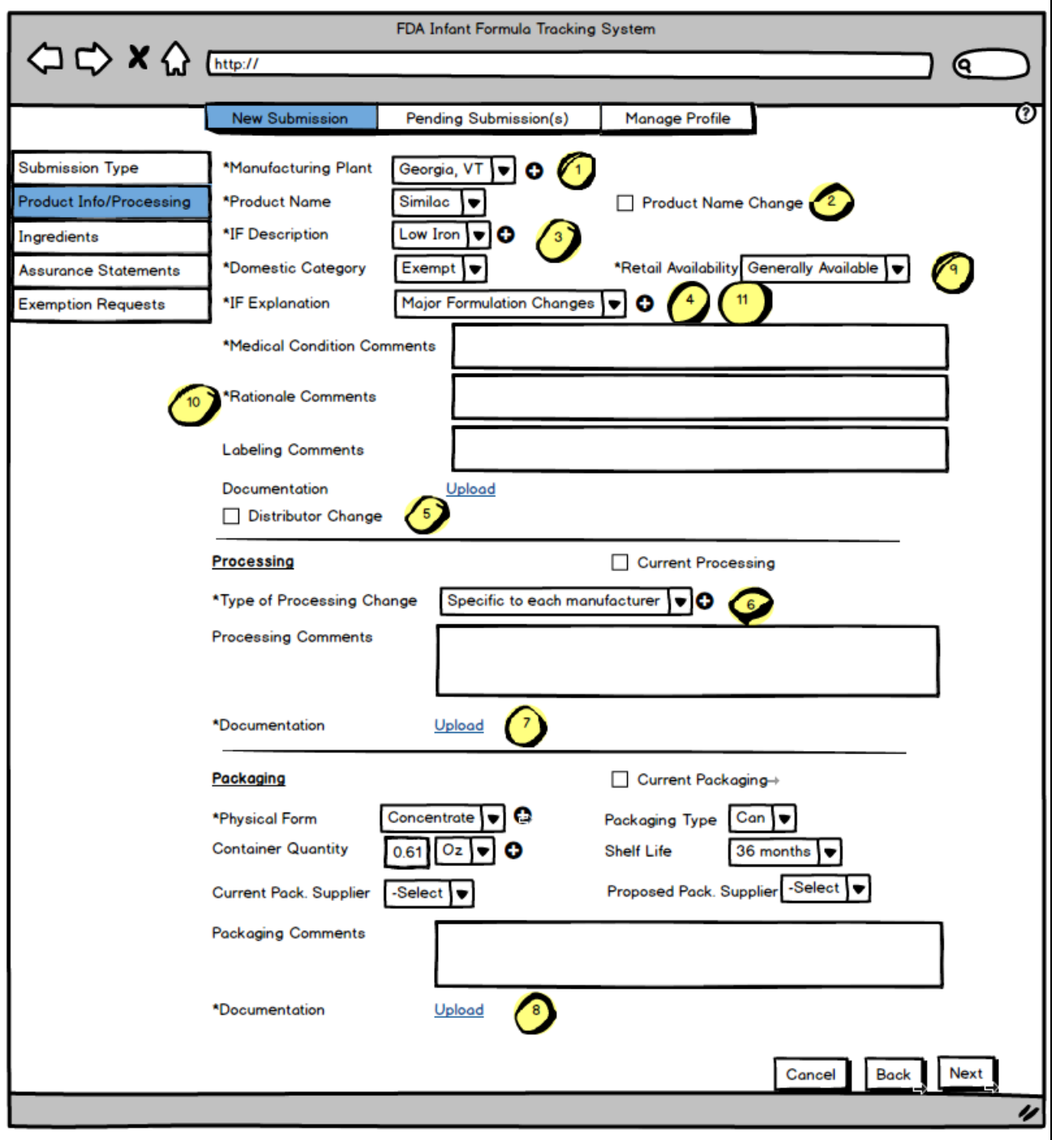
7 The user will be required to add either Processing comments or Processing documentation if Major processing change and/or Non Major processing change is selected for all submission types.

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.

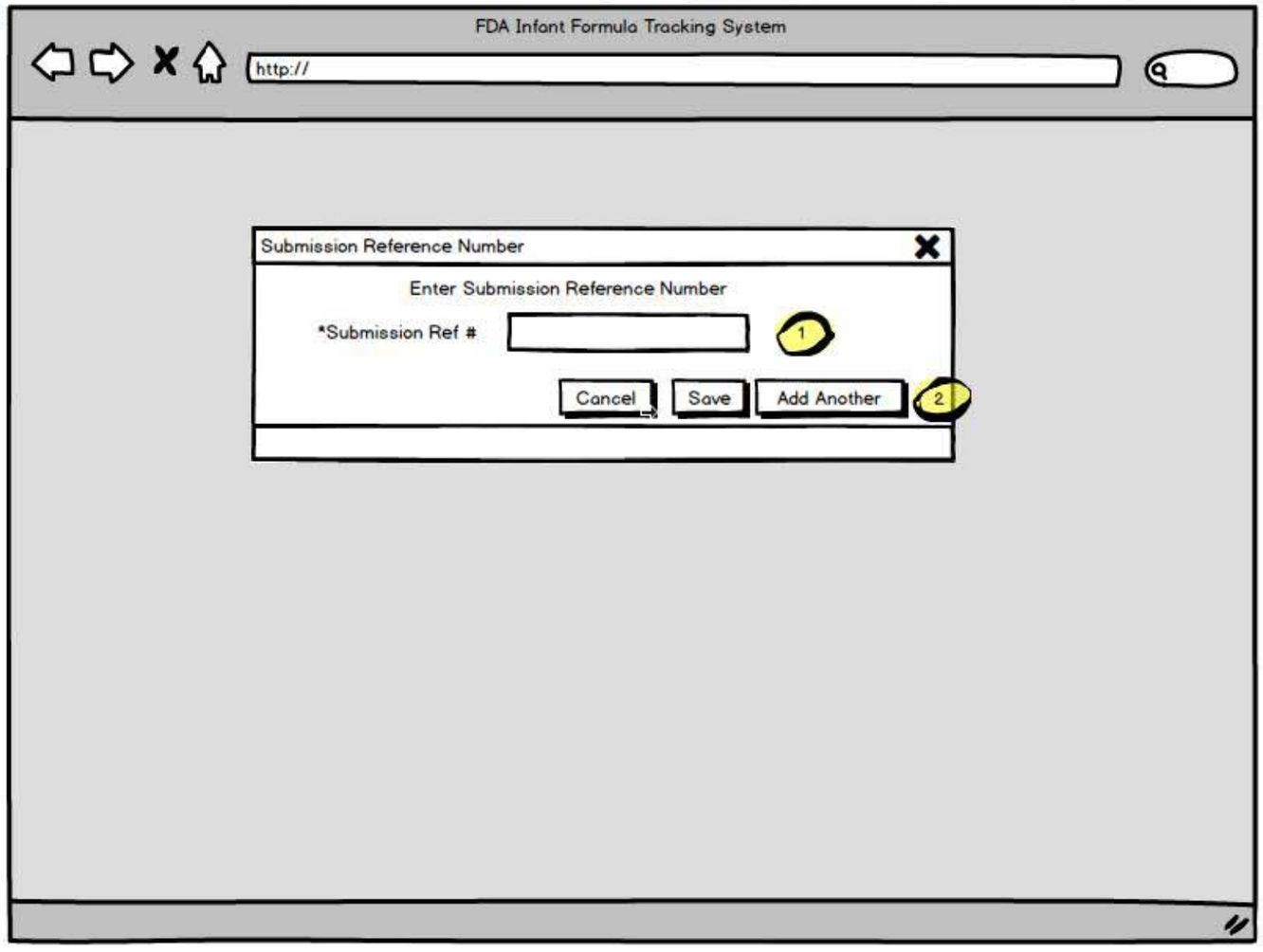


FDA CFSAN IFTRACK II Wireframes

WF.IFTRACK II.3B_Processing_SubmissionRef#

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

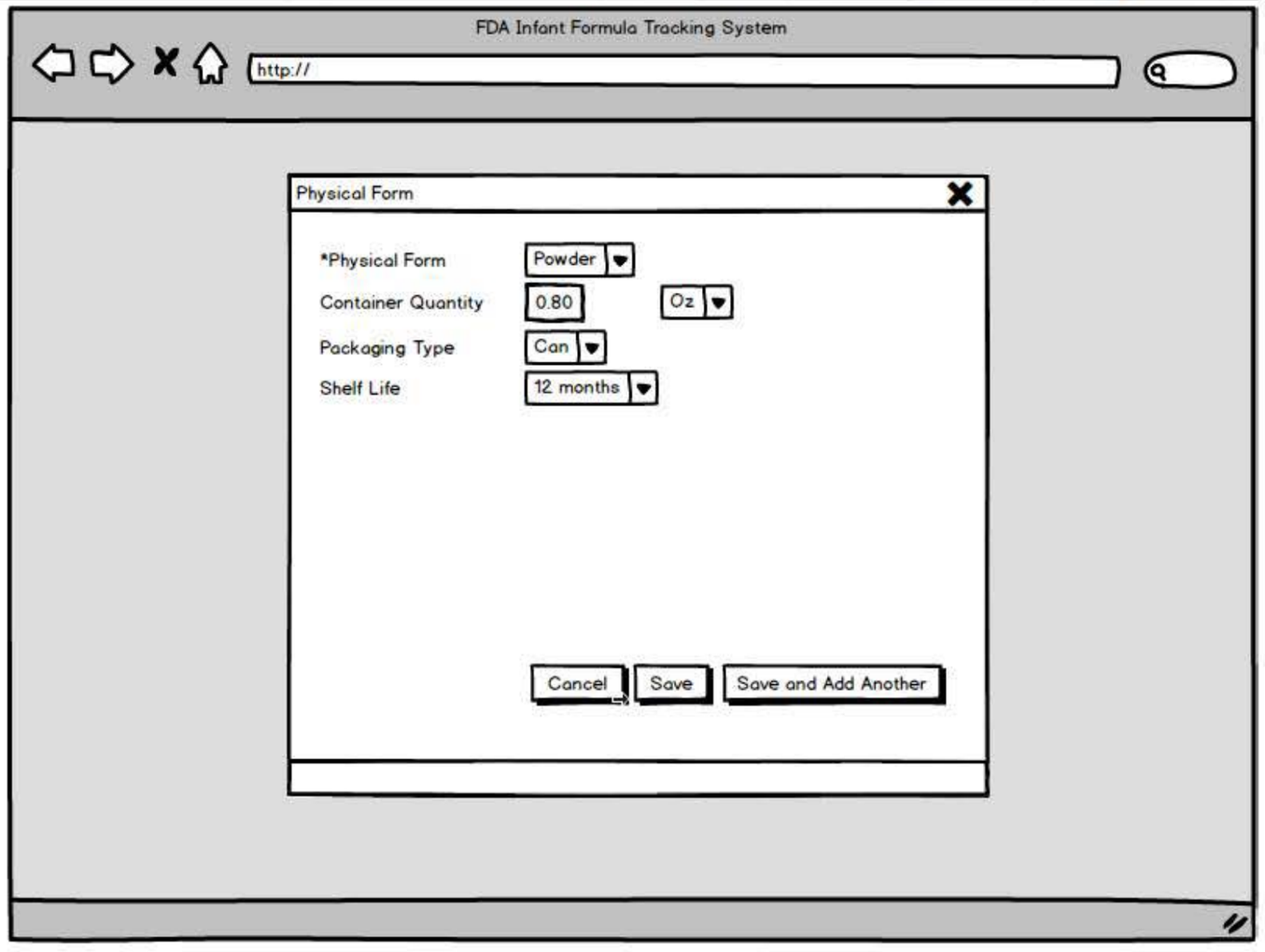
1. Submission Ref # field is required if the user selects Current Packaging or Current Processing option.
2. The user will be able to add more than one Submission Reference Number.



FDA CFSAN IFTRACK II Wireframes

WF.IFTRACK II.3A_Processing_AddNewPhysicalForm

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

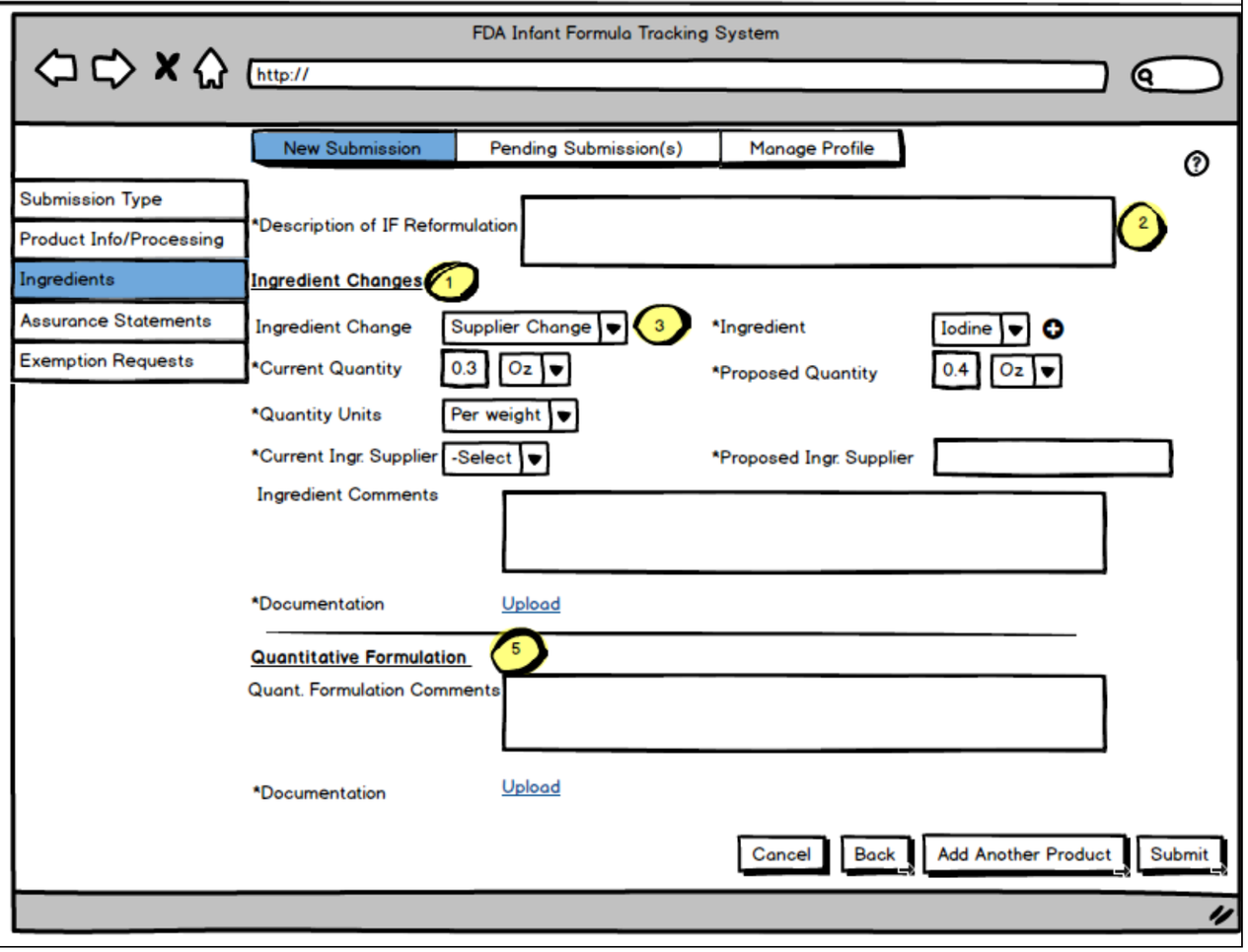


FDA CFSAN IFTRACK II Wireframes

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 # .

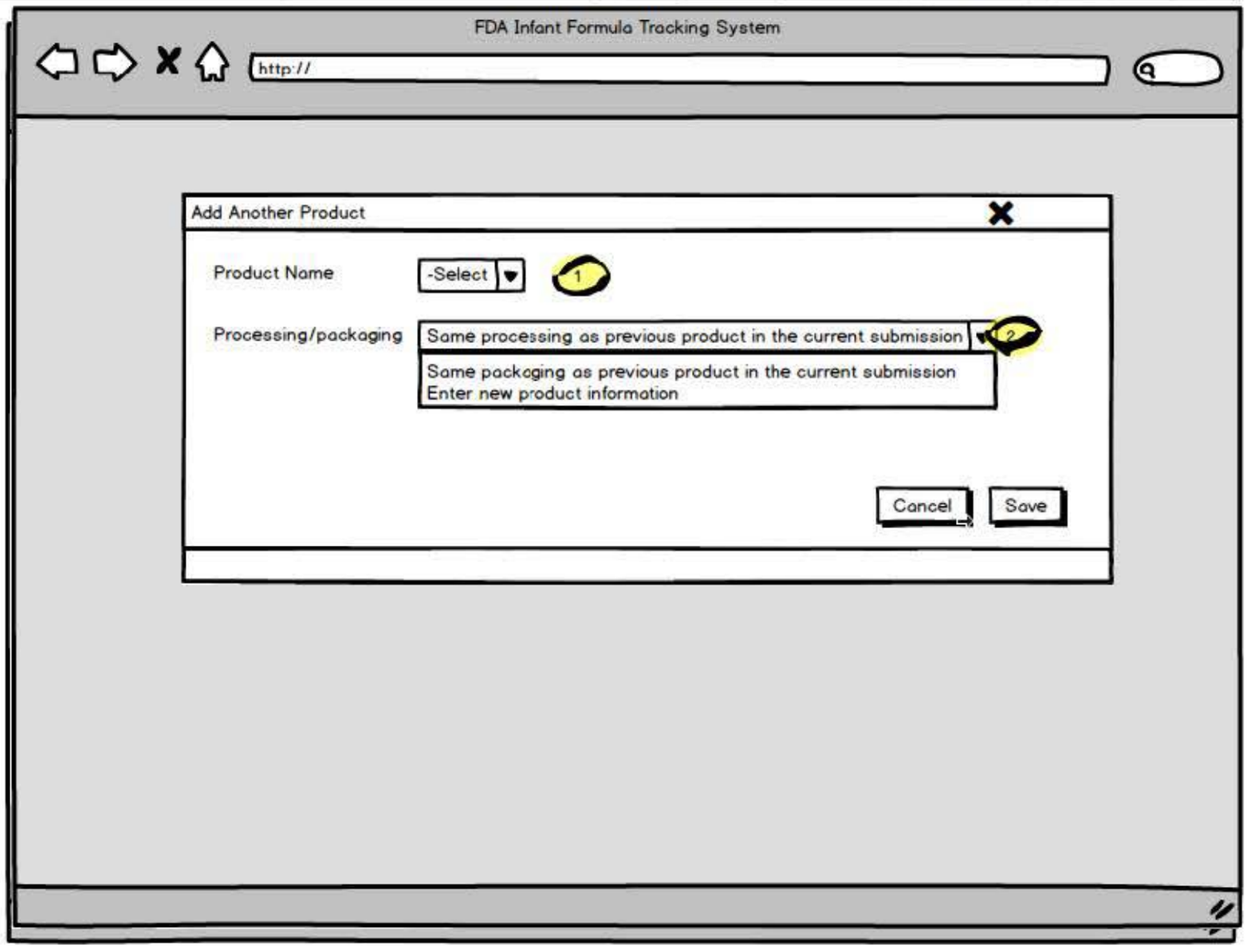


FDA CFSAN IFTRACK II Wireframes

WF.IFTRACK II.7A_AddAnotherProduct

Purpose: To enter additional product name.

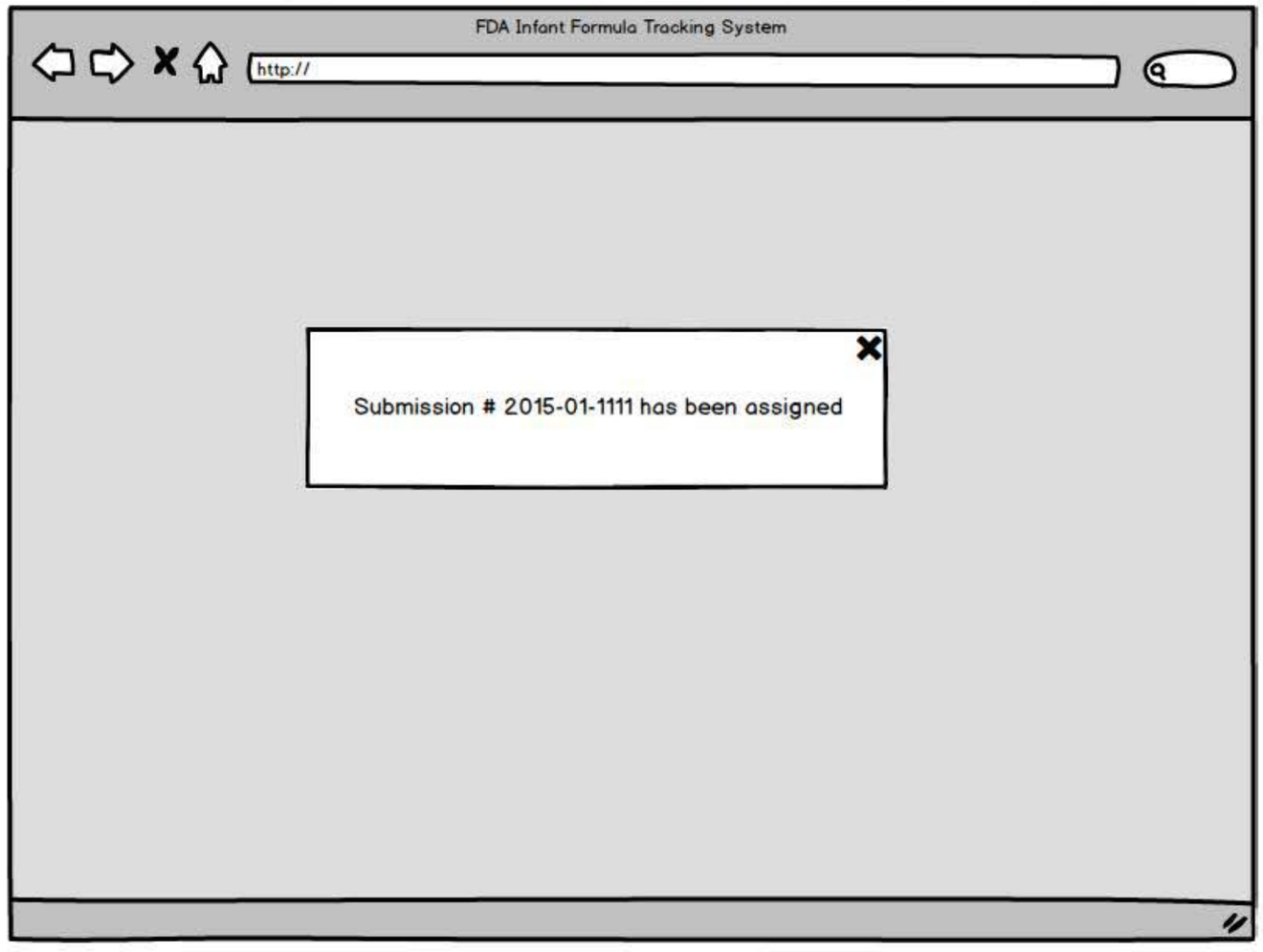
1. The user will be allowed to add Another product after all information for the first product has been enetered.
2. If the user selects "Same processing as previous product in the current submission" for Processing/packaging field, processing information will be automatically populated for the next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



