

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

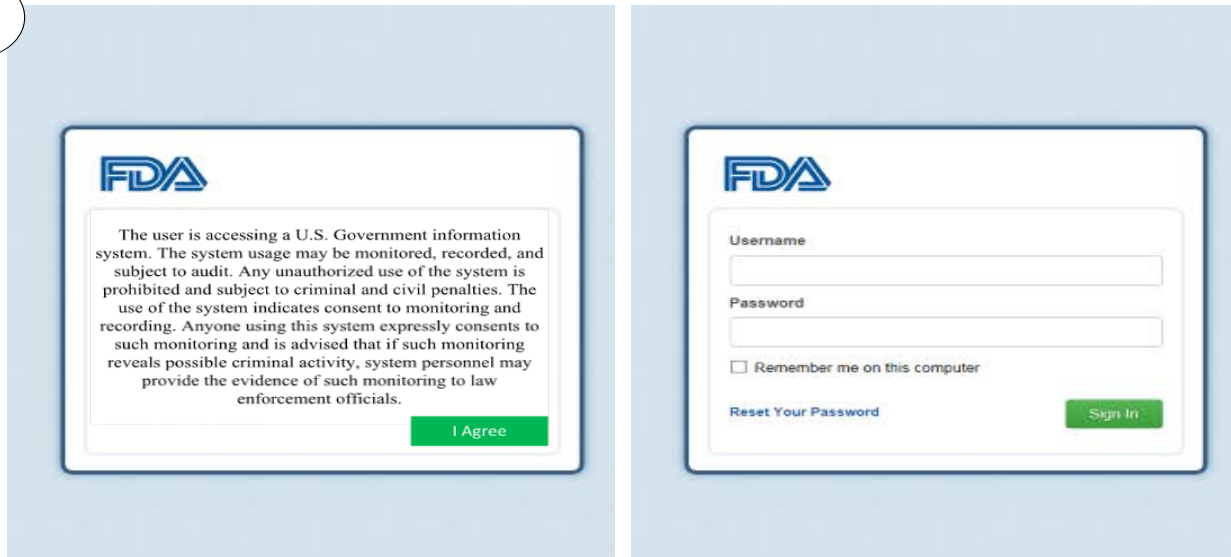
<http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/InfantFormula/default.htm>.

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Login Page and Home Page For Form FDA 3978

1



2

HOME
CREATE NEW SUBMISSION
MANAGE SUBMISSIONS
MANAGE PROFILE
SEND INFORMATION

Information from FDA

Submission(s) Reviewed By FDA

Submission	Submitted Date	Completed Date	Final Letter Document	Additional Attachment(s)
AX350	1/5/2017 2:53 PM EST	1/5/2017 4:38 PM EST	Manufacturer_X_AX350_Final_Letter.pdf	View Additional Attachments
AX369	1/11/2017 11:16 AM EST	1/11/2017 11:32 AM EST	Manufacturer_X_AX369_Final_Letter.pdf	View Additional Attachments
AX372	1/11/2017 2:27 PM EST	1/11/2017 3:29 PM EST	Manufacturer_X_AX372_Final_Letter.pdf	View Additional Attachments
AX380	1/12/2017 2:59 PM EST	1/12/2017 3:10 PM EST	Manufacturer_X_AX380_Final_Letter.pdf	View Additional Attachments
AX386	1/17/2017 11:18 AM EST	1/17/2017 11:26 AM EST	Manufacturer_X_AX386_Final_Letter.pdf	View Additional Attachments

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Submission Rejected By FDA

Submission	Reason
AX351	The submission does not comply with CFR 107.50. Please review the CFR located, link provide below and resubmit. http://www.ecfr.gov/cgi-bin/text-idx?SID=826625cd31f309661442e5469d72dd95&mc=true&node=se212.107_150&rgn=div8 Thank you, IPMFS Team Lead

Open Tasks

Task Name	Last Modified
Edit Profile	1/27/2017 9:53 AM EST
Amendment Confirmation for Exempt Infant Formula Submission Ref No: AX385	1/27/2017 9:28 AM EST
New Infant Formula Registration and Submission: New Non-Exempt Infant Formula	1/26/2017 12:46 PM EST
Exempt Infant Formula Submission	1/26/2017 11:36 AM EST
Amendments	1/19/2017 3:32 PM EST

Infant Formula Submission Selection Page

3

HOME CREATE NEW SUBMISSION MANAGE SUBMISSIONS MANAGE PROFILE SEND INFORMATION

FDA

Infant Formula Submission

Select an infant formula submission type from the options below.

