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
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### Information from FDA

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<th>Submitted Date</th>
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**Submission Rejected by FDA**

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<td>AX01</td>
<td>The submission does not comply with CFR 107.31. Please review the CFR located link provided below and resubmit. <a href="http://www.scribd.com/CFR/107.31">Link</a></td>
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**Open Tasks**

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<td>1/15/2017 1:32 PM EST</td>
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</table>
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 106.1 for further information about new infant formula registration. See 21 CFR 106.110 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 106.1 for further information about new infant formula registration. See 21 CFR 106.110 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)(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 non-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.
### New Infant Formula Registration and Submission: Non-Exempt Infant Formula

**Product Information**

*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)*

<table>
<thead>
<tr>
<th>Product Name / Physical Form</th>
<th>Name Change</th>
<th>Physical Form</th>
<th>Misc Info</th>
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<tbody>
<tr>
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</table>

*Indicates a required field.

**Infant Formula Description**

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

<table>
<thead>
<tr>
<th>Product Name / Physical Form</th>
<th>Infant Formula Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Items Available</td>
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</table>

**Establishments**

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

<table>
<thead>
<tr>
<th>Product Name / Physical Form</th>
<th>Establishments</th>
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**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.

<table>
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<th>Type of Process Change</th>
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**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.

<table>
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**Processing Comments**

**Packaging Comments**

**Processing Documentation Upload**

**Packaging Documentation Upload**
New Infant Formula Registration and Submission: Non-Exempt Infant Formula – Quantitative Formulation

* 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)

<table>
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<th>Change</th>
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<th>Current Qty</th>
<th>Units</th>
<th>Proposed Qty</th>
<th>Units</th>
<th>Per Qty Units</th>
<th>Current Supplier</th>
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No Items Available

Select Ingredient Changes

**Ingredient Change Comments**

No Items Available

**Ingredient Change Documentation Upload**

Documents

No Items Available

Select Document

**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

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(g)(1) 21 CFR 106.96(g)(1)

By checking this box, the manufacturer requests an exemption and provides assurances, as required under 21 CFR 106.96(g)(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).

If the manufacturer is requesting an exemption from the growth monitoring study requirements under 21 CFR 106.96(g)(1), then the change 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(g)(1).

By checking this box, the manufacturer requests an exemption and provides assurances, as required under 21 CFR 106.96(g)(1), which demonstrate that an alternative method or study design is based on sound scientific principles, and the data that demonstrate 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(g)(1), the manufacturer shall include a detailed description of the alternative method or study design 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(g)(2) 21 CFR 106.121(c)

By checking this box, the manufacturer requests an exemption and provides assurances, as required under 21 CFR 106.96(g)(2), 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(g)(2), the manufacturer shall include a detailed description of the alternative method or study design 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(g)(3) 21 CFR 106.121(d)

By checking this box, the manufacturer requests an exemption and provides assurances, as required under 21 CFR 106.96(g)(3), which demonstrate that the change made by the manufacturer to an existing infant formula is 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(e). 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(d) 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(e)(1) 21 CFR 106.96(e)(1)

By checking this box, the manufacturer requests an exemption and provides assurances, as required under 21 CFR 106.96(e)(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).

If the manufacturer is requesting an exemption from the requirements of 21 CFR 106.96(e)(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(e)(1).

☐ Exemption under 21 CFR 106.96(e)(2) 21 CFR 106.96(e)(2)

By checking this box, the manufacturer requests an exemption and provides assurances, as required under 21 CFR 106.96(e)(2), that 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 does not affect the bioavailability of the protein.

If the manufacturer is requesting an exemption from the requirements of 21 CFR 106.96(e)(2), the manufacturer shall include a detailed description of the alternative method or study design that is based on sound scientific principles, and the data that demonstrate the formula supports the quality factor for the biological quality of the protein.

Exemption under 21 CFR 106.96(e)(3) 21 CFR 106.121(h)

By checking this box, the manufacturer requests an exemption and provides assurances, as required under 21 CFR 106.96(e)(3), 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(e)(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

Additional Assurances and Exemption

*Assurance Statement

21 CFR 106.121(i) 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 108 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

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<thead>
<tr>
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<tbody>
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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)(ii). 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

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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

## 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.*

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Name Change</th>
<th>Physical Form</th>
<th>Misc Info</th>
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</thead>
<tbody>
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</table>

### Infant Formula Description

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

<table>
<thead>
<tr>
<th>Product Name / Physical Form</th>
<th>Infant Formula Description</th>
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</thead>
<tbody>
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</table>

### Eligible Infant Formula

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

- [ ] Yes
- [x] No

### Establishments

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

<table>
<thead>
<tr>
<th>Product Name / Physical Form</th>
<th>Establishments</th>
</tr>
</thead>
<tbody>
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</tr>
</tbody>
</table>

## 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.

### 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.

## Documents

### Processing Comments

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

### Packaging Comments

- By checking this box the manufacturer confirms the submission complies with 21 CFR 106.120(b)(4)
Before First Processing (BFP) Submission: Non-Exempt Infant Formula – Quantitative Formula

* Indicates a required field.

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

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)

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)

Ingredient Change Comments

Ingredient Change Documentation Upload

No Items Available

 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

By checking this box the manufacturer confirms the submission complies with 21 CFR 106.120(b)(3).
Before First Processing (BFP) Submission: Non-Exempt Infant Formula - Continued Compliance

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 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.