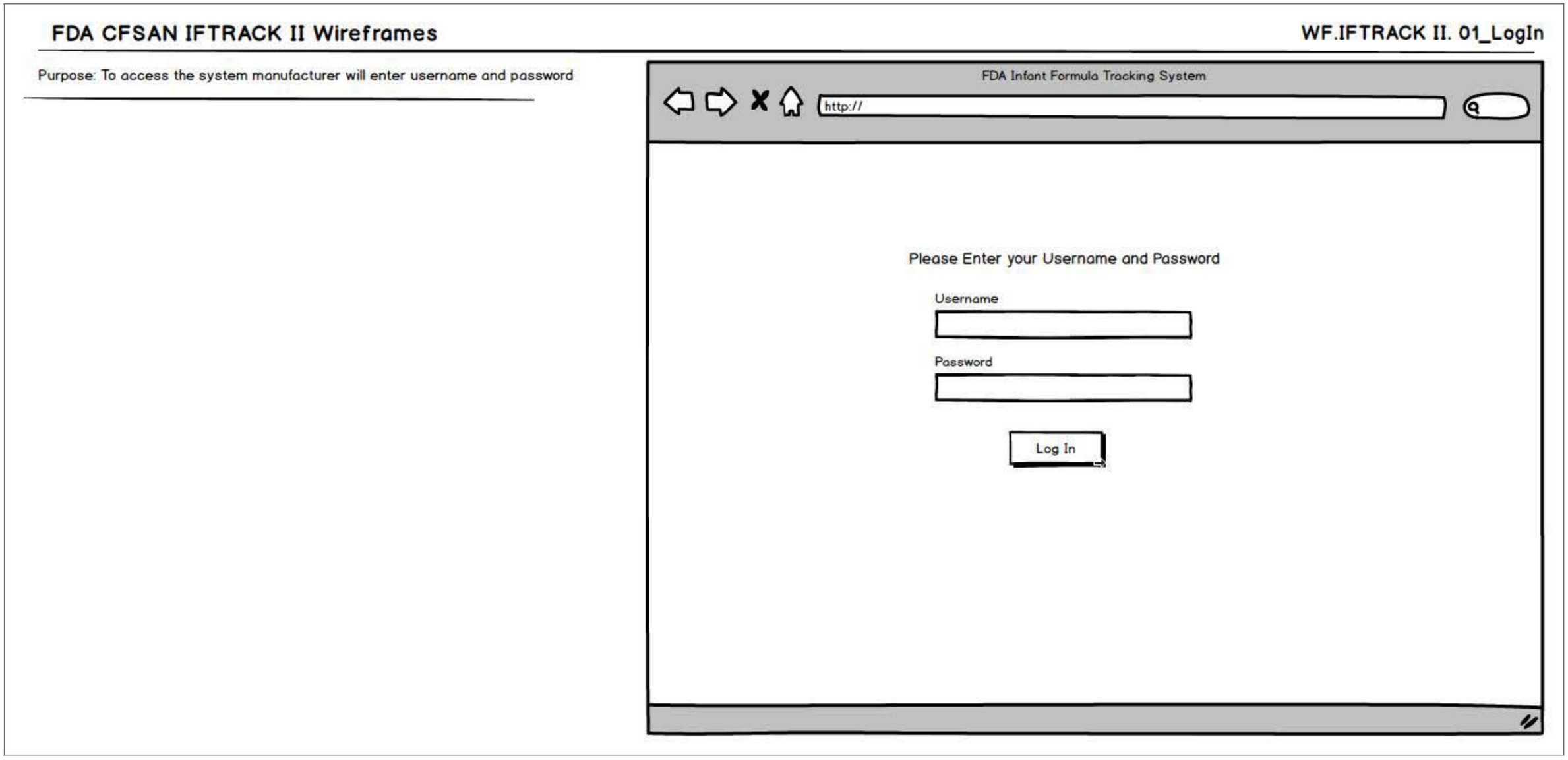
FDA CFSAN IFTRACK II Wireframes

WF.IFTRACK II.8A_AssignedSubmissionRef#

Purpose: To view assigned Submission Reference Number

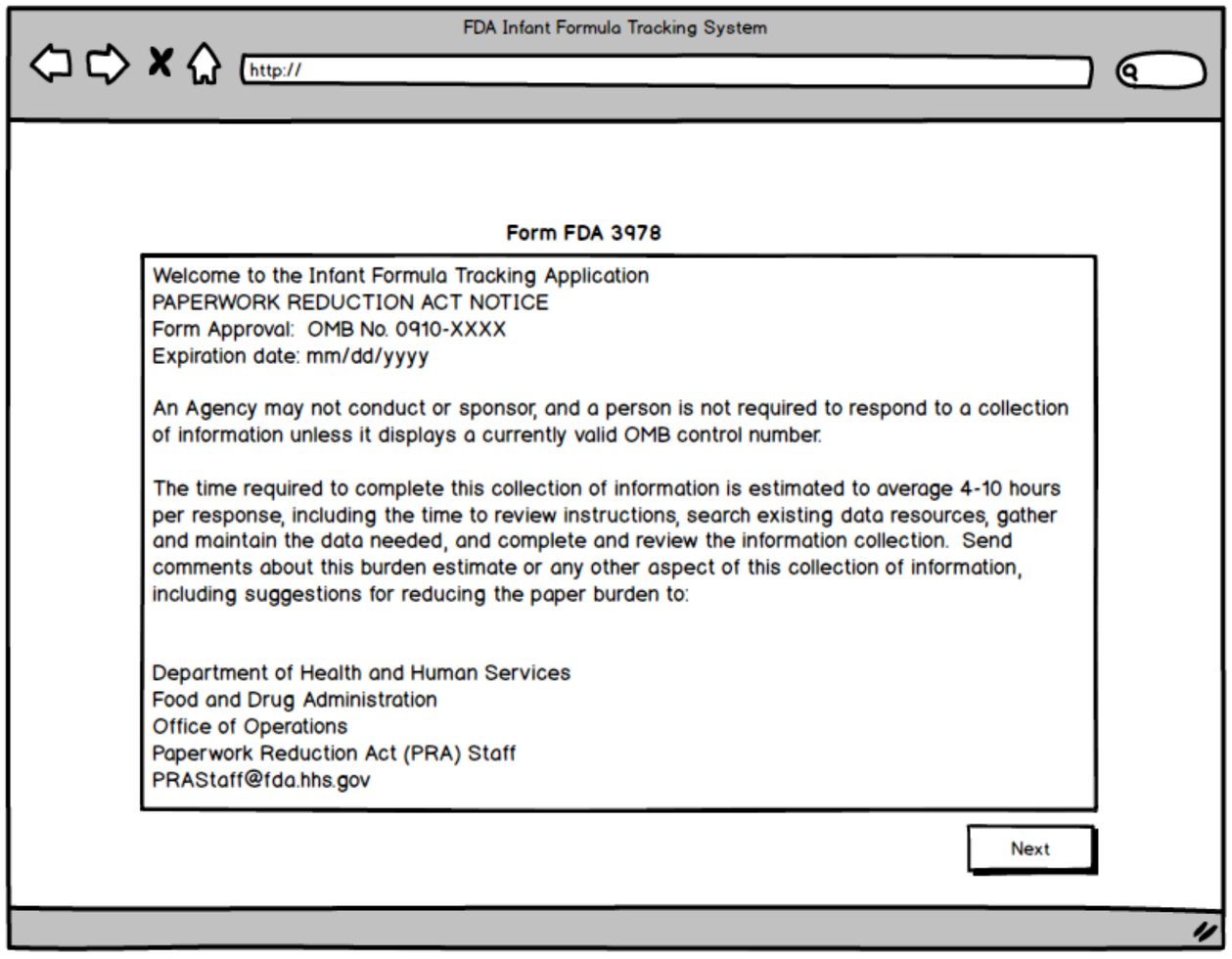


1.2 90 DAYS NON-EXEMPT SUBMISSION



FDA CFSAN IFTRACK II Mockups

WF.IFTRACK II_001_Welcome

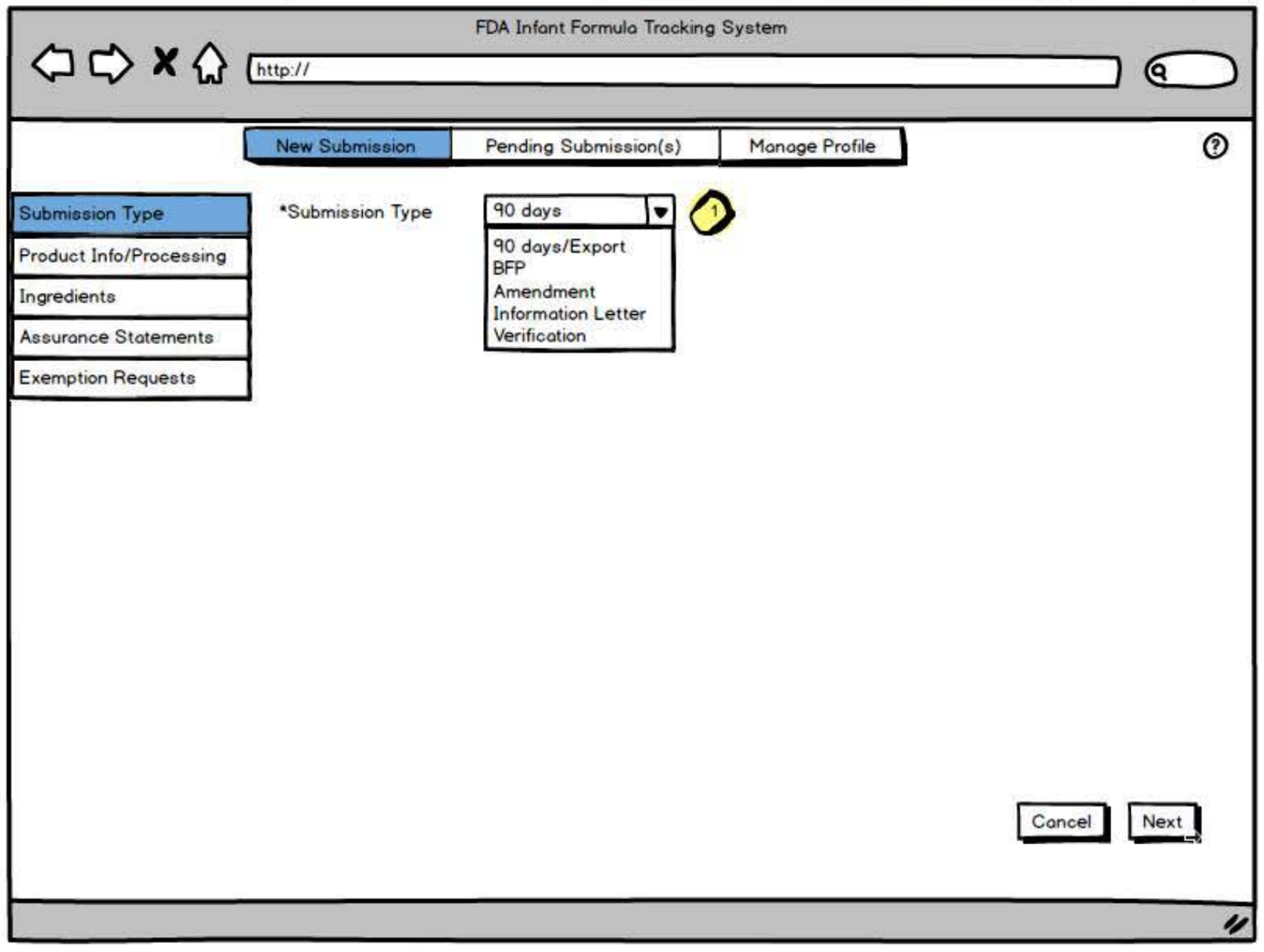


FDA CFSAN IFTRACK II Wireframes

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 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.

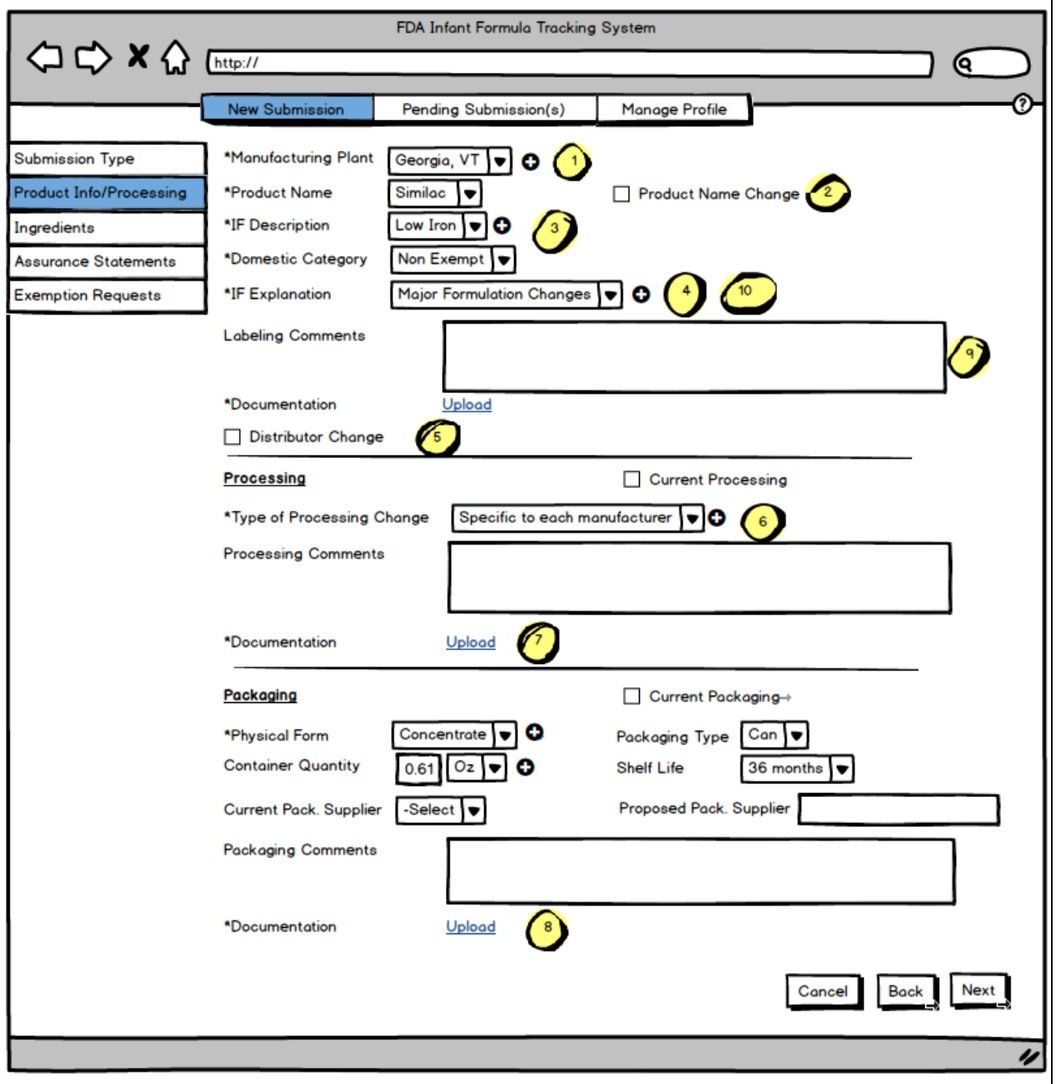
6 1. Type of Processing Change is only required if Major processing change and/or Non Major processing change are selected for 90 days/IF Explanation.
2.The user will be able to add more than one value under Type of Processing Change field.

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.

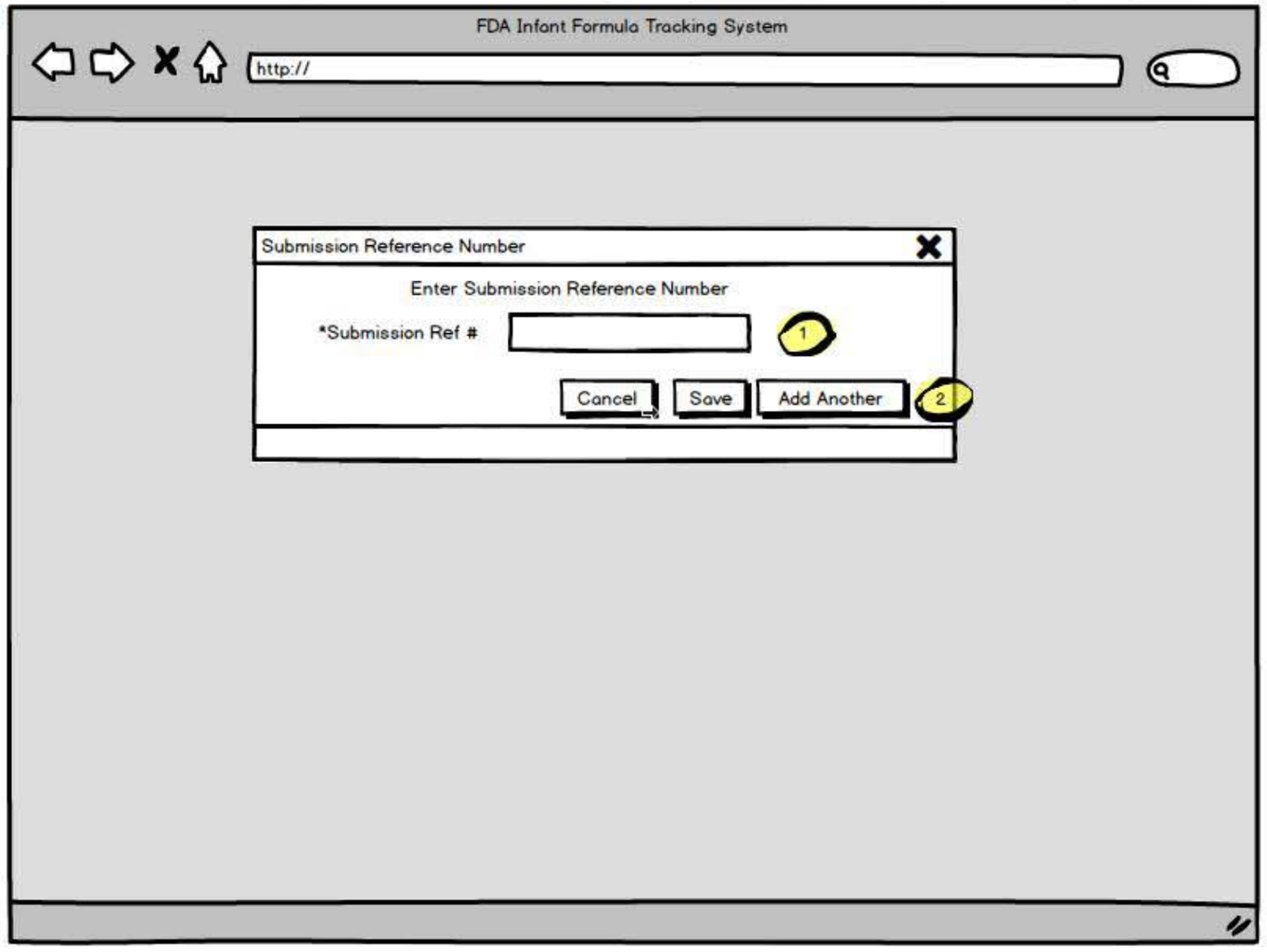


FDA CFSAN IFTRACK II Wireframes

WF.IFTRACK II.3B_Processing_SubmissionRef#

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

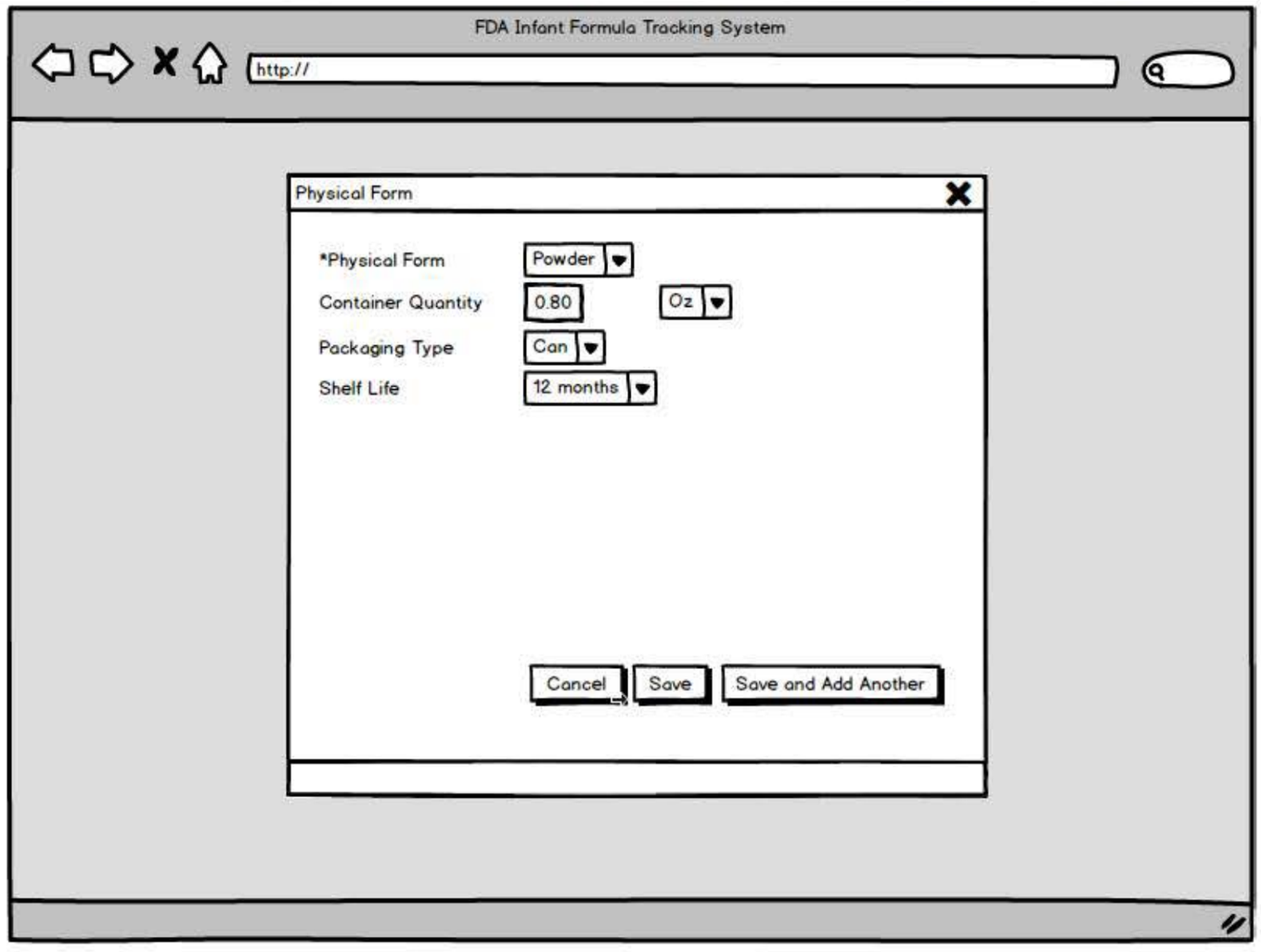
1. Submission Ref # field is required if the user selects Current Packaging or Current Processing option.
2. The user will be able to add more than one Submission Reference Number.



FDA CFSAN IFTRACK II Wireframes

WF.IFTRACK II. 3A_Processing_AddNewPhysicalForm

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

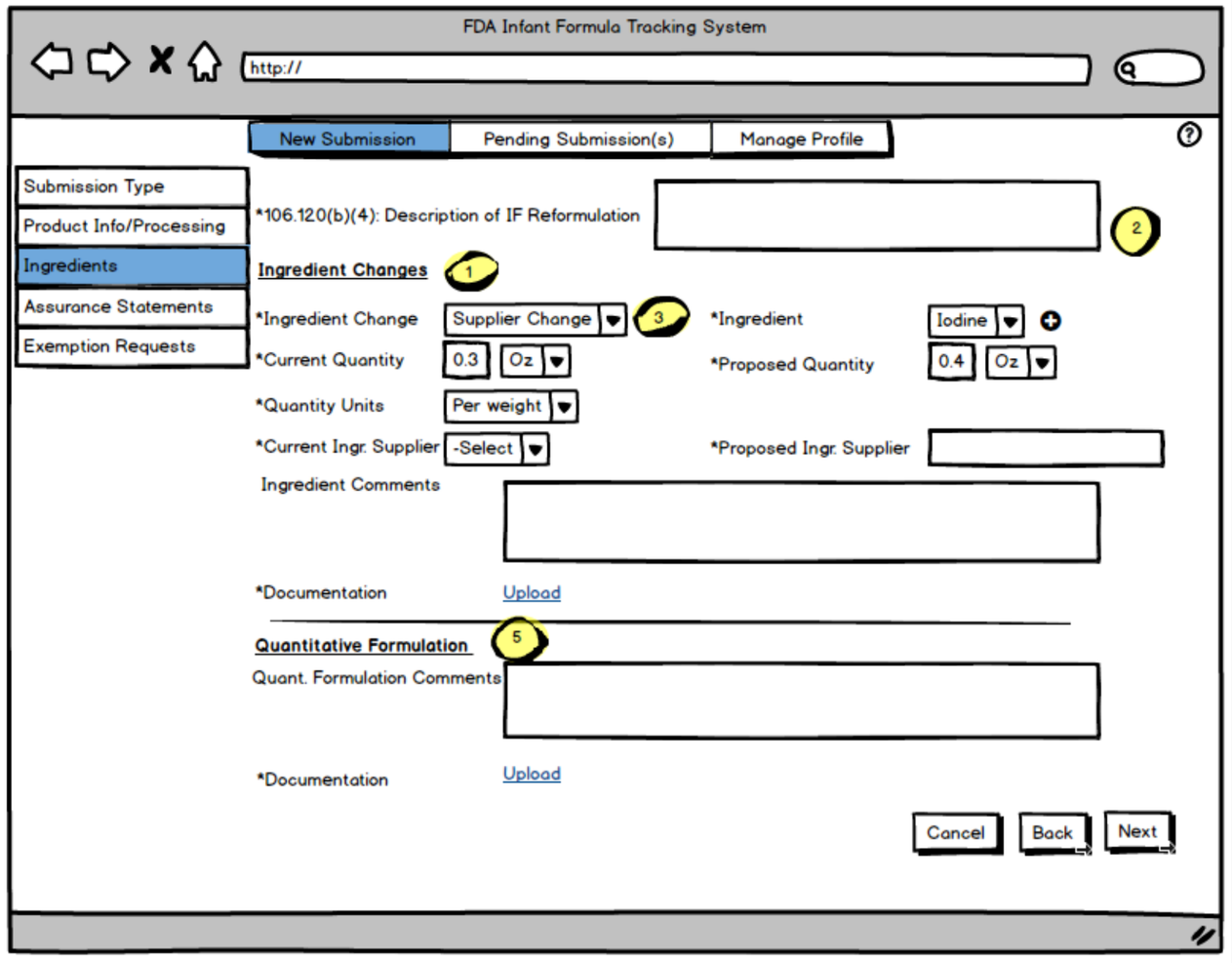


FDA CFSAN IFTRACK II Wireframes

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 # .

