DRAFT SCREENSHOTS AND DRAFT INSTRUCTIONS FOR FORM FDA 3978

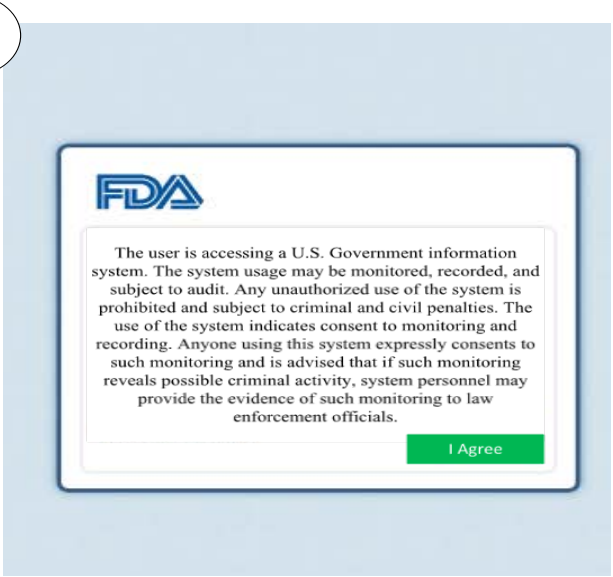
FDA has developed a draft electronic form, Form FDA 3978. Form FDA 3978 will prompt a respondent to register and include the required submission in a standard electronic format. This will help the respondent organize their registration and submission to include the information needed for FDA's review and will give the respondent access to the status of the review as well as access to their previous registrations and submissions. Manufacturers that prefer to submit paper registrations and submissions in a format of their own choosing will still have the option to do so. FDA is seeking comments on this draft electronic form. Draft screenshots of Form FDA 3978 and draft instructions are available below for review and comments.

For more information, visit
http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/InfantFormula/default.htm.

Contents

Login Page and Home Page For Form FDA 3978

1



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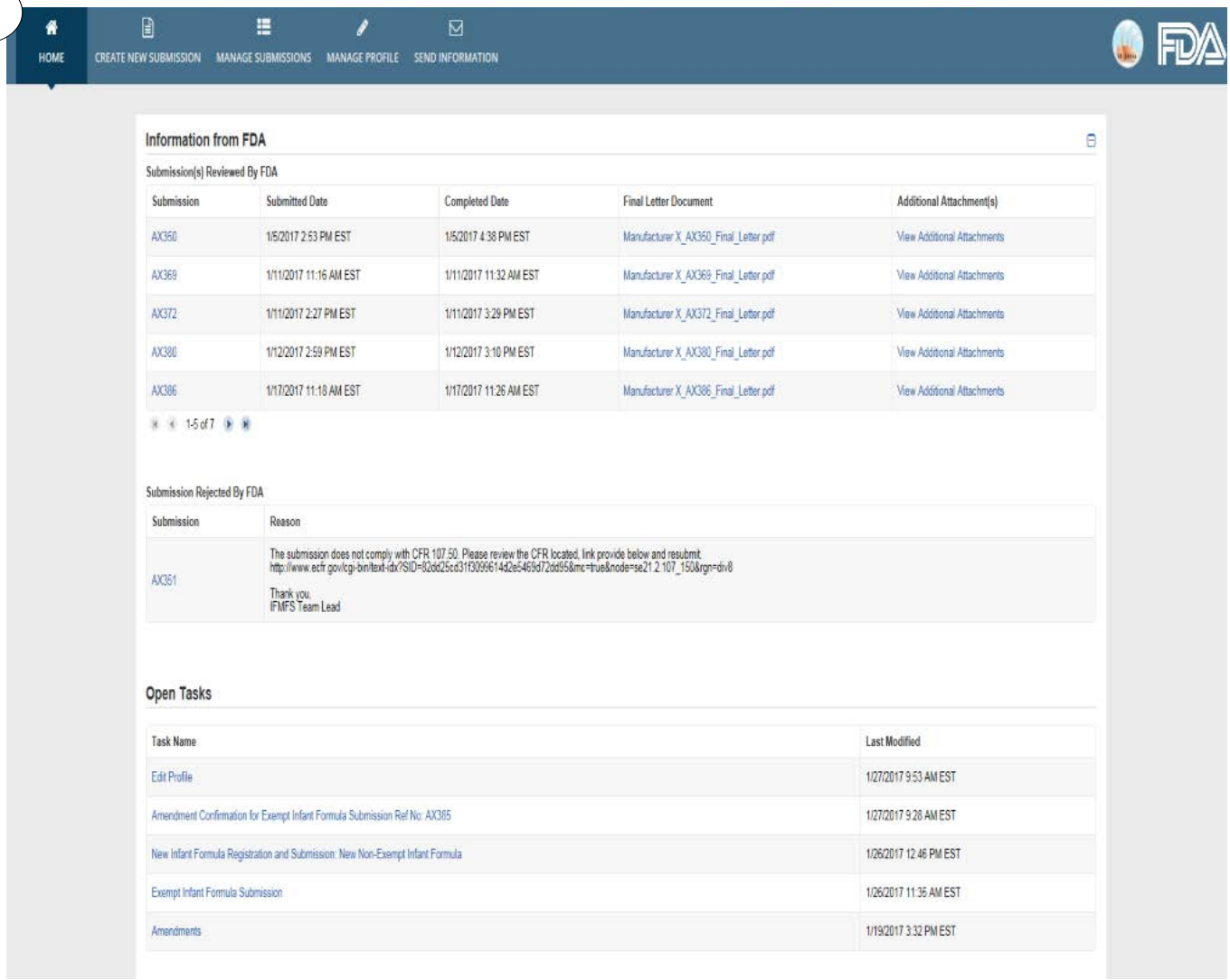
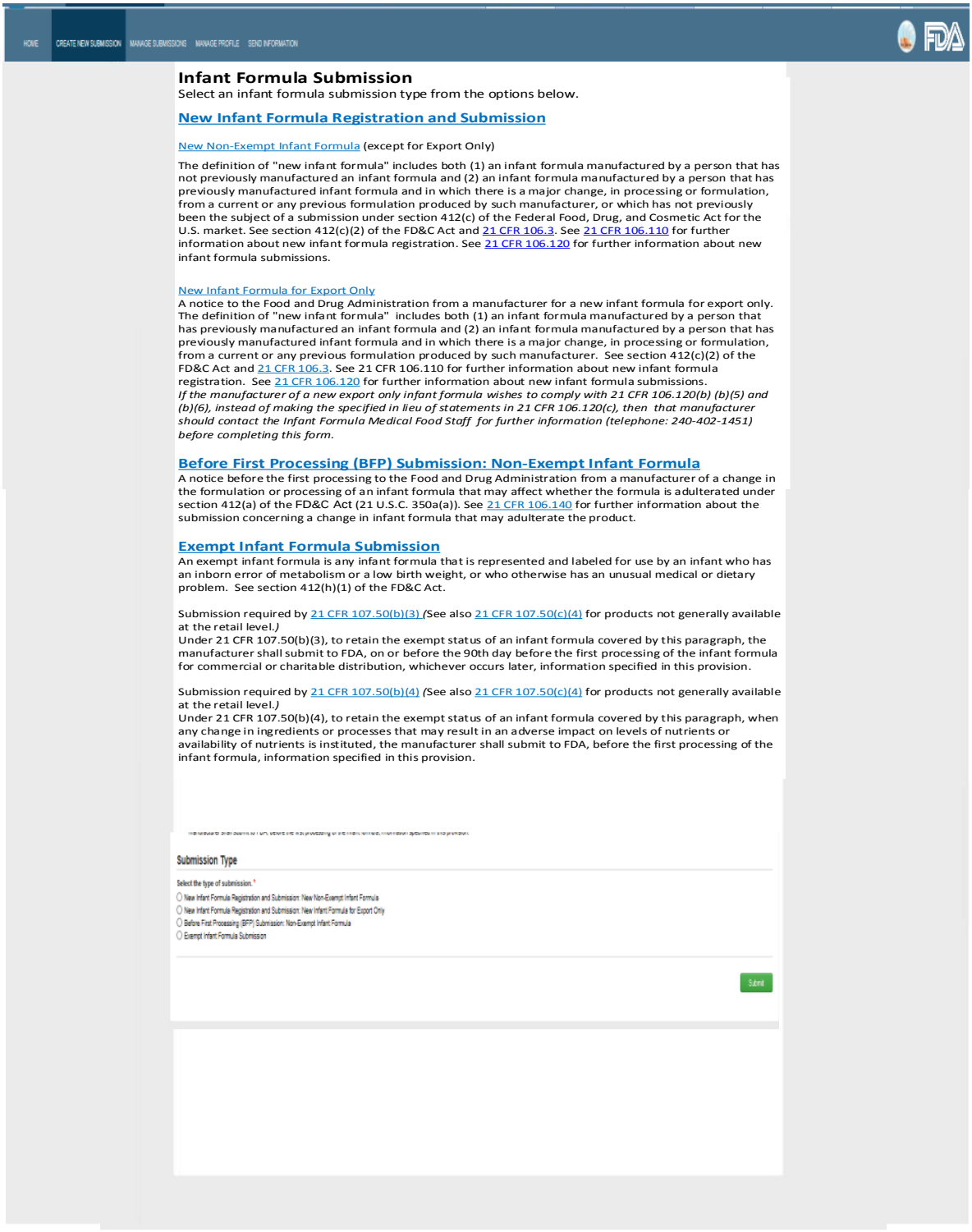


Infant Formula Submission Selection Page

3



Form FDA 3978

New Infant Formula Registration and Submission: Non-Exempt Infant Formula

4

New Infant Formula Registration and Submission: Non-Exempt Infant Formula

* Indicates a required field.