[New Infant Formula Registration and Submission](#)

[New Non-Exempt Infant Formula](#) (except for Export Only)

The definition of "new infant formula" includes both (1) an infant formula manufactured by a person that has not previously manufactured an infant formula and (2) an infant formula manufactured by a person that has previously manufactured infant formula and in which there is a major change, in processing or formulation, from a current or any previous formulation produced by such manufacturer, or which has not previously been the subject of a submission under section 412(c) of the Federal Food, Drug, and Cosmetic Act for the U.S. market. See section 412(c)(2) of the FD&C Act and [21 CFR 106.3](#). See [21 CFR 106.110](#) for further information about new infant formula registration. See [21 CFR 106.120](#) for further information about new infant formula submissions.

[New Infant Formula for Export Only](#)

A notice to the Food and Drug Administration from a manufacturer for a new infant formula for export only. The definition of "new infant formula" includes both (1) an infant formula manufactured by a person that has previously manufactured an infant formula and (2) an infant formula manufactured by a person that has previously manufactured infant formula and in which there is a major change, in processing or formulation, from a current or any previous formulation produced by such manufacturer. See section 412(c)(2) of the FD&C Act and [21 CFR 106.3](#). See 21 CFR 106.110 for further information about new infant formula registration. See [21 CFR 106.120](#) for further information about new infant formula submissions. *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.*

[Before First Processing \(BFP\) Submission: Non-Exempt Infant Formula](#)

A notice before the first processing to the Food and Drug Administration from a manufacturer of a change in the formulation or processing of an infant formula that may affect whether the formula is adulterated under section 412(a) of the FD&C Act (21 U.S.C. 350a(a)). See [21 CFR 106.140](#) for further information about the submission concerning a change in infant formula that may adulterate the product.

[Exempt Infant Formula Submission](#)

An exempt infant formula is any infant formula that is represented and labeled for use by an infant who has an inborn error of metabolism or a low birth weight, or who otherwise has an unusual medical or dietary problem. See section 412(h)(1) of the FD&C Act.

Submission required by [21 CFR 107.50\(b\)\(3\)](#) (See also [21 CFR 107.50\(c\)\(4\)](#) for products not generally available at the retail level.)

Under 21 CFR 107.50(b)(3), to retain the exempt status of an infant formula covered by this paragraph, the manufacturer shall submit to FDA, on or before the 90th day before the first processing of the infant formula for commercial or charitable distribution, whichever occurs later, information specified in this provision.

Submission required by [21 CFR 107.50\(b\)\(4\)](#) (See also [21 CFR 107.50\(c\)\(4\)](#) for products not generally available at the retail level.)

Under 21 CFR 107.50(b)(4), to retain the exempt status of an infant formula covered by this paragraph, when any change in ingredients or processes that may result in an adverse impact on levels of nutrients or availability of nutrients is instituted, the manufacturer shall submit to FDA, before the first processing of the infant formula, information specified in this provision.

Manufacture of infant formula for use before the first processing of the infant formula, must occur before the first processing.

Submission Type

Select the type of submission.*

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

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

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

Exempt Infant Formula Submission

Submit

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

↑
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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

↑
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↓

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 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 manufacturer 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\(b\)\(1\)\(iii\)](#) 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	

*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	Establishments
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 formulation 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\(b\)\(3\)](#) Generally not available at retail
 Submission includes information required by [21 CFR 107.50 \(b\)\(4\)](#) 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	

Exempt Infant Formula Submission *continued*

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 Before Submitting

Exempt Infant Formula Submission - Review Form

Please verify accuracy of the information below before continuing.

Compliance: Submission includes information required by 21 CFR 107.50(b)(2) Retail Availability: Not generally available

Product Information

Product Name/ Physical Form: Product X - Ready to Feed Establishments: Establishment X

Infant Formula Descriptions: Post-hospital pattern Reason(s) for Submission: Packaging Change

Labeling

Labeling Comments: Comment Document: No items available

Medical Conditions

Medical Comments: Comment Document: No items available

Rationale for Deviation

Rationale for Deviation Comments: Comment Document: No items available

Processing

Current Processing: No Infant Formula Number (IFN): N/A

Processing Type: N/A Changes

Processing Comments: This is a comment Document: No items available

Quantitative Formulation

Quantitative Formulation Comments: Testing Quantitative Formulation Comments Document: No items available

Assurance Statements

Title	Regulation No.	Documentation
Quality Factors	105.120(b)(5)(i)	N/A
Nutrition Content Requirements	105.121(b)(5)(i)	View Documentation
Current OMP & Quality Control	105.120(b)(5)(i)	N/A
Current OMP & Quality Control	105.120(b)(5)(i)	View Documentation