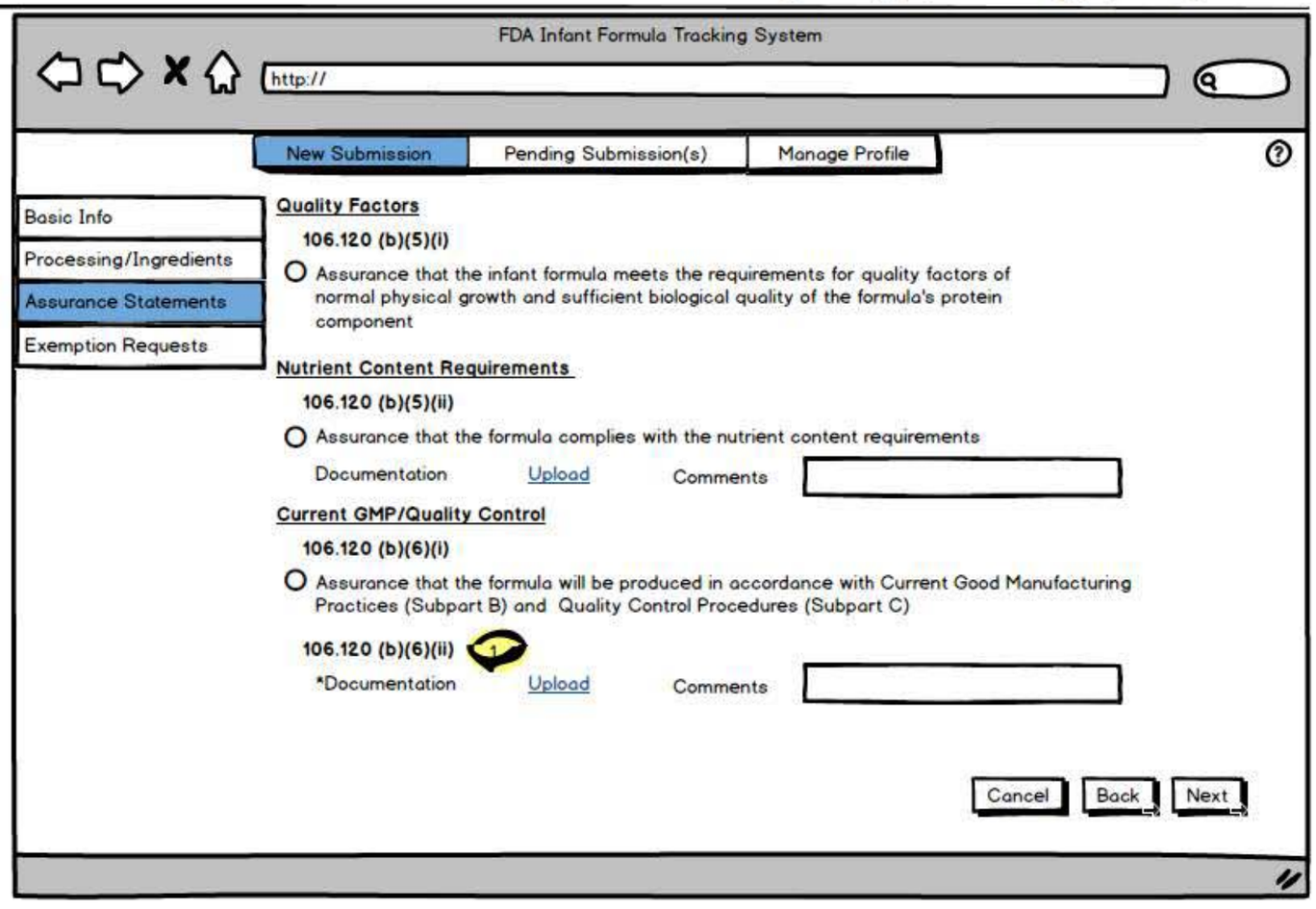


FDA CFSAN IFTRACK II Wireframes

WF.IFTRACK II.5A_90Days_Non Exempt_QualityFactors

Purpose: To select Quality Factors and enter Quality Factors information

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



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

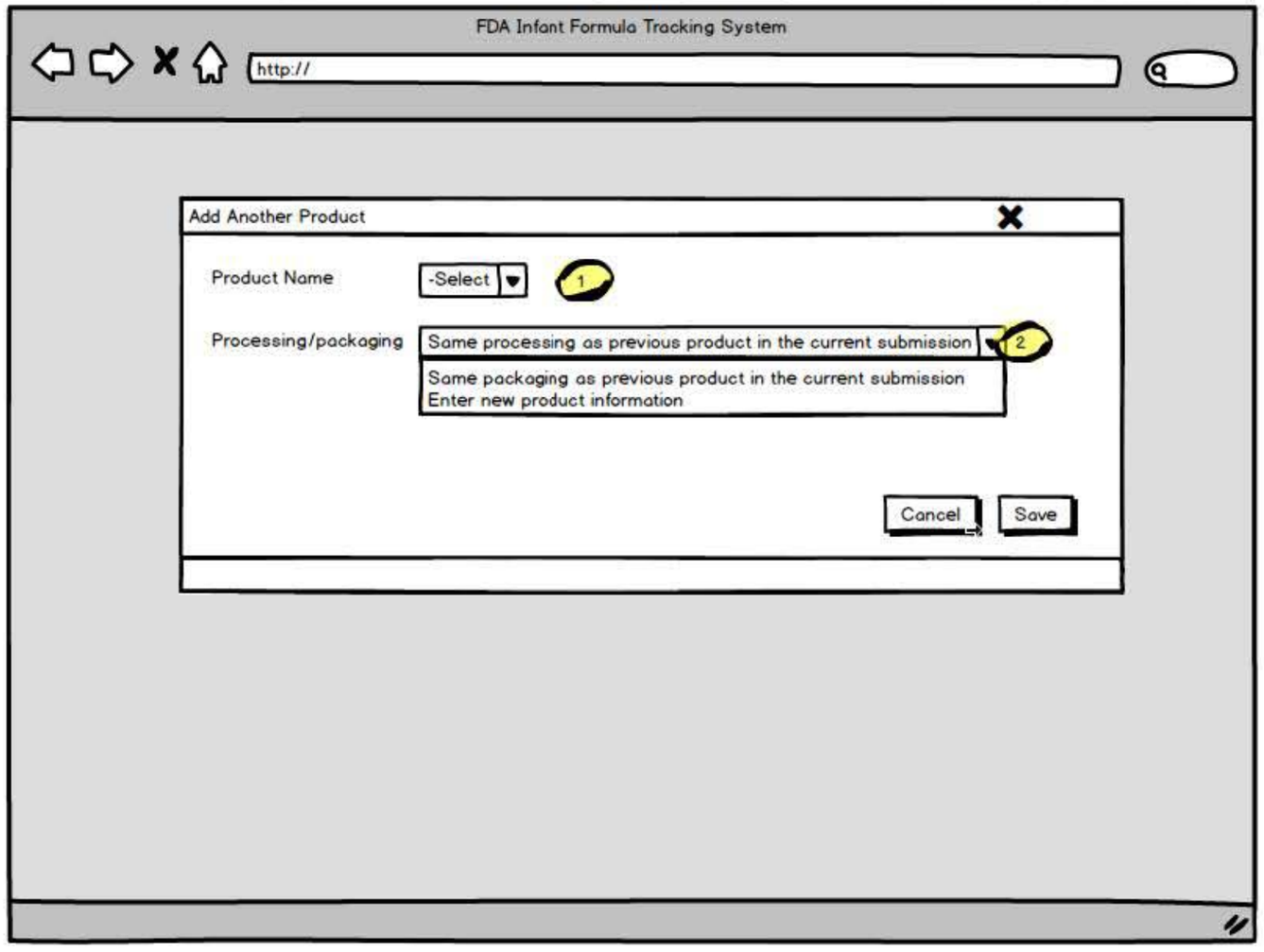
Cancel | Back | Add Another Product | Submit

FDA CFSAN IFTRACK II Wireframes

WF.IFTRACK II.7A_AddAnotherProduct

Purpose: To enter additional product name.

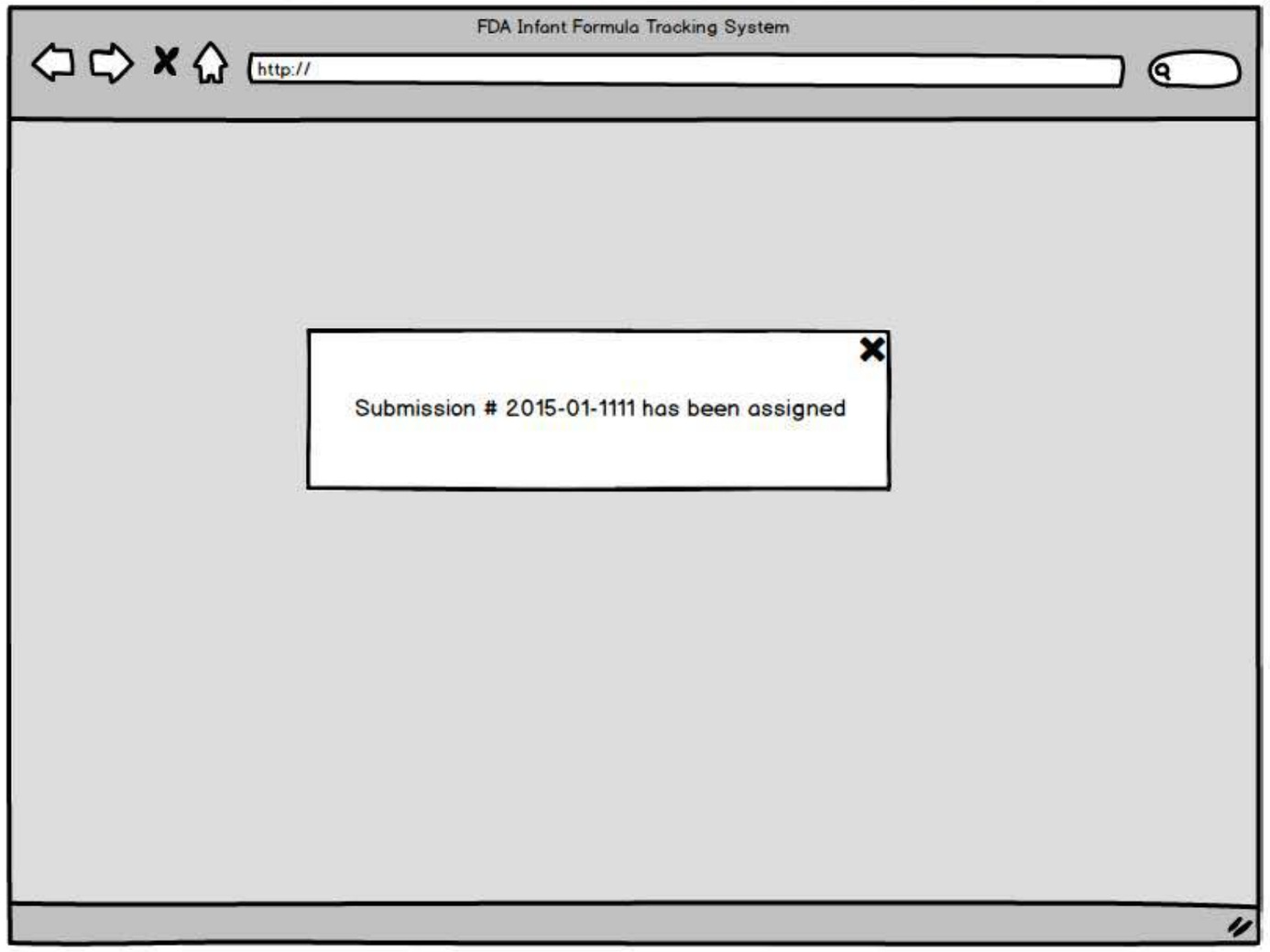
1. The user will be allowed to add Another product after all information for the first product has been enetered.
2. If the user selects "Same processing as previous product in the current submission" for Processing/packaging field, processing information will be automatically populated for the next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



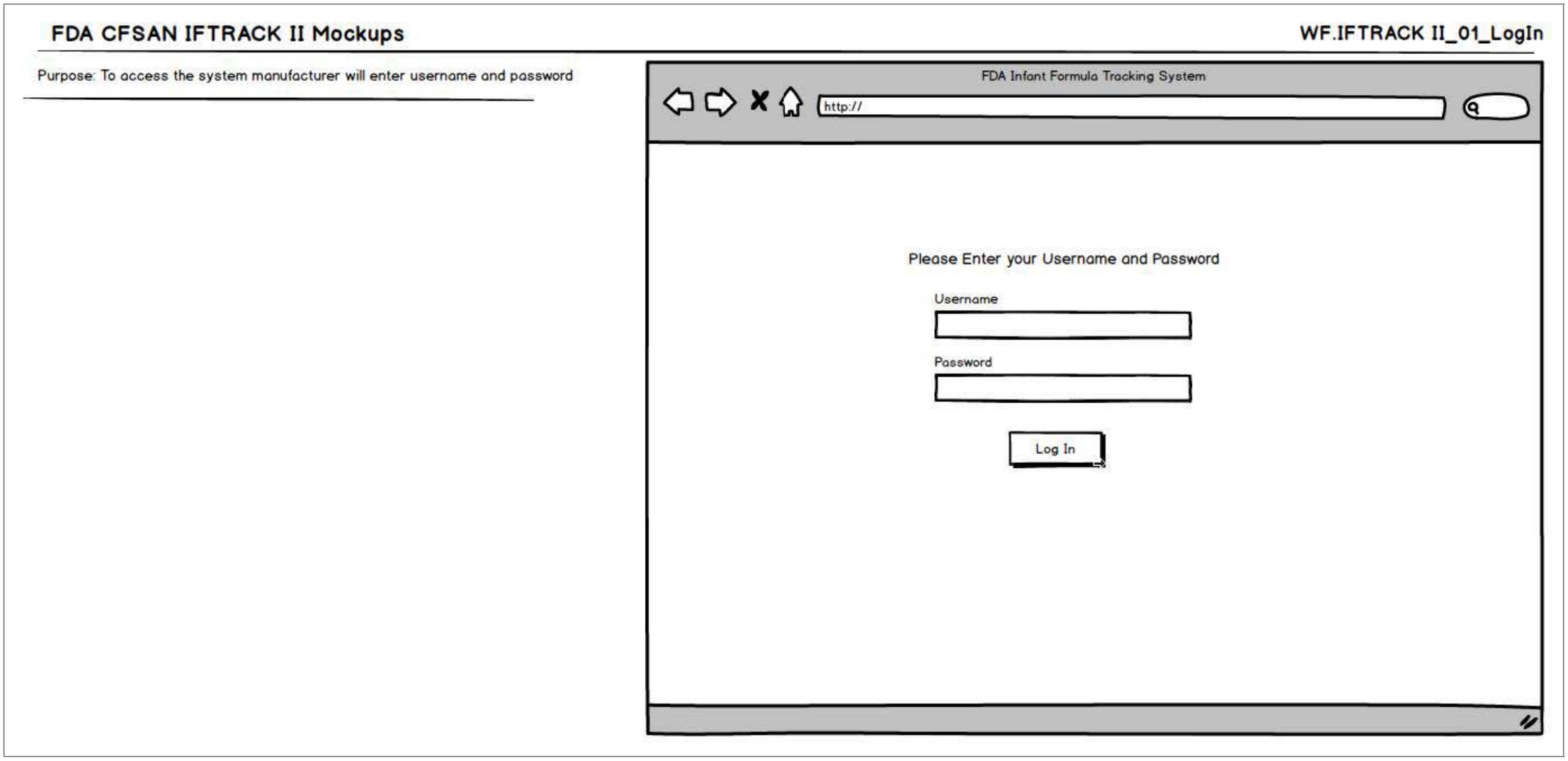
FDA CFSAN IFTRACK II Wireframes

WF.IFTRACK II.8A_AssignedSubmissionRef#

Purpose: To view assigned Submission Reference Number

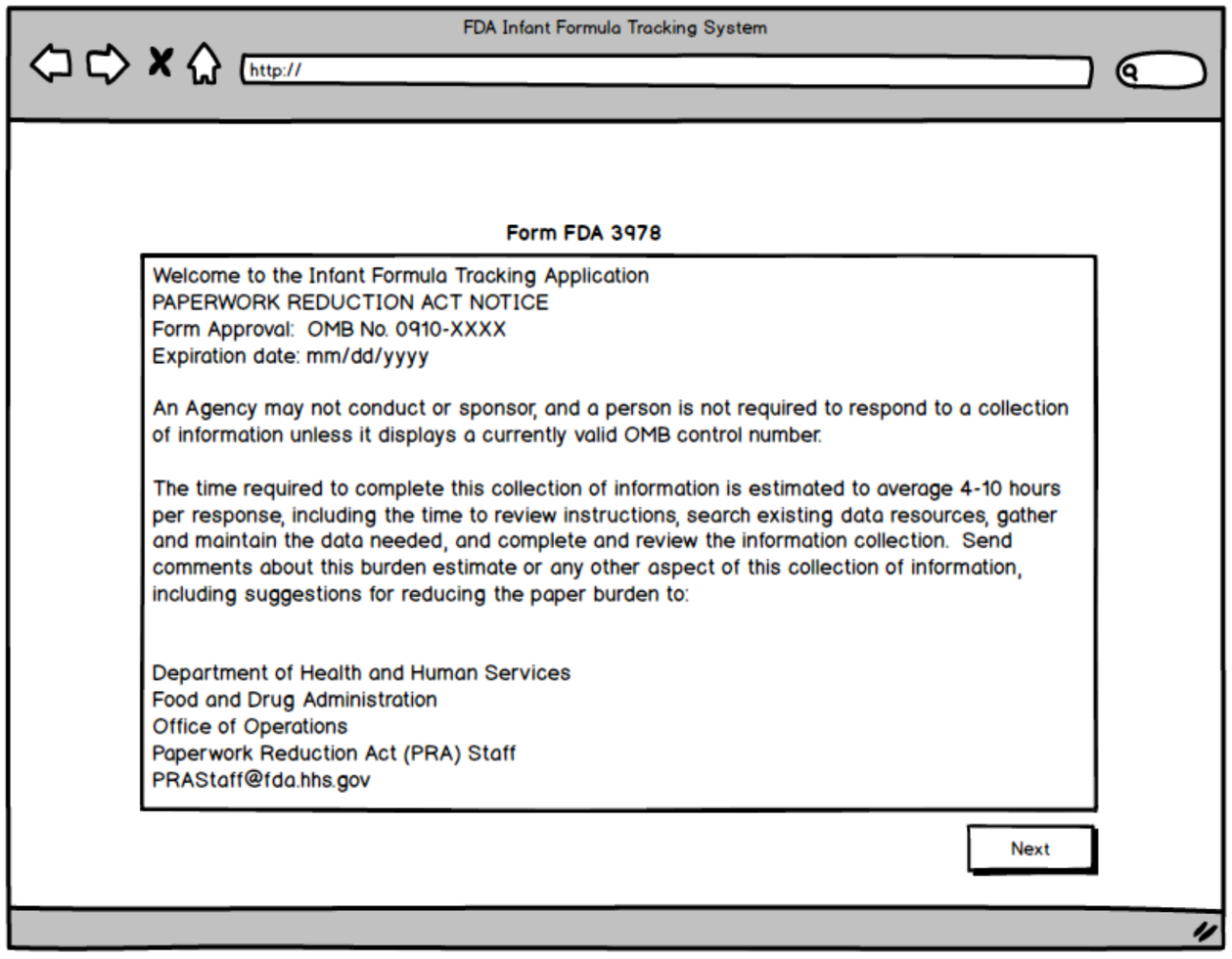


1.3 90 DAYS EXPORT SUBMISSION



FDA CFSAN IFTRACK II Mockups

WF.IFTRACK II_001_Welcome

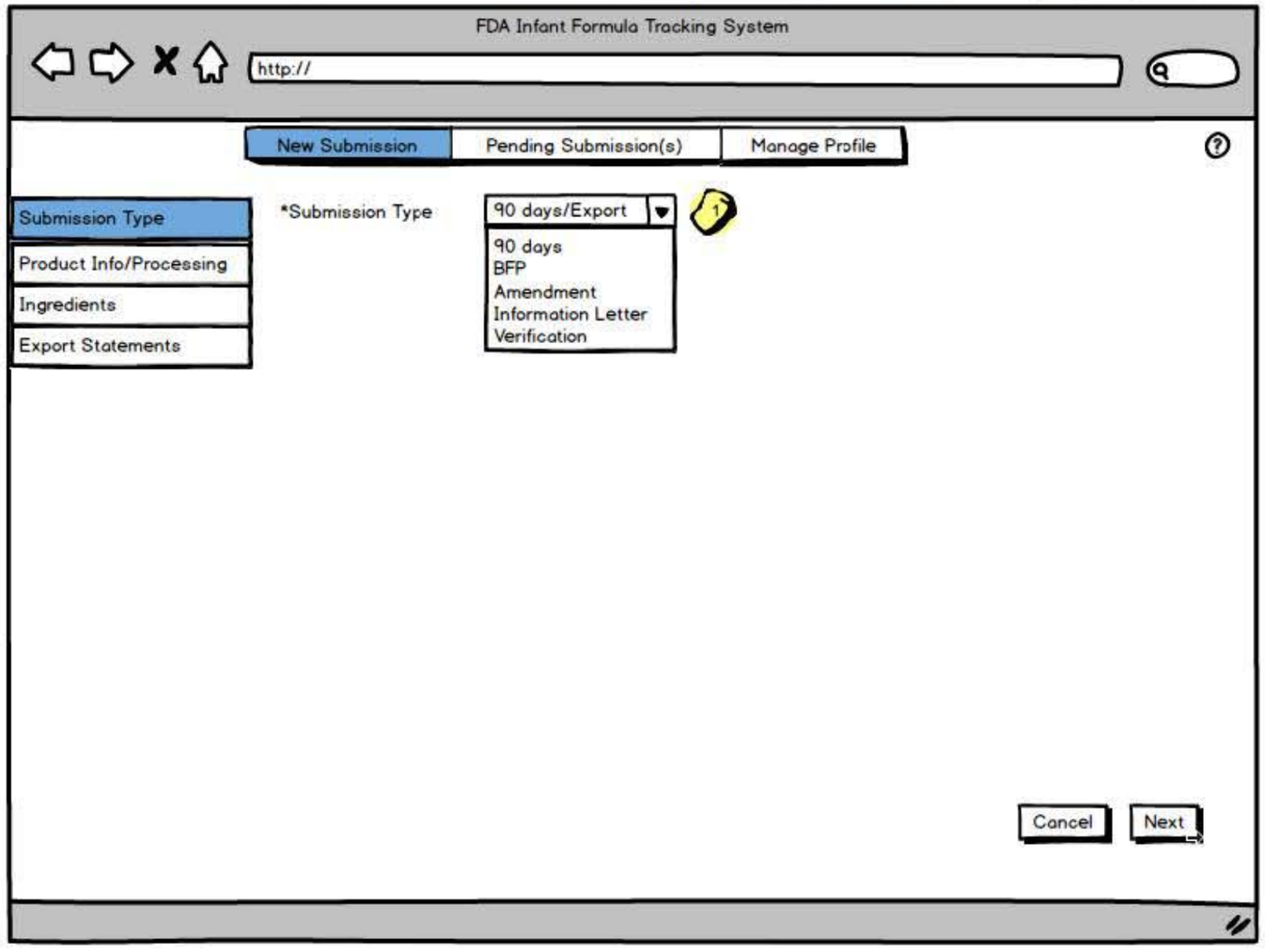


FDA CFSAN IFTRACK II Mockups

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.



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.

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.