Product Information

Product Name / Physical Form

*Select one or more product names and description of the physical forms (e.g., powder, ready-to feed, concentrate) of the infant formula. 21 CFR 106.120 (b) (1)

Product Name	Name Change	Physical Form	Misc Info	
No Items Available				
Select Product				

Infant Formula Description

* Select the description(s) that applies to your product.

Product Name/Physical Form	Infant Formula Description
No Items Available	
Select Infant Formula Description	

Reason(s) for Submission

* Select one or more explanations of why the formula is a new infant formula. 21 CFR 106.120 (b) (2)

Product Name/Physical Form	Reason(s) for Submission
No Items Available	
Select Reason(s) for Submission	

Establishments

* Select the name of each establishment at which the manufacturer intends to manufacture such new infant formula. 21 CFR 106.110 (b) (4)

Product Name/Physical Form	Establishments
No Items Available	
Select Establishments	

Processing

Select "Current Processing" if there are no processing changes included with this submission. If there are changes in processing, in the comments and/or document upload sections describe the specific change in processing, including side-by-side, detailed schematic diagrams comparing the new processing to the previous processing and processing times and temperatures.

☐ Current Processing

Product/Physical Form	Type of Process Change
No Items Available	
Select Type of Processing	

Processing Comments

Processing Documentation Upload

Documents	
No Items Available	
Select Document	

Packaging

Select "Current Packaging" if there are no packaging changes for each infant formula product(s). If there are changes in packaging, in the comments and/or document upload sections describe the packaging types.

☐ Current Packaging

Product Name/Physical Form	Packaging Type	Container Qty	Units	Shelf Life	Current Supplier	Proposed Supplier	
No Items Available							
Select Type of Packaging							

Packaging Comments

Packaging Documentation Upload

Documents	
No Items Available	
Select Document	

Private label brand names

Enter any private label brand names

Labels and Labeling

Enter comments and/or upload any labels/labeling.

New Infant Formula Registration and Submission: Non-Exempt Infant Formula – Quantitative Formulation

4

New Infant Formula Registration and Submission: Non-Exempt Infant Formula

* Indicates a required field.

* Quantitative Formulation

Provide quantitative formulations in units per volume or units per weight for liquid formulas, specified either as sold or as fed, and units per dry weight for powdered formulas, and the weight of powder to be reconstituted with a specified volume of water. Include any comments and additional documentation as needed. 21 CFR 106.120(b)(3)

Quantitative Formulation Comments

Enter any comments and upload required quantitative formulations

Quantitative Formulation Documentation upload

Documents	
No Items Available	
Select Document	

Ingredient Changes (if applicable)

If this submission includes changes to the quantitative formulation(s), then provide a listing of each new or changed ingredient. Select one or more ingredients from the available list, for each product and physical form. For each ingredient selected, select the type of change. Based on the type of change selected the “Current Quantity (Qty)," “Units," “Proposed Quantity (Qty)," “Units," ‘Quantity (Qty) Units," “Current Supplier," and “Proposed Supplier” will be enabled or disabled. Provide comments or documentation covering a discussion of the effect of such changes on the nutrient levels in the formulation. 21 CFR 106.120(b)(3)

Product Name/Physical Form	Change	Ingredient	Current Qty	Units	Proposed Qty	Units	Per Qty Units	Current Supplier	Proposed Supplier	
No Items Available										
Select Ingredient Changes										

Ingredient Change Comments

No Items Available

Ingredient Change Documentation Upload

Documents	
No Items Available	
Select Document	

4a

WHEN ADDING AN INFANT FORMULA NUMBER

Enter Infant Formula Number (IFN)

Add a valid Infant Formula Number (IFN) from a previous submission.

Infant Formula Number (IFN)	
No Items Available	
Select Infant Formula Number	

New Infant Formula Registration and Submission: Non-Exempt Infant Formula – Assurances and Exemptions

4

New Infant Formula Registration and Submission: Non-Exempt Infant Formula

* The manufacturer is required to select assurances or exemption requests.

Quality Factors

***Quality Factors of Normal Physical Growth**

Assurance

☐ By checking this box, the manufacturer provides assurance that the infant formula meets the requirements for quality factors set forth in 21 CFR 106.96(a) and (b) and the required assurance described in 21 CFR 106.121(a).

If these assurances cannot be provided, then the manufacturer must be able to request an exemption. For information about required assurances relating to claimed exemptions under 21 CFR 106.96(c)(1) or (c)(2), see 21 CFR 106.121(b), (c), (d), and (e).

Provide comments and or documentation for assurance that the requirements of 21 CFR 106.96(b) and 21 CFR 106.121(a) are met.

Assurance Documentation Uploads

Documents	
No Items Available	
Select Document	

Exemptions

Select the appropriate request for exemption from 21 CFR 106.96(b) that applies to this submission.

☐ Exemption under 21 CFR 106.96(c)(1) 21 CFR 106.121(b)
By checking this box, the manufacturer requests an exemption and provides assurances, as required under 21 CFR 106.121(b), that the 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).
If the manufacturer is requesting an exemption from the growth monitoring study requirements under 21 CFR 106.96(c)(1) that the 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) then the manufacturer shall include a detailed description of the change made by the manufacturer to an existing infant formula and an explanation of why the change made by the manufacturer to an existing infant formula satisfies the criteria of 21 CFR 106.96(c)(1).

☐ Exemption under 21 CFR 106.96(c)(2)(i) 21 CFR 106.121(c)
By checking this box, the manufacturer requests an exemption and provides assurances, as required under 21 CFR 106.121(c), which demonstrate that an alternative method or study design that is based on sound scientific principles is available to show that the formula supports normal physical growth in infants when the formula is fed as the sole source of nutrition.
If the manufacturer is requesting an exemption from the requirements of 21 CFR 106.96(c)(2)(i), the manufacturer shall include a detailed description of the alternative method or alternative study design, an explanation of why the method or study design is based on sound scientific principles, and data that demonstrate that the formula supports normal physical growth in infants when the formula is fed as the sole source of nutrition.

☐ Exemption under 21 CFR 106.96(c)(2)(ii) 21 CFR 106.121(d)
By checking this box, the manufacturer requests an exemption and provides assurances, as required under 21 CFR 106.121(d), which demonstrate that the change made by the manufacturer to an existing formula does not affect the ability of the formula to support normal physical growth.
If the manufacturer is requesting an exemption from the requirements of 21 CFR 106.96(c)(2)(ii), the manufacturer shall include a detailed description of the change and an explanation of why the change made by the manufacturer to an existing infant formula does not the affect the ability of the formula to support normal physical growth.

☐ Exemption under 21 CFR 106.96(c)(2)(iii)
By checking this box, 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.

The manufacture requests an exemption and provides assurances, as required under 21 CFR 106.121(e), that 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.

***Quality Factor for Sufficient Biological Protein**

☐ By checking this box, the manufacturer of an infant formula shall, in accordance with 21 CFR 106.96(e) and (f), demonstrate that a formula meets the quality factor of sufficient biological quality of protein by establishing the biological quality of the protein in the infant formula when fed as the sole source of nutrition using an appropriate modification of the Protein Efficiency Ratio (PER) rat bioassay described in the "Official Methods of Analysis of AOAC International," 18th ed., sections 45.3.04 and 45.3.05, "AOAC Official Method 960.48 Protein Efficiency Ratio Rat Bioassay," which is incorporated by reference at 21 CFR 106.160. The PER rat bioassay shall be conducted on a formula and the results evaluated prior to the initiation of a growth monitoring study of the formula that is required under 21 CFR 106.96(f). FDA will exempt a manufacturer from the requirements of 21 CFR 106.96(e) with the appropriate exemption requests and assurances. See 21 CFR 106.121(g), (h), and (i).