Exemption Statements

Title	Regulation No.	Documentation
Quality Factor of Normal Physical Growth	21 CFR 105.90(e) (21 CFR 105.121(a))	View Documentation
Exemption Request 1 for Normal Physical Growth	21 CFR 105.90(e)(1) (21 CFR 105.121(a))	View Documentation
Exemption Request 2 for Normal Physical Growth	21 CFR 105.90(e)(2)(i) (21 CFR 105.121(a))	No Documentation Provided
Exemption Request 3 for Normal Physical Growth	21 CFR 105.90(e)(2)(ii) (21 CFR 105.121(a))	No Documentation Provided
Exemption Request 4 for Normal Physical Growth	21 CFR 105.90(e)(2)(iii) (21 CFR 105.121(a))	No Documentation Provided
Quality Factor of Biological Quality of Protein	105.121(b)	View Documentation
Exemption Request 5 for Biological Quality of Protein	21 CFR 105.90(e)(1) (21 CFR 105.121(b))	View Documentation
Exemption Request 6 for Biological Quality of Protein	21 CFR 105.90(e)(2) (21 CFR 105.121(b))	No Documentation Provided
Exemption Request 7 for Biological Quality of Protein	21 CFR 105.90(e)(3) (21 CFR 105.121(b))	No Documentation Provided
Accuracy Statement	105.121(c)	N/A
Stability Exemption Request	105.125(a)(7)	View Documentation

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 Processing Changes
- New Ingredients
- New Infant Formula Descriptions
- New Packaging Types
- 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



Manage Submissions for Manufacturer X

Filter the submissions using the available search criteria. Select the checkbox for a submission to submit an amendment, verification, Withdraw or withdrawn. Select the submission to view the entire submission in read only.

Filters

Submission Reference #

Select up to 5 submission reference numbers

Status

All Active Withdrawn Reject Completed Hold

Submission Type

- All Submission Types -

Submitted After

MM/yyyy

Submitted Before

MM/yyyy

Submissions

<input type="checkbox"/>	Ref #	Submission Type	Date Submitted	Status
<input type="checkbox"/>	XA12	Exempt Infant Formula Submission	1/30/2017	✔
<input type="checkbox"/>	AX30E	New Infant Formula Registration and Submission: New Infant Formula for Export Only	1/18/2017	✔
<input type="checkbox"/>	AX304	New Infant Formula Registration and Submission: New Non-Exempt Infant Formula	1/18/2017	⚠
<input type="checkbox"/>	AX388	New Infant Formula Registration and Submission: New Non-Exempt Infant Formula	1/18/2017	✔
<input type="checkbox"/>	AX388	New Infant Formula Registration and Submission: New Non-Exempt Infant Formula	1/18/2017	✘
<input type="checkbox"/>	AX388	New Infant Formula Registration and Submission: New Non-Exempt Infant Formula	1/17/2017	✔
<input type="checkbox"/>	AX385	Exempt Infant Formula Submission	1/17/2017	✔
<input type="checkbox"/>	AX380	Exempt Infant Formula Submission	1/12/2017	✔
<input type="checkbox"/>	AX379	Exempt Infant Formula Submission	1/12/2017	✘
<input type="checkbox"/>	AX373	New Infant Formula Registration and Submission: New Infant Formula for Export Only	1/11/2017	✔
<input type="checkbox"/>	AX372	New Infant Formula Registration and Submission: New Non-Exempt Infant Formula	1/11/2017	✔
<input type="checkbox"/>	XA10	New Infant Formula Registration and Submission: New Infant Formula for Export Only	1/11/2017	✔
<input type="checkbox"/>	AX365	New Infant Formula Registration and Submission: New Non-Exempt Infant Formula	1/11/2017	✔
<input type="checkbox"/>	AX388	New Infant Formula Registration and Submission: New Non-Exempt Infant Formula	1/11/2017	✘
<input type="checkbox"/>	AX352	Before First Processing (BFP) Submission: Non-Exempt Infant Formula	1/8/2017	✘
<input type="checkbox"/>	AX351	Exempt Infant Formula Submission	1/8/2017	✘
<input type="checkbox"/>	AX350	New Infant Formula Registration and Submission: New Non-Exempt Infant Formula	1/8/2017	✔
<input type="checkbox"/>	AX408	New Infant Formula Registration and Submission: New Non-Exempt Infant Formula	1/2/2017	✔
<input type="checkbox"/>	XA46	New Infant Formula Registration and Submission: New Non-Exempt Infant Formula	12/29/2016	✔
<input type="checkbox"/>	XA42	Exempt Infant Formula Submission	12/29/2016	✔

120 of 38

+ Show Columns

Cancel

Save

Modify a Submission

The screenshot shows a web browser window with the URL <https://fdatest1.appiancloud.com/suite/sites/manufacturer-home/page/manage-submissions/record/1AB2YdHh>. The browser tabs include 'Inside FDA Home', 'BTRACK II - Training Videos', and 'Manufacturer Home'. The navigation bar contains 'HOME', 'CREATE NEW SUBMISSION', 'MANAGE SUBMISSIONS', 'MANAGE PROFILE', and 'SEND INFORMATION'. The FDA logo is in the top right corner.