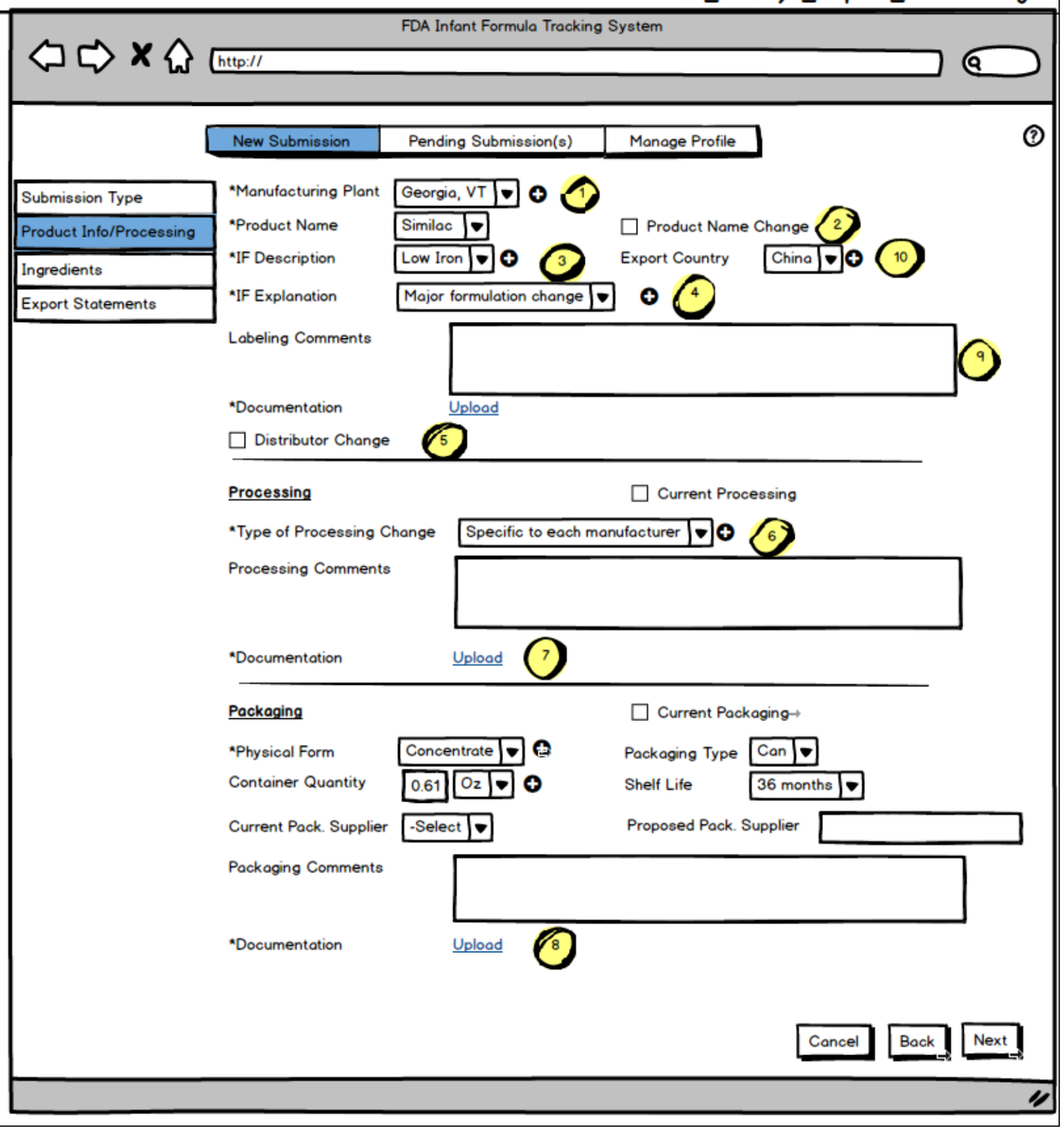
6. 1. Type of Processing Change is only required if Major processing change and/or Non Major processing change are selected for 90 days/IF Explanation.
2.The user will be able to add more than one value under Type of Processing Change field.

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.

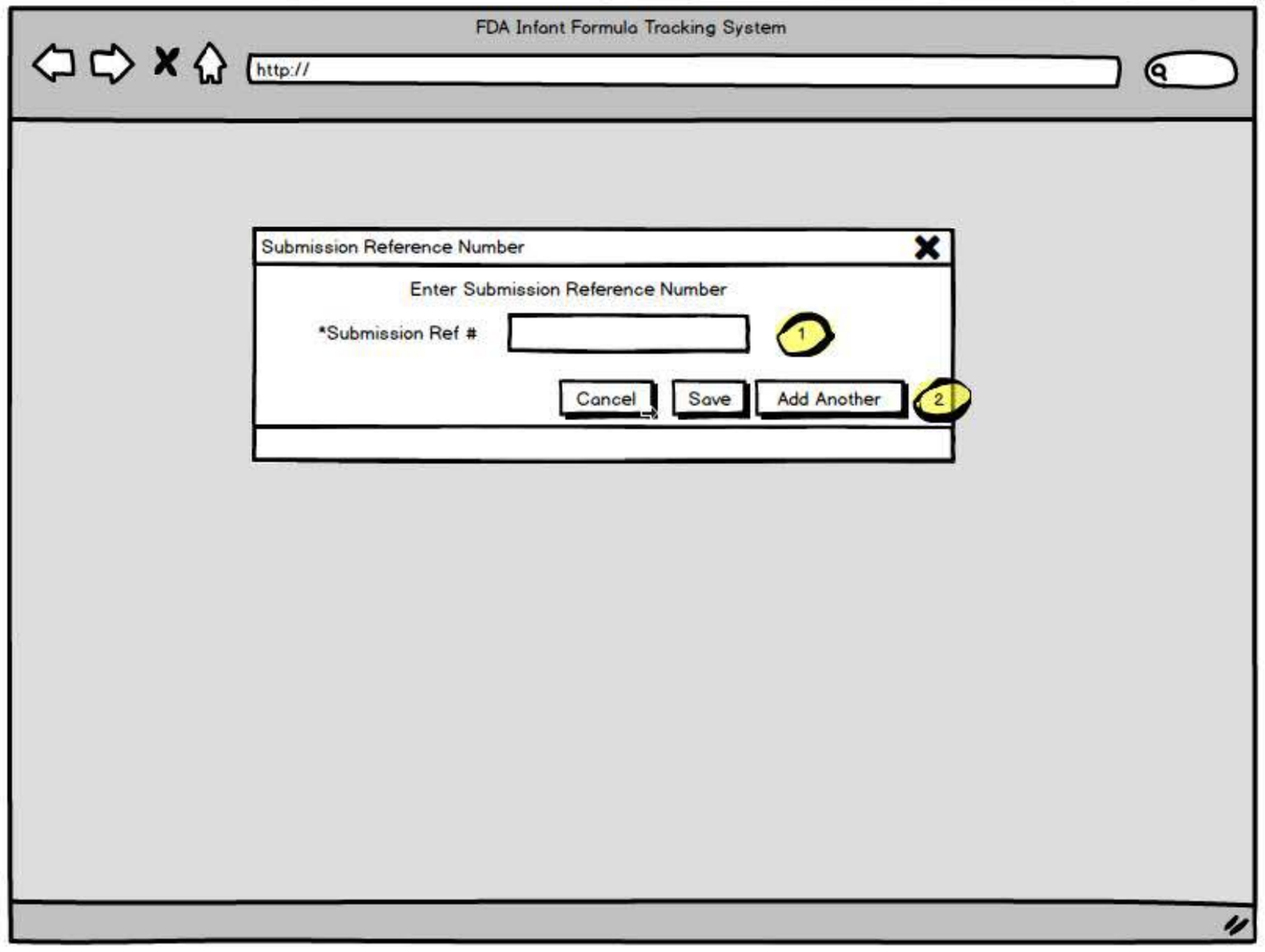


FDA CFSAN IFTRACK II Mockups

WF.IFTRACK II.3B_Processing_SubmissionRef#

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

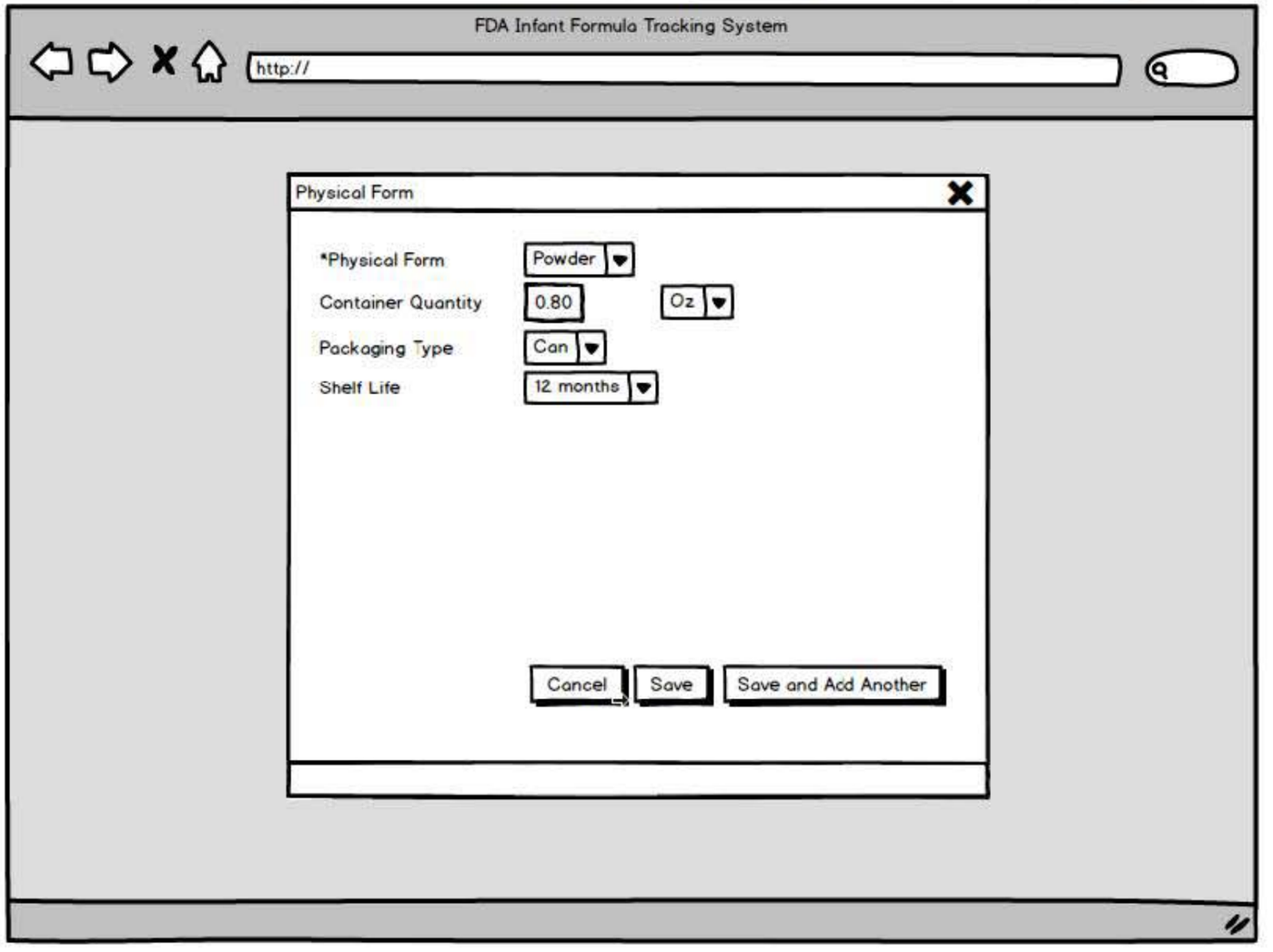
1. Submission Ref # field is required if the user selects Current Packaging option.
2. The user will be able to add more than one Submission Reference Number.



FDA CFSAN IFTRACK II Mockups

WF.IFTRACK II.3A_Processing_AddNewPhysicalForm

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

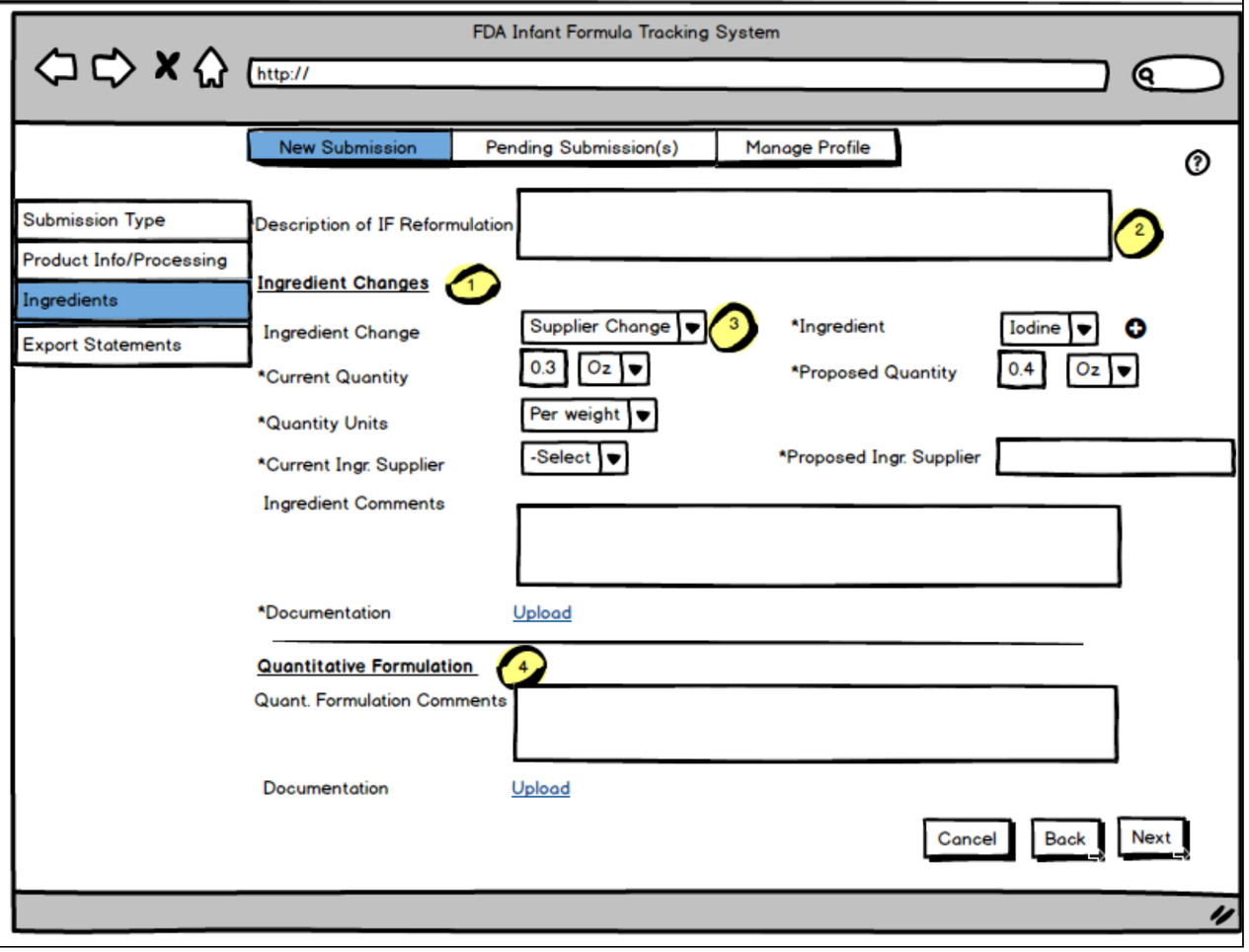


FDA CFSAN IFTRACK II Mockups

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 # .

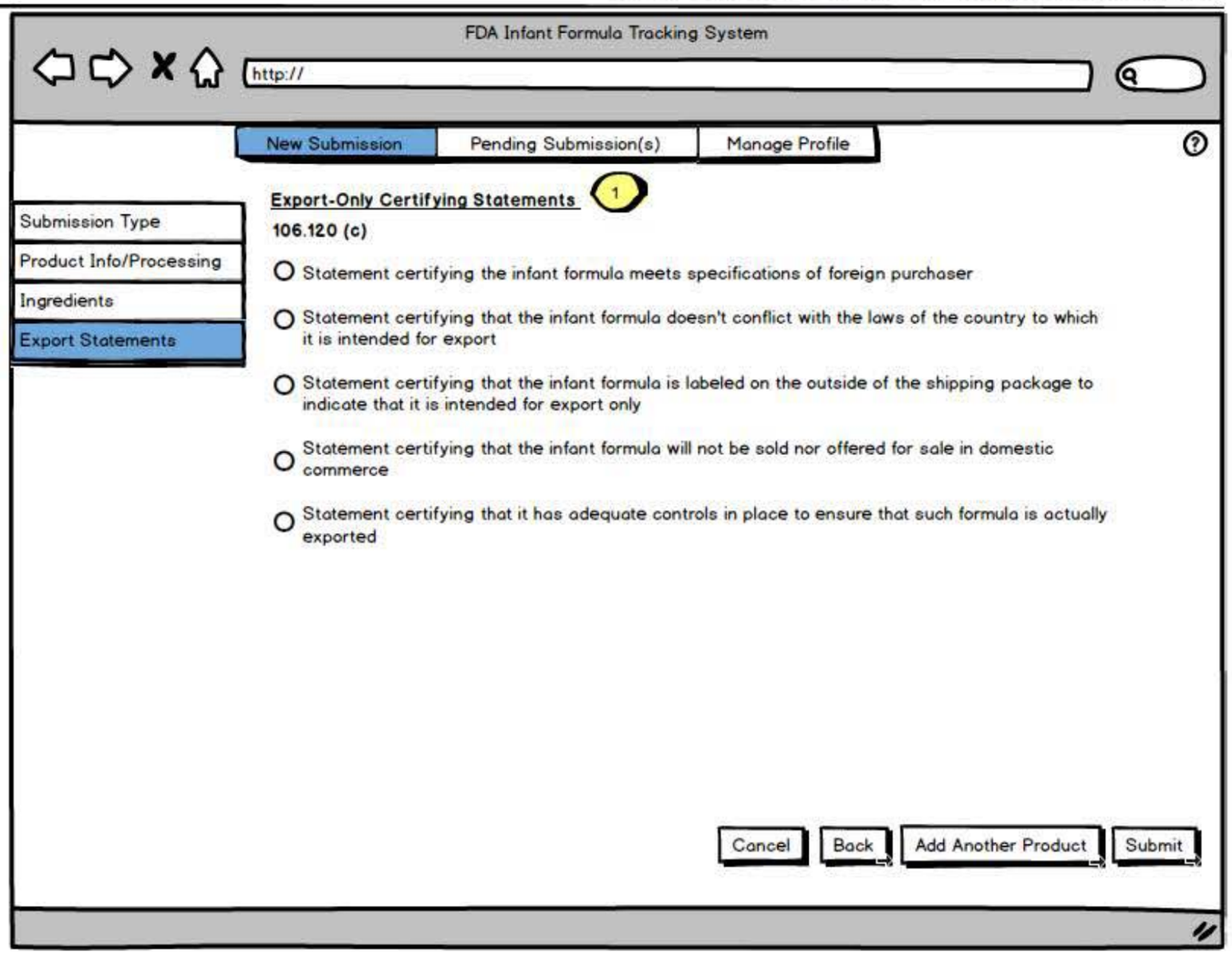


FDA CFSAN IFTRACK II Mockups

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.

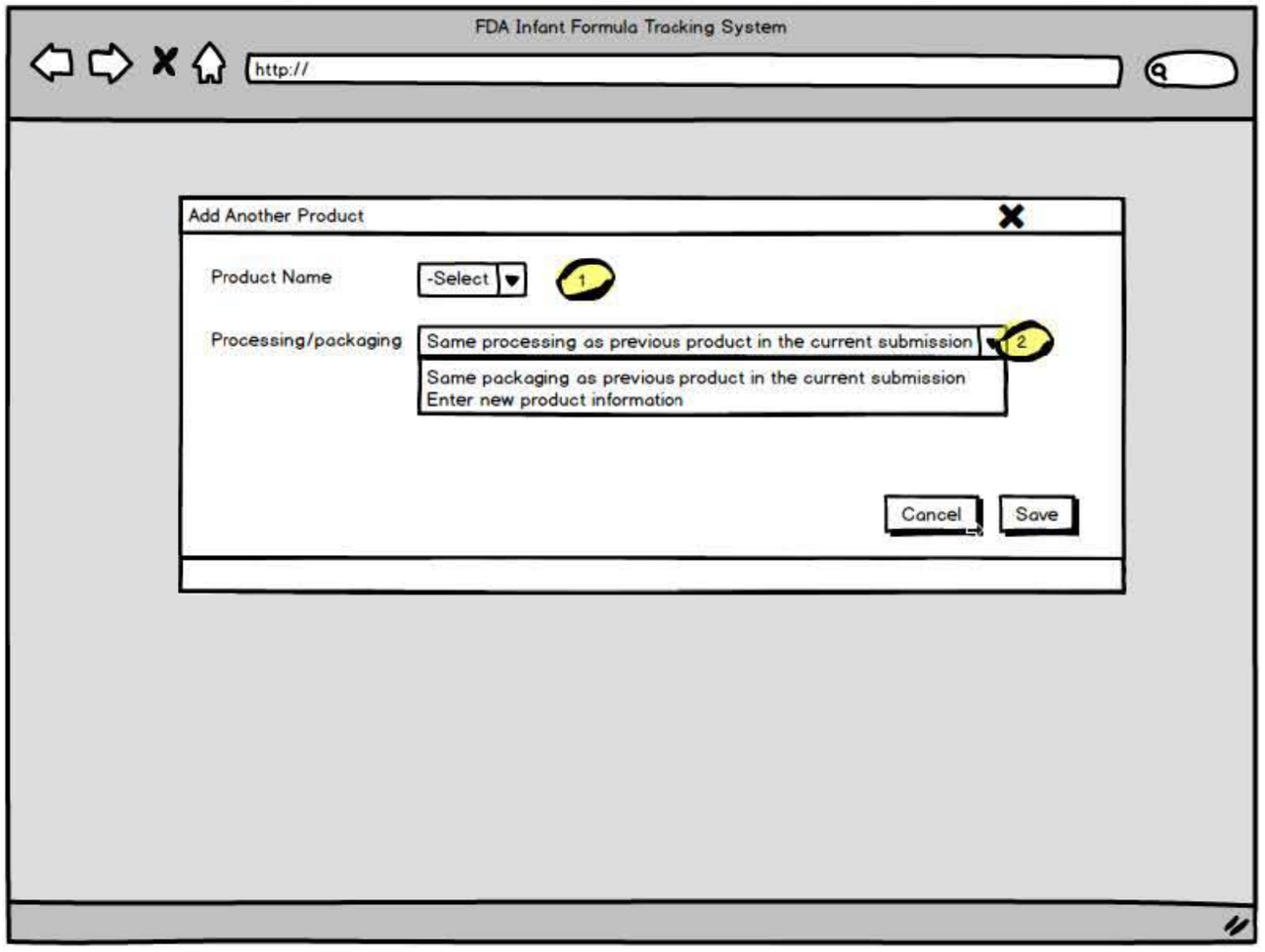


FDA CFSAN IFTRACK II Mockups

WF.IFTRACK II.7A_AddAnotherProduct

Purpose: To enter additional product name.

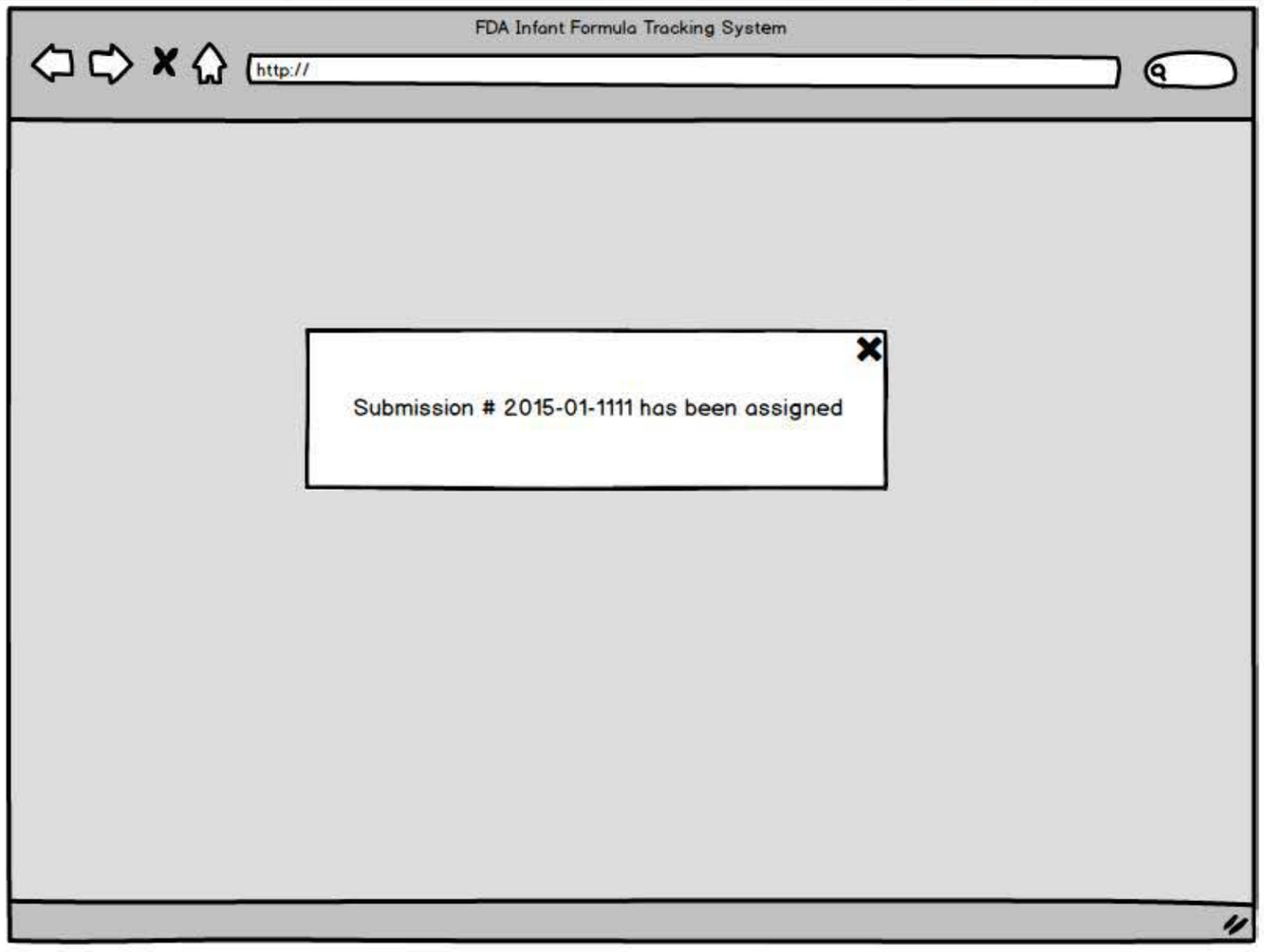
1. The user will be allowed to add Another product after all information for the first product has been enetered.
2. If the user selects "Same processing as previous product in the current submission" for Processing/packaging field, processing information will be automatically populated for the next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