Provide comments and or documentation for 21 CFR 106.121(f) Results of the Protein Efficiency Ratio bioassay.

Comments and/or Documentation Uploads

Documents	
No Items Available	
Select Document	

Exemptions

Select the appropriate request for exemption from 21 CFR 106.96(e) that applies to this submission.

☐ Exemption under 21 CFR 106.96(g)(1) (21 CFR 106.121(g))
By checking this box, the manufacturer requests an exemption and provides assurances as required under 21 CFR 106.121(g) that the 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).
If the manufacturer is requesting an exemption from the requirements of 21 CFR 106.96(g)(1), then the manufacturer shall include a detailed description of the change made by the manufacturer to an existing infant formula and an explanation of why the change made by the manufacturer to an existing infant formula satisfies the criteria listed in 21 CFR 106.96(g)(1).

☐ Exemption under 21 CFR 106.96(g)(2) (21 CFR 106.121(h))
By checking this box, the manufacturer requests an exemption and provides assurances, as required under 21 CFR 106.121(h), that demonstrate that the change made by the manufacturer to an existing formula does not affect the bioavailability of the protein.
If the manufacturer is requesting an exemption from the requirements of 21 CFR 106.96(g)(2), the manufacturer shall include a detailed description of the change and an explanation of why the change made by the manufacturer to an existing infant formula does not affect the bioavailability of the protein.

☐ Exemption under 21 CFR 106.96(g)(3) (21 CFR 106.121(i))
By checking this box, the manufacturer requests an exemption and provides assurances, as required under 21 CFR 106.121(i), that demonstrate that an alternative method to the PER that is based on sound scientific principles is available to demonstrate that the formula supports the quality factor for the biological quality of the protein.
If the manufacturer is requesting an exemption from the requirements of 21 CFR 106.96(g)(3), the manufacturer shall include a detailed explanation of the alternative method, an explanation of why the method is based on sound scientific principles, and the data that demonstrate that the quality factor for the biological quality of the protein has been met.

New Infant Formula Registration and Submission: Non-Exempt Infant Formula – Assurances and Exemptions Continued

4 New Infant Formula Registration and Submission: Non-Exempt Infant Formula

* Indicates a required field.

Additional Assurances and Exemption

***Assurance Statement**

☐ 21 CFR 106.121(j) By checking this box, the manufacturer provides assurance that the manufacturer has collected and considered all information and data concerning the ability of the infant formula to meet the requirements for quality factors, and manufacturer is not aware of any information or data that would show that the formula does not meet the requirements for quality factors.

***Nutrient Content Requirements**

☐ 21 CFR 106.121(b)(5) By checking this box, the manufacturer provides assurance that the infant formula will not be marketed unless the formula meets the requirements for quality factors of section 412(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351a(b)(11)) and the nutrient content requirements of section 412(i) of the Federal Food, Drug, and Cosmetic Act.

☐ 21 CFR 106.121(b)(5)(ii) By checking this box, the manufacturer provides assurance that the formula complies with the nutrient content requirements, which are set forth in 21 CFR 107.100, and that the formula will not be marketed unless it meets the nutrient requirements of 21 CFR 107.100, as demonstrated by testing required under 21 CFR 106 subpart C.

***Current GMP/Quality Control**

☐ 21 CFR 106.120 (b)(6)(i) By checking this box, the manufacturer provides assurance that the processing of the infant formula complies with section 412(b)(2) of the Federal Food, Drug, and Cosmetic Act. Such assurance shall include:

The basis on which each ingredient meets the requirements of 21 CFR 106.40(a), e.g. that it is an approved food additive, that it is authorized by a prior sanction, or that it is generally recognized as safe (GRAS) for its intended use. Any claim that an ingredient is GRAS shall be supported by a citation to the Agency's regulations or by an explanation, including a list of published studies and a copy of those publications, for why, based on the published studies, there is general recognition of the safety of the use of the ingredient in infant formula.

☐ Provide Infant Formula Number

Current GMP/Quality Control Comments and/or Documentation Uploads

Documents	
No Items Available	
Select Document	

Stability Testing Exemption Request

☐ By checking this box, the manufacturer is requesting an exemption under 21 CFR 106.91(b)(1)(ii) from the requirements of 21 CFR 106.91(b)(1)(i). Include in the comments and/or documentation the scientific evidence that the manufacturer is relying on to demonstrate that the stability of the new infant formula will likely not differ from the stability of formulas with similar composition, processing, and packaging for which there are extensive stability data.

Stability Exemption Request Comments and/or Documentation Upload

Documents	
No Items Available	
Select Document	

*Note the correct regulations for **Nutrient content requirements** are 21 CFR 106.120(b)(5) and 21 CFR 106.120(b)(5)(ii) (not 21 CFR 106.121(b)(5) and 21 CFR 106.121(b)(5)(ii)).*

Before First Processing (BFP) Submission: Non-Exempt Infant Formula

5 Before First Processing (BFP) Submission: Non-Exempt Infant Formula

* Indicates a required field.

Product Information

Product Name / Physical Form

*Select one or more product names and description of the physical forms (e.g., powder, ready-to feed, concentrate) of the infant formula. 21 CFR 106.140(b)(1)

Product Name	Name Change	Physical Form	Misc Info	
No Items Available				

Select Product

Infant Formula Description

* Select the description(s) that applies to your product.

Product Name/Physical Form	Infant Formula Description
No Items Available	

Select Infant Formula Description

Reason(s) for Submission

*Select one or more explanations of why the change in formulation or processing may affect whether the formula is adulterated. 21 CFR 106.140(b)(2)(i)

Product Name/Physical Form	Reason(s) for Submission
No Items Available	

Select Reason(s) for Submission

Eligible Infant Formula

* Select whether the infant formula can be lawfully distributed in the United States on or before December 8, 2014.

◯ Yes

◯ No

***21 CFR 106.140(b)(2)(ii)/Explanation concerning adulteration prevention**

Provide documentation explaining what steps will be taken to prevent adulteration before introduction into market.

Documentation Uploads

Documents	
No Items Available	

Select Document

Establishments

* Select the name of each establishment at which the manufacturer intends to manufacture such new infant formula.

Product Name/Physical Form	Establishmens
No Items Available	

Select Establishments

Statements of Compliance with 21 CFR 106.140(b)(3)

Processing

Select "Current Processing" if there are no processing changes included with this submission. If there are changes in processing, in the comments and/or document upload sections describe the specific change in processing, including side-by-side, detailed schematic diagrams comparing the new processing to the previous processing and processing times and temperatures.

☐ Current Processing

Product/Physical Form	Type of Process Change
No Items Available	

Select Type of Processing

Processing Comments

Processing Documentation Upload

Documents	
No Items Available	

Select Document

Packaging

Select "Current Packaging" if there are no packaging changes for each infant formula product(s). If there are changes in packaging, in the comments and/or document upload sections describe the packaging types.

☐ Current Packaging

Product Name/Physical Form	Packaging Type	Container Qty	Units	Shelf Life	Current Supplier	Proposed Supplier	
No Items Available							

Select Type of Packaging

Packaging Comments

Packaging Documentation Upload

Documents	
No Items Available	

Select Document

☐ * By checking this box the manufacturer confirms the submission complies with 21 CFR 106.120(b)(4)

Private label brand names

Enter any private label brand names

Labels and Labeling

Enter comments and/or upload any labels/labeling.

Before First Processing (BFP) Submission: Non-Exempt Infant Formula – Quantitative Formula

5

Before First Processing (BFP) Submission: Non-Exempt Infant Formula

* Indicates a required field.

*Quantitative Formulation

Select current quantitative formulalation if there are no changes to the quantitative formulation. If there are change to the quantitative formulation, enter any comments and upload required quantitative formulation changes.

☐ Current Quantitative Formulation

Provide quantitative formulations in units per volume or units per weight for liquid formulas, specified either as sold or as fed, and units per dry weight for powdered formulas, and the weight of powder to be reconstituted with a specified volume of water. Include any comments and additional documentation as needed. 21 CFR 106.120(b)(3)

Quantitative Formulation Comments

Quantitative Formulation Documentation upload

Documents	
No Items Available	
Select Document	

Ingredient Changes (if applicable)

If this submission includes changes to the quantitative formulation(s), then provide a listing of each new or changed ingredient. Select one or more ingredients from the available list, for each product and physical form. For each ingredient selected, select the type of change. Based on the type of change selected the "Current Quantity (Qty)," "Units," "Proposed Quantity (Qty)," "Units," "Quantity (Qty) Units," "Current Supplier," and "Proposed Supplier" will be enabled or disabled. Provide comments or documentation covering a discussion of the effect of such changes on the nutrient levels in the formulation. 21 CFR 106.120(b)(3)

Product Name/Physical Form	Change	Ingredient	Current Qty	Units	Proposed Qty	Units	Per Qty Units	Current Supplier	Proposed Supplier	
No Items Available										
Select Ingredient Changes										

Ingredient Change Comments

No Items Available

Ingredient Change Documentation Upload

Documents	
No Items Available	
Select Document	

☐ *By checking this box the manufacturer confirms the submission complies with 21 CFR 106.120(b)(3).