Summary
Related Actions

Update Submission: AX394

Select one of the following for the submission selected.

Amendments - An amendment to a submission either submitted in response to agency questions or to correct the submission.
Verifications (Infant Formula Submission) - A notice to the Food and Drug Administration from a manufacturer, after the first production and before the introduction into interstate commerce of a new infant formula (except for a new infant formula that is for export only for which a submission is received in compliance with 21 CFR 105.120(c), that the infant formula complies with the requirements of the Federal Food, Drug, and Cosmetic Act and is not adulterated.
Follow Ups (Infant Formula Submission Export Only) - A follow-up for information needed to update the New Infant Formula Submissions for export-only.
Submission Withdrawal - A withdrawal of the entire submission. The submission will no longer be reviewed by the Infant Formula and Medical Food staff.

Modification Type*
-- Select a Value --

Withdraw a Submission

The screenshot shows the 'Submission Withdrawal Confirmation' page. The navigation bar is the same as in the previous screenshot. The page content is as follows:

Summary
Related Actions

Submission Withdrawal Confirmation

Are you sure? By clicking Withdraw, you are confirming the withdrawal of Submission Reference AX394

Amend a Submission

Summary
Related Actions >

Submit an Amendment

Select the amendment type, add comments and upload documentation. If responding to the CSO select the question. If withdrawing a product, select the product being withdrawn

Amendment Details

Amendment Type *

- Respond to question from CSO
- Make changes to original submission
- Withdraw a product from submission

Amendment Contents

Amendment Description *

Amendment Attachments

Documents

No items available

[Select Document](#)

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

Verification {Submission Reference Number}, {Submission Received Date}

Select the product(s) and add comments and/or documentation for the verification.

Product Selection

	IFN Number	Product Name	Physical Form	Establishment	Packaging Type	Container Qty	Units
<input type="checkbox"/>	IFN123P	Product1	Powder	New Brunswick	Container	3	Oz.
<input type="checkbox"/>	IFN123R	Product2	Ready to Feed	New Rochelle	Bottle	4	Oz.

106.130(a) *

By checking this box, the manufacturer verifies that the infant formula complies with the requirements of the Federal Food Drug, and Cosmetic Act and is not adulterated.

106.130(b)(2) *

By checking this box, the manufacturer verifies 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) *

By checking this box, the manufacturer verifies that the submission provides a summary of test results of the level of each nutrient required by 21 CFR 107.100 and any nutrient added by the manufacturer in the formula, presented in units per 100 kilocalories at the final production stage.

Documentation Upload

Document	Comments
No items available	

[Add Document or Comments](#)

106.130(b)(4) *

By checking this box, the manufacturer verifies the 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 (21 CFR 106, Subpart B) and Quality Control Procedures (21 CFR 106, Subpart C) have been established.

[Back](#) [Verify](#) [Next](#)

12 If Current Packaging, display: Current IFNs
IFN123R, IFF123CR,

Follow Up for Submission AN319

A follow-up is submitted with information needed to update a "New Infant formula Submission Export Only".

Product Selection

<input type="checkbox"/> IFN Number	Product Name	Physical Form
<input type="checkbox"/> NJD-EX14R	D-Infant Premium	Ready to Feed

Follow Up Contents

Follow Up Comments *	Follow Up Attachments		
<input type="text"/>	<table border="1"> <thead> <tr> <th>Document</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">No items available</td> </tr> </tbody> </table> <p>Add Document</p>	Document	No items available
Document			
No items available			

[Next](#)

View Submission in Read-Only

Summary >
Related Actions

Submission Overview

Manufacturer: Manufacturer X
 Reference #: A1234
 Review Start Date: 1/19/2017
 Days Remaining: 63
 Submission Type: New Infant Formula Registration and Submission; New Non-Exempt Infant Formula
 Date Received: 1/19/2017
 50th Date: 4/19/2017
 Review Status: ●

Amendments

Summary

The original submission has been modified by the manufacturer.

Description
 This is a comment.