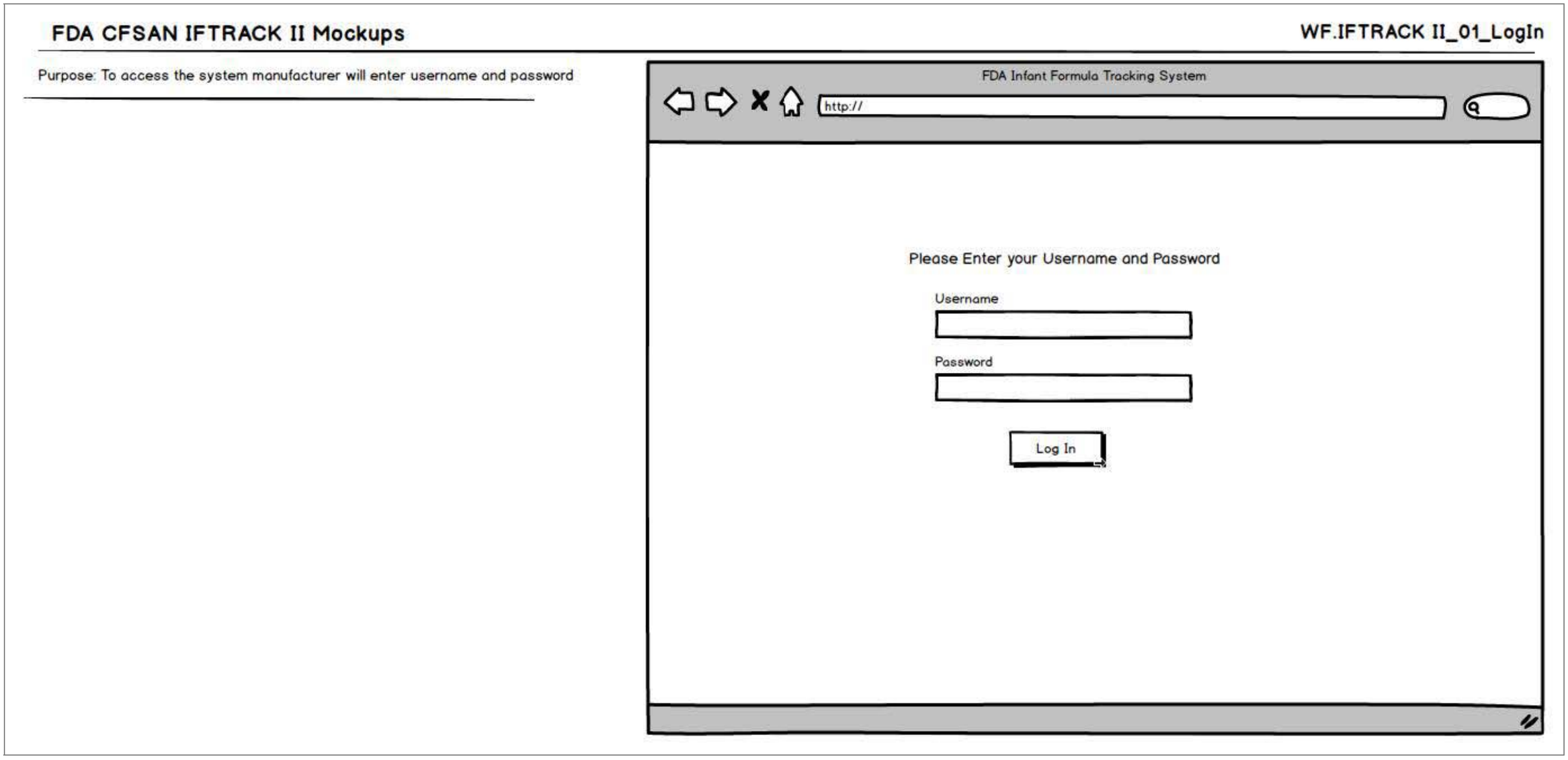
FDA CFSAN IFTRACK II Mockups

WF.IFTRACK II.8A_AssignedSubmissionRef #

Purpose: To view assigned Submission Reference Number

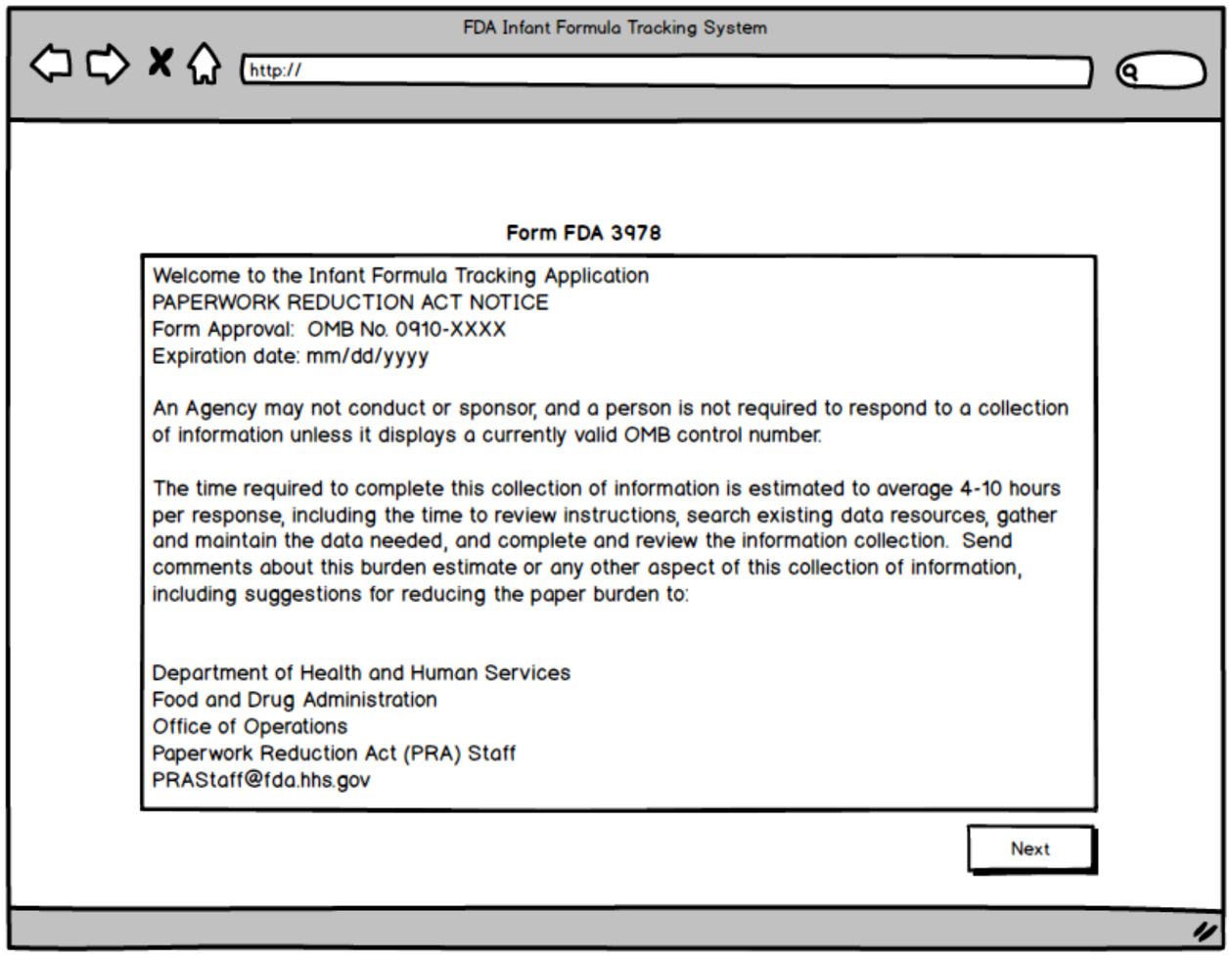


1.4 AMENDMENT SUBMISSION



FDA CFSAN IFTRACK II Mockups

WF.IFTRACK II_001_Welcome



FDA CFSAN IFTRACK II Mockups

WF.IFTRACK II.1E_Amendment_SubmissionType

Purpose: To create Infant Formula Amendment submission

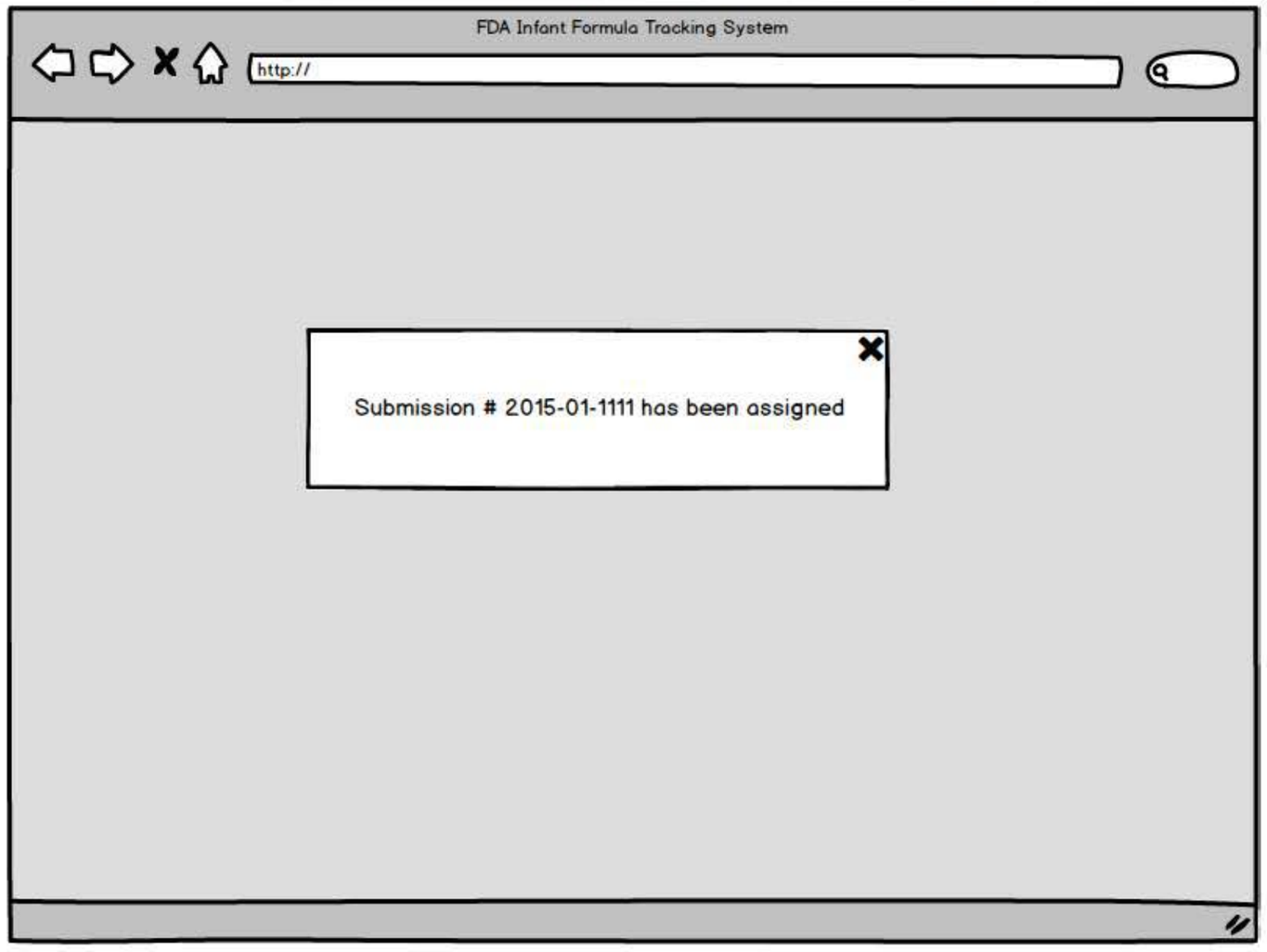
1. The user will be able to view Product, Processing and Ingredients information, but won't be able to update it if Amendment Submission type is selected .

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

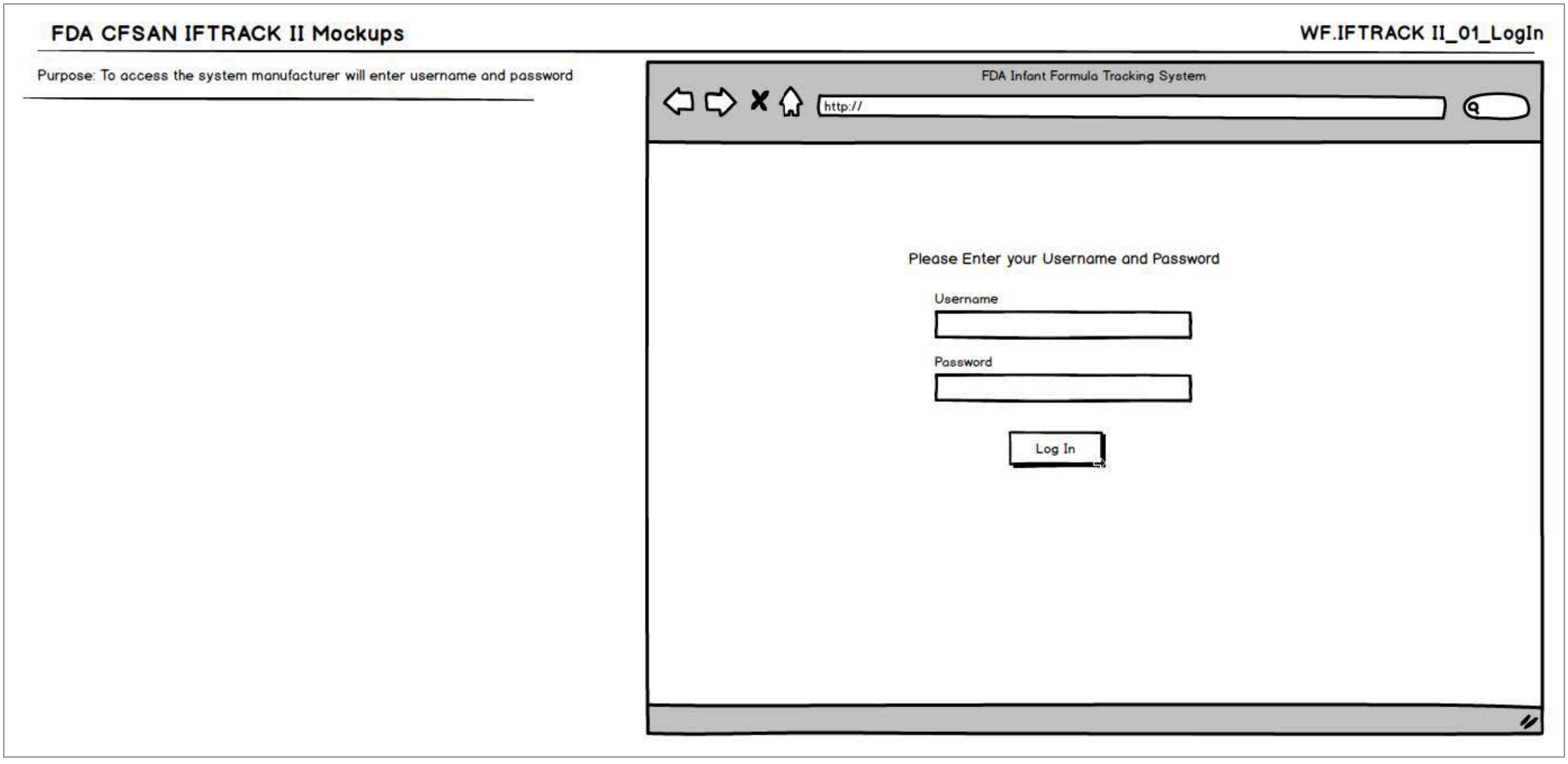
FDA CFSAN IFTRACK II Mockups

WF.IFTRACK II. 8A_AssignedSubmissionRef

Purpose: To view assigned Submission Reference Number

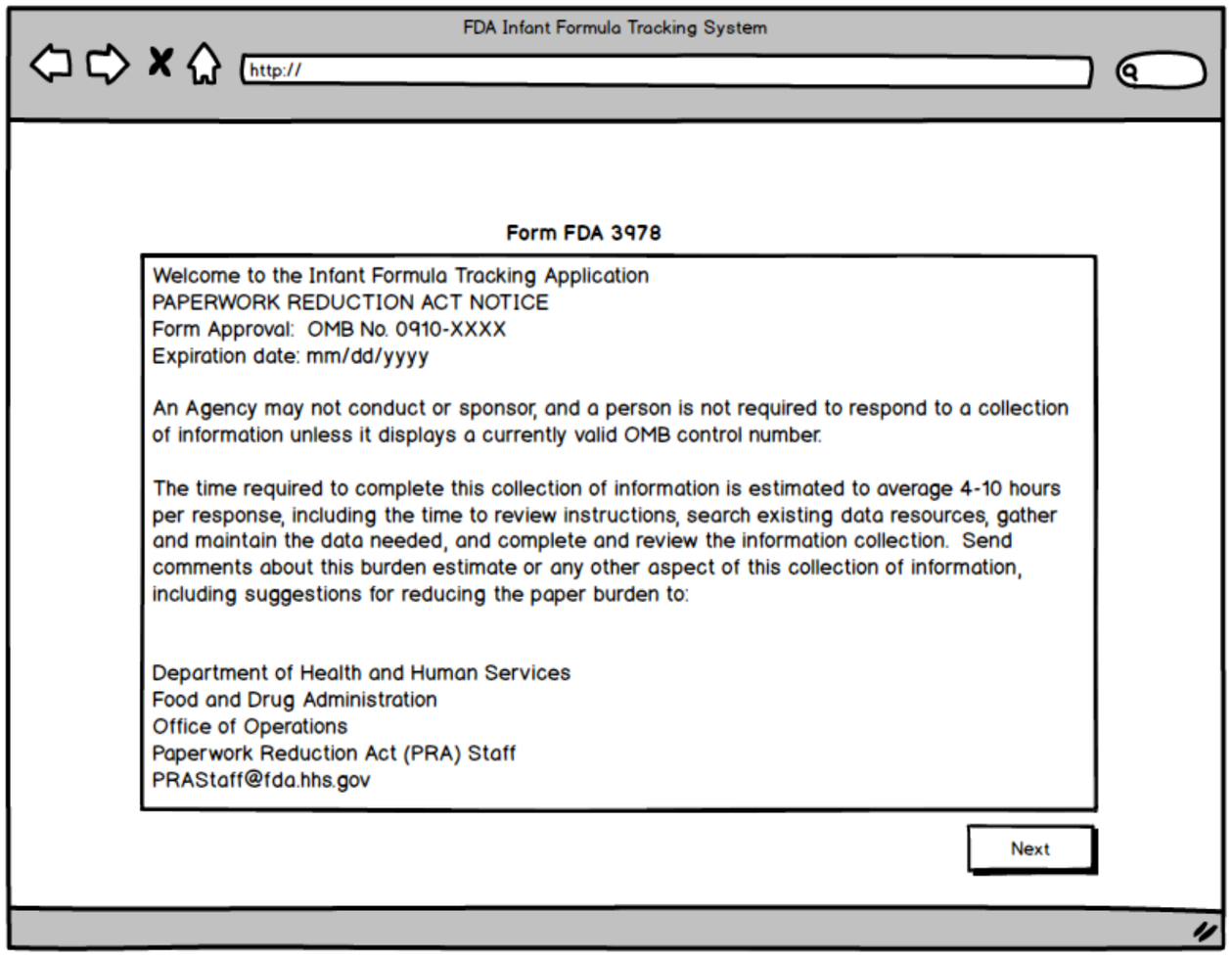


1.5 BFP EXEMPT SUBMISSION



FDA CFSAN IFTRACK II Mockups

WF.IFTRACK II_001_Welcome

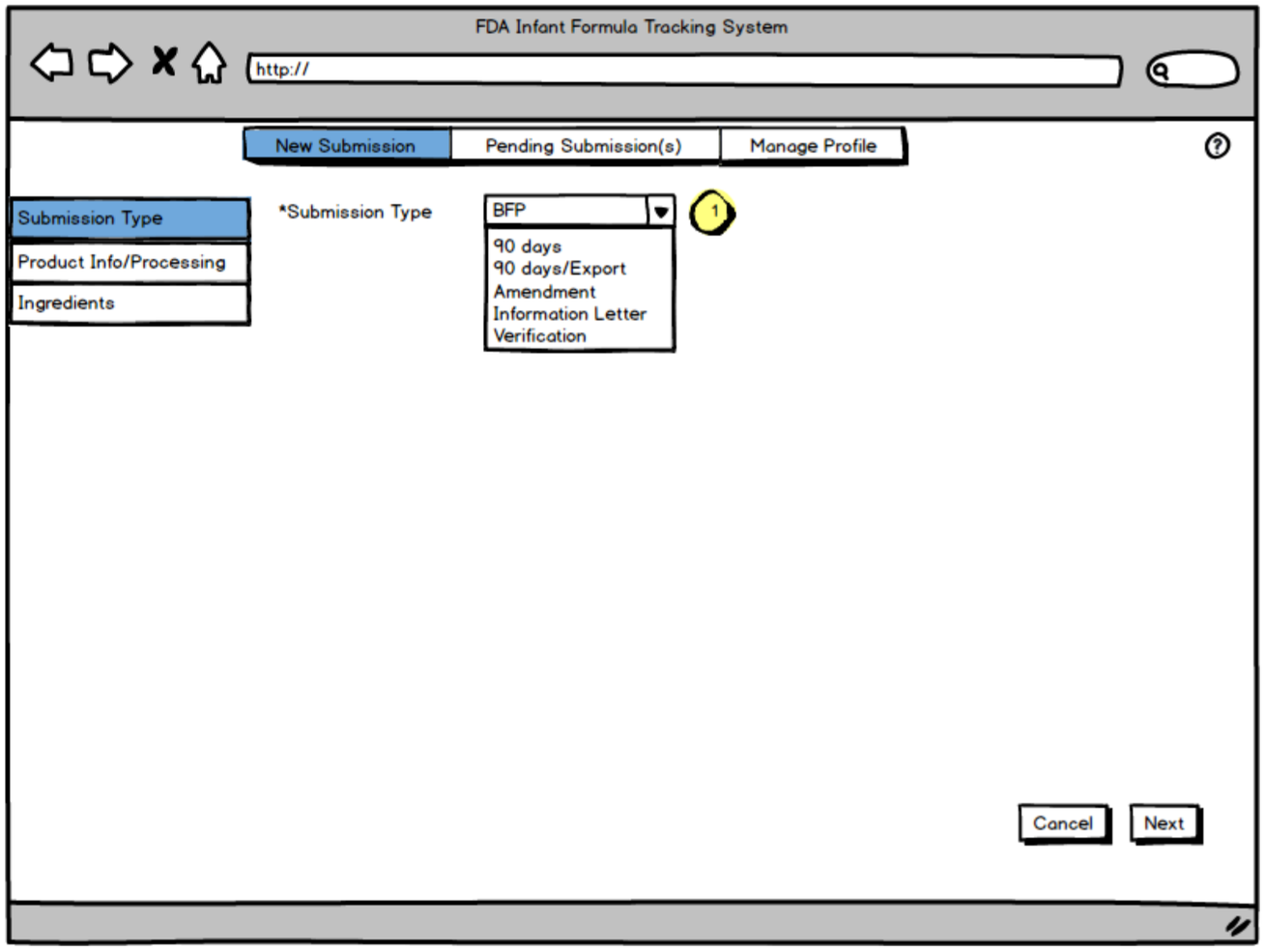


FDA CFSAN IFTRACK II Mockups

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.



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.