5a

WHEN ADDING AN INFANT FORMULA NUMBER

Enter Infant Formula Number (IFN)

Add a valid Infant Formula Number (IFN) from a previous submission.

☐ Assurance is given that the information previously provided to the Agency has not been affected by the changes that are the subject of the current submission. 21 CFR 106.140.

Infant Formula Number (IFN)	
No Items Available	
Select Infant Formula Number	

Before First Processing (BFP) Submission: Non-Exempt Infant Formula - Continued Compliance

5

Before First Processing (BFP) Submission: Non-Exempt Infant Formula

* Indicates a required field.

CONTINUED COMPLIANCE WITH 21 CFR 106.140(b)(3)

Quality Factors

If this is an eligible infant formula then this section is optional. The manufacturer of each eligible infant formula shall make and retain records to demonstrate that such formula supports normal physical growth in infants when fed as the sole source of nutrition (21 CFR 106.100(p)(2)) and records to demonstrate that that the protein in such infant formula is of sufficient biological quality (21 CFR 106.100(q)(2)).

If this is not an eligible infant formula then provide an infant formula number (IFN) referencing previously supplied quality factor information/data, or any comments and documentation as necessary.

☐ By checking this box, the manufacturer is assuring compliance with the following:
21 CFR 106.120(b)(5) Assurance that the infant formula will not be marketed unless the formula meets the requirements for quality factors of section 412(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(b)(1)) and the nutrient content requirements of section 412(i) of the Federal Food, Drug, and Cosmetic Act.

(i) Assurance that the formula meets the requirements for quality factors, which are set forth in 21 CFR 106.96, shall be provided by a submission that complies with 21 CFR 106.121;

(ii) Assurance that the formula complies with the nutrient content requirements, which are set forth in 21 CFR 107.100 of this chapter, shall be provided by a statement that the formula will not be marketed unless it meets the nutrient requirements of 21 CFR 107.100 of this chapter, as demonstrated by testing required under subpart C of this part.

☐ Provide Infant Formula Number (IFN)

Comments and/or Documentation Uploads

Documents	
No Items Available	
Select Document	

*Current GMP/Quality Control

By checking this boxes below, the manufacturer provides assurance that the processing of the infant formula complies with section 412(b)(2) of the Federal Food, Drug, and Cosmetic Act.

☐ *Submission complies with 21 CFR 106.120(b)(6)(i) The formula will be produced in accordance with 21 CFR 106 Subpart B and 21 CFR 106 Subpart C.

☐ *Each ingredient meets the requirements of 21 CFR 106.40(a): e.g., it is an approved food additive, authorized by a prior sanction, or is generally recognized as safe (GRAS) for its intended use. Each claim that an ingredient is GRAS is supported by a citation to the Agency's regulations or by an explanation, including a list of published studies and a copy of those publications, for why, based on the published studies, there is general recognition of the safety of the use of the ingredient in infant formula.

Provide a previous Infant Formula Number (IFN) with the bases and/or any comments and documentation as necessary.

☐ Provide Infant Formula Number (IFN)

Comments and/or Documentation Uploads

Documents	
No Items Available	
Select Document	

New Infant Formula Registration and Submission: Infant Formula for Export Only

6

New Infant Formula Registration and Submission: Infant Formula for Export Only

If the manufacturer of a new export only infant formula wishes to comply with 21 CFR 106.120(b) (b)(5) and (b)(6), instead of making the specified in lieu of statements in 21 CFR 106.120(c), then that manufacturer should contact the Infant Formula Medical Food Staff for further information (telephone: 240-402-1451) before completing this form.

* Indicates a required field.

Product Information

Product Name / Physical Form

*Select one or more product names and description of the physical forms (e.g., powder, ready-to feed, concentrate) of the infant formula. 21 CFR 106.120 (b)(1)

Product Name	Name Change	Physical Form	Misc Info	
No Items Available				
Select Product				

Infant Formula Description

* Select the description(s) that applies to your product.

Product Name/Physical Form	Infant Formula Description
No Items Available	
Select Infant Formula Description	

Reason(s) for Submission

* Select one or more explanations of why the formula is a new infant formula. 21 CFR 106.120 (b)(2)

Product Name/Physical Form	Reason(s) for Submission
No Items Available	
Select Reason(s) for Submission	

Establishments

* Select the name of each establishment at which the manufacturer intends to manufacture such new infant formula.

Product Name/Physical Form	Establishments
No Items Available	
Select Establishments	

Processing

Select "Current Processing" if there are no processing changes included with this submission. If there are changes in processing, in the comments and/or document upload sections describe the specific change in processing, including side-by-side, detailed schematic diagrams comparing the new processing to the previous processing and processing times and temperatures.

☐ Current Processing

Product/Physical Form	Type of Process Change
No Items Available	
Select Type of Processing	

Processing Comments

Processing Documentation Upload

Documents	
No Items Available	
Select Document	

Packaging

Select "Current Packaging" if there are no packaging changes for each infant formula product(s). If there are changes in packaging, in the comments and/or document upload sections describe the packaging types.

☐ Current Packaging

Product Name/Physical Form	Packaging Type	Container Qty	Units	Shelf Life	Current Supplier	Proposed Supplier	
No Items Available							
Select Type of Packaging							

Packaging Comments

Packaging Documentation Upload

Documents	
No Items Available	
Select Document	

New Infant Formula Registration and Submission: Infant Formula for Export Only – Quantitative formulation

6 New Infant Formula Registration and Submission: Infant Formula for Export Only

* Indicates a required field.

* Quantitative Formulation

Provide quantitative formulations in units per volume or units per weight for liquid formulas, specified either as sold or as fed, and units per dry weight for powdered formulas, and the weight of powder to be reconstituted with a specified volume of water. Include any comments and additional documentation as needed. 21 CFR 106.120(b)(3)

Quantitative Formulation Comments

Enter any comments and upload required quantitative formulations.

Quantitative Formulation Documentation upload

Documents	
No Items Available	
Select Document	

Ingredient Changes (if applicable)

If this submission includes changes to the quantitative formulation(s), then provide a listing of each new or changed ingredient. Select one or more ingredients from the available list, for each product and physical form. For each ingredient selected, select the type of change. Based on the type of change selected the "Current Quantity (Qty)," "Units," "Proposed Quantity (Qty)," "Units," 'Quantity (Qty) Units," "Current Supplier," and "Proposed Supplier" will be enabled or disabled. Provide comments or documentation covering a discussion of the effect of such changes on the nutrient levels in the formulation. 21 CFR 106.120(b)(3)

Product Name/Physical Form	Change	Ingredient	Current Qty	Units	Proposed Qty	Units	Per Qty Units	Current Supplier	Proposed Supplier	
No Items Available										
Select Ingredient Changes										

Ingredient Change Comments

No Items Available

Ingredient Change Documentation Upload

Documents	
No Items Available	
Select Document	

6a

WHEN ADDING AN INFANT FORMULA NUMBER

Enter Infant Formula Number

Add a valid Infant Formula Number (IFN) from a previous submission.

Infant Formula Number (IFN)	
No Items Available	
Select Infant Formula Number	

Export Country

Enter country where product will be exported.

Labels and Labeling

Enter comments and/or upload any labels/labeling.

New Infant Formula Registration and Submission: Infant Formula for Export Only - Export Statements

6

New Infant Formula Registration and Submission: Infant Formula for Export Only

* Indicates a required field.

* Export Statements

For new export only infant formulas, a manufacturer may in lieu of the information required under 21 CFR 106.120(b)(5) and (b)(6), submit a statement certifying the following. 21 CFR 106.120(c)

- [ ] By checking this box, the manufacturer is certifying the infant formula meets specifications of foreign purchaser.
- [ ] By checking this box, the manufacturer is certifying the infant formula doesn't conflict with the laws of the country to which it is intended for export.
- [ ] By checking this box, the manufacturer is certifying the infant formula is labeled on the outside of the shipping package to indicate that it is intended for export only.
- [ ] By checking this box, the manufacturer is certifying that the manufacturer has adequate controls in place to ensure that such formula is actually exported.

Exempt Infant Formula Submission

7

Exempt Infant Formula Submission

* Indicates a required field.