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.

Comments and/or Documentation Uploads

Documents

No Items Available

Select Document
**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)(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.

### 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 106.320(b)(1)*

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Name Change</th>
<th>Physical Form</th>
<th>Misc Info</th>
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<tbody>
<tr>
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<td>No Items Available</td>
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</table>

**Select Product**

**Infant Formula Description**

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

<table>
<thead>
<tr>
<th>Product Name/Physical Form</th>
<th>Infant Formula Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No Items Available</td>
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</table>

**Select Infant Formula Description**

**Establishments**

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

<table>
<thead>
<tr>
<th>Product Name/Physical Form</th>
<th>Establishments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No Items Available</td>
</tr>
</tbody>
</table>

**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.

**Select Type of Processing**

<table>
<thead>
<tr>
<th>Product/Physical Form</th>
<th>Type of Process Change</th>
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</tbody>
</table>

**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.

**Select Type of Packaging**

<table>
<thead>
<tr>
<th>Product Name/Physical Form</th>
<th>Packaging Type</th>
<th>Container Qty</th>
<th>Units</th>
<th>Shelf Life</th>
<th>Current Supplier</th>
<th>Proposed Supplier</th>
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<tbody>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

* 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)]

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

* 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

* 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.*

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Name Change</th>
<th>Physical Form</th>
<th>Misc Info</th>
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</thead>
<tbody>
<tr>
<td>No Items Available</td>
<td></td>
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</tbody>
</table>

**Infant Formula Description**

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

<table>
<thead>
<tr>
<th>Product Name/Physical Form</th>
<th>Infant Formula Description</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

**Reason(s) for Submission**

*Select one or more explanations for this submission.*

<table>
<thead>
<tr>
<th>Product Name/Physical Form</th>
<th>Reason(s) for Submission</th>
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<tbody>
<tr>
<td>No Items Available</td>
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</table>

**Establishments**

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

<table>
<thead>
<tr>
<th>Product Name/Physical Form</th>
<th>Establishments</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Items Available</td>
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</table>

**Label/Labeling**

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

<table>
<thead>
<tr>
<th>Label/Labeling Comments</th>
<th>Label/Labeling Documentation upload</th>
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</thead>
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<tr>
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**Description of Medical Conditions**

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

<table>
<thead>
<tr>
<th>Description of Medical Conditions</th>
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</thead>
<tbody>
<tr>
<td>Documents</td>
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**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).

<table>
<thead>
<tr>
<th>Rationale for deviation Comments</th>
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## Exempt Infant Formula Submission

### 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.

<table>
<thead>
<tr>
<th>Product/Physical Form</th>
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Select Type of Processing

### Processing Comments

### Processing Documentation Upload

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</table>

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.

<table>
<thead>
<tr>
<th>Product Name/Physical Form</th>
<th>Packaging Type</th>
<th>Container Qty</th>
<th>Units</th>
<th>Shelf Life</th>
<th>Current Supplier</th>
<th>Proposed Supplier</th>
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<tbody>
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Select Type of Packaging

### Packaging Comments

### Packaging Documentation Upload

<table>
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</thead>
<tbody>
<tr>
<td>No Items Available</td>
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</tr>
</tbody>
</table>

Select Document

---
Exempt Infant Formula Submission:

Quantitative Formulation

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

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.

Ingredient Change Comments

Ingredient Change Documentation Upload

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

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. | Submit |
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

Verification {Submission Reference Number}, {Submission Received Date}
Select the product(s) and add comments and/or documentation for the verification.

Product Selection

<table>
<thead>
<tr>
<th>IFN Number</th>
<th>Product Name</th>
<th>Physical Form</th>
<th>Establishment</th>
<th>Packaging Type</th>
<th>Container Qty</th>
<th>Units</th>
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</thead>
<tbody>
<tr>
<td>IFN123P</td>
<td>Product1</td>
<td>Powder</td>
<td>New Brunswick</td>
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<td>Oz.</td>
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<tr>
<td>IFN123R</td>
<td>Product2</td>
<td>Ready to Feed</td>
<td>New Rochelle</td>
<td>Bottle</td>
<td>4</td>
<td>Oz.</td>
</tr>
</tbody>
</table>

106.130(e) *
☐ 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

- 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.

If Current Packaging, display:

IFN123R, IFN123CR, IFN123CR, IFN123CR, IFN123CR.
Send Informational Correspondence

Send Correspondence to Infant Formula and Medical Food Staff

Send Correspondence to Infant Formula and Medical Food Staff (INF-MF) is 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

<table>
<thead>
<tr>
<th>Comments</th>
<th>File</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</table>

No items available.

Add Letter
Manage Company Profile

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

Manufacturer X

Address
1234 Manufacturer Drive

City
Factorytown

State
VA

Zip/Postal Code
12345

Contact Information

Add New Contacts

<table>
<thead>
<tr>
<th>Position</th>
<th>Title</th>
<th>First Name</th>
<th>Last Name</th>
<th>Phone</th>
<th>Email</th>
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Add Contact

Manage Existing Contacts

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<th>Phone</th>
<th>Email</th>
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</thead>
<tbody>
<tr>
<td>Director of Product</td>
<td>Dr.</td>
<td>Davis</td>
<td>Smith</td>
<td>301-896-0963</td>
<td><a href="mailto:davis@xyz.com">davis@xyz.com</a></td>
<td>X</td>
</tr>
</tbody>
</table>

1 item