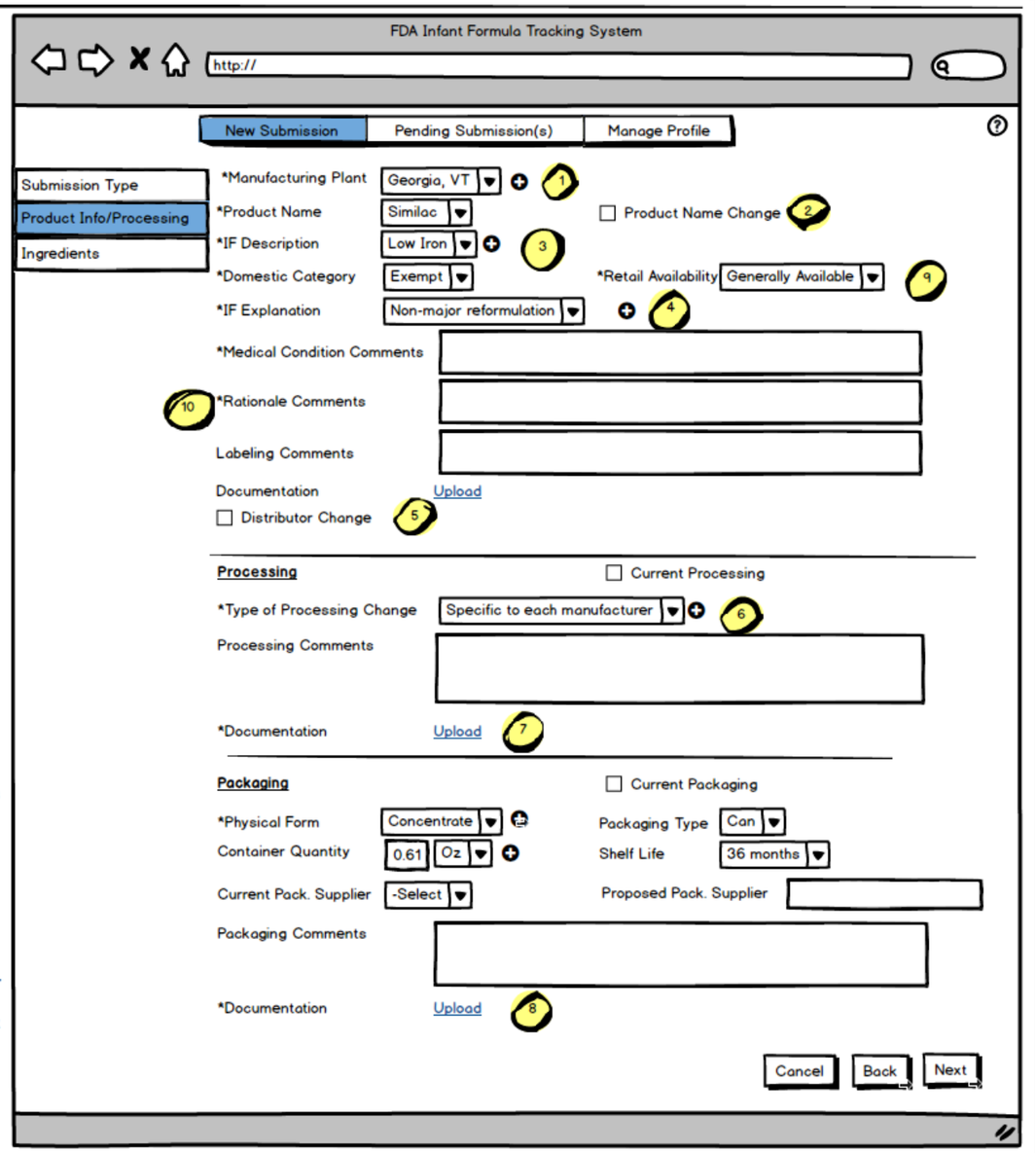
6. 1. Type of Processing Change is only required if Major processing change and/or Non Major processing change are selected for 90 days/IF Explanation.
2.The user will be able to add more than one value under Type of Processing Change field.

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.

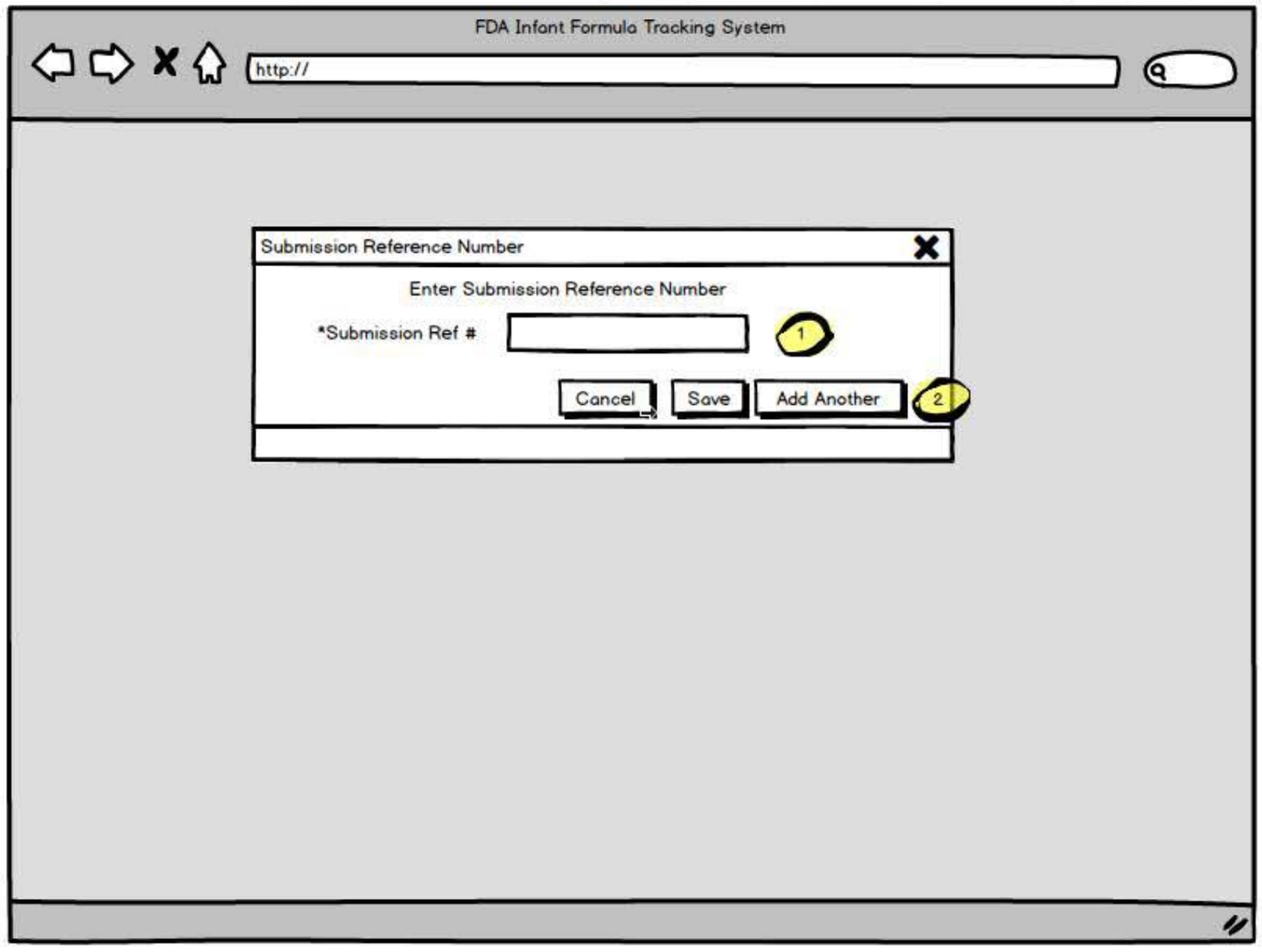


FDA CFSAN IFTRACK II Mockups

WF.IFTRACK II.3B_Processing_SubmissionRef#

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

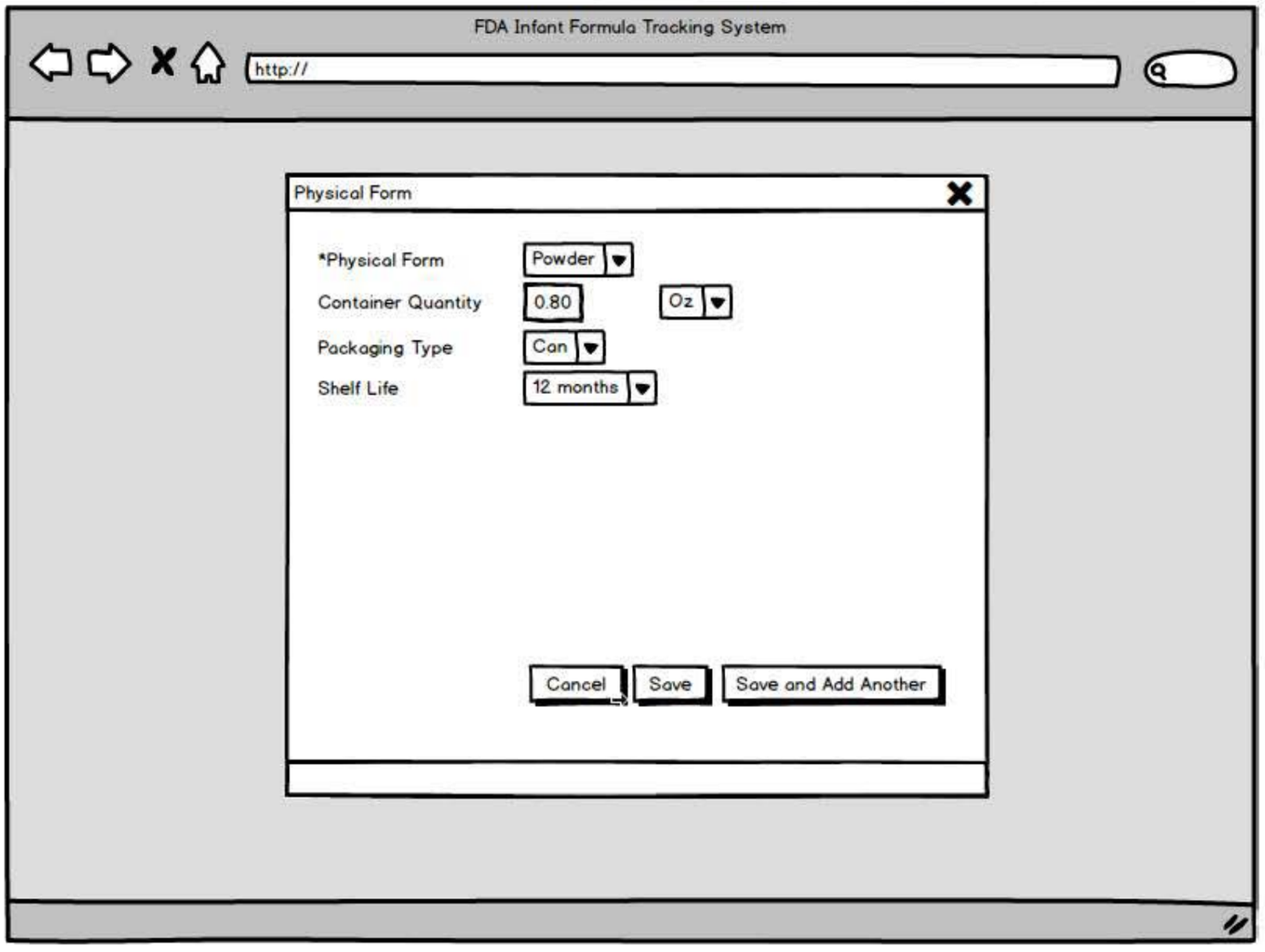
1. Submission Ref # field is required if the user selects Current Packaging option.
2. The user will be able to add more than one Submission Reference Number.



FDA CFSAN IFTRACK II Mockups

WF.IFTRACK II.3A_Processing_AddNewPhysicalForm

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

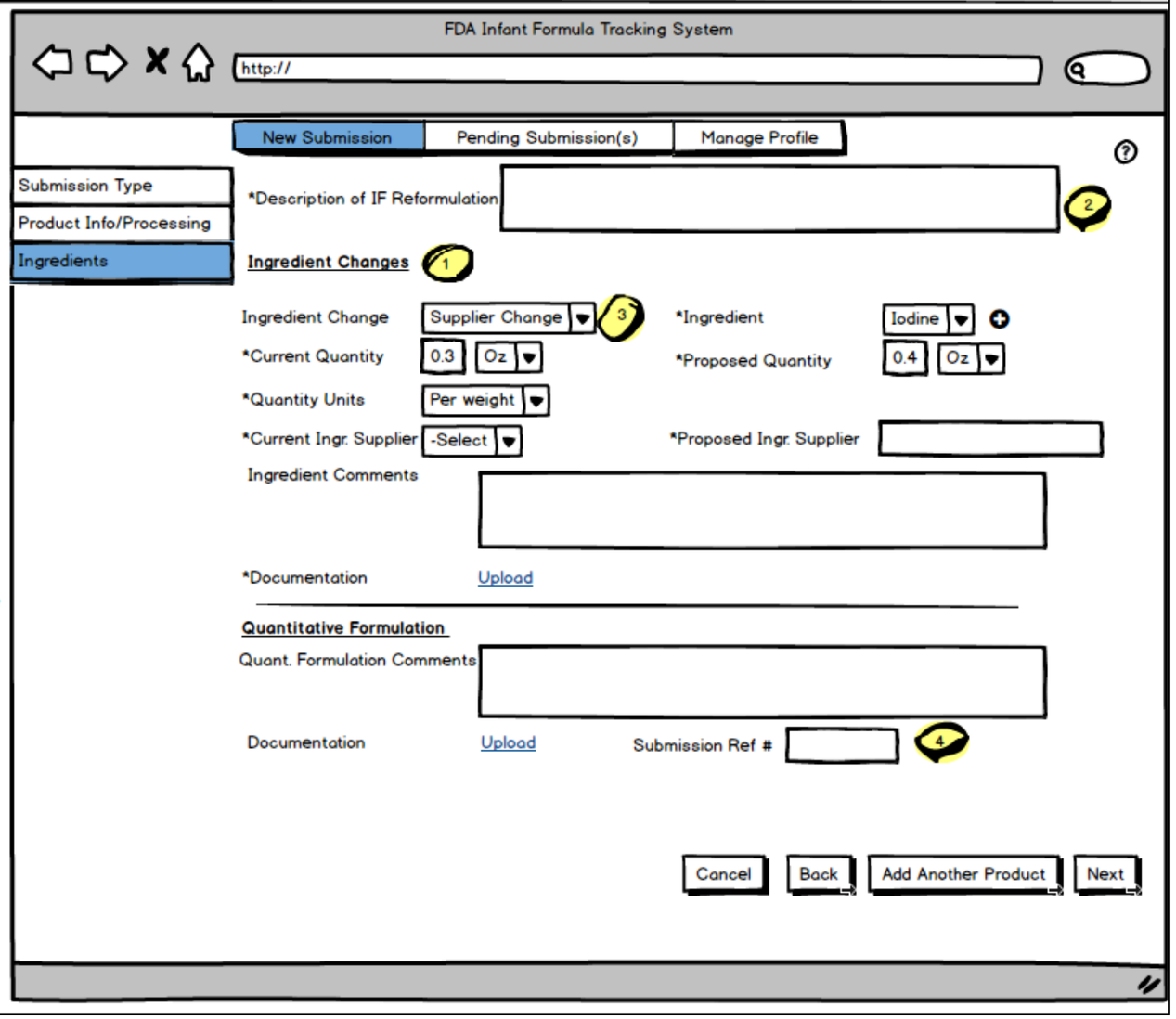


FDA CFSAN IFTRACK II Mockups

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 # .

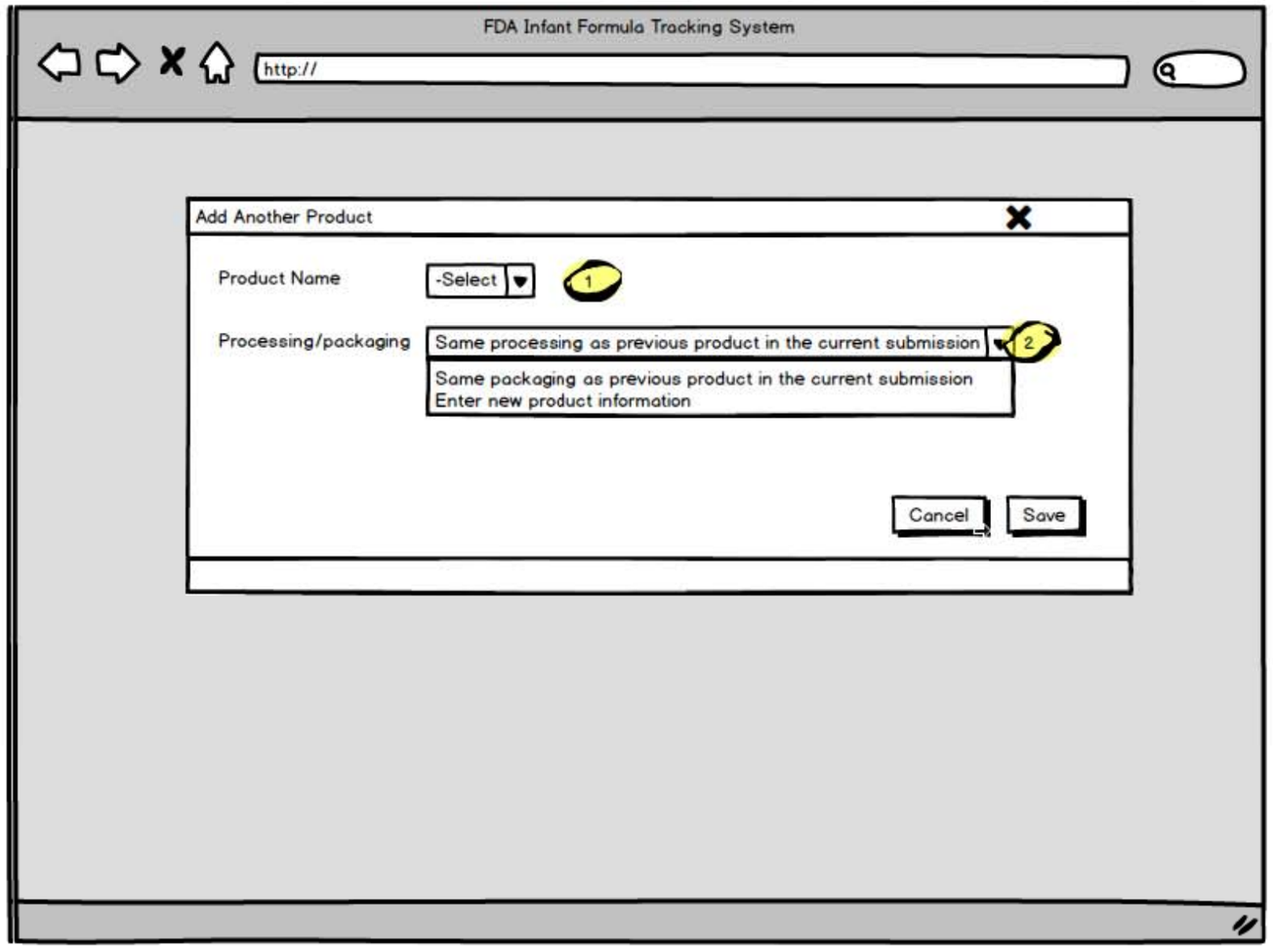


FDA CFSAN IFTRACK II Mockups

WF.IFTRACK II.7A_AddAnotherProduct

Purpose: To enter additional product name.

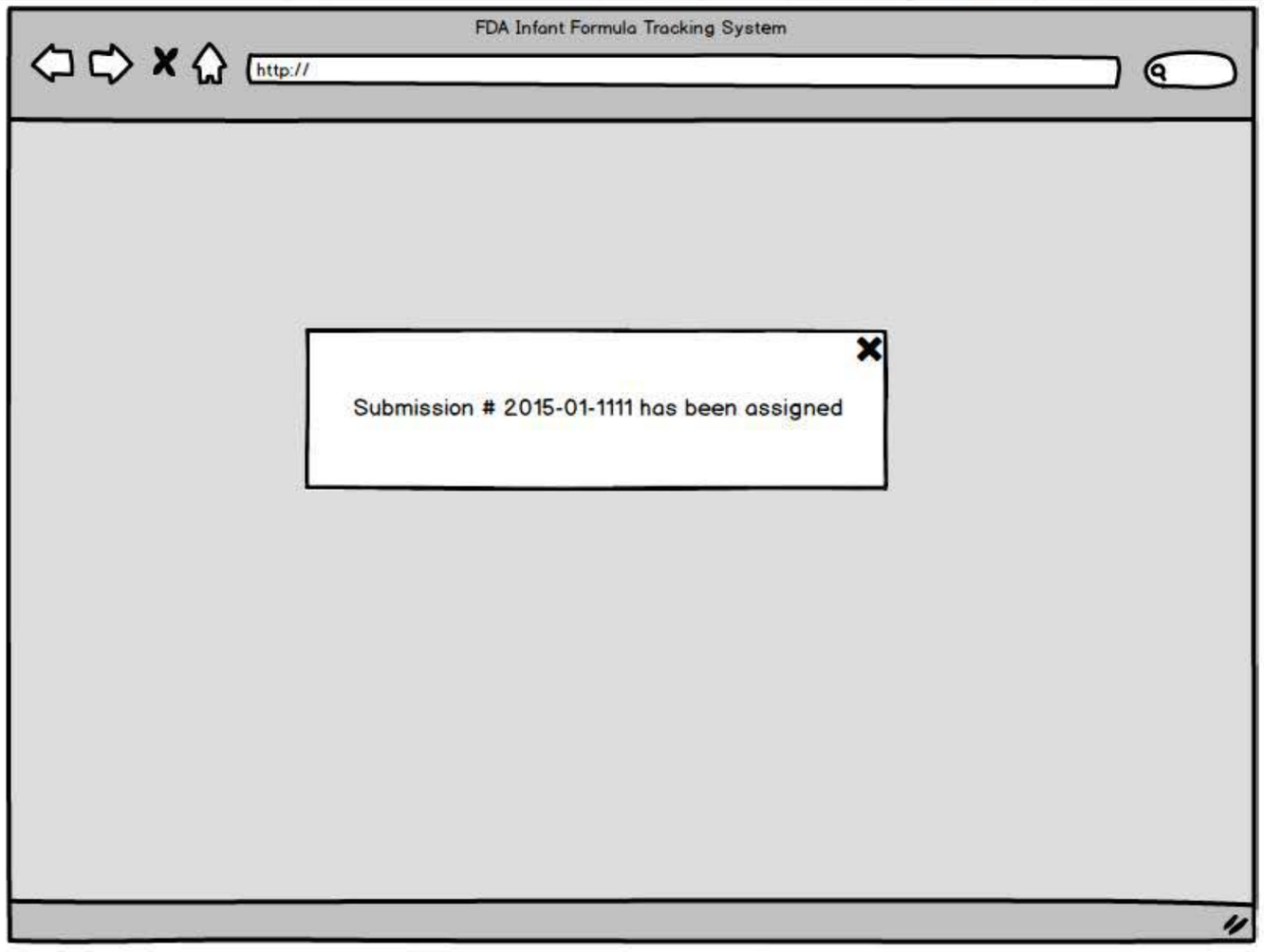
1. The user will be allowed to add Another product after all information for the first product has been enetered.
2. If the user selects "Same processing as previous product in the current submission" for Processing/packaging field, processing information will be automatically populated for the next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