☐ Submission includes information required by 21 CFR 107.50(b)(3)
☐ Submission includes information required by 21 CFR 107.50 (b)(4)
☐ Generally not available at retail
☐ Generally available at retail

Product Information

Product Name / Physical Form

*Select one or more product names and description of the physical forms (e.g., powder, ready-to feed, concentrate) of the infant formula.

Product Name	Name Change	Physical Form	Misc Info	
No Items Available				

Select Product

Infant Formula Description

* Select the description(s) that applies to your product.

Product Name/Physical Form	Infant Formula Description
No Items Available	

Select Infant Formula Description

Reason(s) for Submission

*Select one or more explanations for this submission.

Product Name/Physical Form	Reason(s) for Submission
No Items Available	

Select Reason(s) for Submission

Establishments

* Select the name of each establishment at which the manufacturer intends to manufacture such new infant formula.

Product Name/Physical Form	Establishments
No Items Available	

Select Establishments

***Label/Labeling**

Enter comments and/or upload any labels and labeling for product(s) listed.

Label/Labeling Comments

Label/Labeling Documentation upload

Documents	
No Items Available	

Select Document

Description of Medical Conditions

* Provide a detailed description of the medical conditions for which the infant formula is represented.

Description of Medical Conditions

Description of Medical Conditions Documentation upload

Documents	
No Items Available	

Select Document

Rationale for deviation

Provide the medical, nutritional, scientific, or technological rationale (including any appropriate animal or human clinical studies) for deviations under 21 CFR 107.50 (b)(2) or 21 CFR 107.50 (c)(2).

Rationale for deviation Comments

Rationale for deviation Documentation upload

Documents	
No Items Available	

Select Document

7

Exempt Infant Formula Submission

* Indicates a required field.

CONTINUED FROM PREVIOUS PAGE

Processing

Select "Current Processing" if there are no processing changes included with this submission. If there are changes in processing, in the comments and/or document upload sections describe the specific change in processing, including side-by-side, detailed schematic diagrams comparing the new processing to the previous processing and processing times and temperatures.

☐ Current Processing

Product/Physical Form	Type of Process Change
No Items Available	
Select Type of Processing	

Processing Comments

Processing Documentation Upload

Documents	
No Items Available	
Select Document	

Packaging

Select "Current Packaging" if there are no packaging changes for each infant formula product(s). If there are changes to the packaging, in the comments and/or document upload sections describe the packaging types.

☐ Current Packaging

Product Name/Physical Form	Packaging Type	Container Qty	Units	Shelf Life	Current Supplier	Proposed Supplier	
No Items Available							
Select Type of Packaging							

Packaging Comments

Packaging Documentation Upload

Documents	
No Items Available	
Select Document	

Exempt Infant Formula Submission: Quantitative Formulation

7

Exempt Infant Formula Submission

* Indicates a required field.

Reformulation

Rationale for Reformulation

Description of Infant Formula Reformulation.

* Quantitative Formulation

Provide quantitative formulations in units per volume or units per weight for liquid formulas, specified either as sold or as fed, and units per dry weight for powdered formulas, and the weight of powder to be reconstituted with a specified volume of water. Include any comments and additional documentation as needed.

Quantitative Formulation Comments

Enter comments and/or upload any labels and labeling for product(s) listed.

Quantitative Formulation Documentation upload

Documents	
No Items Available	
Select Document	

Ingredient Changes (if applicable)

If this submission includes changes to the quantitative formulation(s), then provide a listing of each new or changed ingredient. Select one or more ingredients from the available list, for each product and physical form. For each ingredient selected, select the type of change. Based on the type of change selected the “Current Quantity (Qty)," “Units," “Proposed Quantity (Qty)," “Units," ‘Quantity (Qty) Units," “Current Supplier," and “Proposed Supplier” will be enabled or disabled. Provide comments or documentation covering a discussion of the effect of such changes on the nutrient levels in the formulation.

Product Name/Physical Form	Change	Ingredient	Current Qty	Units	Proposed Qty	Units	Per Qty Units	Current Supplier	Proposed Supplier	
No Items Available										
Select Ingredient Changes										

Ingredient Change Comments

No Items Available

Ingredient Change Documentation Upload

Documents	
No Items Available	
Select Document	

7a

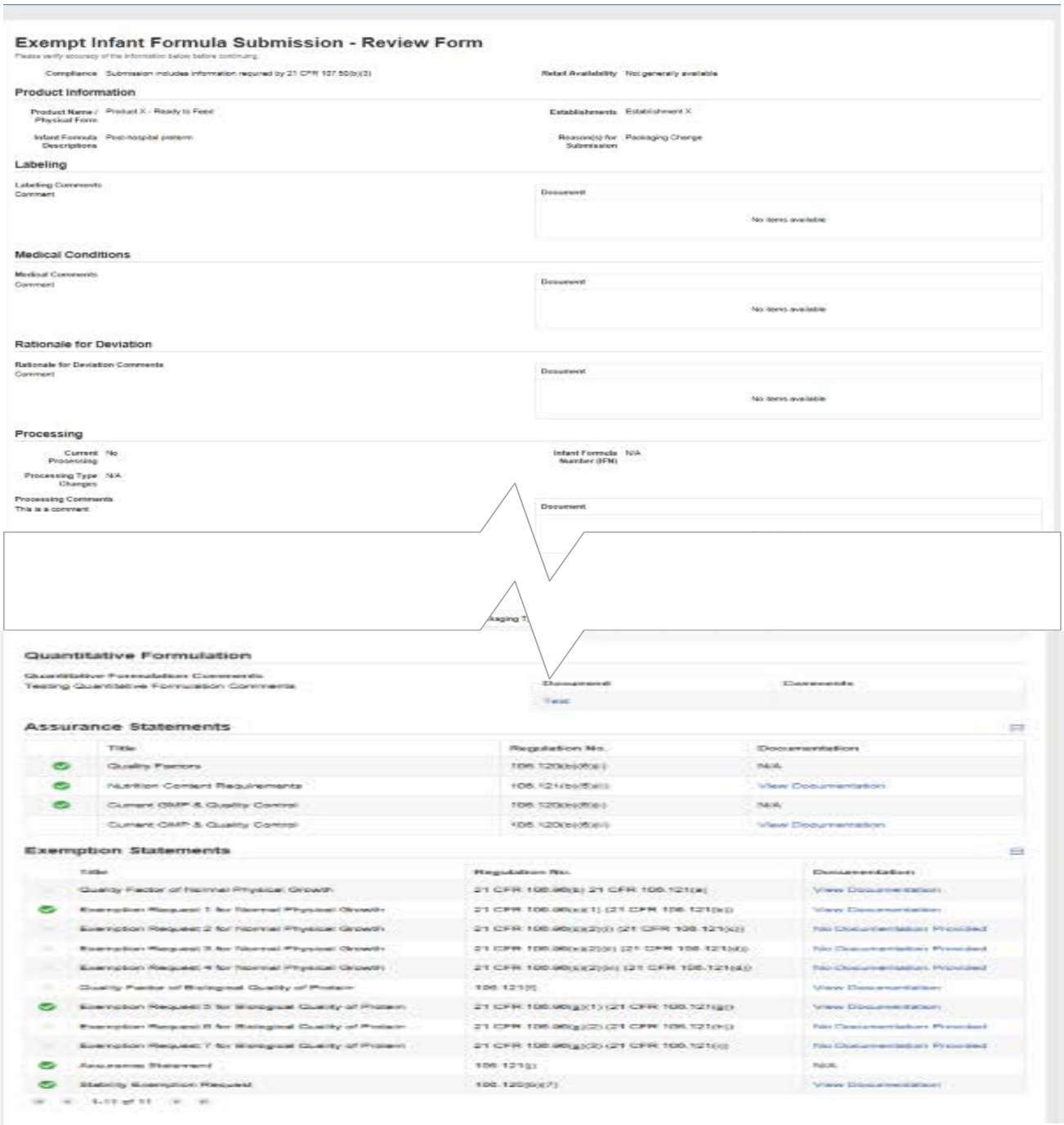
WHEN ADDING AN INFANT FORMULA NUMBER

Enter Infant Formula Number
Add a valid Infant Formula Number (IFN) from a previous submission.

Infant Formula Number (IFN)	
No Items Available	
Select Infant Formula Number	

Review Form in Read-Only Cefore Submitting

8



Review and Submit

Before making the submission, review and confirm the information entered is accurate.

All new items added to the following lists will be reviewed by Food and Drug Administration (FDA) Infant Formula Medical Food Staff (IFMFS) internally before adding permanently to the respective lists. Until the reviews are complete new items will not be displayed on the respective lists.