Amendment Documents

[Presentation1](#)

Product Information

Product Name I: XyzPro44EEO Product Y - Concentrate
 Physical Form: Infant Formula
 Infant Formula: 24 Cal / oz
 Descriptions: Establishments: Establishment Y
 Reason(s) for Submission: Major Processing Changes

Processing

Current Processing: No
 Processing Type Changes: Processing X
 Processing Comments: N/A
 Infant Formula Number (IFN): N/A
 Document: [XYZ-ProcessChanges](#)

Packaging

Current Packaging: No
 Infant Formula Number (IFN): N/A

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

Packaging Comments
 N/A

Document

No items available

Ingredient Changes

Product Name / Physical Form	Change	Ingredient	Current Qty	Units	Proposed Qty	Units	Qty Units	Current Supplier	Proposed Supplier
Nutli-EE1P D-Enfamil Premium - Powder	Increase or Decrease	D-Salt	1	D-Oz	2	D-Oz	D-Per container		

Ingredient Changes Comments
 Testing Ingredient Changes Comments

Document

[Test](#)

Quantitative Formulation

Quantitative Formulations Comments
 Testing Quantitative Formulation Comments

Document

[Test](#)

Assurance Statements

Title	Regulation No.	Documentation
<input checked="" type="checkbox"/> Quality Factors	105.120(b)(5)(i)	N/A
<input checked="" type="checkbox"/> Nutrition Content Requirements	105.121(b)(5)(i)	View Documentation
<input checked="" type="checkbox"/> Current OMP & Quality Control	105.120(b)(5)(i)	N/A
<input checked="" type="checkbox"/> Current OMP & Quality Control	105.120(b)(5)(i)	View Documentation

Exemption Statements

Title	Regulation No.	Documentation
<input type="checkbox"/> Quality Factor of Normal Physical Growth	21 CFR 105.96(b) (21 CFR 105.121(a))	View Documentation
<input checked="" type="checkbox"/> Exemption Request 1 for Normal Physical Growth	21 CFR 105.96(b)(1) (21 CFR 105.121(b))	View Documentation
<input type="checkbox"/> Exemption Request 2 for Normal Physical Growth	21 CFR 105.96(b)(2)(i) (21 CFR 105.121(c))	No Documentation Provided
<input type="checkbox"/> Exemption Request 3 for Normal Physical Growth	21 CFR 105.96(b)(2)(ii) (21 CFR 105.121(c))	No Documentation Provided
<input type="checkbox"/> Exemption Request 4 for Normal Physical Growth	21 CFR 105.96(b)(2)(iii) (21 CFR 105.121(d))	No Documentation Provided
<input type="checkbox"/> Quality Factor of Biological Quality of Protein	105.121(f)	View Documentation
<input checked="" type="checkbox"/> Exemption Request 5 for Biological Quality of Protein	21 CFR 105.96(g)(1) (21 CFR 105.121(g))	View Documentation
<input type="checkbox"/> Exemption Request 6 for Biological Quality of Protein	21 CFR 105.96(g)(2) (21 CFR 105.121(h))	No Documentation Provided
<input type="checkbox"/> Exemption Request 7 for Biological Quality of Protein	21 CFR 105.96(g)(3) (21 CFR 105.121(i))	No Documentation Provided
<input checked="" type="checkbox"/> Assurance Statement	105.121(j)	N/A
<input checked="" type="checkbox"/> Stability Exemption Request	105.120(b)(7)	View Documentation

Send Informational Correspondence



HOME



CREATE NEW SUBMISSION



MANAGE SUBMISSIONS



MANAGE PROFILE



SEND INFORMATION



Send Correspondence to Infant Formula and Medical Food Staff

Send Correspondence to Infant Formula and Medical Foods Staff (IFMFS)(not related to an existing infant formula submission). If there are concerns or questions about an existing infant formula submission then please send a follow-up submission

Informational Letter Upload

Comments	File	
No items available		
Add Letter		

Manage Company Profile



HOME

CREATE NEW SUBMISSION

MANAGE SUBMISSIONS

MANAGE PROFILE

SEND INFORMATION

Manage Company Profile

Modify the corporate address. Add and/or update the company contact details

Manufacturer X

Address

12345 Manufacturer Drive

City

Factorytown

State

VA

Zip/Postal Code

123456

Contact Information

Add New Contacts

Position	Title	First Name	Last Name	Phone	Email	
----------	-------	------------	-----------	-------	-------	--

No items available

[Add Contact](#)

1 item

Manage Existing Contacts

Position	Title	First Name	Last Name	Phone	Email	Remove
Director of Product	Dr.	Davis	Smith	301-895-5963	davis@xyz.com	X

1 item

Cancel

Submit