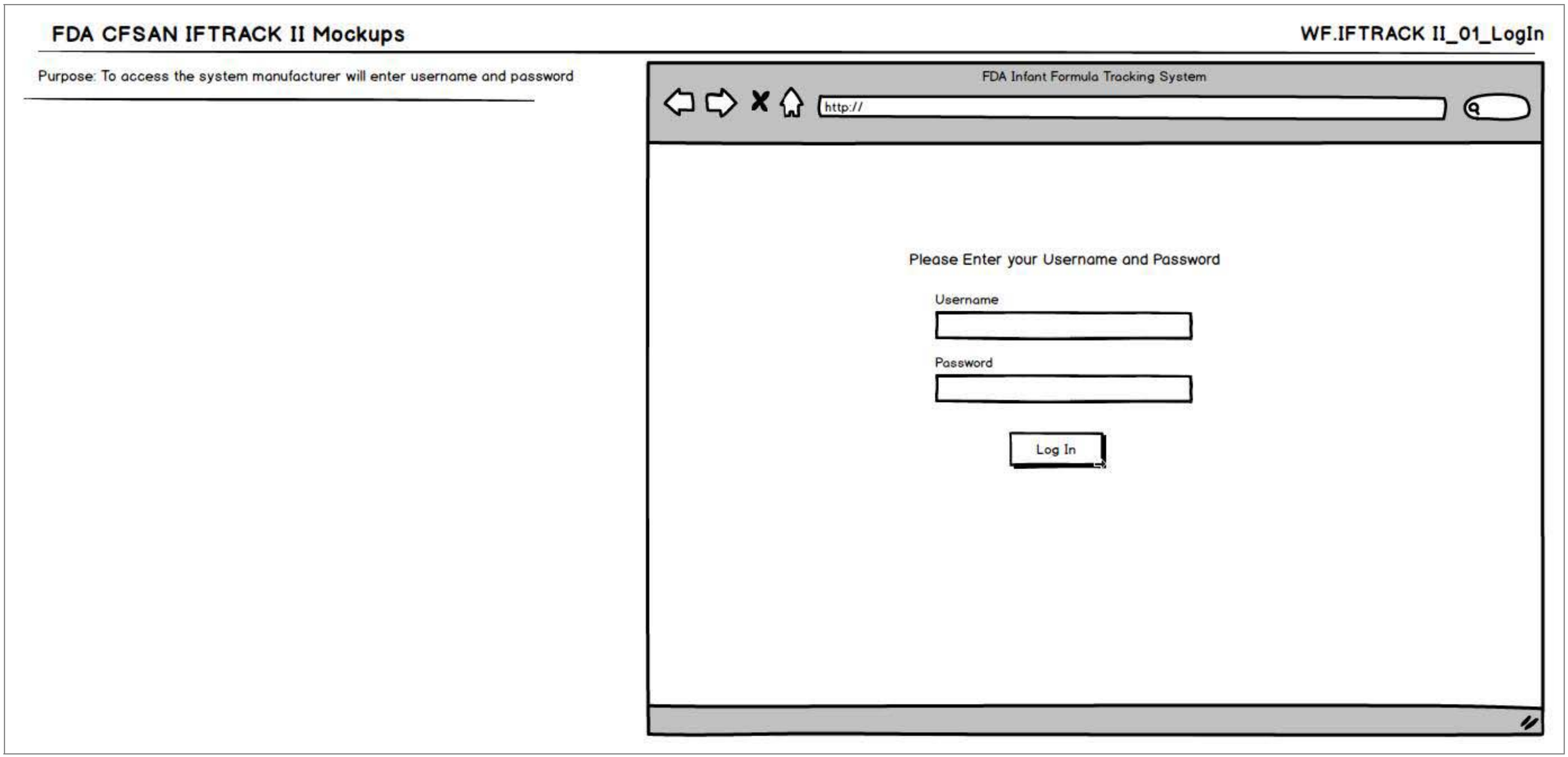
FDA CFSAN IFTRACK II Mockups

WF.IFTRACK II.8A_AssignedSubmissionRef #

Purpose: To view assigned Submission Reference Number

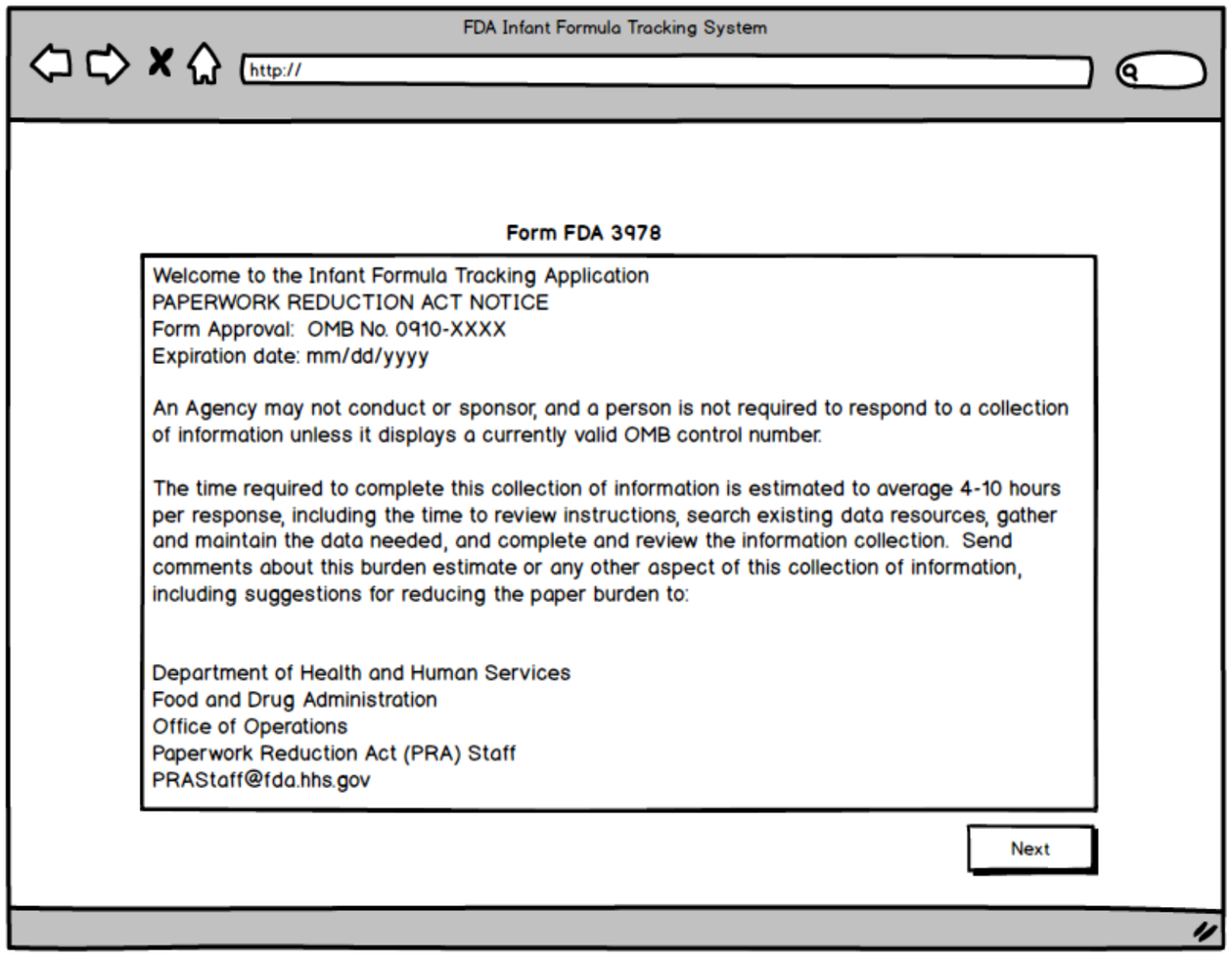


1.6 BFP NON-EXEMPT SUBMISSION



FDA CFSAN IFTRACK II Mockups

WF.IFTRACK II_001_Welcome

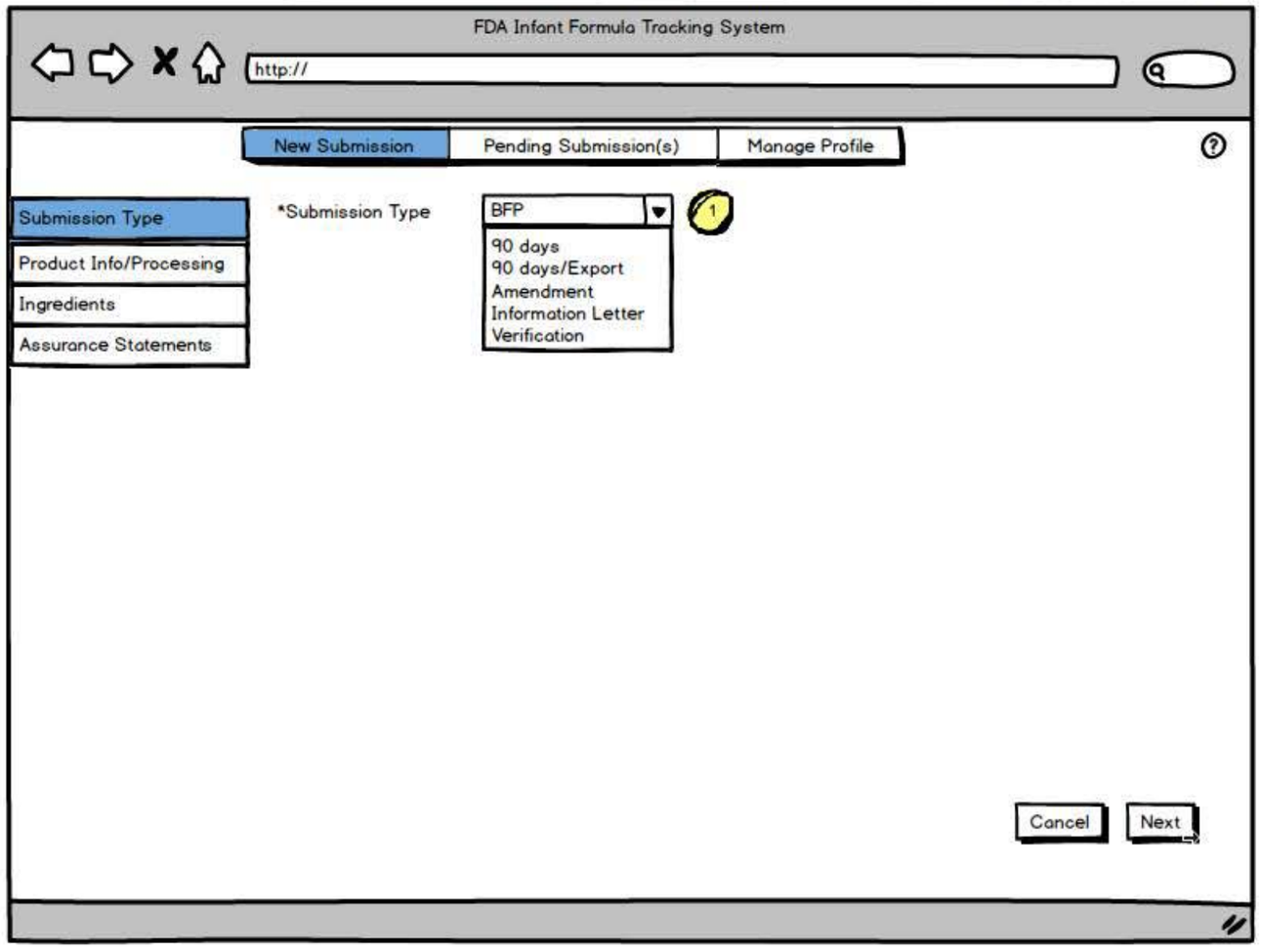


FDA CFSAN IFTRACK II Mockups

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.



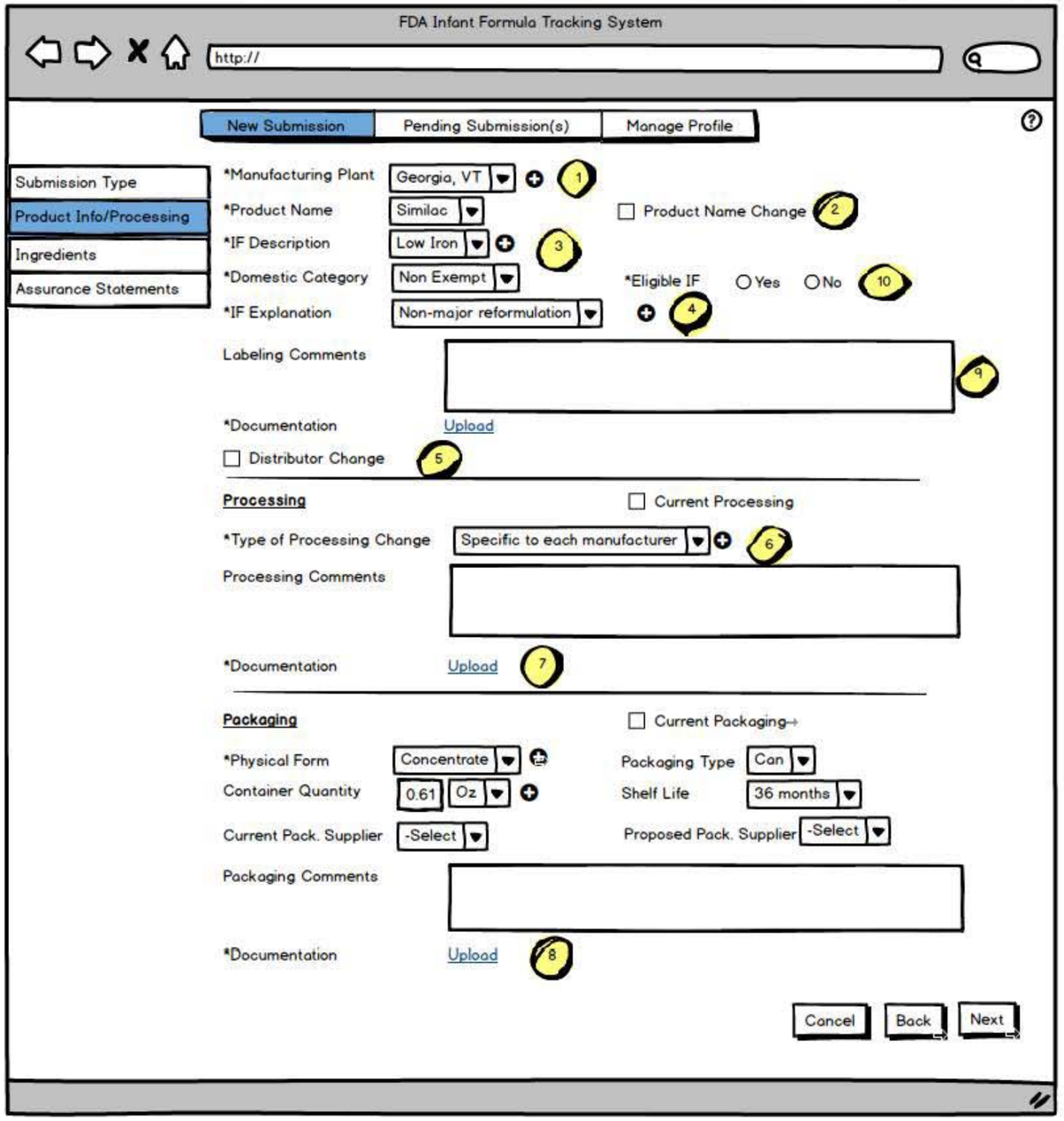
FDA CFSAN IFTRACK II Mockups

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.

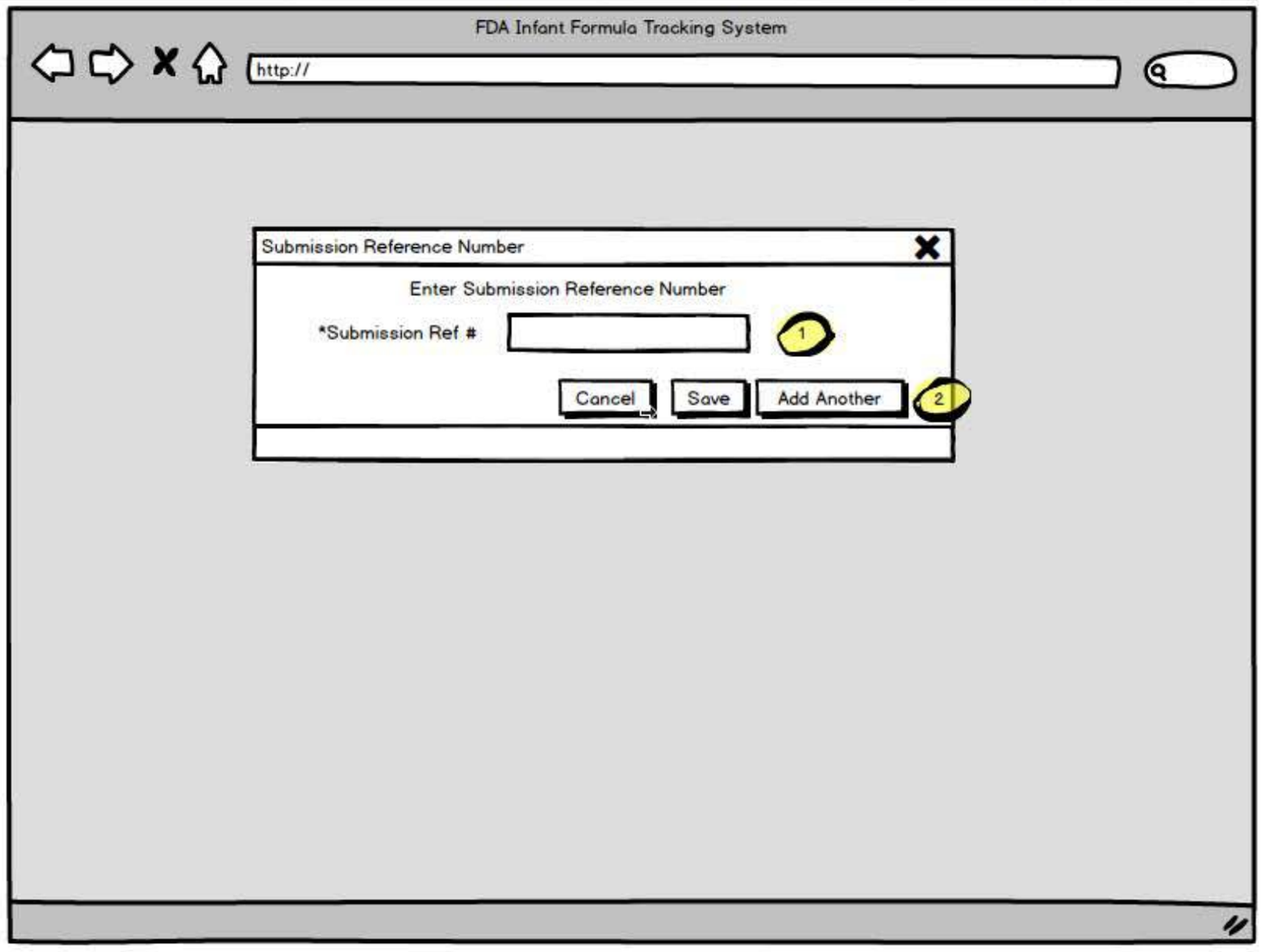


FDA CFSAN IFTRACK II Mockups

WF.IFTRACK.3B_Processing_SubmissionRef#

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

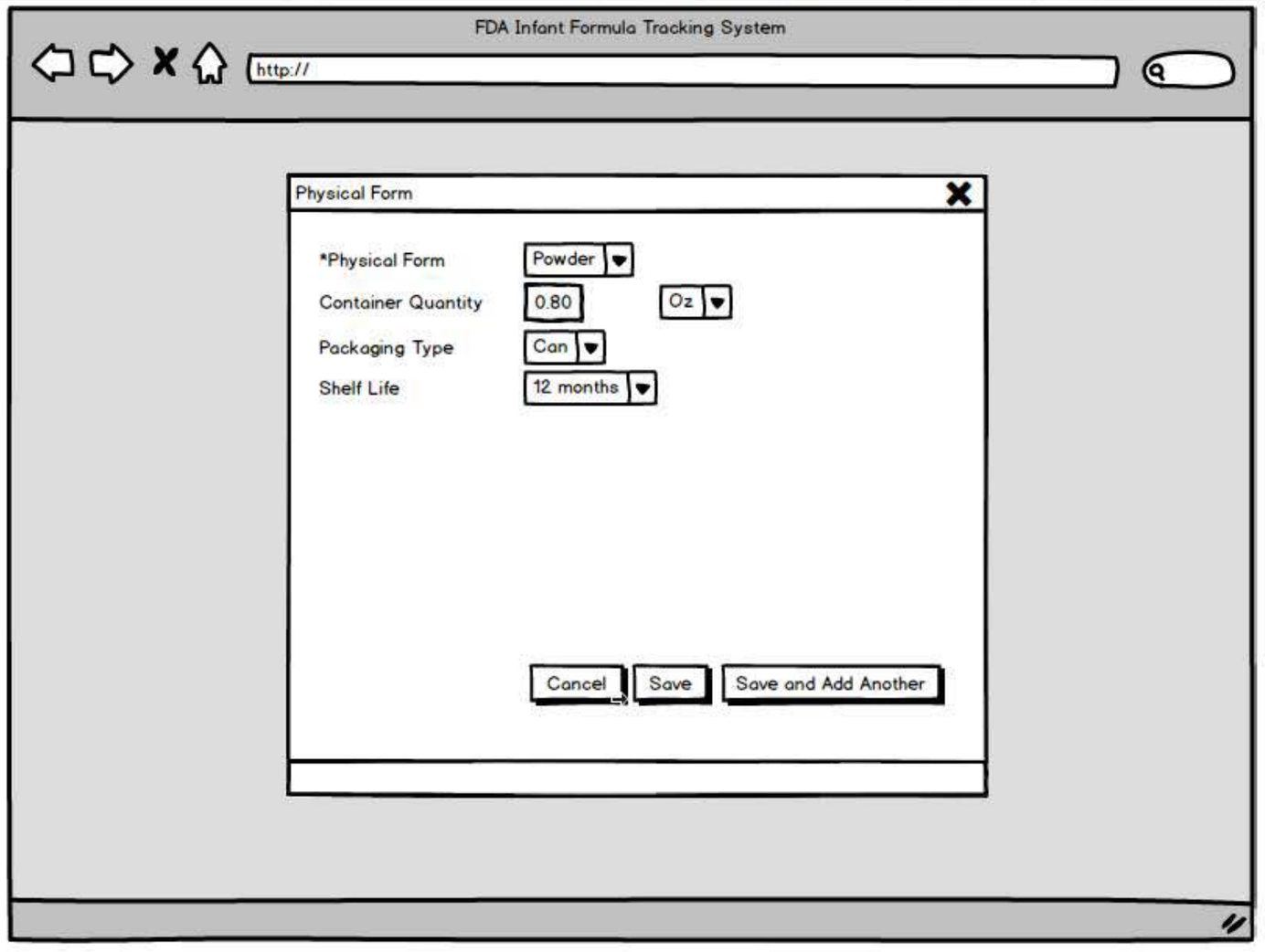
1. Submission Ref # field is required if the user selects Current Packaging option.
2. The user will be able to add more than one Submission Reference Number.



FDA CFSAN IFTRACK II Mockups

WF.IFTRACK.3A_Processing_AddNewPhysicalForm

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

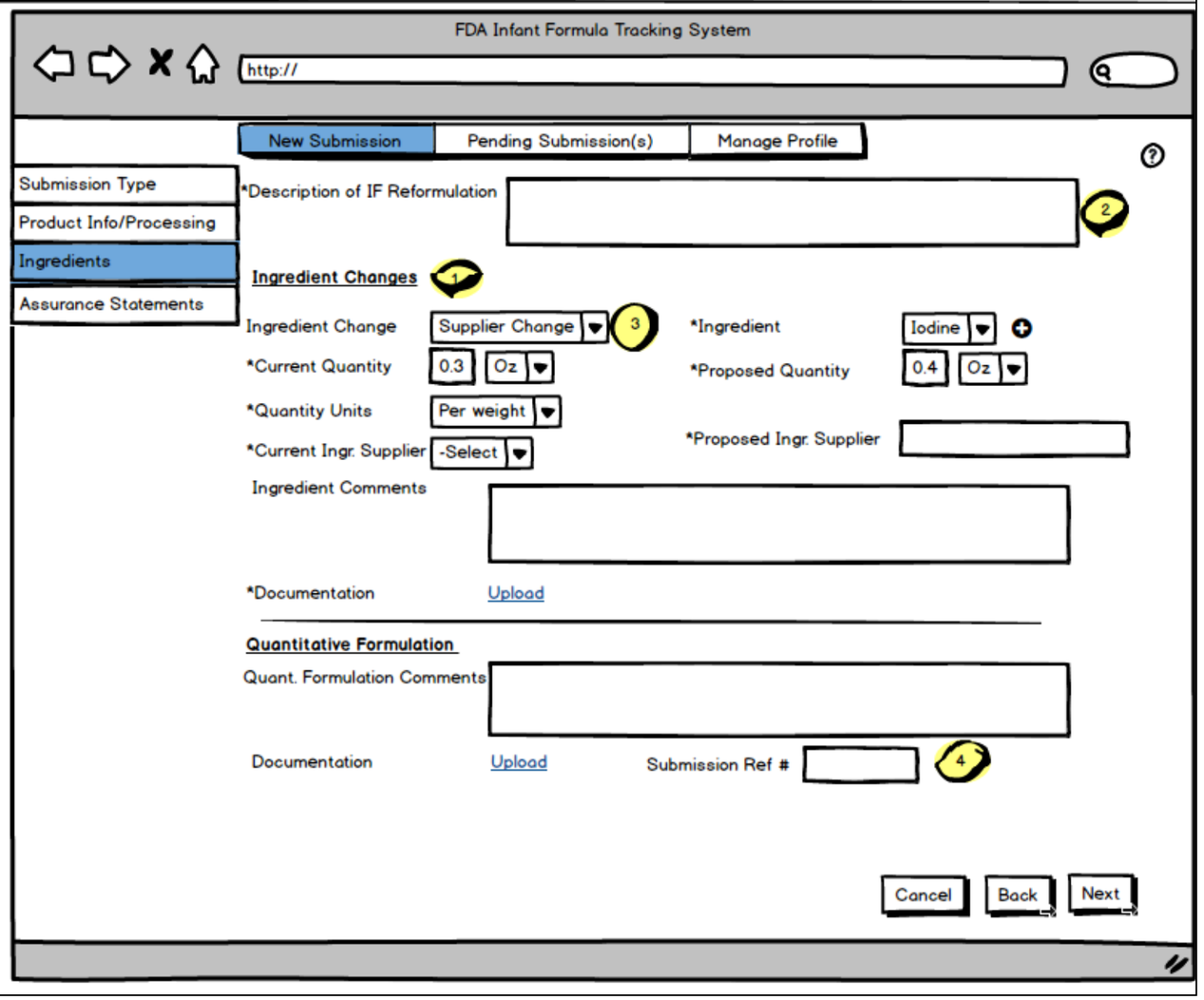


FDA CFSAN IFTRACK II Mockups

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 # .