New Products
New Infant Formula Descriptions

New Processing Changes
New Packaging Types

New Ingredients
New Suppliers

{Manufacturer Contact Person Name}

{Title of Manufacturer Contact Person Name}

I certify that the information in the submission is true and accurate and that I am authorized to make the submission on behalf of the submission owner.

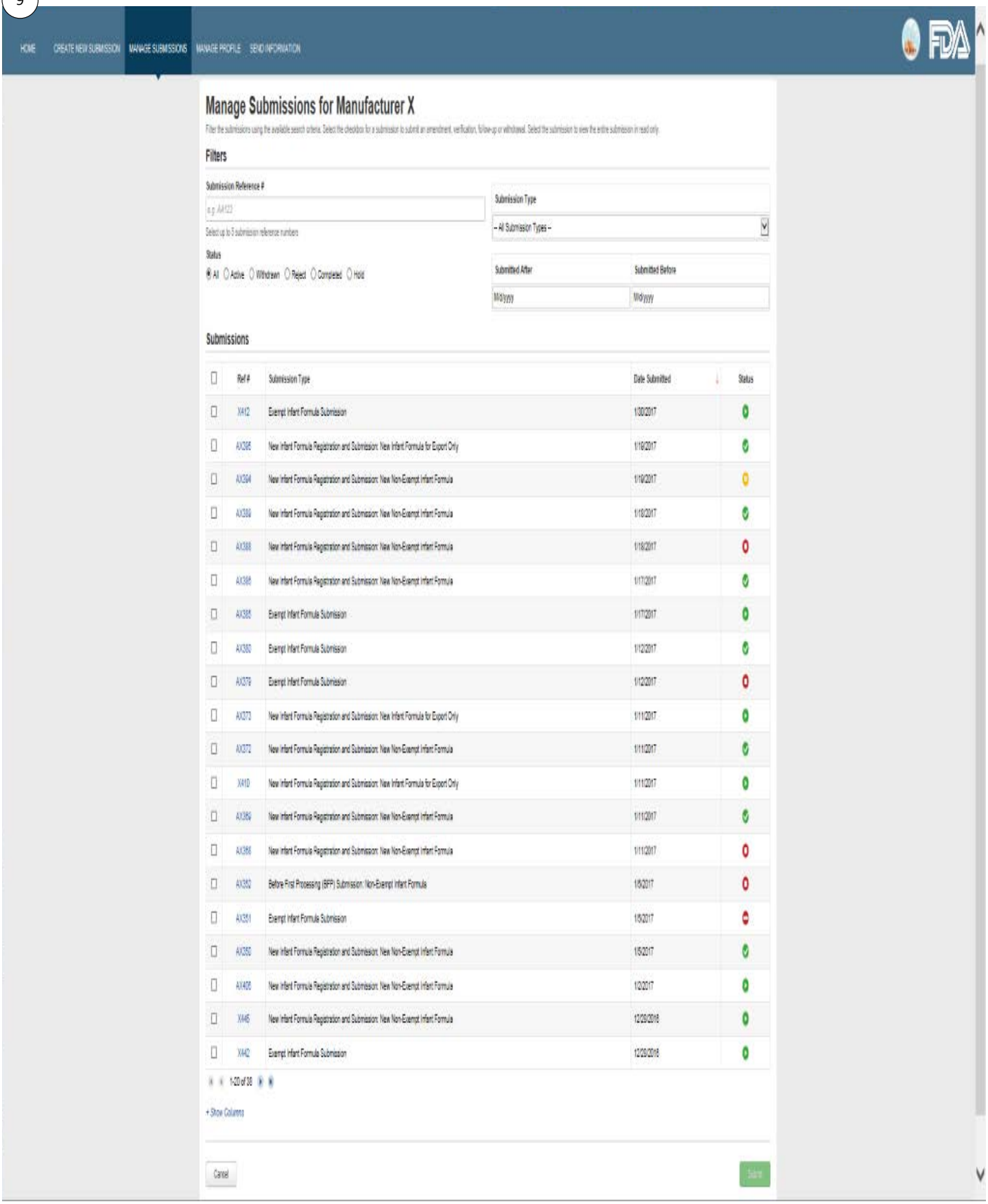
☐ I Agree.