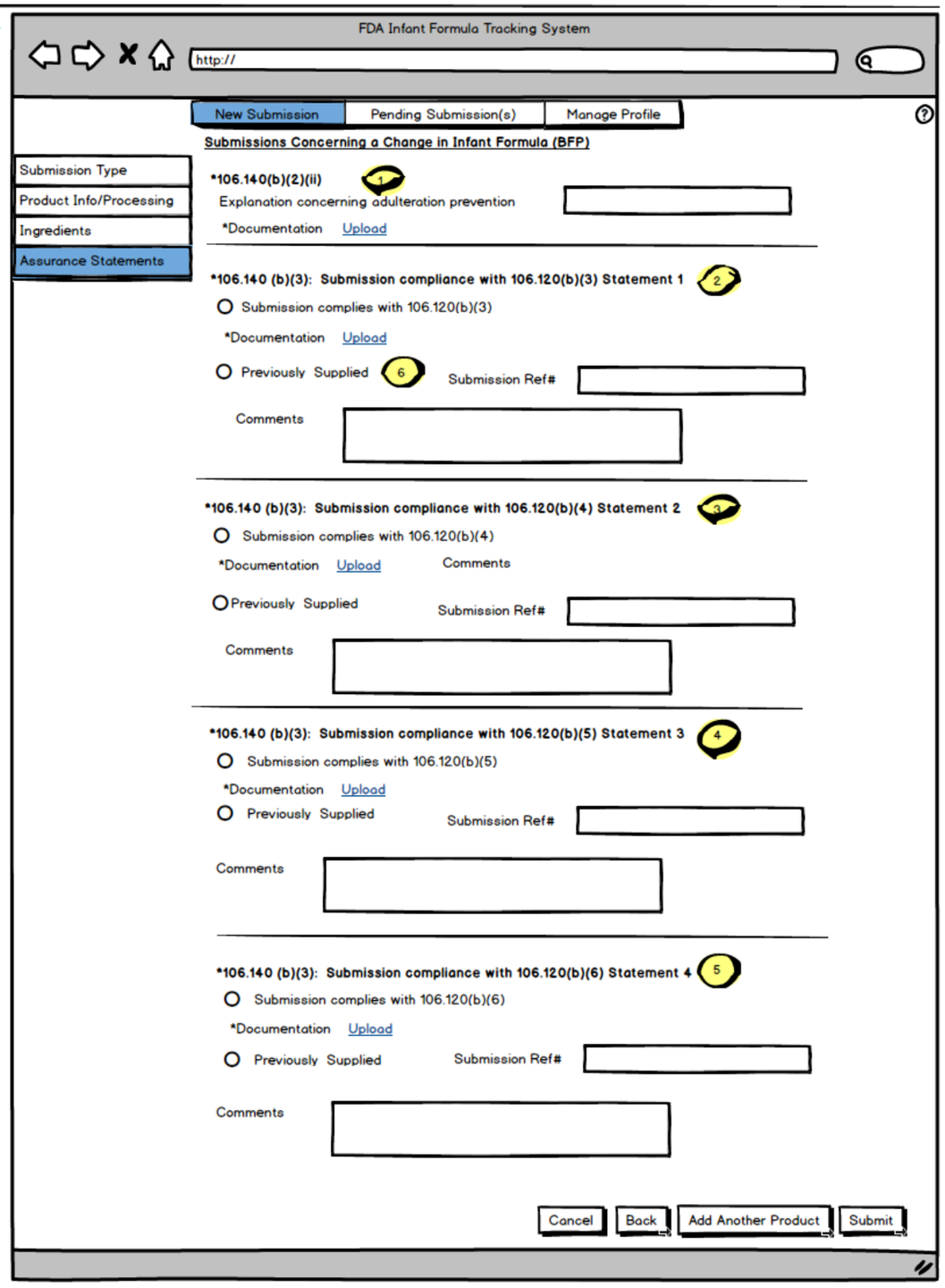


FDA CFSAN IFTRACK II Mockups

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.

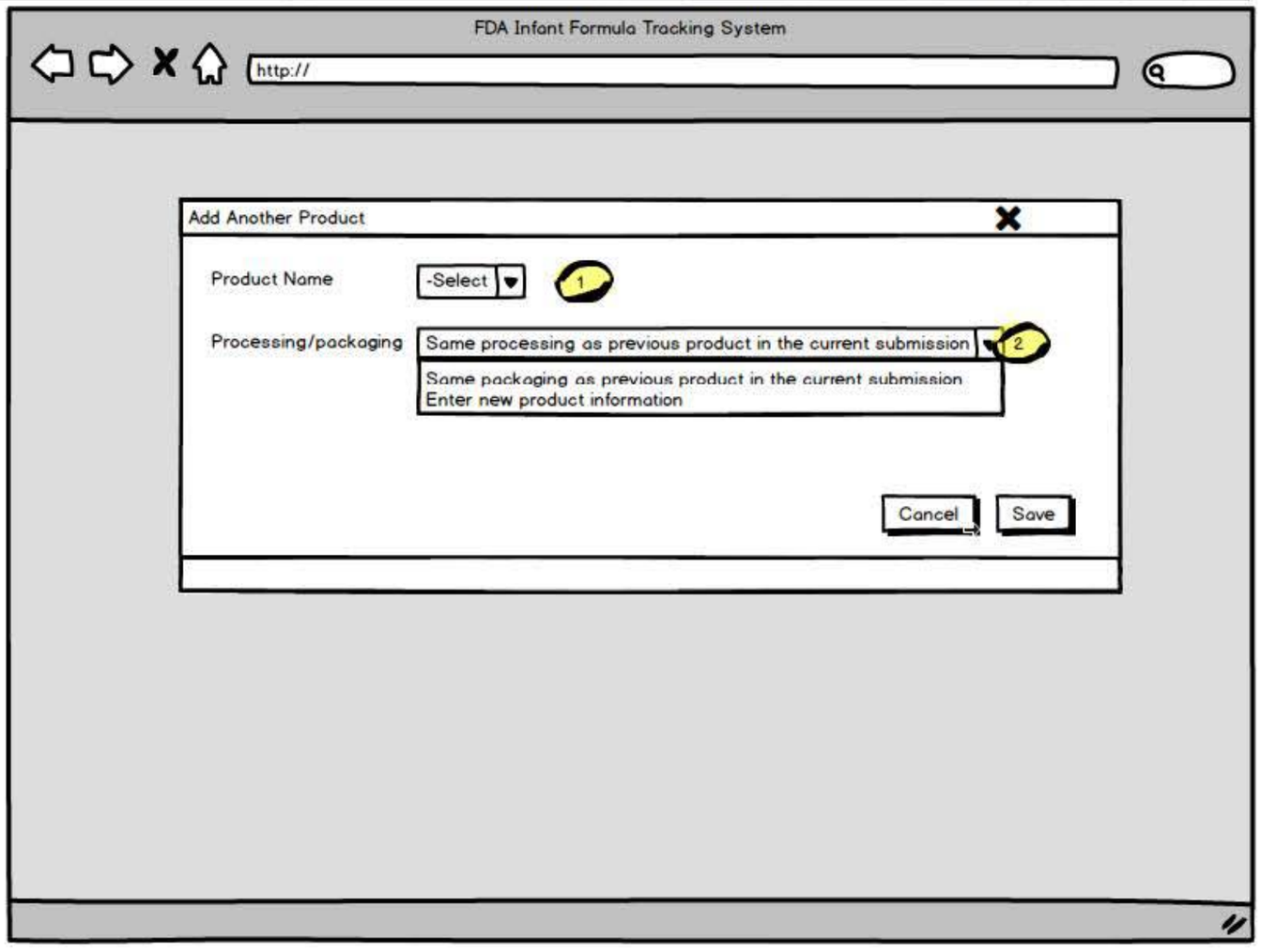


FDA CFSAN IFTRACK II Mockups

WF.IFTRACK.7A_AddAnotherProduct

Purpose: To enter additional product name.

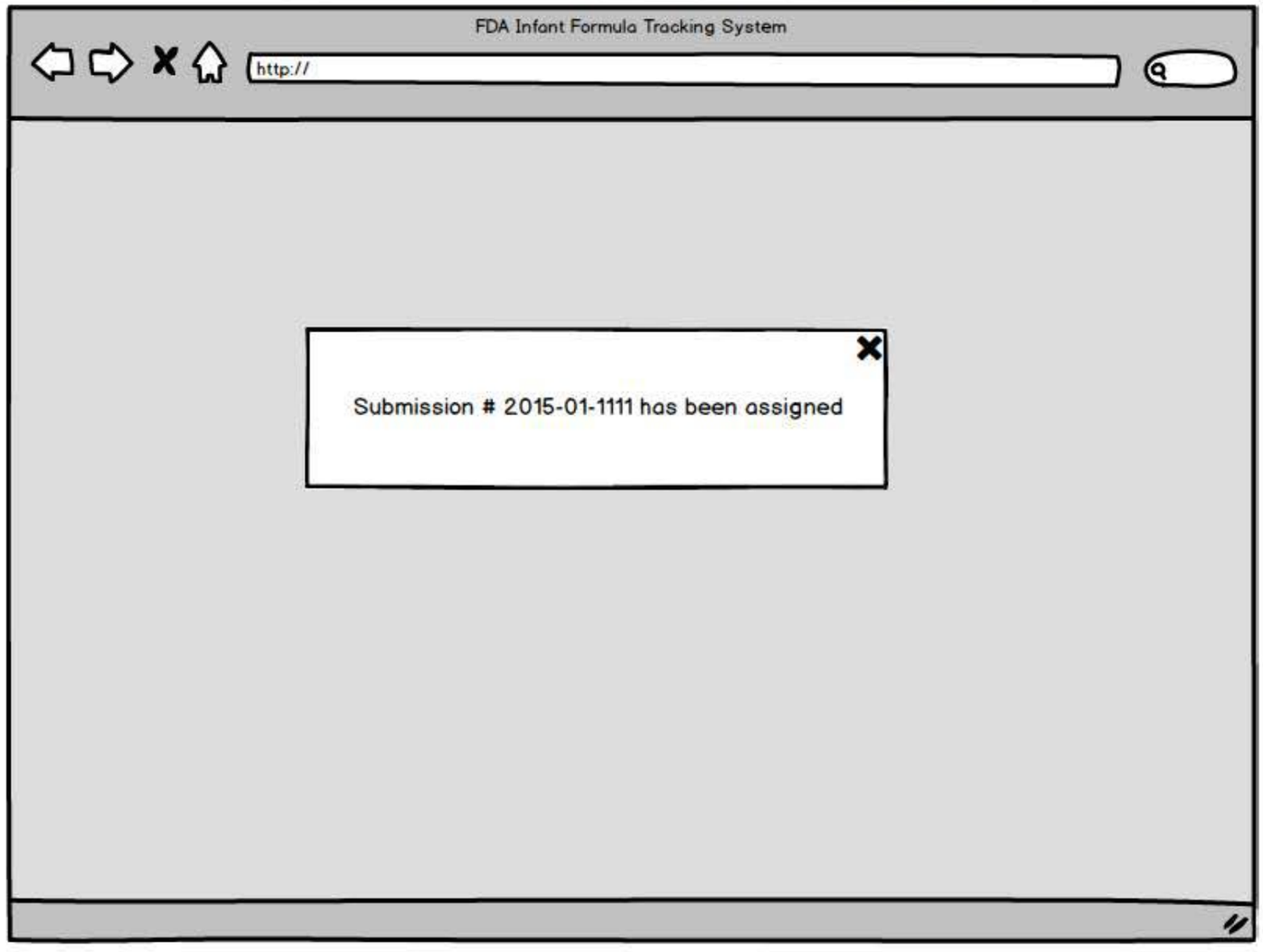
1. The user will be allowed to add Another product after all information for the first product has been enetered.
2. If the user selects "Same processing as previous product in the current submission" for Processing/packaging field, processing information will be automatically populated for the next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



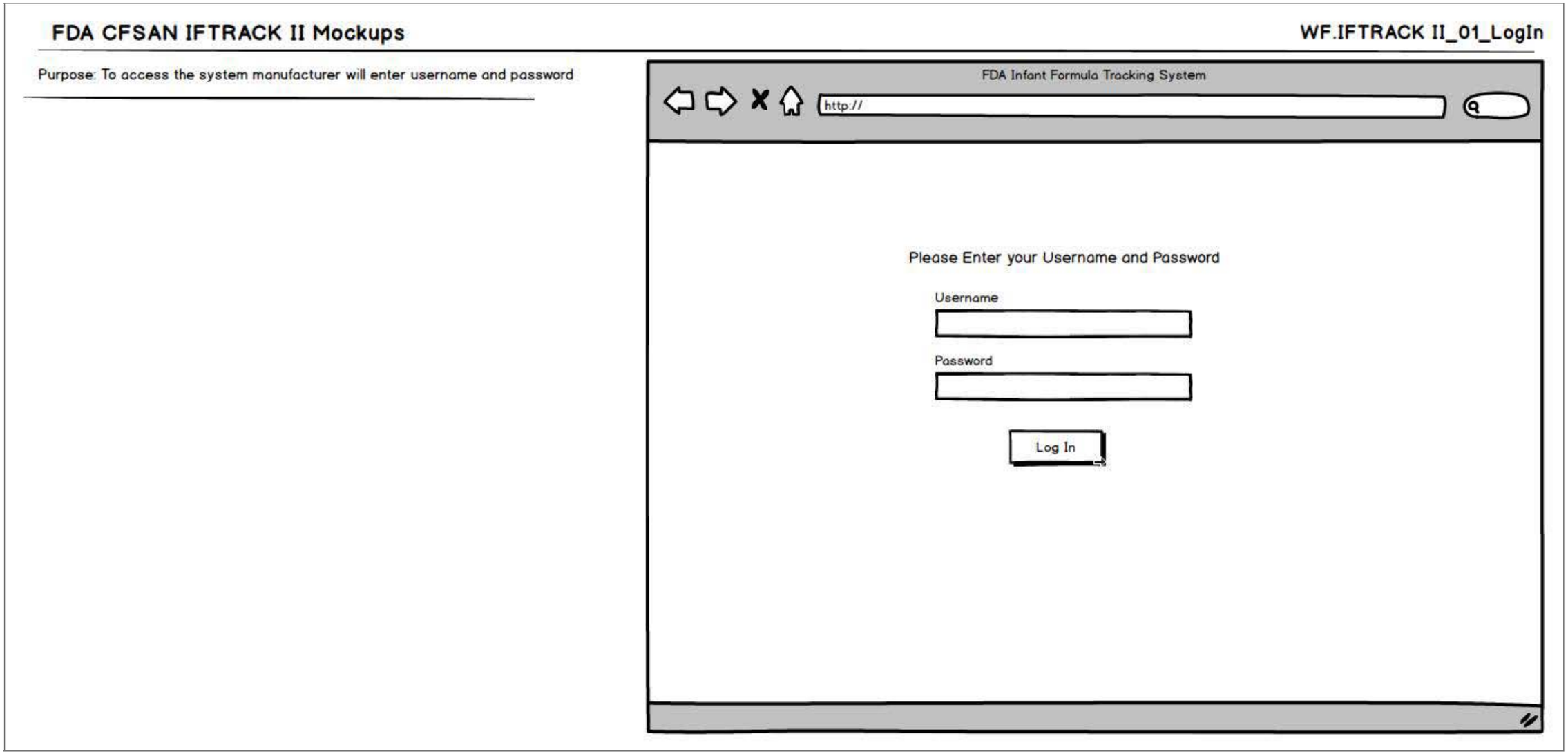
FDA CFSAN IFTRACK II Mockups

WF.IFTRACK.8A_AssignedSubmissionRef

Purpose: To view assigned Submission Reference Number

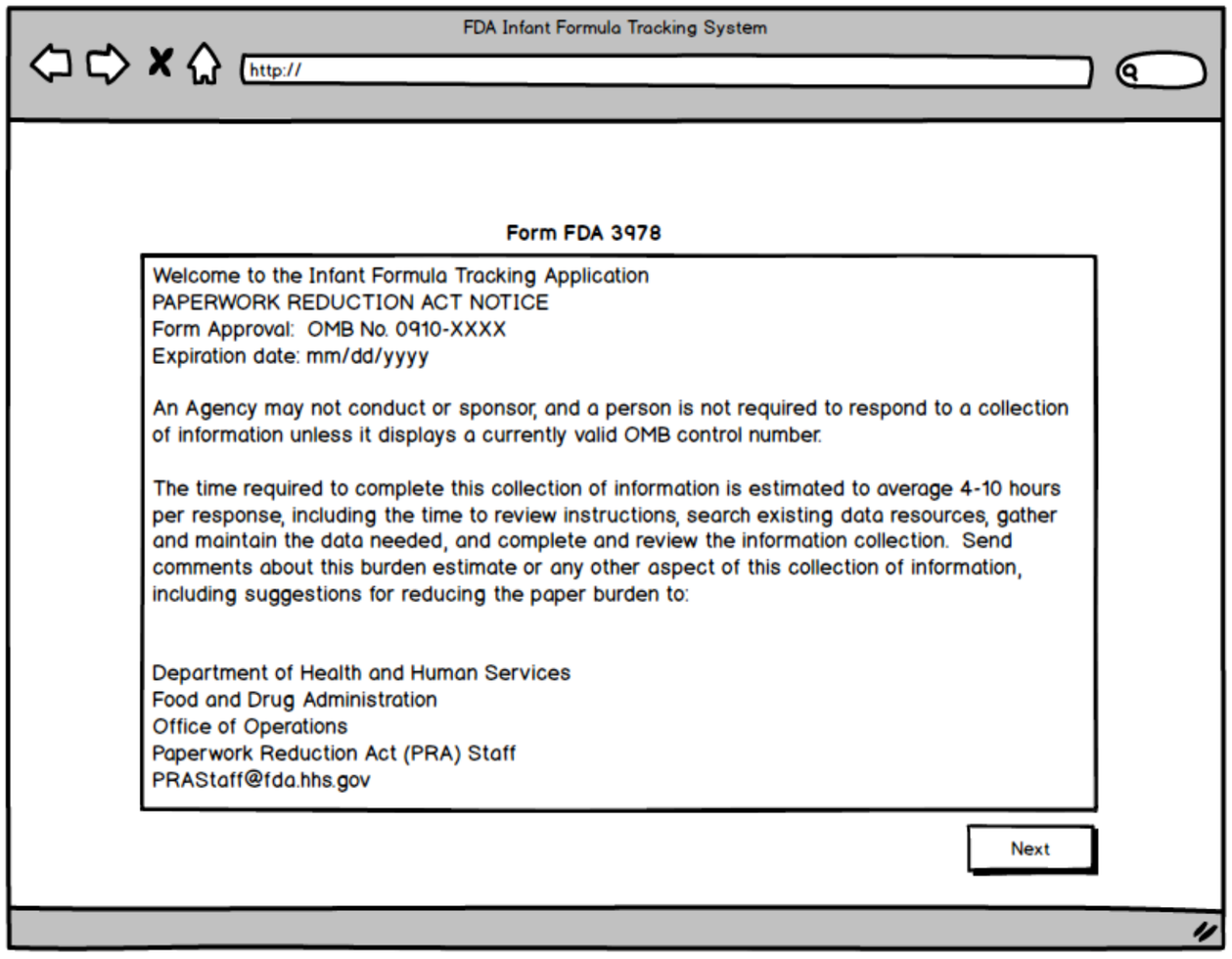


1.7 VERIFICATION SUBMISSION



FDA CFSAN IFTRACK II Mockups

WF.IFTRACK II_001_Welcome



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.

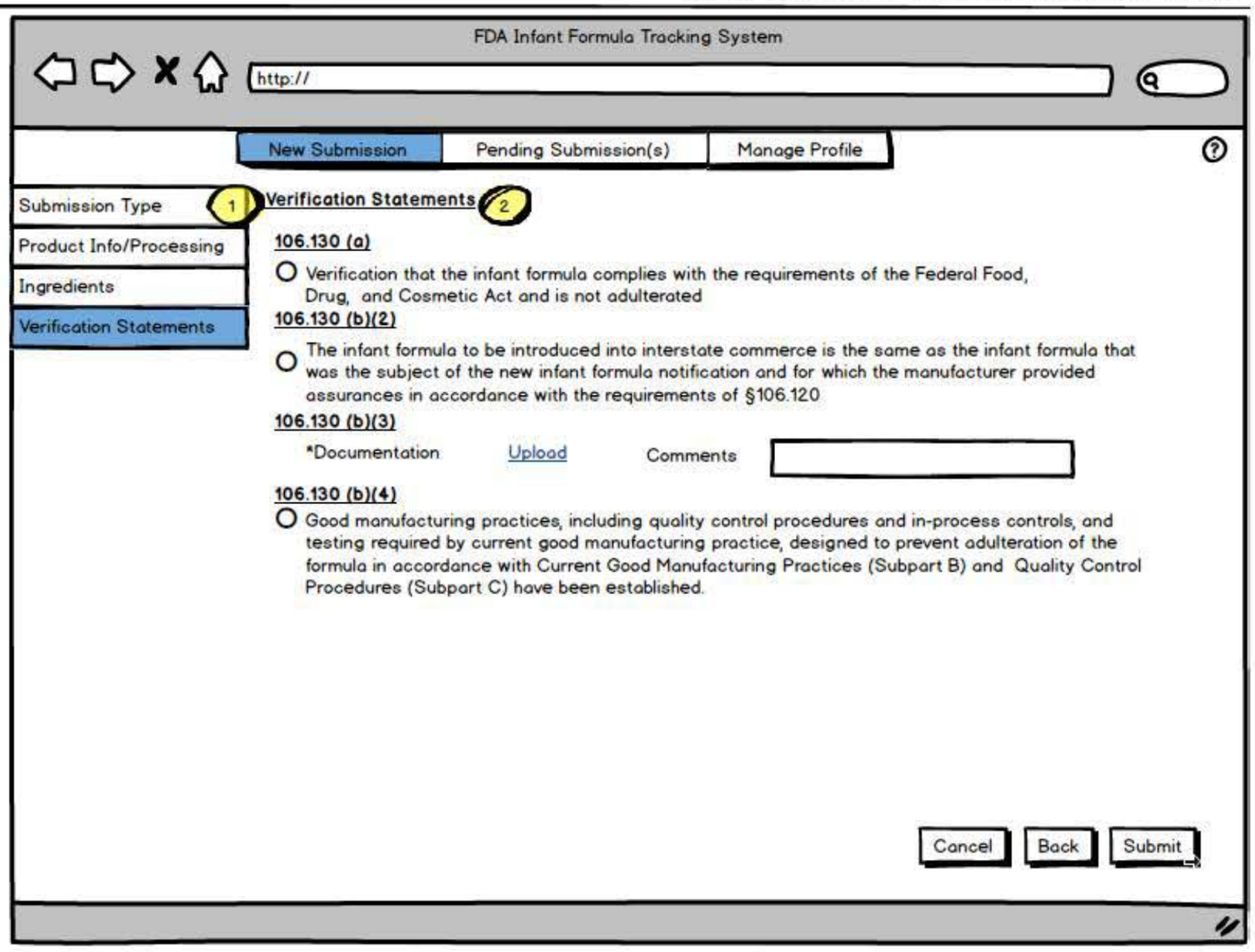
FDA CFSAN IFTRACK II Mockups

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 .

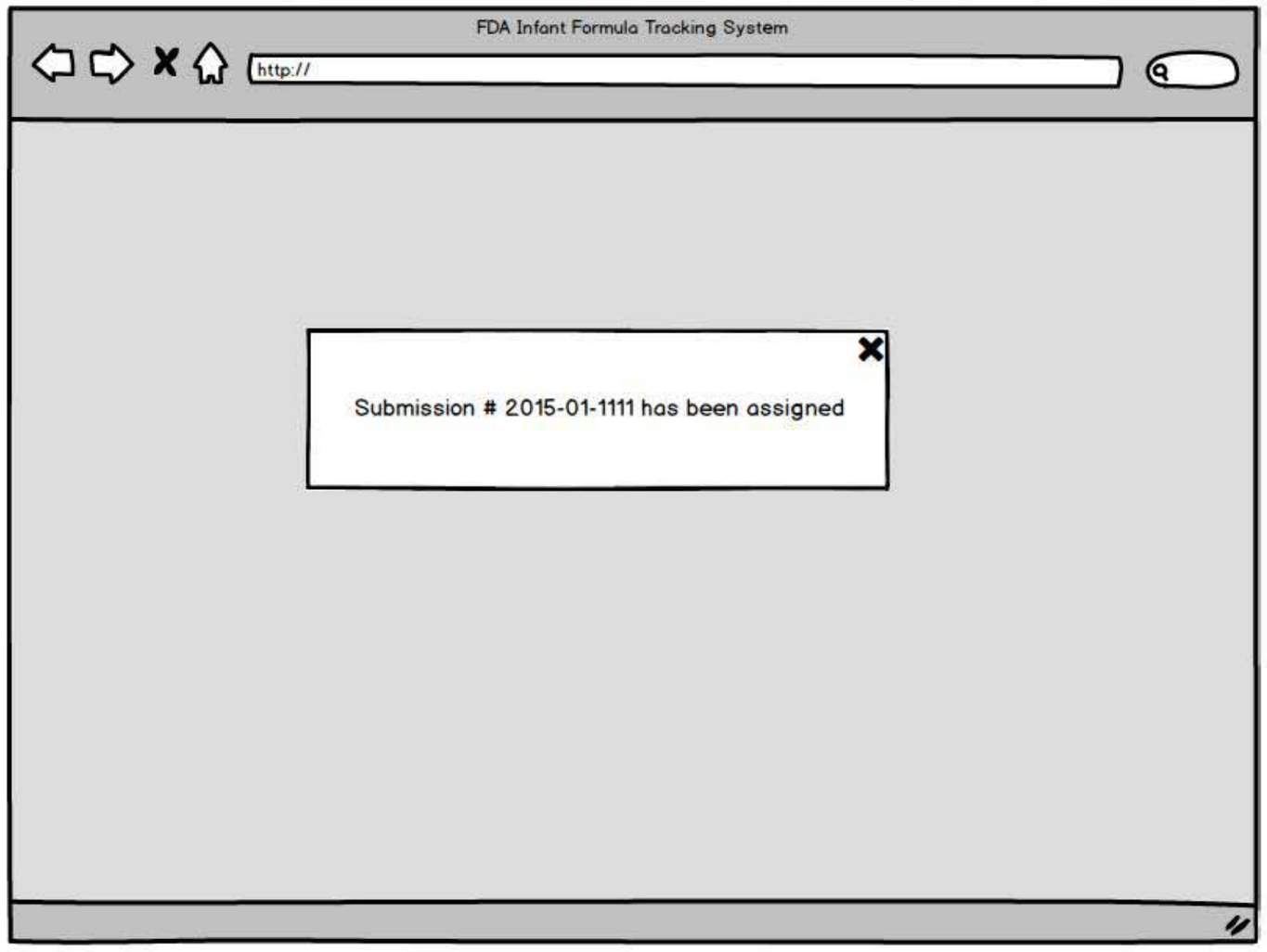
2. Verification Statements are only applicable to Verification Submission type.



FDA CFSAN IFTRACK II Mockups

WF.IFTRACK II.8A_AssignedSubmissionRef #

Purpose: To view assigned Submission Reference Number



1.8 MANUFACTURER PROFILE