Modify

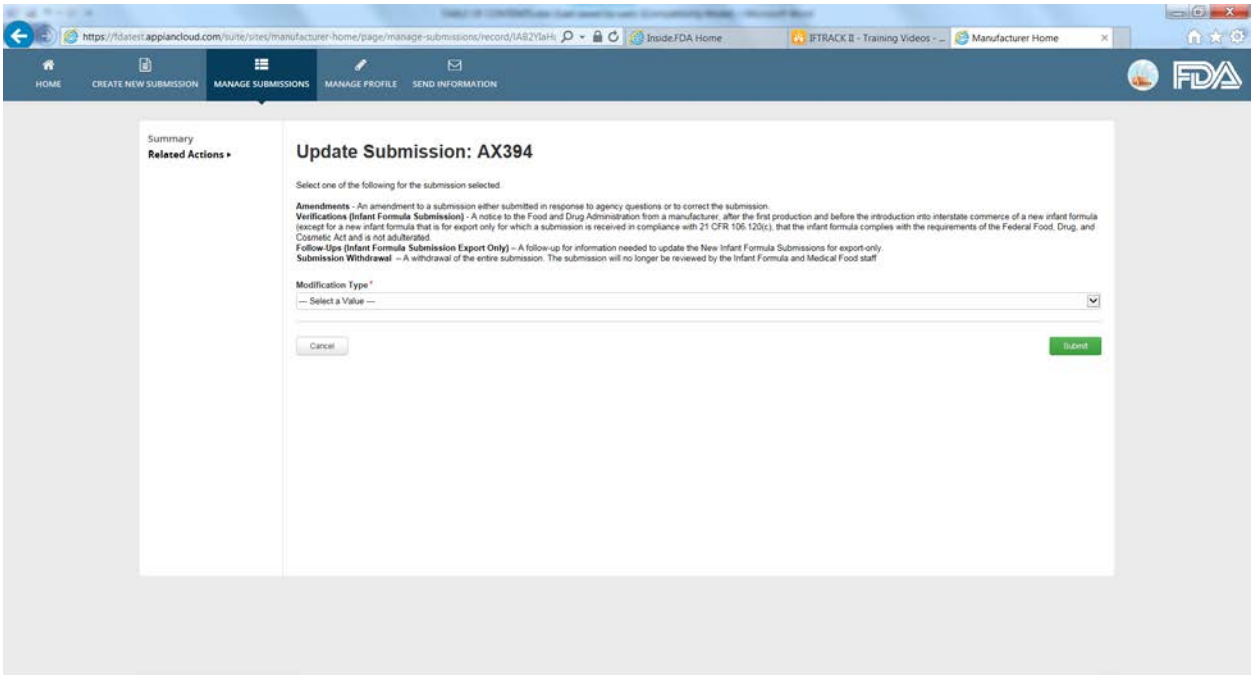
Submit

Manage Submissions

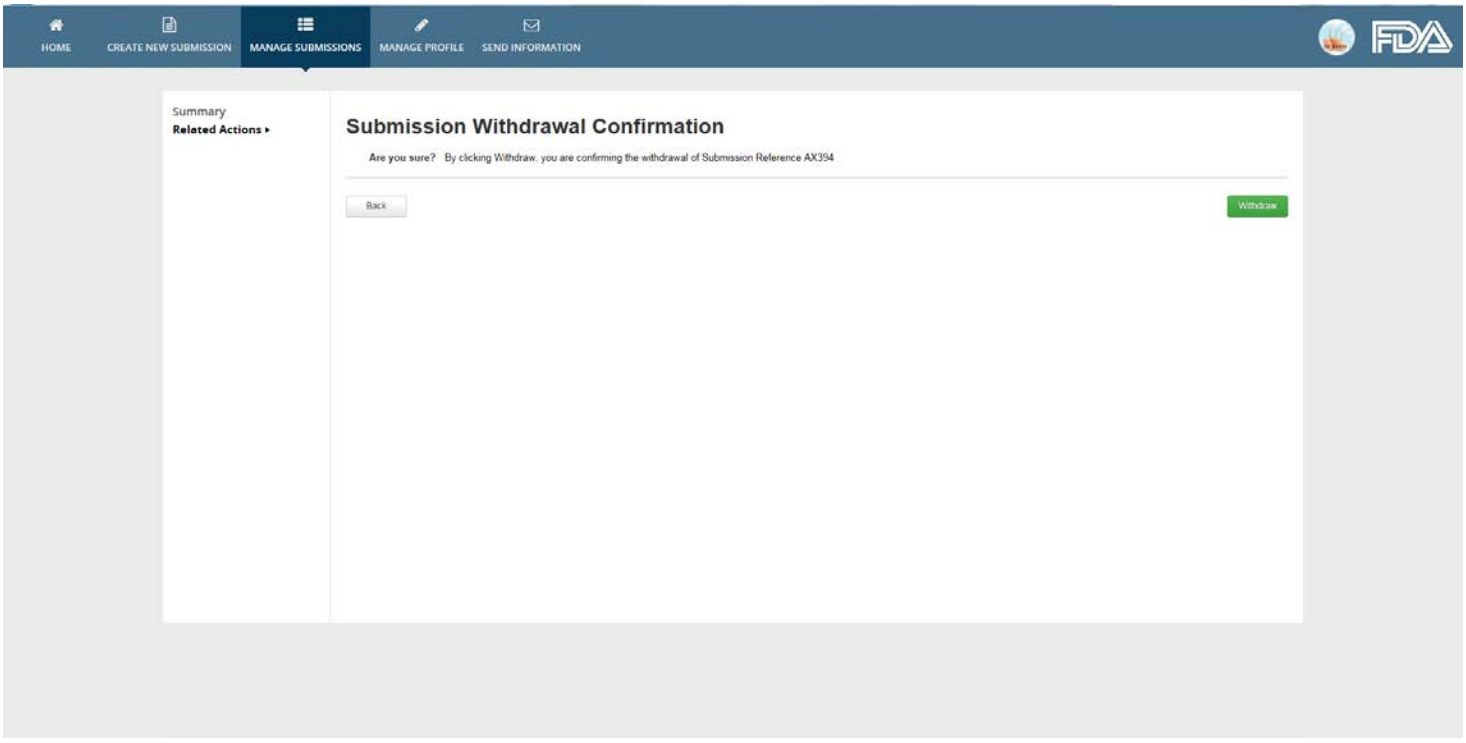
9



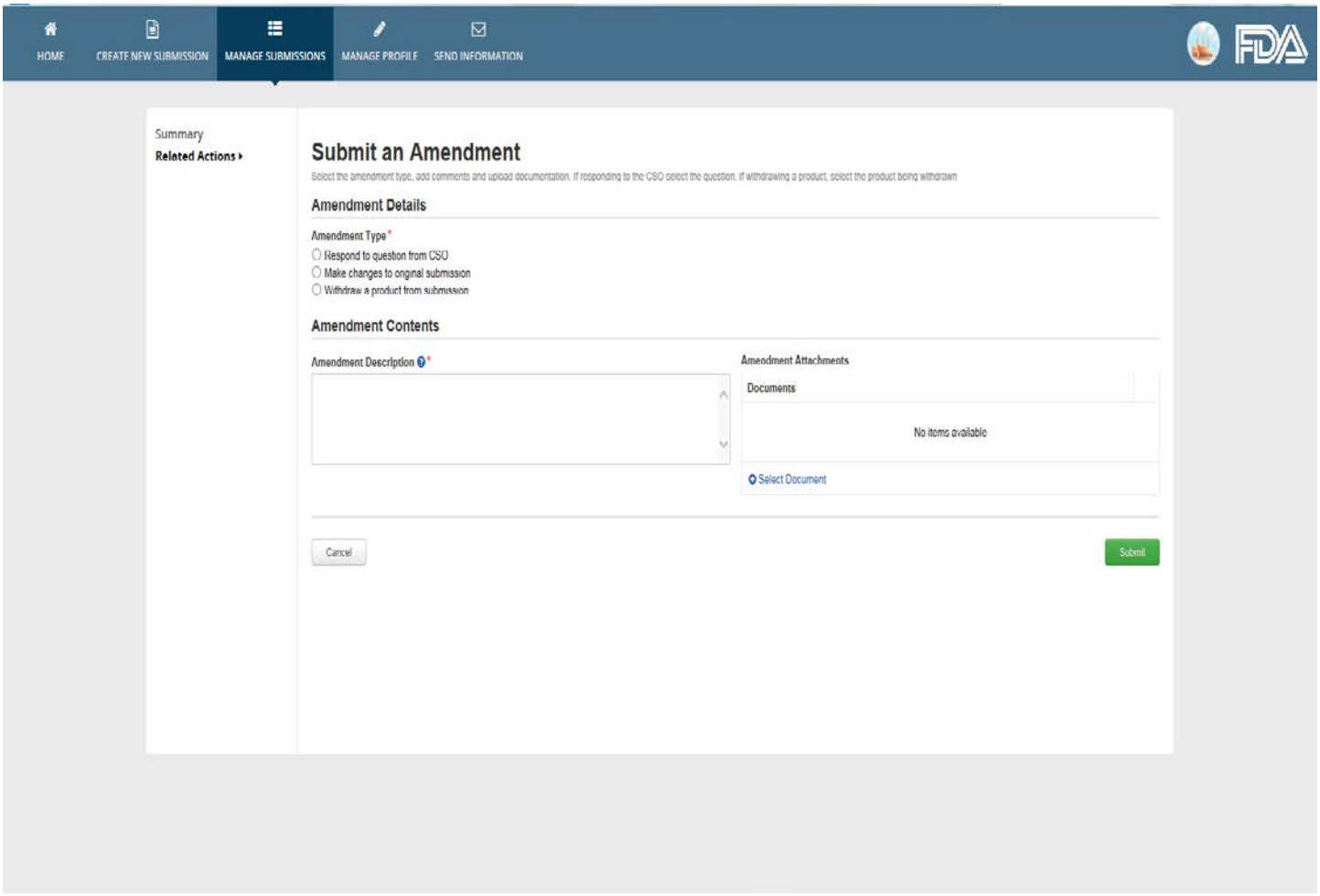
Modify a Submission



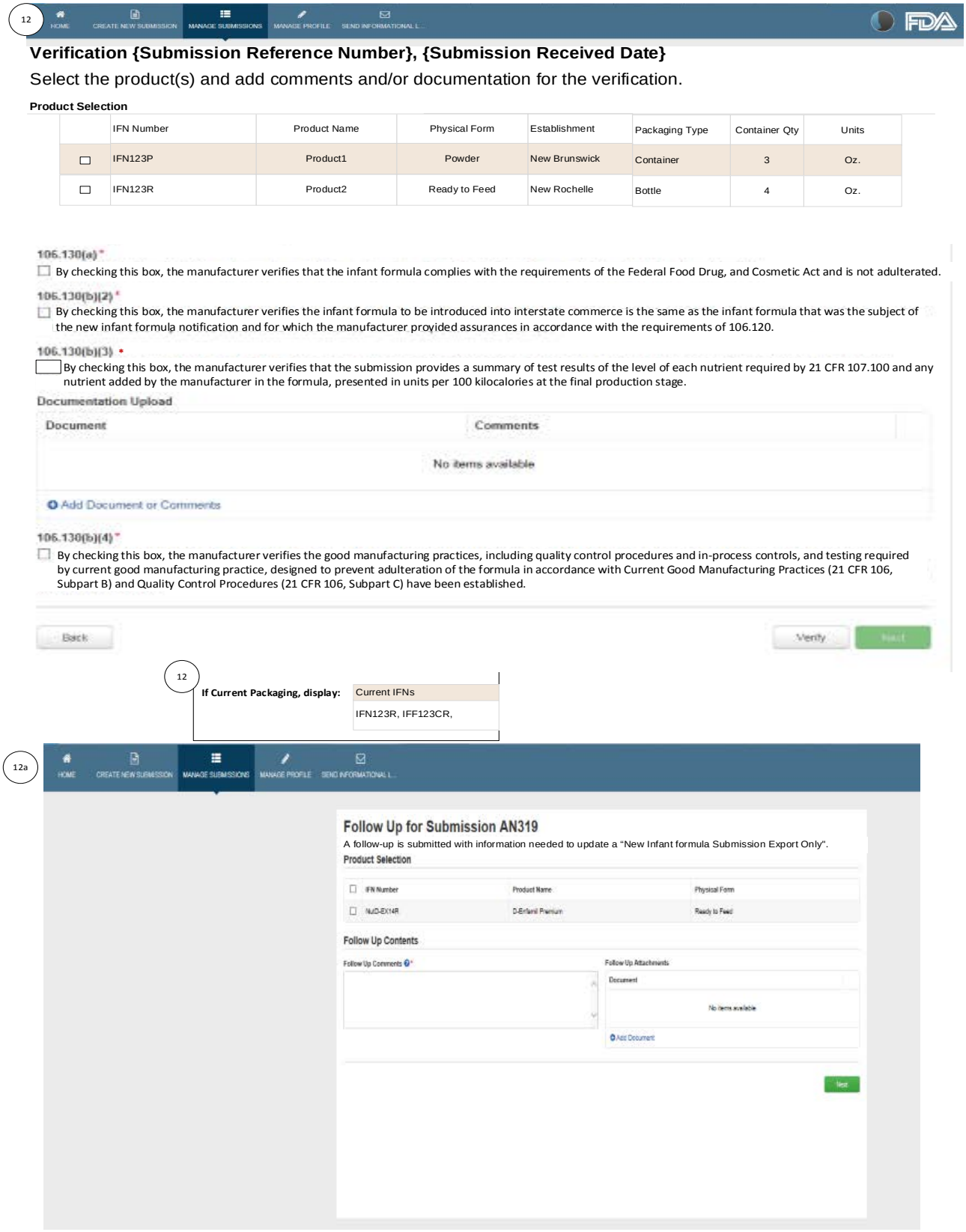
Withdraw a Submission



Amend a Submission

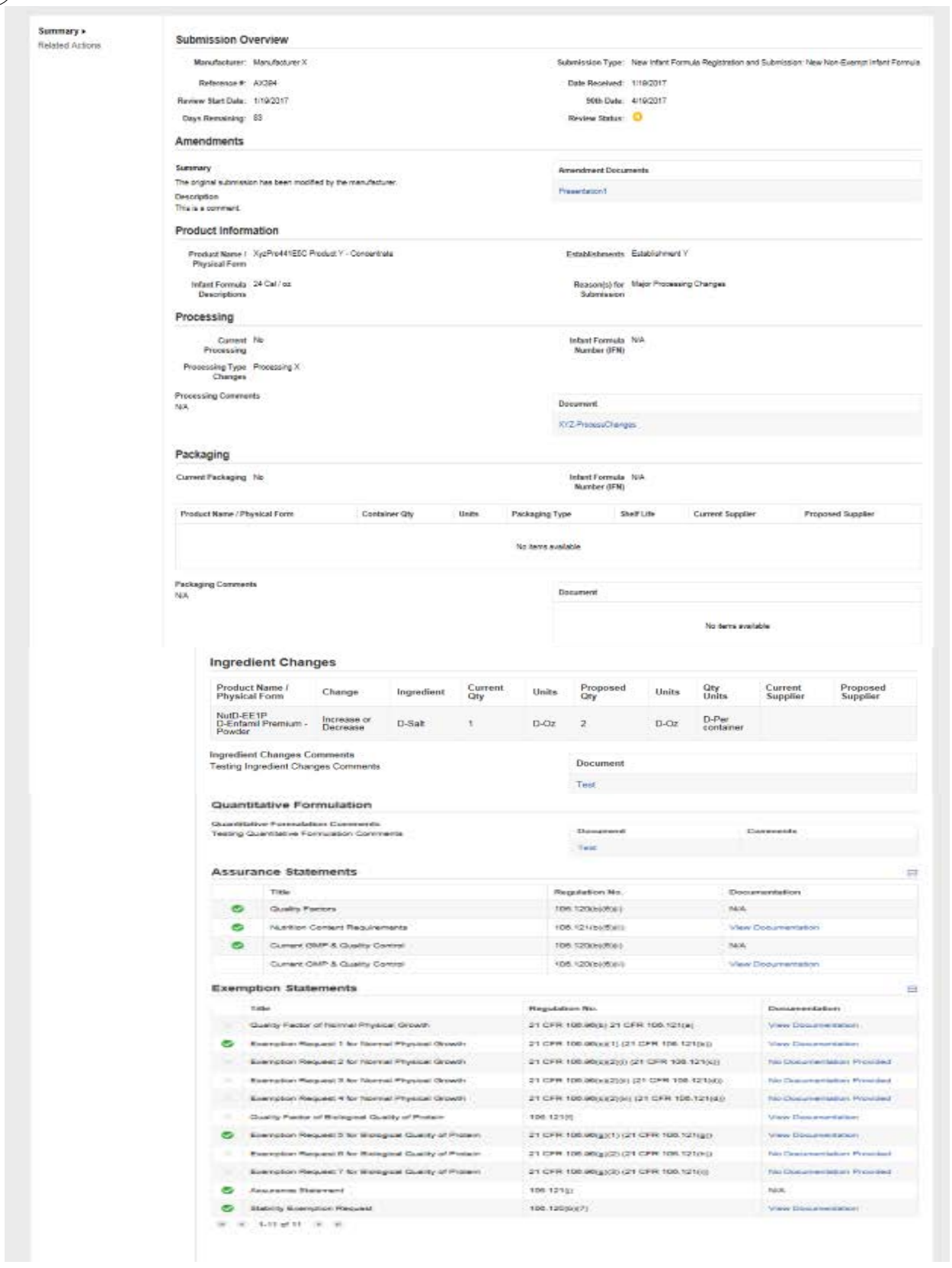


Submission Verification for a New Infant Formula Submission or Follow-Up for an New Infant Formula Submission for Export

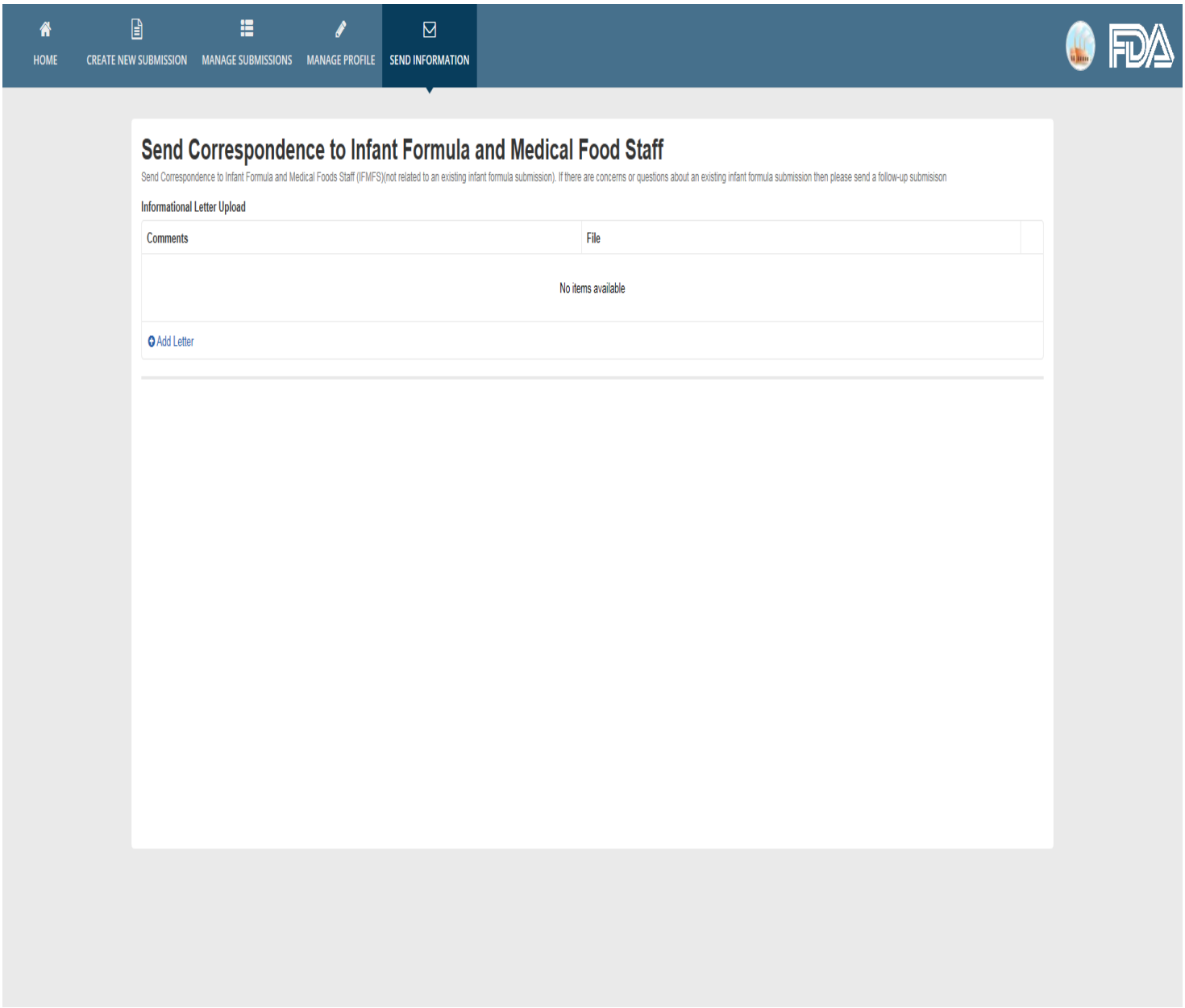


View Submission in Read-Only

13



Send Informational Correspondence



Manage Company Profile